



September 20, 2023

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.

**Re: Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans:
Draft Part One Guidance**

Dear Deputy Administrator Seshamani:

AARP, which advocates for the more than 100 million Americans over age 50, appreciates the opportunity to comment on the August 21, 2023, draft guidance pertaining to the new Medicare Prescription Payment Plan (MPPP) that was created by the Inflation Reduction Act of 2022. This policy will help ensure greater payment flexibility to help make drugs more accessible.

Overall, we appreciate Centers for Medicare & Medicaid Services' (CMS) 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 new process will provide 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 focus on benefiting consumers.

With respect to the draft memorandum guidance, we offer the following comments:

1. Education and Outreach (Overview)

Education and Outreach Materials and Methods: AARP believes that both public and private sectors should prioritize consumer and family caregiver engagement and support in health care. We urge CMS to ensure that all MPPP-related materials are culturally competent and readily available in multiple languages. We also encourage CMS to conduct listening sessions and focus groups with Medicare beneficiaries, caregivers, and other patient advocates to help ensure that MPPP education and outreach materials meet their needs.

Decision Tools: AARP appreciates that not all enrollees will benefit from the MPPP and strongly supports CMS' commitment to providing decision support tools that will help Medicare Part D enrollees determine whether to participate. We also encourage CMS to use focus groups to ensure that these tools meet the needs of enrollees and their families.

AARP also believes that CMS should consider developing online decision support tools to provide real-time, individualized assistance with MPPP enrollment. Such tools should be easily accessible and understandable, and ideally available on websites that Part D enrollees already utilize, including Medicare.gov, Medicare Plan Finder, and Part D plan sponsors' 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 decision support tools.

Lastly, AARP supports the requirement that Part D plan materials contain a variety of information, including information about the Low-Income Subsidy (LIS) "Extra Help" program. It is critical that Medicare Part D enrollees and their loved ones are fully informed about the eligibility, benefits, and enrollment process for both the MPPP program and the LIS "Extra Help" program to ensure consumers have the opportunity to select the most appropriate program to meet their needs.

2. Leveraging Existing Resources to Reach Medicare Enrollees Who May Benefit from MPPP (Overview)

Leveraging Existing Resources for Outreach: AARP urges CMS to utilize all potential and appropriate resources to conduct outreach to Medicare enrollees who may benefit from the MPPP. This includes existing resources such as monthly Medicare Part D premium and explanation of benefits (EOB) statements, State Health Insurance Assistance Programs (SHIPs), Federally Qualified Health Centers (FQHCs), and programs under the Older Americans Act, such as senior centers. We also encourage the utilization of Medicare.gov and 1-800-MEDICARE to communicate information about the MPPP program, particularly before Medicare annual open enrollment periods.

3. General and Targeted Enrollee Outreach Prior To and During the Plan Year

Requirements Related to Part D Enrollee Outreach (Section 60): AARP believes that it is imperative that outreach occurs every year well in advance of Medicare's annual open enrollment period. We urge CMS to ensure that outreach occurs over multiple points in time and that communications are clear, consistent, and easy to understand. We agree that this outreach should be from both CMS and Part D plan sponsors, with targeted attention on individuals who are most likely to benefit from enrolling in the MPPP. Such outreach should include a list of factors that could help Part D enrollees self-identify as someone who could benefit from the program, as well as an explanation of the billing process for their out-of-pocket costs. Further, any MPPP-related information included in monthly Medicare Part D premium and EOB statements should be delineated as a separate program and payment.

General Outreach (Section 60.1): We applaud CMS' commitment to providing additional guidance on marketing and communications procedures at the pharmacy, model language, and

standardized materials, including language about the LIS program under Part D. Again, we urge CMS to ensure that all MPPP-related materials are culturally competent and readily available in multiple languages. We also strongly encourage CMS to conduct further listening sessions and focus groups with Medicare beneficiaries, caregivers, and other patient advocates to obtain feedback on the types of education and outreach materials that would be effective and which communications materials would benefit from CMS templates, samples, or model language.

Targeted Outreach (Section 60.2): As CMS notes, while the MPPP program is open to all Part D enrollees, enrollees incurring high OOP costs earlier in the plan year are generally more likely to benefit. AARP strongly supports targeted early outreach, ideally well before the plan year starts. As previously noted, we strongly encourage CMS to leverage existing resources in outreach to Medicare enrollees who may benefit from the MPPP. This includes existing monthly statements, SHIPs, FQHCs, and programs under the Older Americans Act, such as senior centers.

Further, there should be outreach from both CMS and Part D plan sponsors, with special attention/targeted attention on individuals who have high OOP costs in the prior plan year. AARP also urges CMS to consider focusing on enrollees utilizing specialty pharmacies, which typically dispense high-priced medications. Finally, AARP strongly encourages CMS to 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 efforts.

Targeted Part D Enrollee Notification at Point-of-Sale (POS) (Section 60.2.3): AARP appreciates CMS’ efforts to provide guidance to ensure that Medicare Part D enrollees who are likely to benefit from the MPPP are notified at the point-of-sale, which is where many enrollees realize that they are facing high out-of-pocket costs. We support the creation of a POS notification threshold that can help identify which enrollees could benefit from the MPPP. We also encourage CMS to consider applying this proposed POS notification threshold range to OOP costs for all prescriptions filled in a single day.

However, AARP is also aware that the benefits of enrolling in MPPP are dependent on a variety of factors that often cannot be quickly or easily explained. For example, it is unlikely that retail pharmacists will have time to fully explain the implications of enrollment, and a general brochure may not provide information for an enrollee to make an informed decision. Thus, any materials or information shared at the POS should include where and how to obtain more individualized information. Similarly, efforts to develop real-time election for MPPP should include a comprehensive assessment of what level of assistance is available and feasible at the POS, as well as whether that assistance will support appropriate enrollee decision making.

4. Consumer Protections

Participant Billing Requirements (Sections 40 and 40.1): AARP believes that consumers should have access to a variety of meaningful options to ensure choice in consumer products and services. In that spirit, AARP strongly supports CMS encouraging Part D plan sponsors to offer multiple means of payment in the MPPP, including electronic fund transfer mechanisms, cash, or check and the prohibition on late fees, interest payments, or other fees (such as for certain payment mechanisms). We also strongly support encouraging Part D sponsors to offer

participants flexibility around requesting a specific day of the month for the program charges and withdrawals from a bank account.

AARP believes that consumers should also have the right to accessible, appropriate, and adequate redress, including the full range of legal remedies. We strongly support consumer protections that prohibit termination from the MPPP program if the enrollee pays overdue balances within the required grace period of at least two months.

Further, in circumstances where an MPPP enrollee makes a payment directly to the Part D sponsor and it is unclear whether a payment should go towards the Part D plan premium or the MPPP balance, we support CMS' encouragement of prioritization of payments towards Part D plan premiums to avoid an enrollee losing their overall Part D coverage.

Lastly, AARP strongly encourages CMS to track any downstream effects from this change, including the number of people who do not meet their financial obligations under the program and any related implications for beneficiary premiums.

Thank you again for the opportunity to express our views on this important program, which will help provide financial relief and flexibility to Medicare enrollees with high OOP 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@aarp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "David Certner", with a long horizontal flourish extending to the right.

David Certner
Legislative Counsel and Legislative Policy Director
Government Affairs



September 20, 2023

Submitted via Electronic Filing:
PartDPaymentPolicy@cms.hhs.gov

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

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

Dear Administrator Brooks-LaSure,

AbbVie Inc. ("AbbVie") appreciates the opportunity to provide feedback on the August 21, 2023, draft guidance implementing §11202 of the Inflation Reduction Act of 2022 (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 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 practical solutions to some of the policies set out in the draft guidance.

Overview

The new annual \$2,000 cap on beneficiary OOP costs, coupled with the new MPPP, will significantly improve affordability for Part D patients with high OOP drug costs. Without the MPPP, beneficiaries with high monthly OOP costs would still face significant hardship if asked to pay the year's entire costs in just a month or two. For these patients, the MPPP promises to serve as a critical companion program to the new annual cap and will promote patient adherence to therapy by addressing affordability barriers.

The true measure of this program's success will be beneficiary participation rates and positive experiences. In the early years, CMS can help drive consistency and fairness by establishing clear standard procedures, communications, and outreach protocols. AbbVie believes CMS can help foster success by ensuring patients are provided ample opportunity to opt-in and out of the program regardless of where they live or which carrier provides their Part D coverage. Additionally, program administration must be consistent regardless of carrier, timing, or method of election.

To ensure the success of the MPPP, it is essential that the draft guidance be a comprehensive resource to guide implementation, and that CMS and plans provide clear, patient-friendly

beneficiary communications. Beneficiaries deserve to learn about how the MPPP can help them afford their medicines, understand how to enroll in the program, anticipate what to expect in monthly bills, and how to resolve disputes with a plan.

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

- **Enhance Beneficiary Education and Outreach (Section 60)**
 - AbbVie recommends refinements to the targeting approach described in the draft guidance to ensure that a range of enrollees can benefit from outreach and education.
 - We also recommend that CMS leverage the Medicare Plan Finder and Explanation of Benefits (EOB) in outreach and education efforts.
- **Enable Real-Time Election at Point-of-Sale (POS) in 2025 (Section 70)**
 - AbbVie strongly recommends CMS pursue a real-time POS election solution beginning in 2025 that leverages the telephone-only option, coupled with pre-populating a plan-specific BIN/PCN for the MPPP.
 - We also recommend CMS consider alternative approaches to facilitate POS election, such as a real-time enrollment verification system and/or a one-time transition fill at \$0 while the election is processed.
- **Improve Beneficiary Protections Related to Billing, Terminations, and Appeals (Sections 40, 80 & 90)**
 - AbbVie recommends that CMS adopt uniform standards and templates for billing, clarify that lock-out provisions only apply to a single-year prohibition, and require plans to resolve disputes within a 24-hour timeframe.

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I. **Enhance Beneficiary Outreach and Education (Section 60)**

AbbVie generally supports the proposed approach for beneficiary outreach and education leading up to and throughout the 2025 plan year, as described in Section 60 of the draft guidance. We agree with the need for early identification of Part D patients who are likely to benefit from the program, and to require both general and targeted outreach. We write to offer suggested refinements to the targeting approach described by CMS in the draft guidance. We also recommend that CMS leverage the existing Medicare Plan Finder and EOB in outreach and education efforts.

Feedback on Thresholds for Targeting and Opting Out

Both general and targeted education efforts are vital to the success of the program. The proposal to use an OOP spending threshold to identify individuals likely to benefit from the program is reasonable but limiting outreach to that population is not sufficient. In addition, it is important to recognize that every patient is unique and certain patients may see benefits from the program that are not obvious to CMS or captured by a dollar threshold. We urge CMS to ensure patients have the information they need to make their own decisions regarding MPPP election and to preclude plan sponsors or pharmacists from actively discouraging enrollment or steering patients away from the program. Such conduct could be discriminatory and harmful to certain sub-populations of patients, for example, and must be strictly prohibited.

While we are generally supportive of targeted outreach to individuals that meet the minimum single script threshold of between \$400 to \$700 that CMS put forward in the draft guidance, CMS should also consider targeting different groups of beneficiaries at different times of the plan year. We encourage CMS to pursue further analysis and consider other scenarios to ensure that patients have a well-informed understanding of the program.

We specifically encourage CMS to consider the cost burdens borne by beneficiaries with high prescription drug costs at the end of a given plan year and adjust targeting and education efforts accordingly. For example, the draft guidance removes targeting for December prescription starts, regardless of cost, from the standard protocol for patient notification. We agree with CMS that there are limited benefits from opting into the program in the final months of the year. In fact, a significant cost-sharing “spike” in December, as shown in the example at the top of page 22 in the draft guidance, could be a hardship for beneficiaries and cause confusion if amounts become past-due and carry forward into the next year. However, CMS should also take additional steps and consider special communication materials for individuals opting into the program in September or later to ensure they are aware of their financial responsibilities and can prepare for a potentially high bill in December.

In addition, flexibility should be available throughout the plan year, including the ability to opt-out of the program and resume normal OOP payments, if they so choose.

Recommendations Related to Medicare Plan Finder and Explanation of Benefits (EOB)

Today, the Medicare Plan Finder is an effective tool for helping Medicare beneficiaries understand and evaluate their Part D coverage options based on their specific drug utilization and preferred pharmacy/pharmacies. The lack of references to Plan Finder in the draft guidance was a notable omission. We urge CMS to leverage and enhance this platform to reach large numbers of beneficiaries and their caregivers with customizable information about how the MPPP may work in advance of plan year 2025.

Additionally, during the plan year, CMS should consider targeted follow-up and outreach through the monthly EOB if cumulative OOP spending across multiple prescriptions exceeds the established targeting thresholds. This approach may be particularly beneficial if a patient fills multiple prescriptions on different days of the month where the pharmacy may not have full visibility into the cumulative OOP spend, but the patient may still benefit from the MPPP moving forward. In addition, we urge CMS to establish clear communications for EOB-based outreach and education.

II. Enable Real-Time Election at Point-of-Sale (POS) in 2025 (Section 70)

We appreciate the approach that CMS took in Section 70 of the draft guidance to address concerns with required beneficiary notices at pharmacies and the likely resulting demand for a real-time election option. We support the overall approach, which relies heavily on existing Part D program requirements in the Eligibility, Enrollment, and Disenrollment chapter of the Medicare Prescription Drug Benefit Manual.

While we appreciate the proactive request for comment on potential real-time approaches for 2026, we believe more can be done to facilitate rapid access to the MPPP’s benefits for 2025. Even with robust early education and outreach before the start of the plan year, there will always be circumstances where enrollees will need to make mid-year elections, such as when they are diagnosed with a new condition that requires a new prescription medication. Because some

mid-year elections will result from required plan and pharmacist notifications at POS, it would be ideal for beneficiaries to have access to the program's benefits in real-time, and to avoid the need to leave and return to the pharmacy to receive their prescription under the MPPP. If plan sponsors are required to notify enrollees at the pharmacy counter that they are likely to benefit from the program without also providing enrollees the option to enroll in real-time, enrollees may be confused and/or discouraged from enrolling later.

Even if real-time solutions for 2025 are limited to certain types of pharmacies (e.g., retail pharmacies only) or processes (e.g., telephone-only), these approaches would still benefit many patients and should be considered. AbbVie urges CMS to continue its work to implement rapid election procedures and options for real-time access to program benefits in advance of the 2025 plan year and refine these approaches in future years. A real-time election solution at the POS in the first year of the program would improve adoption and affordability for patients. It may also negate the need for other requirements laid out in this section of the draft guidance, including the retroactive election process described in section 70.3.6.

CMS already contemplates a real-time or near real-time POS election for 2026 or later in Section 70.3.9. We see no reason why this option cannot be implemented for 2025, if CMS works diligently with stakeholders to develop the necessary infrastructure. As noted before, implementation of this option in 2025 does not have to be perfect as a real-time enrollment option will be refined in future iterations.

In Section 70.3.9 of the draft guidance, CMS proposes three methods for real-time or near real-time POS election:

- Telephone-only
- Mobile or web-based application
- Clarification code

For purposes of 2025 implementation, the telephone-only option presents the most feasible path forward while building toward multiple options, including a mobile or web-based application, in 2026 and beyond. This approach would also allow for appropriate Part D sponsor and PBM coordination and communication on the election in real-time.

In conjunction with this telephone-only option, CMS describes previously in the draft guidance under section 50 a coordination of benefits (COB) approach to processing claims and billing the plan-specific BIN/PCN for the MPPP. We support this COB approach and recommend that CMS explore with Part D plan sponsors the possibility of requiring plans to pre-populate their unique MPPP BIN/PCN as part of every enrollee's prescription drug card. This would allow pharmacies to have this information readily available if, and when, an enrollee elects to opt-in to the MPPP at the POS. The enrollee could be "pre-activated" at the PBM but would not be considered enrolled in the MPPP until a pharmacy submits a COB claim to the specific MPPP BIN/PCN. The telephone option would allow the plan to verify that the enrollee in fact opted into the MPPP. CMS could also consider whether the third option outlined in the draft guidance, the clarification code, could be leveraged by the pharmacy with a new value to verify that a member has opted into the MPPP.

Sections 70.3.3 and 70.3.5 of the draft guidance also discuss requirements related to processing an enrollee election request during the plan year. We recommend that CMS require pharmacies to provide the overview of the program, examples of calculations, and general information about the low-income subsidy (LIS) program in a standardized form at the POS,

similar to how they provide the “Medicare Prescription Drug Coverage and Your Rights Standardized – Pharmacy Notice (CMS-10147)” today. The effective date of the enrollee’s election could then be provided by the plan sponsor in the following month’s EOB or in a separate communication to the enrollee through mail, email, text, or a separate application.

Alternative Approaches to Consider for 2025 & Beyond

The approach described above is the most viable path for a real-time POS election in 2025. However, we recognize that CMS may still need to explore other alternative options. One other option to consider is to follow the model of the real-time enrollment verification system that CMS established at the outset of the Medicare Part D program. It allows pharmacists to access, in real-time at the pharmacy counter, a beneficiary’s Part D enrollment status and benefit information even if the beneficiary was unable to present physical evidence of their enrollment. The process relies on a standard transaction (E1), and information exchanges between pharmacy “switches,” a transaction facilitator, and CMS. CMS could explore options for upgrading this technology to support real-time POS elections.

Another approach that CMS could consider is establishing a specific, one-time “transition fill” policy that applies in the following context: a Part D enrollee could convey to the pharmacist their intent to opt into the MPPP or provide an oral confirmation code after initiating the election, which would then trigger a one-time transition fill at \$0. The Part D plan would be expected to cover the OOP costs the patient would have otherwise paid, as is the case under the MPPP.

Beyond 2025, Part D enrollees should be provided with a range of mechanisms for opting into the program at the POS, including through an accessible mobile or web-based application. CMS should consider whether a standardized/uniform approach could be beneficial rather than requiring each Part D plan sponsor to develop their own application. This approach would have the added benefit of ensuring a consistent enrollee experience regardless of Part D plan.

III. Improve Beneficiary Protections Related to Billing, Terminations, and Appeals (Sections 40, 80 & 90)

Throughout the draft guidance, CMS relies on existing Part D procedures relating to billing, notification of delinquencies, termination, reinstatement, and appeals and grievances. In general, we support this approach since beneficiaries and their advocates may already be familiar with those practices. However, we do have specific recommendations for improvement in some areas.

With respect to billing, we note the guidance at Section 40 “encourages” Part D sponsors to offer multiple means of payment, and “encourages” plans to offer flexibility to request billing on a specific day of the month. It is unclear why these best practices are merely encouraged. To ensure a consistent beneficiary experience, we recommend adopting uniform standards. The guidance takes a standard approach (prohibition) to charging fees and interest payments to beneficiaries, which we support. We suggest the same standardization apply for billing and payment to ensure that enrollees have the maximum flexibility to receive bills and make payments.

We are also concerned with the potential for beneficiary confusion following termination of an election, whether voluntary or involuntary. Because plan sponsors ultimately can terminate a beneficiary from the MPPP due to non-payment, it is critical that all beneficiaries receive clear and consistent billing statements from their plan. These statements should be obviously



distinguishable from EOBs. If the two are combined, we would recommend including a payment voucher to make sure beneficiaries understand a payment is due. Any outstanding past due amounts also should be clearly delineated. We encourage CMS to develop a standard template for billing statements and to circulate it for review and comment by all stakeholders prior to finalizing. Upon opting into the program, and in general educational materials, beneficiaries should be provided with a model billing statement so it will look familiar when received.

Additional clarification is needed in Section 80.3 of the guidance, regarding subsequent plan year elections. As drafted, it is unclear whether a plan's ability to preclude an individual from opting into the payment plan might extend for multiple years. The statute at § 1860D-2(b)(2)(E)(v)((IV)(bb) of the Social Security Act permits a plan to "preclude the enrollee from making an election . . . in **a** subsequent year," (emphasis added). We believe Congress' use of the singular "a" and "year" clearly reflects an intent for a single-year prohibition, and we urge CMS to clarify this in the final guidance.

Finally, we are concerned that the high-level approach to disputes in Section 90 of the guidance leaves room for confusion and delay. Because the program requires monthly recalculation of amounts due, errors left unaddressed could snowball. At a minimum, we request additional information and examples from CMS as to how existing guidelines¹ might apply to foreseeable scenarios under the program. In most cases it would seem in the best interests of all to resolve disputes within 24 hours. Given that individuals opting into this program will be patients facing high OOP costs with relatively more complex needs, it would be reasonable to presume they are in need of expedited (24-hour) review in most if not all cases.

* * *

Thank you for the opportunity to provide feedback on implementation on this important program for patients. If you have any questions, please feel free to contact Ashley Flint, Director of U.S. Policy & Analytics, at ashley.flint@abbvie.com.

Sincerely,

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

¹ See <https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf>

September 20, 2023

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

Submitted electronically: PartDPaymentPolicy@cms.hhs.gov

RE: Medicare Prescription Payment Plan Guidance

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 One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, Solicitation of Comments*. ACAP is an association of 80 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 Special Needs Plans for dually-eligible individuals, include Fully Integrated and Highly Integrated Dual-Eligible Special Needs Plans.

First, we would like to thank CMS for all the work that the agency has done, and continues to do, to improve care for individuals dually eligible for Medicare and Medicaid. ACAP fully supports the Medicare Prescription Payment Plan's overarching goals. In this letter, we offer several recommendations to improve the implementation and operation of this program for D-SNPs and the dually eligible individuals they serve.

We respectfully submit the following comments for CMS' consideration. More detail on our comments is available in the expanded comments section below.

- **Considerations for LIS and dually eligible beneficiaries:**
 - Due to how Part D cost-sharing is proposed to be spread out over the year, we are concerned that an LIS enrollee who is enrolled in the MPPP, could experience higher cost-sharing in later months, if their cost-sharing in the early months of a year is shifted to the later months. We request that CMS address this concern and describe current, or develop new, processes that will prevent this higher cost-sharing in later months from occurring. We also request that CMS provide more specific examples and modeling of the impact of the MPPP on the LIS and dually eligible populations, including examples or profiles of LIS and dually eligible beneficiaries that will benefit from the MPPP. We also ask that CMS not initially require D-SNPs to conduct marketing and outreach to members enrolled in D-SNPs, including to enrollees with no monthly Part D cost-sharing (i.e., \$0 monthly Part D cost-sharing).

- We also ask that the MPPP program not apply if the cost-sharing for a particular drug is *de minimus*. Such instances would alleviate the administrative costs for those LIS beneficiaries who elect to participate in the MPPP.
- **Operational Considerations:**
 - Given the different and new claims that will need to be created for reconciling payment, and the fact that managed care organizations that only operate D-SNPs may not currently have existing billing capabilities for dually eligible and LIS enrollees, we respectfully request the following temporary flexibility in operational requirements for this program:
 - ACAP requests that CMS allow plans to modify bids through the summer of 2024 as they will need time to add a new service or contract with a collection agency (for non-payment); manage PBM and other entities' new admin fees; and to understand and incorporate these new costs; and
 - We request that CMS provide enforcement discretion regarding meeting the strict timelines associated with enrollment and payment for at least plan year 2025, and that CMS extend the 24-hour election processing time to 2 or 3 business days.
- **Beneficiary Education and Enrollment:**
 - To assist Part D beneficiaries in making an informed decision about MPPP participation, we suggest that CMS create an online calculator and/or paper-based tool that could help individuals understand whether the MPPP will be beneficial to them.
 - We also note that it may not always be feasible for pharmacists to engage a beneficiary at the point-of-service or for D-SNPs to monitor and ensure that these conversations are occurring.
 - ACAP encourages CMS to consider how plan materials should be updated so that members are not confused by the charges and payments associated with the MPPP program. We recommend that CMS develop suggested language and templates for MPPP monthly bills as this may be a point of confusion for dually eligible beneficiaries, at least in the early years of the program.
 - With respect to beneficiary outreach and enrolment, ACAP supports several of the proposed policies for enrollment, including that members elect participation each year, that plans have no requirement to facilitate the continuation of the MPPP if the member elects a new Part D plan, and limiting member-specific outreach to beneficiaries with one or more high-cost OOP obligations. However, we are concerned with a plan's ability to implement retrospective enrollment in 2025 via the urgent enrollment election proposal, and we ask for flexibility for D-SNPs in implementing this provision.
- **Billing and Collection:**
 - We request additional guidance on how plans should proceed with unpaid MPPP balances, and for CMS to confirm that plans can continue billing members with outstanding balances following the end of the plan year, not just for mid-year disenrollments.
 - ACAP also requests CMS to provide guidance on how non-payments should be accounted for in bids and MLR reporting.
- **Potential Impact on Quality Measures:**

- As previously discussed, ACAP is concerned about unintended consequences of the MPPP on dually eligible beneficiaries' cost-sharing as well as beneficiary confusion that may occur during the early years of the program. These unintended consequences and confusion could negatively impact a D-SNPs' Star Rating, particularly on CTM and CAHPS. It is unknown whether the effects on measures will be similar across all MA-PDs, or whether D-SNPs will be affected differently. We ask that CMS develop mechanisms to hold plans harmless, such as by creating a new CTM category for MPPP-related complaints.
 - We also ask CMS to investigate whether MPPP enrollment has any effect on Part D CAHPS measures and to conduct analysis on Part D CAHPS measures and determine if a hold-harmless provision is appropriate for the 2026 Star Ratings.
- **Timeline of Guidance Releases & Implementation:**
 - Looking toward the proposed start date of January 1, 2025, and the extent of details that will need to be considered before implementation, we ask that CMS provide plans with the necessary information with enough advance time. With this in mind, we respectfully propose a detailed timeline in the expanded comments section of this letter.

Expanded Comments

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

Concerns about the MPPP Impact on Out-of-Pocket Costs for LIS/Duals Population

ACAP's D-SNP members exclusively serve individuals dually eligible for Medicare and Medicaid, and predominantly the full-benefit dually eligible population. As CMS noted in its guidance, almost all of these individuals are LIS-eligible and thus have very little Part D cost-sharing. **Because of how cost-sharing is proposed to be spread out over the year under the MPPP, we are concerned that an LIS enrollee enrolled in the MPPP could incur higher cost-sharing in later months than they would absent the MPPP, if their cost-sharing in the early months of a year is shifted to the later months.** We request that CMS address this potential concern and describe current, or develop new, processes that will prevent this higher cost-sharing for LIS enrollees from occurring in later months. We also request that CMS provide more specific examples and modeling of the impact of the MPPP on the LIS and dually eligible populations, including examples or profiles of LIS and dually eligible beneficiaries that will benefit from the MPPP.

Given the potential for higher cost-sharing for LIS and dually eligible individuals under the MPPP, we also ask CMS to not require D-SNPs to conduct marketing and outreach to members enrolled in D-SNPs, particularly enrollees with no monthly Part D cost-sharing (i.e., \$0 monthly Part D cost-sharing). This would include the option to leave MPPP information off annual enrollment forms for D-SNP enrollees. While this would not prevent a D-SNP enrollee from electing to participate in the MPPP, it would dramatically reduce those who chose participation because they do not understand its interaction with the LIS program. Additionally, if somehow the D-SNP enrollee could benefit from the program, they could be made aware of that benefit through the mid-year "likely-to-benefit" outreach.

Second, we note that there is a cost to administer this program for these beneficiaries; these costs reduce investments plans can make to support dual-eligible beneficiaries in other areas (e.g., additional benefits, quality programs, or improved networks). As such, we ask that the MPPP program not apply if

the cost-sharing for a particular drug is *de minimums* (e.g., less than \$10 or the cost-sharing associated with generic 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.

Operational Considerations

Given the different, new claims that will need to be created for reconciling payment, as well as the new billing processes, payment systems, and collection processes that will be needed to support the MPPP program, we are seeking temporary flexibility in operational requirements for this program. Specifically, this program will require systems changes (enrollment file formats to indicate a new cost-share type and NCPDP changes so pharmacists are aware of the election at point of sale, etc.) and new processes (plans will need to build education tools, billing and collecting processes, enrollment/election processes, etc.). We also note that managed care organizations that only operate D-SNPs may not currently have any existing billing capabilities for beneficiaries as there are limited premiums and cost-sharing for most D-SNPs.

To better assist plans during this transition, we ask for several accommodations for the 2025 benefit year. First, we ask that CMS allow plans to modify bids through the summer of 2024 as they will need time to add a new service or contract with a collection agency (for non-payment); manage PBM and other entities' new admin fees; and to understand and incorporate these new costs. Second, we ask that CMS provide enforcement discretion regarding meeting the strict timelines associated with enrollment and payment for at least plan year 2025 (and perhaps beyond based on plan experience). We believe while plans will operate in good faith to meet the proposed timelines, there may be unforeseen operational challenges that will need to be resolved early in the implementation process. Third, we ask that CMS extend the election processing timeframe from 24 hours to at least 2 or 3 business days. Plans will have to communicate about the change in the enrollees' cost-sharing with pharmacies via an enrollment change. Such enrollment changes generally take longer than 24 hours to process.

Lastly, we request efforts by CMS, in partnership with plans and standards organizations, to simplify and standardize claim transactions for OOP payments. Front end work to align all stakeholders will help minimize operational complexity and administrative burden for pharmacies, Part D plans and PBMs. Standardized claim processes would also ensure consistency in the calculation and tracking of the smoothing payments. We also suggest that CMS consider rulemaking to address the backend process that will be needed to simplify, streamline, and expedite the process of effectuating participation (i.e., NCPDP updates).

Beneficiary Education and Enrollment

We thank CMS for providing flexibility to tailor the MPPP for those most in need/likely to benefit through targeted education campaigns. To assist Part D beneficiaries in making an informed decision about MPPP participation, we suggest that CMS create an online calculator and/or paper-based tool that could help individuals understand whether the MPPP will be beneficial to them. We note that the tool would need to enable beneficiaries to enter their monthly out-of-pocket costs (either actual or estimated) for each month of the year. The tool would then use this information to demonstrate to the beneficiary what their monthly cost-sharing would be under the MPPP. To improve beneficiary

education, the tool could include infographics or other visual displays that demonstrate to dually eligible beneficiaries how the MPPP works under different scenarios.

In addition, while we support using high-cost prescriptions to identify those likely to benefit from the MPPP, we are concerned with CMS' expectation that D-SNPs ensure pharmacies inform enrollees who are likely to benefit from the program. Current contractual relationships between D-SNPs and pharmacies may not enable this level of oversight and given the existing burdens on pharmacies, it may not always be feasible to engage a beneficiary at the point-of-service. One suggestion to alleviate burden on pharmacists is for CMS to develop information or language that pharmacists could hand out to beneficiaries at the point-of-service.

Moreover, we encourage CMS to consider how plan materials should be updated so that members are not confused by the charges and payments associated with the MPPP program. We also would like suggested language and templates for MPPP monthly bills as again, this may be a point of confusion—at least in the early years of the program. Beneficiary focus groups could help CMS with the creation of appropriate materials.

With respect to beneficiary outreach and enrollment in the MPPP program, ACAP supports several of the proposed policies for enrollment, including that members elect participation each year, that plans have no requirement to facilitate the continuation of the MPPP if the member elects a new Part D plan, and limiting member-specific outreach to beneficiaries with one or more high-cost OOP obligations. However, we are concerned with a plan's ability to implement retrospective enrollment in 2025 via the urgent enrollment election proposal, and we ask for flexibility for D-SNPs in implementing this provision.

As CMS continues to provide guidance and other materials for the implementation of this program, we ask that CMS provides information on any flexibilities that plans are allowed on model materials. Specifically, our member plans would appreciate the ability to tailor some of the program language to the needs of their 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.

Billing and Collection

As stated above, ACAP is very concerned that those with high MPPP balances at the end of the year will be unable to pay and/or feel unduly stressed by this burden. We ask CMS to confirm that plans can continue billing members with outstanding balances following the end of the plan year, not just for mid-year disenrollments. Moreover, we request additional guidance on how plans should proceed with unpaid MPPP balances, without having to engage a collection agency. For example, we request clarification on whether plans should apply similar guidelines for non-payment of smoothing costs that are applicable to cases involving non-payment of premiums, and whether plans have any discretion for forgiving bad debt over time.

Lastly, we ask that CMS provide guidance on how non-payments should be accounted for in bids and MLR reporting. Specifically, we request that CMS provide flexibility for good faith loss estimations in bids until historical data can be established. Additionally, we request that CMS specify that non-payment is still counted as a medical expenditure for MLR purposes. We also request that CMS consider reimbursing plans for losses that are incurred due to the MPPP in the early year of the program until

plans have sufficient experience with the program to develop accurate assumptions in their bids. Finally, we request that CMS clarify whether modifications will be needed to the EOB/QEOB for MPPP participants.

Potential Impact on Quality Measures

As previously discussed, ACAP is concerned about unintended consequences of the MPPP on dually eligible beneficiaries' cost-sharing as well as beneficiary confusion that may occur during the early years of the program. We are also concerned that the unintended consequences and confusion may negatively impact a D-SNPs' Star Rating. 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 MA-PDs, or whether D-SNPs will be affected differently. Therefore, in instances where Star Ratings may be affected as a result of the MPPP, we ask that CMS develop mechanisms to hold plans harmless. For example, CMS could create a new CTM category for MPPP-related complaints. CMS could then analyze the effect 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 effect 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 analysis on Part D CAHPS measures and determine if a hold-harmless provision is appropriate for the 2026 Star Ratings.

Timeline of Guidance Releases & Implementation

Looking toward the proposed start date of January 1, 2025, and the extent of details that will need to be considered before implementation, we ask that CMS provide plans with the necessary information with enough advance time. With this in mind, we suggest the following proposed timeline:

- Fall 2023 to Feb 2024
 - *Finalize all guidance that is necessary for MPPP implementation.* Because of the operational requirements that will need to be built, if the requirements are not finalized before February, we believe additional time will be needed for implementation.
 - *Release any model materials that can be finalized.* We ask that CMS work to release model materials as soon as practical.
- February to May 2024
 - *Implement any necessary changes to the enrollment files and NCPDP.*
- April 2024
 - *Final bid and financial impact information (including MLR impacts) provided to plans in the final Rate Notice/2025 MAPD final rule.*
- June 3, 2024

- *CY 2025 Part D bids and formularies due to CMS.* To implement a smoothing program, plans will need to add a new service or contract with a collection agency (for non-payment). PBM and other entities will also incur admin fees. We will need additional time to understand and incorporate these new costs. Therefore, we urge CMS to allow plans to modify bids through the summer of 2024 to account for these expenses.
- January 1, 2025
 - *Policy go-live with 1 year enforcement discretion to allow us to address any identified issues because the timeline does not allow for sufficient testing.*

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

Sincerely,

/s/

Margaret A. Murray
Chief Executive Officer
Association for Community Affiliated Plans



September 20, 2023

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

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

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 ensuring the cost of prescription drugs is not a barrier to care and lowering the price of drugs for all Americans. 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 members recognize 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. As our member companies operationalize this new option, three main challenges arise: (1) operational challenges and intricacies, (2) enrollment and disenrollment issues and (3) billing and payment processing.

Operational Challenges and Intricacies

Operationalizing the Medicare Prescription Payment Plan (MPPP) will require building new infrastructure. The timing outlined in the draft guidance presents significant challenges for updating systems to meet expectations. Ideally, CMS would provide final guidance including models and standardized language by May 2024 to meet the timelines for renewal materials, outreach and January 2025 readiness. Additionally, we request CMS develop standardized communication to assist in



conveying program details to beneficiaries. Health plans should have consistent communication with consumers about the details of how payments are applied, the prioritization of premium payments, and the consequences of failure to pay.

Enrollment and Disenrollment Issues

In 70.3.5, CMS proposes to establish a 24-hour requirement for processing election requests during the plan year. While we admire the goal of avoiding delays in dispensing drugs, the turnaround time is not feasible for the majority of plans working with limited resources. We request three business days to process an enrollment, set it up within a plan system and communicate with additional parties such as pharmacy benefit managers. The guidance should be based on business days rather than hours.

We also request additional guidance on program eligibility. The threshold dollar amount that consumers meet within the first three months of the year to determine eligibility is unclear on whether it is based on actual spend, or expected spend, as well as single bill or total monthly expected spend. Clearer guidance on eligibility will assist plans in predicting those likely to benefit and preparing for enrollment.

Billing and Payment Processing

The amount of drug and other information needed to process claims is complex and will require a significant amount of time, effort and financial commitment to build and test the system. Additional guidance and support is requested on the logistics of billing and payment. Given the number of changes that will be needed to implement MPPP, we request limiting program charges and bank account withdrawals to the first or fifteenth of the month for some stability. The Part D plan is also at financial risk based on the current guidance. For example, there is the risk of a consumer passing away or switching plans while they have an outstanding balance on their payment plan. Additional definitions and guidance are needed for collection expectations and requirements, the overlap with existing rules about prioritizing outstanding premium and plan authority to collect unpaid balances.

We appreciate the continued engagement with you and members of your team and look forward to working with you to ensure the success of the Inflation Reduction Act. Please contact Michael Bagel, ACHP Associate Vice President of Public Policy, at mbagel@achp.org or (202) 897-6121 with any questions.

Sincerely,

Dan Jones

Dan Jones



Senior Vice President, Federal Affairs
Alliance of Community Health Plans



September 20, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, D.C. 20201

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

Re: Draft Part One Guidance on Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans

Dear Administrator Brooks-LaSure and Deputy Administrator Seshamani:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the first draft guidance related to the maximum monthly cap on cost-sharing payments under 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.

ACS CAN strongly advocated for inclusion in the *Inflation Reduction Act* of both an annual cap on total Part D out-of-pocket costs and a mechanism that would allow an enrollee the option to pay the required cost-sharing in capped monthly installments because we know from research that high out-of-pocket costs can decrease medication adherence, which results in negative health outcomes.¹ We appreciate CMS' release of the draft guidance, which is instructive for the first year of implementation of the Medicare Prescription Payment Plan. We strongly encourage CMS to actively monitor implementation of the Medicare Prescription Payment Plan in real time and use the lessons learned to revise the guidance accordingly in future years. We offer the following comments on the draft guidance:

20. Overview

We appreciate that CMS has conducted extensive consumer testing regarding the appropriate naming of the "maximum monthly cap" or "smoothing" program. This testing has resulted in CMS referring to the program as the "Medicare Prescription Payment Plan." We believe this title accurately provides a description of the program and will be easily understood by beneficiaries. We would encourage CMS to retain this name.

40. Participant Billing Requirements

We appreciate CMS' clarifying that Part D sponsors must offer participants multiple methods of payment, including an electronic funds transfer mechanisms (such as automatic charges of an account at a financial institution or credit or debit card account) and payment by cash or check. CMS is also encouraging Part D sponsors to offer participants flexibility to choose a specific day of the month for program charges. We support

¹ Dusetzina SB, Winn AN, Abel GA, Huskamp HA, Keating NL. Cost sharing and adherence to tyrosine kinase inhibitors for patients with chronic myeloid leukemia. *K Clin Oncol*. 2014; 32:302-311; Nekhlyudov L, Madden J, Graves A, Zhang F, Soumerai S, Ross-Degnan D. Cost-related medication nonadherence and cost-sharing strategies used by elderly Medicare cancer survivors. *J Cancer Surviv*. 2011;5:395-404.

these clarifications – particularly as they relate to allowing individuals the opportunity to choose a specific day of the month for which program charges will be deducted from the individual’s account. We also encourage CMS to permit individuals the option to have their Medicare Prescription Payment Plan cost sharing obligations deducted from their Social Security checks (which is also an option for Part D premiums)

CMS also provided a list of information that Part D sponsors need to include on billing statements, which are to be provided to individuals. We strongly support the list of required elements. We would also encourage CMS to require the inclusion of some additional information:

- Information on Medicare.gov and 1-800-MEDICARE, which can provide individuals with non-biased information about the Medicare Prescription Payment Plan and information on how to contact a Medicare State Health Insurance Assistance Program (SHIP) counselor who can provide one-on-one information.
- Information on how the participant can change their method of payment. Individuals may initially choose to pay via credit card and may later opt for a different method of payment.
- For individuals who have met their annual out-of-pocket cap, clear information noting that the individual’s monthly out-of-pocket costs will not increase over the course of the year.
- For individuals who have not met their annual out-of-pocket cap, clear information noting that the individual’s monthly out-of-pocket costs may increase if the individual takes additional prescription drugs, but in no case will their out-of-pocket costs exceed the value of the annual cap (which is \$2,000 in 2025).

60. Requirements Related to Part D Enrollee Outreach

The draft guidance notes that “CMS will develop tools (e.g., model documents and training materials) to help Part D enrollees decide whether the program is right for them.”² We very much appreciate CMS’ efforts and welcome the opportunity to work with CMS to better educate enrollees, their families, and other stakeholders about the Medicare Prescription Payment Plan option. As CMS conducts outreach and education, we strongly encourage the Agency to use the Medicare Plan Finder tool as one means to educate individuals. Just as the Plan Finder currently estimates an individual’s monthly out-of-pocket costs for selected drugs under a given plan, the Plan Finder could provide an estimate of the individual’s monthly out-of-pocket costs if the individual were to select to enroll in the Medicare Prescription Payment Plan.

60.2.3 Targeted Part D Enrollee Notification at POS

The statute requires Part D sponsors to have a mechanism to notify a pharmacy when a Part D enrollee is likely to benefit from participating in the Medicare Prescription Payment Plan. We appreciate the modeling CMS has conducted to help determine which individuals are “likely to benefit” but we caution that the trigger should not be based on a single prescription counting towards a potential threshold. Enrollees in the Part D program are a diverse group and have different financial situations which vary considerably from individual to individual.

70. Requirements Related to Part D Enrollee Election

70.3.5 Processing Election Request During a Plan Year

We strongly support CMS’ proposal to establish a 24-hour requirement for processing election requests during the plan year. We agree this timeframe is operationally feasible for plans given that it is consistent with existing

² Draft guidance, page 19.

requirements for the processing of expedited coverage requests.

70.3.8 Standards for Urgent Medicare Prescription Payment Plan Election

CMS is requiring Part D plans to have a process to allow individuals to retroactively elect to enroll in the Medicare Prescription Payment Plan when they have urgent prescription drug fills for which they paid the corresponding cost-sharing before the individual's election was received and processed. Under the process, individuals must request retroactive election within 72-hours of the adjudication of the claim.

We are concerned that under the proposal, individuals are still required to pay at the point of sale the cost sharing corresponding to their prescription drugs and would not be assessed cost-sharing provided under the Medicare Prescription Payment Plan option. While individuals would be permitted to retroactively seek reimbursement from their Part D plan, this policy would still require individuals to incur large up-front costs, which can create a financial hardship for many individuals and cause them to decline filling prescriptions. We are also concerned that under the proposal, Part D sponsors have 45 days to reimburse the individual. We believe this timeframe is too long and imposes an undue burden on individuals. We would recommend that CMS consider a timeframe of 14 days in which the Part D plan has to process reimbursement to the individual.

We encourage CMS to allow individuals to enroll in the Medicare Prescription Payment Plan at the point of sale. This would obviate the need for an urgent election process.

70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs

We are disappointed that CMS is not allowing individuals to enroll in the Medicare Prescription Payment Plan option at the point of sale, regardless of whether an enrollee chooses to fill their prescription via mail order or a brick-and-mortar pharmacy. We believe that allowing individuals to enroll at the point of sale is the best option for individuals to benefit from this program. We strongly encourage CMS to reevaluate the feasibility of a point-of-sale enrollment process beginning in 2025.

80. Procedures for Termination of Election, Reinstatement, and Preclusion

We seek clarification in cases where an individual is enrolled in the Medicare Prescription Payment Plan but dies in the middle of the plan year. We are not aware of an instance within the Medicare program where the individual's estate would bear responsibility for cost-sharing obligations. We therefore assume that in cases where an individual dies in the middle of the plan year (or owing any cost-sharing obligation under the Medicare Prescription Payment Plan) that the plan sponsor and/or the Medicare program bear responsibility for those costs. We urge CMS to provide clarification.

80.2 Involuntary Terminations

CMS is requiring plan sponsors to provide specific notices to individuals who fail to pay a monthly billed amount. CMS requires Part D sponsors to provide a grace period of at least 2 months before the individual can be terminated from the Medicare Prescription Payment Plan.

We appreciate CMS modeling the involuntary termination requirements of the Medicare Prescription Payment Plan program after those of non-payment of Part D premiums. As noted above, we urge CMS to allow individuals the option to have their cost sharing deducted from their Social Security checks. Current CMS regulations³ prohibit Part D plans from disenrolling individuals who elect to have their Part D premiums directly deducted from their Social Security check and we encourage CMS to adopt a similar prohibition for individuals who elect to have their cost sharing obligations under the Medicare Prescription Payment Plan deducted from their Social

³ 45 C.F.R. § 423.44(d)(v).

Security check.

80.3 Preclusion of Election in a Subsequent Plan Year

The statute provides that Part D sponsors may preclude an individual from opting into the Medicare Prescription Payment Plan in a subsequent year if the individual fails to pay the amount billed as required under the program. We urge CMS to clarify this prohibition lasts for a single year and that an individual would be permitted to enroll in the Medicare Prescription Payment Plan in subsequent years.

CMS is proposing that a Part D sponsor that offers more than one Part D plan may have different preclusion policies for its different plan but must apply the same policy to every participant in the same plan. We are concerned that this could lead to confusion among individuals. We urge CMS to encourage Part D sponsors maintain standard preclusion policies.

90. Participant Disputes

CMS is requiring that each Part D sponsor must provide meaningful procedures for the timely hearing and resolution of grievances between Part D enrollees and Part D plan sponsors. However, CMS fails to articulate specific timeframes associated with disputes related to the Medicare Prescription Payment Plan program. The Medicare appeals process is complicated.⁴ We urge CMS to clarify specific timeframes and amend sections 30 and 40 of the Parts C&D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance accordingly.

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.

Sincerely,



Lisa A. Lacasse, MBA
President

American Cancer Society Cancer Action Network

⁴ See American Cancer Society Cancer Action Network. The Medicare Appeals Process: Reforms Needed to Ensure Beneficiary Access. Nov. 17, 2020. Available from: <https://www.fightcancer.org/sites/default/files/Medicare%20Appeals%20Paper%20FINAL.pdf>.



Connecting Older Adults with Community-based Resources and Options

September 19, 2023

Chiquita Brooks-LaSure, Administrator
United States Department of Health and Human Services
Centers for Medicare and Medicaid.

Dear Administrator Brooks-LaSure:

Thank you for the opportunity to provide input regarding the 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 Comment. AgeOptions is the Area Agency on Aging serving suburban Cook County Illinois surrounding the City of Chicago.

Section 60 – Requirements Related to Part D Enrollee Outreach

AgeOptions encourages developing language and messaging that is straightforward and easy to understand. CMS should consider investing and partnering with communication experts familiar with the Medicare population to tailor messaging around the program so beneficiaries and the professionals who work with them understand how this program works.

AgeOptions strongly support Part D sponsors reaching-out to plan enrollees with a history of high cost prescriptions and providing them with education during the open enrollment period about how the Medicare Prescription Payment Plan may assist them so they are able to take advantage of the program and spread- out their costs for the entire following plan year.

AgeOptions also suggests providing specialized and ongoing education and outreach to disease-specific organizations, providers, and pharmacies that assist beneficiaries who take high-cost prescriptions so they can relay information about the program to their patients. This includes standardized model notices, outreach materials, and communication notices sent to program participants that includes language that an enrollee's **monthly payment cap may change** if they fill additional or new covered drugs at any point during the year. This special communication should be sent to participating program enrollees that switch plans mid-year that explains how they will continue to be liable for payments to their prior Part D plan. If the beneficiary chooses to opt-in to the program with a new plan mid-year, the notice should explain that the payments under the new plan may be different since cost sharing structures vary by plan.

Section 70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs

Real-time or near-real time POS election should be utilized for beneficiaries that have high prescription drug cost sharing amounts and for beneficiaries who accrue costs earlier in the year to allow the program's payment structure to be beneficial. In addition, beneficiaries who are enrolled at the POS should be provided with a detailed explanation of the program so they are aware that despite not having a co-pay at the POS, they are liable for the payments in subsequent calendar months.

The Area Agency on Aging in Suburban Cook County, since 1974

AgeOptions
1048 Lake Street, Suite 300
Oak Park, Illinois 60301-1102

Phone (800) 699-9043
(708) 383-0258
Fax (708) 524-0870

www.ageoptions.org

70.4 Mid-Year Plan Election Changes

Enrollees that choose to opt-in later in the year should be notified that enrollment in the program may not be of benefit to them since their drug cost sharing will not be spread out over enough months. In addition, enrollment during the month of December should not be allowed since it will not benefit an enrollee.

If AgeOptions can be of any further service, please let us know. We take our role as defined in the Older Americans Act seriously in advocating for the health, welfare and safety of older Americans.

Sincerely,



Diane Slezak
CEO and President

September 20, 2023

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

Submitted via email to: PartDPaymentPolicy@cms.hhs.gov

Dear Dr. Seshamani:

AHIP appreciates the opportunity to provide feedback on the draft part one 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.¹

The MPPP allows 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 is a fundamental change to the administration of the Part D benefit. It presents significant financial and operational uncertainties to Part D sponsors, especially when combined with other statutory changes as outlined in the IRA as well as other regulatory changes. Part D sponsors must be able to appropriately estimate impacts, understand operational implications and dependencies, and implement changes in ways that minimize costs to the program and potential disruptions to Part D enrollees and MPPP participants. **As discussed in more detail below, we are urging CMS to finalize all relevant MPPP guidance, release for comment a re-calibrated risk adjustment model, and publish model materials for the MPPP, on a faster timeline than CMS has indicated. This should also include guidance on bids and potential plan losses.**

We appreciate the detailed topics addressed and examples provided in the part one guidance, along with provisions designed to address certain operational realities for the start of the program. For example, we support CMS' approach to an electronic claims processing methodology to facilitate the processing of claims for MPPP participants, utilizing the BIN/PCN model. We also support not requiring Part D sponsors to retroactively include under the program paper claims submitted to the Part D sponsor by an MPPP participant. We also appreciate CMS' recognition that it is not feasible to implement real-time or near-real-time POS elections beginning in 2025.

¹ Visit www.ahip.org to learn how working together, we are Guiding Greater Health.

We also have a number of recommendations relating to the part one guidance. For example:

- AHIP remains concerned about the potential for enrollee confusion. **We strongly recommend that CMS develop and release a national communications strategy and associated materials to guide both general and targeted outreach.** Enrollees need to understand the financial implications of participating in the MPPP – including whether they are likely to benefit from participating in the program – to inform decision-making. AHIP agrees that it is important to target communications and outreach to enrollees most likely to benefit from participating in the MPPP. Communications also should address individuals unlikely to benefit, such as those receiving low-income subsidies. Targeted outreach prior to the plan year will be critical to try to limit the need for POS notifications, as POS processes can create operational challenges for pharmacies. Moreover, there should be an attempt as much as possible to avoid the operational complexities associated with mid-year enrollments into the MPPP.
- As noted, real-time or near-real-time POS elections cannot be implemented beginning in 2025. **However, we urge CMS to extend the processing timeframe for election requests made by an enrollee during the plan year from 24 hours to at least 72 hours for 2025. We also urge that the requirement for retroactive elections be made optional.**
- We are concerned with the mandate in the guidance that MPPP bills be sent separately from monthly billing statements for Part D premiums. **We encourage CMS to allow Part D sponsors flexibility to send a single monthly bill that clearly shows monthly premium amounts owed, any cost sharing amounts owed for the prior month under the MPPP (including any past due amounts), and the total amount owed to the plan for the month.**
- Given the operational complexities of this program, **we recommend that CMS apply enforcement discretion for good faith efforts made by plans for the first year of the program.**

Our attached detailed comments address these specific recommendations as well as other recommendations in response to the draft part one guidance. 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,



Mark Hamelburg
Senior Vice President, Federal Programs

Section 10 – Introduction

CMS indicates that the draft part one guidance for operationalizing the Medicare Prescription Payment Plan (MPPP) released on August 21, 2023, will be finalized by spring 2024, after consideration of public comments. Additionally, CMS plans to issue part two guidance, model language and supporting materials in draft form by early 2024 and expects to finalize the additional MPPP guidance in spring or early summer 2024. The draft part two guidance is expected to cover Part D enrollee education and outreach, monitoring and compliance, bids and potential plan losses and other policy topics. CMS also notes that the MPPP applies to all Part D sponsors, including employer group waiver plans (EGWPs).

AHIP Recommendation: We appreciate CMS' plans to issue guidance on the MPPP and related materials in draft form for public comments. However, we are concerned about the timelines for issuance of draft and final guidance. Plans will need sufficient lead time to comment on draft documents and operationalize final guidance, model documents and other communication materials. We urge CMS to modify its timelines as recommended below.

Specifically, we recommend that before the end of 2023, CMS should:

- **Provide final part one guidance and draft guidance on bids and potential plan losses** by no later than December 31, 2023. **Due to the level of uncertainty of financial liability, we urge CMS to provide detailed, draft guidance on bids and potential plan losses as soon as possible.**
- **Issue the re-calibrated risk adjustment model** to reflect the IRA Part D redesign for public comment and finalize the model by December 1, 2023.
- **Issue the draft part two guidance** with a comment period by no later than December 31, 2023.
- **Develop a uniform, national communications strategy** to educate Medicare enrollees and others about the MPPP. During the fourth quarter of 2023, CMS should also work with AHIP, our member plans, and others on developing and rolling out initial communications.

Additionally, we recommend that CMS issue the part two guidance and draft model materials and finalize them by April 1, 2024, to ensure that plans have sufficient lead time to operationalize revisions to existing beneficiary materials, including any new required language. Given the variety and volume of plan documents (e.g., Annual Notice of Change (ANOC), Evidence of Coverage (EOC), Explanation of Benefits (EOB)) that need to be modified, plans will need a minimum of six months lead time to make changes to these documents in time for the Fall 2024 annual enrollment period (AEP) for plan year 2025. In recent years, CMS has released model materials in late spring with corrections being issued in the summer. The delayed issuance and subsequent re-issuance of model documents disrupts the document development and production activities that plans must coordinate with their business partners. These disruptions increase administrative costs and could result in delayed mailings of beneficiary materials needed for the AEP.

Further, we recommend that as part of the agency’s uniform, national communications strategy, CMS develop and provide message guides and call scripts by April 1, 2024, for use by plans and others so that the messaging about this program is consistent to minimize beneficiary confusion.

Finally, we agree that the MPPP is applicable to all Part D sponsors, including EGWPs, but we believe that CMS should apply its waiver authority for EGWPs during the initial years of this program, at a minimum. EGWPs provide millions of individuals with a seamless transition to retiree coverage that is more consistent with the benefits they received as active workers. EGWPs generally offer lower overall out-of-pocket (OOP) costs, including for prescription drugs. Individuals enrolled in EGWPs are therefore not likely to benefit from the MPPP and the costs for operationalizing the MPPP could have adverse impacts on benefits and/or premiums for those covered under EGWPs. **We recommend that CMS use its waiver authority for EGWPs for the initial years of the program.**

Section 20 – Overview

To help inform the next phase of draft guidance, CMS seeks comments on: which model documents or other materials would be helpful for CMS to update and develop for interested parties; ways to most effectively conduct outreach and education to interested parties about the program; how to leverage existing resources and information, including the State Health Insurance Assistance Program (SHIP); and how to communicate about overlapping programs (e.g., low-income subsidy (LIS) and Medicare Savings Programs).

AHIP Recommendation: We appreciate CMS’ request for feedback on ways to educate Part D enrollees about the program. As indicated above, we recommend that CMS develop a uniform, national communications strategy to educate Medicare enrollees and others about the MPPP. CMS should work with AHIP, our member plans, and other stakeholders on developing and rolling out initial communications. There are also a number of plan documents that CMS should revise to include information about the MPPP. As previously mentioned, these documents include the ANOC, EOC and EOB. We also recommend that CMS update the Medicare & You Handbook and the Medicare Plan Finder tool to inform enrollees and others about the program. The use of on-line educational videos would be helpful and effective. Informational pamphlets that could be provided to pharmacies and provider offices would help to raise awareness and educate enrollees and others about the program. Given the complexity of this program, model language and messaging guides should not only be provided to plans but broadly distributed to other stakeholders including pharmacies, providers, SHIP counselors, and agents and brokers. **Encouraging use of uniform communications with beneficiaries about the MPPP would help to promote consistent terminology and messaging.**

Section 30 – Program Calculations and Examples

CMS explains how an individual’s maximum monthly cap is calculated in the first month the individual is enrolled in MPPP for a given year and the maximum monthly cap calculations for each subsequent month.

30.3 Example Calculations

CMS provides examples of how an individual's maximum monthly cap is calculated for the first month of enrollment and each subsequent month under several different scenarios in the main body of the guidance, and offers additional examples in Appendix B.

AHIP Recommendation: AHIP appreciates the examples CMS provides for how plans are to calculate the maximum monthly cap for an MPPP participant under various circumstances. We have identified additional scenarios for which calculation examples would be helpful, as shown below. In addition, **we urge CMS to continue sharing example calculations with plans as the agency identifies additional situations that could impact how the maximum monthly cap is calculated.** Requested examples include:

- Billing updates due to claims reprocessing or adjustments, such as LIS status changes or reversals
- Calculations for specific plan types including enhanced plans, EGWPs, Medicare as secondary payer, and other secondary insurance
- A beneficiary financial assistance program covers OOP costs that are not included in the calculation of an individual's true out-of-pocket (TrOOP) expenses
- A beneficiary financial assistance program covers OOP costs that are included in the calculation of TrOOP (per CMS guidance)
- Situations involving LIS enrollees
- Additional examples and further details on calculations for beneficiaries with State Pharmaceutical Assistance Program (SPAP) coverage

Section 40 – Participant Billing Requirements

CMS specifies that Part D sponsors must bill MPPP participants monthly for amounts due under the program, encourages sponsors to offer flexibility on a specific day of the month for program charges and automatic withdrawals, and lays out information that must be included on the monthly billing enrollment. CMS also notes that fees are not permitted under the program.

AHIP Recommendation: **We ask that CMS allow Part D plan sponsors to use existing billing practices and systems that allow for limited choice in when an individual's payments are due.** For example, sponsors that currently allow an individual to choose whether automatic withdrawals occur on the 1st or 15th day of each month should be allowed to continue this practice. Requiring sponsors to offer flexibility beyond this will make the program more difficult to implement, as it may require adding additional system capabilities, and be more complex to administer. **We urge CMS not to finalize requirements that plans allow MPPP participants to choose which day of the month their program payments would be due, but allow plans to use systems already in use for payment of premiums and other financial obligations.**

We also ask that CMS provide additional clarification surrounding application of any fees resulting from the program, such as returned check fees that may be applied if an individual's bank account has insufficient funds to cover a check used to pay amounts owed under the MPPP. Such fees reflect added costs incurred by Part D sponsors in dealing with the financial institution

and are standard practice in many financial transactions. Further, plans should be given flexibility as to debt collection activities, in accordance with state and federal laws.

Finally, we suggest that CMS conduct focus group testing of the monthly billing statement with Part D enrollees to identify the most effective and understandable ways to present information about the MPPP, amounts owed, payment options, and other required information. The amount of information CMS proposes for inclusion on the monthly billing statement exceeds what is typically provided on such statements.

40.1 Prioritization of Premium Payments

CMS specifies that plans must send a separate bill for amounts owed under the MPPP and any premium amounts owed.

AHIP Recommendation: We are concerned with the mandate in the guidance that MPPP bills be sent separately from monthly billing statements for Part D premiums. **We encourage CMS to allow Part D sponsors flexibility to send either 1) two separate billing statements for monthly premiums owed and amounts owed under the MPPP, or 2) a single monthly bill that clearly shows monthly premium amounts owed, any cost sharing amounts owed for the prior month under the MPPP (including any past due amounts), and the total amount owed to the plan for the month.**

40.2 Financial Reconciliation Process

CMS indicates that when an individual leaves the MPPP during the plan year (for any reason, including either voluntary or involuntary termination), the Part D sponsor must continue to bill the individual on a monthly basis the amounts set by the MPPP formulas. CMS seeks input on additional financial reconciliation standards for the program.

AHIP Recommendation: **We ask that CMS provide additional information regarding collecting amounts owed under the program.** Existing regulations require Part D sponsors to collect copayment amounts. CMS should make clear how Part D sponsors are expected to operationalize that requirement in the context of the MPPP. We also ask that CMS clarify that plans may continue billing program participants monthly amounts due (including any past due amounts) following the end of the plan year, and an individual's obligation to pay amounts owed under the MPPP remain when the individual disenrolls from the program or the plan.

In addition, we are concerned that requiring continued monthly billing for an individual who has disenrolled from the MPPP will be confusing, especially if the individual enrolls in the MPPP with another plan. **We urge CMS to allow Part D sponsors to bill an individual in full in addition to providing them with payment plan options that extend over a shorter period of time when the individual chooses to disenroll from MPPP.**

We also request that CMS provide specific information about how Part D sponsors are to inform MPPP participants when payments have been applied to premiums.

Section 50 – Pharmacy Payment Obligations and Claims Processing

50.1 Pharmacy Claims Processing Requirements

CMS seeks feedback on a claims processing methodology to ensure a timely, uniform, and seamless implementation for all interested parties; provide a consistent participant experience; and minimize disruption to existing processes. CMS encourages the adoption of an electronic claims processing methodology that would entail Part D sponsor utilization of an additional Bank Identification Number (BIN) and/or Processor Control Number (PCN) unique to the MPPP to facilitate electronic processing of supplemental coordination of benefits (COB) transactions for program participants. This approach would result in pharmacies submitting two transactions to the same Part D sponsor for each claim. The Part D claim would be submitted using one BIN/PCN combination, and then a second transaction would be submitted using a separate BIN/PCN combination for the final MPPP participant liability amount.

AHIP Recommendation: We support CMS’ approach to an electronic claims processing methodology to facilitate the processing of claims for MPPP participants. The submission of two transactions by pharmacies to the same Part D sponsor, one of which uses a BIN/PCN unique to the MPPP, is consistent with the COB process, and would allow Part D sponsors to continue to adhere to Medicare Secondary Payer (MSP) laws and any other federal and state laws establishing payers of last resort (e.g., AIDS Drug Assistance Programs (ADAPs)). The electronic claims processing approach outlined by CMS would require minimal participant involvement at the point of sale (POS) to enable \$0 OOP cost sharing, providing a more seamless process for plan participants, and ensure that only Part D covered drugs are included in the MPPP.

50.3 Requirements for Different Pharmacy Types

CMS indicates that, except as otherwise required in this guidance or under other applicable requirements, all MPPP requirements are the same for every pharmacy type, including mail-order, home infusion, specialty, and long-term care pharmacies. CMS seeks feedback regarding unique scenarios that may arise related to different pharmacy types participating in the program that may require alternative payment or claims processing standards.

AHIP Recommendation: We appreciate the recognition by CMS that different pharmacy types participating in the MPPP may require alternative payment or claims processing standards. Pertaining to long-term care pharmacies, we seek clarification from CMS as to whether Part D sponsors would bill the MPPP participant, the participant’s caregiver or the long-term care facility.

50.4 Paper Claims

CMS indicates that Part D sponsors are not required to retroactively include under the program paper claims submitted to the Part D sponsor by an MPPP participant. CMS seeks input on whether or how paper claims should be processed for MPPP participants.

AHIP Recommendation: We strongly support CMS not requiring Part D sponsors to retroactively include under the program paper claims submitted to the Part D sponsor by an MPPP participant. We seek clarification from CMS that this includes instances of direct member reimbursement. Accurate calculations of monthly caps based on OOP costs incurred in a calendar month and monthly amounts to be billed to MPPP participants are dependent upon online, real-time adjudication of the Part D claims of MPPP participants. Paper claims could be submitted after an MPPP billing period has ended, after Part D sponsors determine the monthly amount to be billed, and after Part D sponsors have sent monthly bills to plan participants. **We seek further specification and clarification from CMS that by not requiring Part D sponsors to retroactively include under the program paper claims submitted, that out-of-network (OON) pharmacy claims are excluded under MPPP. We strongly support the exclusion of OON pharmacy claims from MPPP to enable plans to implement and operationalize the requirements of the program.**

Section 60 – Requirements Related to Part D Enrollee Outreach

60.1 General Part D Enrollee Outreach Requirements

CMS indicates that Part D sponsors must provide clear information about the program to Part D enrollees through communication and marketing materials during open enrollment. CMS notes that it will provide additional guidance on marketing and communications procedures and content in the next phase of guidance, including guidance on communications at the pharmacy, model language, and standardized materials (where appropriate), as well as language about the availability of the LIS program under Part D. CMS requests feedback on which Part D enrollee communication materials would benefit from CMS templates, samples, or model language. CMS indicates that it will develop tools (e.g., model documents and training materials) to help Part D enrollees decide whether the program is right for them.

AHIP Recommendation: We appreciate that CMS will provide additional guidance on marketing and communications procedures and content, including guidance on communications at the pharmacy, model language, and standardized materials (where appropriate), as well as language about the availability of the LIS program under Part D. But we reiterate the need for CMS to issue such guidance and draft model materials and finalize them by April 1, 2024, to ensure that plans have sufficient lead time to operationalize revisions to existing beneficiary materials, and develop new materials, if necessary, including any new required language. In addition, before the end of 2023, CMS should develop a uniform, national communications strategy to educate Medicare enrollees and others about the MPPP. As indicated above, CMS should work with AHIP, our member plans, and other stakeholders on developing and rolling out initial communications, which have the potential to include the issuance of communications materials unique to the MPPP. As such, samples and templates for any standalone communications about the MPPP will be necessary to ensure Part D sponsors can provide consistent information about the program to Part D enrollees in communication and marketing materials. Such samples should include example scenarios of enrollees likely to benefit, and not benefit, from participating in the MPPP. As indicated previously, numerous enrollee communication materials would benefit from CMS templates, samples or model language, including the ANOC, EOC and EOB.

We also recommend that CMS update the Medicare & You Handbook and the Medicare Plan Finder tool to inform enrollees and others about the program. Addressing the Medicare Plan Finder tool specifically, such update should incorporate the criteria to identify enrollees likely to benefit from participating in the MPPP to help notify enrollees that they are likely to benefit, and encourage enrollment in the MPPP as part of the plan selection process. If the Medicare Plan Finder tool is updated to incorporate MPPP “likely to benefit” criteria, a link to the tool can be provided on print communication and marketing materials, and there can be a redirect from online MPPP materials to the tool so enrollees can calculate whether they would be likely to benefit from participating in the MPPP. Online educational videos about the MPPP, and examples of enrollees of who would benefit and not benefit from participating, would be helpful and effective. Informational pamphlets provided to pharmacies and provider offices would help ensure that general outreach about the MPPP reaches Part D enrollees where they are – not only at their place of residence, but at provider sites they are likely to visit. Training materials developed by CMS can educate individuals who assist Medicare beneficiaries in enrolling in Part D coverage, including call center employees, SHIP counselors, agents and brokers, about the MPPP, as well as stakeholders notifying Part D enrollees about the MPPP, such as pharmacy employees. We reiterate that any training materials should be finalized by April 1, 2024.

60.2 Targeted Part D Enrollee Outreach Requirements

CMS indicates that Part D sponsors must undertake targeted outreach, both prior to and during the plan year, to Part D enrollees likely to benefit from the MPPP. This includes the pharmacy notification process and direct outreach to identified Part D enrollees.

AHIP Recommendation: We agree with CMS on the need to conduct outreach efforts specifically targeted to enrollees likely to benefit from participating in the MPPP. **We underscore that targeted outreach efforts, through existing enrollment channels, 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 look forward to working in cooperation and coordination with CMS to develop and implement targeted outreach strategies that leverage resources and tools with which Medicare enrollees are already familiar. For example, incorporating the criteria to identify enrollees likely to benefit from participating in the MPPP into the Medicare Plan Finder tool can help notify enrollees that they are likely to benefit, and encourage enrollment in the MPPP as part of the plan selection process. Targeted communications by Part D sponsors should be coupled with CMS outreach efforts and tools – that involve additional stakeholders including pharmacies – to ensure that enrollees likely to benefit from participating in the program gain awareness of how and when to enroll in the program; the financial implications of enrollment in the program; what program billing will look like; and their experience at the POS, paying \$0 OOP.

60.2.1 Identification of Part D Enrollees Who Are Likely to Benefit

CMS developed a framework for assessing “likely to benefit,” which will be used to inform targeted outreach both prior to and during the plan year, including POS notifications. CMS found that to be “likely to benefit” from the program, the Part D enrollee would have to incur some level of substantial OOP costs, and the Part D enrollee’s highest monthly OOP cost incurred would be more than the highest monthly paid amount under the MPPP (if the program had applied).

AHIP Recommendation: We agree with CMS that Part D enrollees with high OOP costs earlier in the plan year, in particular, are more likely to benefit from participating in the MPPP. We welcome CMS’ definition and framework to identify enrollees likely to benefit from the MPPP to guide the implementation of the pharmacy notification requirement. **The examples provided by CMS of Part D enrollees who are likely to benefit from participating in the MPPP, as well as those who are not, could be built upon, made into model materials, and included in general outreach materials as well as at the time of online MPPP enrollment. Increasing enrollee understanding of the financial implications of participating in the MPPP – both positive and negative, depending on whether they are likely to benefit from participating in the program – can help inform enrollee decisions of whether to participate in the MPPP.**

60.2.2 Targeted Part D Enrollee Notification Prior to POS

CMS indicates that Part D sponsors must also conduct outreach directly to individuals who are likely to benefit from the program, both prior to and during the plan year. CMS notes that, in part two guidance, the agency will specify parameters for identifying enrollees prior to the plan year who are likely to benefit, building upon the concept of identifying Part D enrollees who are “likely to benefit” from the program, as discussed in section 60.2.1.

AHIP Recommendation: We look forward to future guidance on how the “likely to benefit” definition and framework are to be implemented vis-à-vis direct, targeted enrollee outreach by Part D sponsors. We and our member plans would appreciate model language and materials for use in targeted outreach directly to enrollees who are identified as likely to benefit from participating in the MPPP to facilitate consistent and clear communications to those likely to benefit from key stakeholders – CMS, Part D sponsors, pharmacies, beneficiary advocacy organizations, agents and brokers. **We reiterate the need for CMS to issue and finalize such guidance and model language and materials by April 1, 2024, to ensure that plans have sufficient lead time to operationalize the guidance in their targeted outreach efforts.**

60.2.3 Targeted Part D Enrollee Notification at POS

For the purposes of the pharmacy notification requirement, CMS is proposing to base the determination of whether an enrollee is likely to benefit from participating in the program on when they incur OOP costs for a single prescription that equal or exceed the POS threshold. However, CMS seeks comment on whether it would be preferable to use a value based on the OOP costs for all prescriptions filled in a single day. CMS also seeks comment on the range of potential POS notification thresholds from \$400 to \$700, along with specific factors for CMS to

take into consideration when determining the threshold for 2025, including using a single prescription versus single day accumulation to count toward the threshold.

AHIP Recommendation: We appreciate CMS taking operational and implementation concerns into account in proposing using the OOP cost of any single prescription as a trigger for the POS notification, versus a value based on the OOP costs for all prescriptions based on a single day. Using the OOP cost of any single prescription as the trigger will also be clearer and more understandable for beneficiaries. **We recommend that the POS notification threshold should be \$700, to address implementation and operational complexities associated with the POS notification for both Part D plan sponsors and pharmacies.**

60.2.4 POS Notification Requirements

CMS is proposing to establish requirements for identifying Part D enrollees at the POS who are likely to benefit from participating in the program. CMS indicates it will provide guidance on additional specifics on the notification process, such as the contents of notifications, as well as model language for educational materials in the next phase of guidance and welcomes input on these topics. CMS seeks comment on whether and what alternative notification processes or standards should be established for different types of pharmacies (for example, requiring notification via a phone call as opposed to via a paper notice).

AHIP Recommendation: We appreciate CMS' guidance that POS notifications should not be provided to enrollees who would clearly not benefit from participating in the MPPP, including in the last month of the plan year, as well as enrollees who have already opted into participating into the MPPP. We reiterate the need for CMS to issue and finalize guidance on additional specifics on the notification process, such as the content of notifications, as well as model language for educational materials, by April 1, 2024, to ensure that plans have sufficient lead time to operationalize the POS notification requirements. We appreciate the recognition by CMS that alternative notification processes or standards may need to be established for different types of pharmacies. **We recommend that mail-order pharmacies should be allowed to include materials about the MPPP in prescription packaging once the enrollee reaches the threshold for notification, instead of in advance of dispensing the prescription drug.** Mail-order pharmacies should not be required to educate enrollees on the MPPP in advance of dispensing the prescription drug products if it could result in a delay of the medication delivery.

Section 70 – Requirements Related to Part D Enrollee Election

70.1 Part D Enrollee Eligibility

CMS provides guidance on program eligibility including the following: all Part D enrollees are eligible to opt into the MPPP program, the program is voluntary for Part D enrollees, and that there is no minimum OOP cost sharing amount that Part D enrollees must incur to participate in the program.

AHIP Recommendation: To promote common understanding and minimize beneficiary confusion, we recommend that the program eligibility requirements be included in all relevant model documents and other communication materials.

70.2 Interactions Between LIS and Medicare Prescription Payment Plan

CMS indicates that while the statute requires that an LIS enrollee must have the option to become an MPPP participant, individuals with low, stable drug costs such as enrollees eligible for the LIS “are not likely to benefit from the program.” CMS further notes that Part D sponsors must provide individuals with information about both the MPPP and LIS program to educate and help them determine which program will be most suitable to address their needs and circumstances.

AHIP Recommendation: We agree with CMS that LIS enrollees are not likely to benefit from the MPPP. We recommend that the model language and other communication materials developed by CMS explain the differences between the MPPP and LIS program and reasons that LIS enrollees are not likely to benefit from the MPPP. CMS should also encourage plans and other stakeholders through the agency’s communication materials to educate Part D enrollees who may be eligible for the LIS program or who are already in the LIS program that participation in the MPPP is unlikely to benefit them.

70.3 Election Procedures

70.3.1 Format of Election Requests

CMS indicates that Part D sponsors must make the following mechanisms available for election requests: an election option through the Part D (or MA-PD) plan enrollment process; paper option that can be faxed or mailed; toll-free telephone number that must provide the enrollee with evidence the election request was received (e.g., a confirmation number); and website application that must provide the individual with evidence the election request was received (e.g., a confirmation number). CMS also provides guidance on additional requirements for each mechanism.

AHIP Recommendation: We agree that enrollees should be provided with options to make elections. We are concerned about the use of outdated technology such as a fax for election requests and ask that CMS provide its rationale for requiring plans to accept election requests via fax.

70.3.2 Completion of Election Request

CMS indicates that Part D enrollees (or their legal representative) must complete an election request, provide the required information to the Part D sponsor, and be approved by the Part D sponsor to opt into the MPPP. The election request elements are also limited to only those necessary for processing the election request including: the name of the enrollee eligible for Part D coverage; the enrollee’s Medicare Beneficiary Identifier; and the record of the enrollee’s

(and/or their legal representative's) agreement to the Part D sponsor's terms and conditions, if applicable.

AHIP Recommendation: We support CMS' criteria for a completed election request.

70.3.3 Processing Election Request at the Time of Enrollment in a New Plan

CMS provides guidance on the processing, including processing deadlines, for election requests for Part D enrollees at the time of enrollment in a new plan. CMS notes that it will provide more specific information, including model language in the next round of guidance.

AHIP Recommendation: We look forward to reviewing the model language during the next phase of guidance. It would be helpful if CMS could provide examples to illustrate the processing deadlines for handling complete and incomplete election requests in the final guidance. We also recommend that CMS apply exceptions on timelines for paper election requests. Additionally, CMS should apply enforcement discretion for good faith efforts made by plans to meet processing deadlines under the program for plan year 2025.

70.3.4 Processing Election Request Before a Plan Year Begins While Remaining in Same Plan

CMS provides guidance on the processing, including processing deadlines, for election requests for Part D enrollees prior to the start of the plan year while remaining in the same plan. CMS notes that it will provide more specific information, including model language in the next round of guidance.

AHIP Recommendation: We look forward to reviewing the model language during the next phase of guidance. Examples demonstrating the processing deadlines for handling complete and incomplete election requests would be helpful as noted above. We also recommend that CMS apply exceptions on timelines for paper election requests. Additionally, CMS should apply enforcement discretion for good faith efforts made by plans to meet processing deadlines under the program for plan year 2025.

70.3.5 Processing Election Request During a Plan Year

CMS indicates that Part D sponsors must process an enrollee's election request within 24 hours when an enrollee is already enrolled in a Part D plan and requests to opt into the MPPP during the plan year.

AHIP Recommendation: We are concerned about the operational feasibility for processing of election requests made by an enrollee during the plan year within 24 hours. We recommend that CMS extend the timeframe for processing election requests to at least 72 hours for plan year 2025. We also recommend that plans be permitted to provide their enrollees the option to determine their program participation effective date. This approach enables enrollees who are having difficulty paying their OOP cost sharing to enroll sooner than other individuals who are learning about the program for the first time and wish to elect to participate in the program on the first day of the following month, which would ensure that their participation effective date aligns

with the start of the month. **Additionally, we recommend that CMS apply enforcement discretion for good faith efforts made by plans to meet processing deadlines for plan year 2025.**

70.3.6 Retroactive LIS Eligibility and Election

CMS provides guidance on retroactive LIS eligibility and steps that Part D sponsors and pharmacy benefit managers (PBMs) should take to determine appropriate reimbursement amounts within the 45-day timeframe after taking into consideration the LIS-eligible individual's payments already made and remaining outstanding balances as an MPPP participant.

AHIP Recommendation: We reiterate our recommendation that CMS' communication materials should educate Part D enrollees who may be eligible for the LIS program that participation in the MPPP is unlikely to benefit them. As indicated above, CMS' outreach and communications strategy and materials will be critical to increase enrollee understanding of the financial implications of participating in the MPPP. Messaging to enrollees should clearly explain both positive and negative implications for electing to participate in the program.

70.3.7 Retroactive Election in the Event the Part D Sponsor Fails to Process an Election within 24 Hours

CMS indicates that in cases where a Part D sponsor is unable to process an enrollee's election into the MPPP in the required amount of time due to no fault of the individual, the Part D sponsor must process a retroactive election back to the original date when the individual should have been admitted into the program. CMS also requires the Part D sponsor to reimburse the MPPP participant for any OOP cost sharing paid on or after that date and include those amounts, as appropriate, in a monthly bill under the program within 45 days.

AHIP Recommendation: Given the operational complexity involved with retroactive elections, we recommend that CMS make this requirement optional for the first year of the program. If CMS finalizes its requirement on retroactive elections, we recommend that CMS apply enforcement discretion for good faith efforts made by plans to meet the processing deadlines for retroactive elections for plan year 2025. Additionally, we recommend that CMS provide plans with the model notice for these cases. As recommended above, CMS should issue draft model notices and finalize them by April 1, 2024, to ensure that plans have sufficient lead time to operationalize them.

70.3.8 Standards for Urgent Medicare Prescription Payment Plan Election

CMS indicates that Part D sponsors must have a process to effectuate a retroactive election into the MPPP when an enrollee has certain urgent prescription fill(s) (that meet certain conditions) for which the enrollee already paid the associated cost sharing before the enrollee's program election was received and processed.

AHIP Recommendation: Given the operational complexity involved with retroactive elections, we recommend that CMS make this requirement optional for the first year of the

program. If CMS finalizes its requirement on retroactive elections, we recommend that CMS apply enforcement discretion for good faith efforts made by plans to meet the processing deadlines for retroactive elections for plan year 2025. AHIP members would also appreciate more clarity on the scope and circumstances that would trigger retroactive elections under this provision.

70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs

CMS requests feedback on requirements for Part D sponsors to enable real-time or near-real-time POS elections beginning in 2026 or later.

AHIP Recommendation: **We appreciate and agree with CMS' position that it is not feasible to implement real-time or near-real-time POS elections beginning in 2025.** Regarding feasibility for 2026, we recommend that CMS hold user group calls with plans to evaluate implementation activities during plan year 2025 and discuss and assess technology and processes that could be leveraged to enable real-time or near-real-time POS election, and pursue testing and evaluate the results prior to making a determination for 2026.

70.3.10 Prohibition on Part D Enrollee Discrimination

CMS requires Part D sponsors to offer the MPPP to all Part D enrollees and ensure that the plan's program does not discriminate against or inhibit access to the program by any Part D enrollee.

AHIP Recommendation: **We support CMS' anti-discrimination policy.**

70.4 Mid-Year Plan Election Changes

CMS provides guidance for Part D sponsors when an individual changes their plan during the plan year and wants to continue participating in the program under their new plan. CMS also indicates that Part D sponsors should follow the plan-to-plan (P2P) transition timeline and process outlined in the prescription drug event (PDE) guidance to implement the MPPP benefit for individuals who switch their plan in any month during the plan year.

AHIP Recommendation: **We support the requirement for an enrollee who switches their plan during the plan year to be able to opt into their new plan's MPPP.** However, CMS should not allow an MPPP participant with unpaid past due invoices under their previous plan to enroll in the MPPP under a new plan until the enrollee has paid off their past due invoices with their previous plan, as further discussed under Section 80.5.

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

80.1 Voluntary Terminations

CMS indicates that Part D sponsors must have a process to allow an MPPP participant to opt out of the program during the plan year and provide the individual who has requested to opt out of the program with a notice of termination.

AHIP Recommendation: We recommend that CMS provide plans with the model notice to acknowledge receipt of voluntary terminations from an individual who notifies their plan about their intention to opt out of the MPPP. As recommended above, CMS should issue draft model notices and finalize them by April 1, 2024, to ensure that plans have sufficient lead time to operationalize them.

80.2 Involuntary Terminations

CMS refers to the statutory provision that requires Part D sponsors to terminate an individual's MPPP participation if the individual fails to pay their monthly billed amount. In the guidance CMS further notes that an MPPP participant will be considered to have failed to pay their monthly billed amount only after the conclusion of the required grace period.

Part D sponsors are not prohibited from billing an individual for outstanding amounts owed; however, sponsors must continue to bill amounts owed under the program in monthly amounts not to exceed the maximum monthly cap for the duration of the plan year after an individual has been terminated.

AHIP Recommendation: It may be confusing to beneficiaries to continue to receive monthly bills after being terminated from the MPPP. If an individual switches plans and enrolls in MPPP in the new plan after terminating with the previous plan they may receive multiple monthly bills. It may be less confusing to the beneficiary to receive a single final cost-sharing bill from the previous plan. CMS should consider allowing plans to require a single final MPPP payment, rather than continued monthly billing after termination, particularly if the enrollee has completely left the plan. CMS should also consider giving plans additional tools to collect delinquent MPPP payments.

80.2.1 Notice Requirement

CMS describes the content and timing for issuance of the notices to an MPPP participant for: failure to pay their monthly billed amount and termination notice for failure to pay the amount due by the end of the grace period.

AHIP Recommendation: We recommend that CMS provide plans with the model notices associated with involuntary terminations addressed under Sections 80.2 and 80.2.1. As recommended above, CMS should issue draft model notices and finalize them by April 1, 2024, to ensure that plans have sufficient lead time to operationalize them.

80.2.2 Required Grace Period and Reinstatement

CMS would require Part D sponsors to provide individuals with a grace period of at least two months before terminating from the MPPP when that individual has failed to pay amounts billed under the program by the payment due date. Sponsors would have to reinstate any individual who has been terminated from MPPP if they can show good cause for failure to pay. Sponsors may reinstate an individual who pays overdue billed amounts.

AHIP Recommendation: **CMS should consider shortening the minimum grace period before disenrollment from the MPPP.** Given uncertainties with the program particularly in the first year, allowing plans to use a shorter minimum grace period could reduce potential risk for non-payments. Minimum grace periods could be revisited in future years as more experience is gained with the program.

80.3 Preclusion of Election in a Subsequent Plan Year

CMS states that a Part D sponsor may preclude an individual from participating in the MPPP in a subsequent year if that individual owes an overdue balance for monthly billed amounts. The individual must be allowed to opt in if they pay off the balance.

AHIP Recommendation: **We support this provision.**

80.4 Prohibition on Part D Plan Enrollment Penalties for Failure to Pay Medicare Prescription Payment Plan Amount Billed

CMS would prohibit Part D sponsors from disenrolling an enrollee from the Part D plan for failure to pay amounts billed under the MPPP. Sponsors also would not be allowed to decline future enrollment into a Part D plan based on failure to pay amounts billed under MPPP.

AHIP Recommendation: **CMS should consider collecting data on unpaid cost-sharing to identify possible changes to make in the future.**

80.5 Disenrollment

CMS states that if an individual is disenrolled from a Part D plan, that individual is also terminated from MPPP in that plan. The individual may opt into MPPP under their new plan. Part D sponsors may bill for any amounts owed under the program.

AHIP Recommendation: **CMS should not allow an MPPP participant with unpaid past due invoices under their previous plan to enroll in the MPPP under a new plan until the enrollee has paid off their past due invoices with their previous plan.** Carrying a past due invoice from a former plan and joining the program in a new plan may cause beneficiary confusion. We also believe that CMS should develop stronger incentives to prevent enrollees from switching plans solely to avoid paying their outstanding cost-sharing bills.

Section 90 – Participant Disputes

CMS indicates that a Part D sponsor must apply their Part D appeals procedures in cases involving disputes over the amount of Part D cost sharing owed by an MPPP participant for a covered Part D drug. As for other disputes raised by an MPPP participant, CMS indicates that a Part D sponsor must apply their Part D grievance procedures. CMS references sections 30 (grievance process) and 40 (appeals process) of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance (Appeals & Grievances Guidance) for dispute process requirements that Part D sponsors would have to follow.

AHIP Recommendation: We support the application of existing Part D appeal and grievance procedures for addressing disputes made by an MPPP participant as proposed by CMS, and note that CMS should provide guidance that makes it clear about which specific sections (or subsections) of the procedures will apply to different types of MPPP disputes, and how such disputes should be handled. Examples of disputes that would qualify as an appeal or grievance should also be included in the revised guidance to promote common understanding. **We recommend that CMS issue the revised Appeals & Grievances Guidance that addresses MPPP disputes in draft form for public comment. Given the complexity of this new program, we also recommend that CMS apply enforcement discretion for good faith efforts made by plans to address participant disputes for plan year 2025.**

On a related note, we ask CMS to establish a complaints tracking module (CTM) category for MPPP related complaints to help CMS and plans track these types of complaints, resolve them and evaluate their frequency rate and impacts. We further recommend CMS consider adjustments to address unanticipated impacts that implementation of the MPPP will have on certain Star Ratings measures and plan performance. **CMS should 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.**

Section 100 – Data Submission Requirements

CMS indicates that Part D sponsors will be required to report information related to the MPPP on PDE records and through new annual reporting requirements. CMS notes that guidance on PDE reporting is forthcoming and the proposed data elements for annual reporting included in the part one guidance will also be formally proposed for public comment through the Paperwork Reduction Act (PRA) notice and process. CMS further notes that for 2025, the agency does not plan to require independent data validation for the new reporting requirements.

AHIP Recommendation: We look forward to reviewing forthcoming guidance and the PRA comment opportunity. **We recommend that CMS provide de-identified aggregate data based on plan reporting on the number of participants, number of terminations (voluntary and involuntary) as well as other data to help inform future changes and improvements to the program.**

September 20, 2023

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

Re: Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments

Dear Deputy Administrator Seshamani:

The American Kidney Fund appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) draft part one guidance on the Medicare Prescription Payment Plan.

The American Kidney Fund (AKF) fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. Through programs of prevention, early detection, financial support, disease management, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator and the Platinum Seal of Transparency from GuideStar.

AKF is a strong supporter of the Medicare Prescription Payment Plan, which when combined with the true out-of-pocket cap (OOP) for Part D coverage, will help alleviate the financial burden for beneficiaries with significant prescription drug needs. This includes beneficiaries with chronic kidney disease, many of whom also have other comorbidities and need access to Part D-covered medications to manage their conditions.

We offer the following comments on certain issues in this draft part one guidance.

Program Calculations

AKF appreciates the detailed calculations and scenarios provided in the draft guidance, as they help illustrate the maximum monthly cap and monthly participant payment for different incurred OOP costs and how they may vary during the year. However, given the complexity of the calculations, we recommend CMS consider simplifying this information as it develops education

materials for beneficiaries that explain the program calculations. Specifically, we recommend CMS clearly explain to beneficiaries that while their monthly payments may vary depending on different factors, their total OOP costs for the entire plan year will not exceed \$2,000. We also suggest that beneficiary educational materials focus on a simple month-to-month total of what their OOP obligations are and exclude the maximum monthly cap column that is in the draft guidance, to minimize confusion.

Participant Billing Requirements

AKF appreciates that CMS encourages plans to offer multiple means of payment and to offer participants flexibility around requesting a specific day of the month for program charges and withdrawals from a bank account. However, we recommend CMS require plans to offer flexibility on billing timing and offer multiple means of payment, including electronic funds transfer, automated payments, credit card, cash, and check. We believe that requiring plans to offer flexibility on billing timing and multiple means of payment will facilitate beneficiary participation in the program and reduce the likelihood of missed payments.

AKF supports CMS's requirement that plans provide robust information within the billing statement. Particularly, we strongly support the requirement that plans include information on applying and enrolling in the Part D Low-Income Subsidy (LIS) program, and explaining that for those who qualify, enrolling in the LIS program is more advantageous than participation in the Medicare Prescription Payment Plan alone.

In addition to the required information in the billing statement that CMS lists in the draft guidance, we recommend that plans should also be required to provide information on the State Health Insurance Assistance Program (SHIP) as a resource for impartial information on Medicare programs. We also recommend billing statements contain clear explanations on the importance of avoiding late or missed payments, as well as clear language that a beneficiary will not pay more than \$2,000 in OOP costs in a plan year and informing them when they have reached that cap and what their remaining payments will be for the year.

Finally, we appreciate CMS's clarification in the guidance that Medicare Prescription Payment Plan participants are protected from actions to collect unpaid debt related to the program.

Enrollee Outreach

The targeted enrollee outreach requirements will be an important tool to inform beneficiaries who may benefit from the Medicare Prescription Payment Plan about the program, and will be a critical part of an effective outreach strategy. However, we have concerns that using specific dollar amount thresholds that trigger targeted notifications may reduce information and outreach to beneficiaries who may benefit from the program. We suggest CMS reconsider a targeted outreach approach that uses specific dollar amount thresholds, or alternatively, set the threshold as low as possible.

We look forward to the opportunity to comment on the draft part two guidance, which will contain more information on enrollee outreach and education. As that guidance is developed, we urge CMS to include information on the Medicare Prescription Payment Plan in the Medicare Plan Finder tool, as well as the Medicare & You handbook and the Medicare website. Additionally, we urge CMS make available by fall 2024 a monthly cost calculator that lets beneficiaries know what their monthly payment obligations would be if they opt-in to the program, and to make this calculator available at each possible decision point.

Enrollee Election

We urge CMS to require plans and pharmacies to offer point-of-sale (POS) program election for beneficiaries by 2025. To avoid the impact of wait times on beneficiaries, CMS should not wait until 2026 or later to implement POS real-time or near-real-time election. POS election is a critical component for beneficiary participation and to minimize beneficiary burden. We and other patient organizations are committed to working with CMS and other stakeholders to ensure POS election is available by 2025.

Grace Periods and Notice Requirements

We recommend CMS implement a 3-month grace period for late payments, instead of the 2-month grace period in the draft guidance. We also recommend CMS clarify that the grace period carries over into the next calendar year if non-payment occurs at the end of a calendar year.

Thank you for the opportunity to provide comments on this draft guidance.

Sincerely,



Holly Bode
Vice President of Government Affairs

Via Electronic Submission: PartDPaymentPolicy@cms.hhs.gov

September 20, 2023

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: Comment on Maximum Monthly Cap on Cost-Sharing Payments Program
Draft Part One Guidance**

Dear Dr. Seshamani:

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

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.

Alexion welcomes the proposed implementation of the Medicare Prescription Payment Plan, as established by section 11202 of the Inflation Reduction Act (IRA).¹ Alexion applauds CMS for prioritizing enrollees’ ease of access to health care through the implementation of the Program. The Program will improve access to critical therapies for patients affected by rare diseases by ameliorating enrollee cashflow concerns that could negatively impact their ability to afford their medications.

Alexion makes the below recommendations to clarify and improve the implementation of the Program. Our comments are based on three core principles:

- **Implementation Should Be Focused on Improving Affordability for Enrollees by Using Enrollee-Centric Approaches.** Alexion supports CMS’ implementation of the Medicare Prescription Payment Plan through enrollee-centric options that are intended to address enrollee cashflow problems that could adversely affect their access to needed medications.

¹ Pub. L. No. 117-169.

- **Implementation Should Minimize Burden on Enrollees.** Alexion believes that implementation of the Program should seek to minimize the burden on enrollees, and that Part D sponsors are best positioned to operationally simplify an enrollee's exercise of their option to participate in the Program, subject to oversight by CMS.
- **Implementation Should Meet Enrollees Where They Are.** Alexion believes that the implementation of the Program should encourage the method of outreach to enrollees that best meets the enrollees' needs. Part D sponsors should use a combination of standardized and easy-to-understand communication methods (e.g., text, email, or paper notices) and payment frameworks (e.g., electronic fund transfer, cash, check, etc.) that maximizes an enrollee's ease of access and use of the Program.

Our specific comments in response to each section of the Draft Guidance, which are explained in more detail below, are summarized as follows:

- Section 20: CMS should ensure that the education of and outreach to enrollees are conducted in a standardized, widespread, understandable, and timely manner.
- Section 30: CMS should provide clarifications regarding the terms "incurred costs" and "OOP costs incurred by the participant."
- Section 40: CMS should revise the Draft Guidance to require, rather than "encourage," Part D sponsors to offer multiple means of payment and to prioritize applying the participant's monthly payments to their Part D premium amounts. Also, CMS should clarify the manufacturers' role in the financial reconciliation process.
- Section 60: CMS should encourage manufacturers and other organizations to also get involved in the education and outreach efforts.
- Section 70: To avoid potential delays that may lead to prescription abandonment, CMS should require Part D sponsors to process an enrollee's election to participate in the Program immediately at the pharmacy point of sale (POS) rather than permitting a 24-hour waiting period before processing the election. CMS should also require the use of the same standardized election request forms across all plans to avoid denials due to omission of information.
- Section 80: CMS should provide clarifying examples of what constitutes "good cause" for failure to pay the program billed amount. Meanwhile, Alexion supports CMS' limitation of a Part D plan's ability to preclude an individual from opting into the Program in a subsequent year for non-payment of amounts billed to each individual plan.

I. Section 20 – Overview

- A. Section 20 – CMS should ensure the education of and outreach to enrollees are conducted in a standardized, widespread, understandable, and timely manner.

CMS requests specific feedback on the best ways to educate Part D enrollees about the Program.² We believe an important mission of the Program is to maximize the number of enrollees who are aware of the Program and that the outreach efforts reach the enrollees in a standardized, understandable, and timely manner.

To ensure robust and effective enrollee outreach and education, CMS should take steps to ensure all enrollees understand the new Program. Specifically, CMS should encourage the Part D sponsors to use the same standardized educational materials and offer the materials in multiple languages. Rather than sending the educational materials using the same, single communication method for all enrollees, the Program should encourage using a combination of communication methods that would best reach the individual enrollees, such as through text, email, and/or paper notices. The materials should also be communicated in a way that is standardized and easy to understand, outlining how enrollees' costs may change if they choose (or choose not) to opt into the Program, so that enrollees are provided with sufficient information on how the Program works. This should also be done in a timely manner as early as feasible to ensure that the enrollees have enough time to process and consider their options.

Alexion also suggests that CMS split the informational materials provided to enrollees into two parts: (1) education provided during plan selection prior to the start of the plan year, and (2) education provided mid-plan year. This is because the details of the Program that enrollees should know or want to know may differ at different stages of participation in the Program.

II. Section 30 – Program Calculations and Examples

A. Section 30.1 – CMS should clarify whether charitable assistance from bona fide charitable organizations would count towards "incurred costs."

CMS defines "incurred costs" broadly as "any costs incurred or treated as incurred under section 1860D-2(b)(4)(C)" of the Social Security Act (the "Act").³ Through the adoption of the IRA, the definition of "incurred costs" was significantly revised such that the term could arguably apply to third-party payments made on behalf of enrollees, such as bona fide charitable organizations. Specifically, section 1860D-2(b)(4)(C)(iii)(II) of the Act provides that, "costs shall be treated as incurred... if such costs... for 2025 and subsequent years, are reimbursed through insurance, a group health plan, **or certain other third party payment arrangements.**"⁴

Despite the ambiguity, CMS has not commented substantively on the differences between the existing "incurred cost" definition, compared to the "incurred cost" definition that will apply beginning in 2025. To avoid confusion regarding the scope of applicability of the term "incurred costs," Alexion requests CMS to clarify whether charitable assistance from bona fide charitable organizations will count towards an enrollee's "incurred costs."

² CMS, Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance (Aug. 21, 2023), p. 5.

³ Draft Guidance at 7.

⁴ Emphasis added.

- B. Section 30.2 – CMS should clarify the difference in meaning between “OOP costs incurred by the participant” and “incurred costs” and provide clarifying mathematical examples.

CMS indicates that for the calculation of the “subsequent month” maximum monthly OOP cap, “OOP cost incurred by the participant” differs from “incurred costs” as defined in the statute and as applied to the “first month” maximum monthly OOP cap.

Specifically, the Draft Guidance states that:

“OOP costs incurred by the participant” refers only to the patient pay portion for covered Part D drugs that a program participant would have paid at the POS if they had not opted into the Medicare Prescription Payment Plan, not to all incurred costs as defined under section 1860D–2(b)(4)(C) of the Act.⁵

CMS states in several parts of the Draft Guidance that the maximum monthly OOP cap is not intended to affect how an enrollee progresses through the benefit. Rather, the cap is meant to be merely a mechanism to spread the costs incurred by the enrollee across the plan year.

However, Alexion believes the Draft Guidance does not adequately explain how the “OOP costs incurred by the participant” differs from the general “incurred costs” definition in the statute. Alexion interprets CMS’ “OOP costs incurred” variable as a mathematical tool to calculate the enrollee’s OOP costs. Therefore, Alexion requests that CMS clearly state that the “OOP costs incurred by the participant” is a variable that is used only to calculate the “subsequent month maximum cap” and that it does not apply to other contexts. Alexion also requests that CMS provide mathematical examples to illustrate how the “OOP costs incurred by the participant” does not affect the individual enrollee’s “incurred costs” to fully clarify the limited application of the term.

III. Section 40 – Participant Billing Requirements

- A. Section 40 – CMS should require, rather than “encourage,” Part D sponsors to offer multiple means of payment under the Program to ensure optimal enrollee experience.

CMS does not require, but only “encourages Part D sponsors to offer multiple means of payment, such as an electronic fund transfer mechanism (including automatic charges of an account at a financial institution or credit or debit card account) and payment by cash or check.”⁶

By only “encouraging” the Part D sponsors to offer this flexibility, many enrollees may find themselves without the option of paying through their preferred, or (in some cases) the only, method of payment. We note that many enrollees may not have access to specific methods of payment. If the Part D sponsors choose to only offer limited means of payment, this limitation may

⁵ Draft Guidance at 7-8 (emphasis added).

⁶ Draft Guidance at 13 (emphasis added).

ultimately discourage or even prohibit enrollees who would otherwise have participated in the Program from opting in or successfully complying with the payments.

Moreover, we note that the objective of the Program is to provide an enrollee-centric option intended to allow for an easier and improved access to the enrollee's needed therapies. Alexion believes that the implementation of the Program should seek to minimize the burden on enrollees, which the Part D sponsors may achieve by operationally simplifying the process in which an enrollee may opt into the Program. Offering enrollees the flexibility in their choice of payment method would help achieve these purposes.

Therefore, Alexion recommends that CMS make offering multiple methods of payment mandatory, rather than optional, for Part D sponsors to ensure that forms of payment do not serve as a barrier for enrollees who desire to participate in the Medicare Prescription Payment Plan.

- B. Section 40.1 – CMS should require, rather than “encourage,” Part D sponsors to apply a participant’s monthly payments to their premium amounts before any other outstanding costs to ensure continuity of coverage.

CMS does not require, but only “**encourages** Part D sponsors to prioritize payments towards Part D plan premiums to avoid a Part D enrollee losing their Part D coverage.”⁷

By allowing Part D sponsors to choose whether the sponsor may apply the participant's payments towards the Part D plan premiums or towards the Medicare Prescription Payment Plan balance, participants may risk losing their Part D coverage despite paying the premium amount and, in turn, may lose their Program eligibility. This may be a likely scenario because of the incentives for Part D plans to mitigate their liability to pharmacies for amounts due under the Medicare Prescription Payment Plan. Circumstances such as this would run contrary to the objective of the Program and may discourage enrollees from participating in the Program.

Alexion recommends that, by default, Part D sponsors should apply payments received from enrollees towards their Part D plan premiums as this would help preserve continuity of coverage for the enrollees. We believe that making the prioritization of payments mandatory for Part D sponsors would contribute to improving affordability for enrollees and mitigate potential concerns regarding enrollee cashflow.

- C. Section 40.2 – CMS should confirm that manufacturers do not have a role in any financial reconciliation processes under the Program.

CMS notes that section 1860D–2(b)(2)(E)(v)(III)(gg) of the Act requires Part D sponsors to have a financial reconciliation process in place to correct inaccuracies in billing and/or payments.⁸ Yet, the Draft Guidance fails to specify whether manufacturers should not be involved in the financial reconciliation processes under the Program. Alexion recommends that CMS make clear that manufacturers have no role to play in the financial reconciliation processes under the Program,

⁷ Draft Guidance at 14 (emphasis added).

⁸ Draft Guidance at 14.

which remains the purview of Part D sponsors to implement, subject to CMS oversight and enforcement.

IV. Section 60 – Requirements Related to Part D Enrollee Outreach

- A. Section 60.1 – CMS should encourage other entities, such as manufacturers and other patient organizations, to educate enrollees on the availability of the Medicare Prescription Payment Plan and should also clarify to what extent the other entities may contribute to the education efforts.

As stated in the Draft Guidance, CMS intends to “develop tools (e.g., model documents and training materials) to help Part D enrollees decide whether the program is right for them.”⁹ Further, the Draft Guidance specifies that Part D sponsors are required to educate the enrollees prior to and during the plan year regarding the availability of the Program.

However, CMS does not specify what roles the other parties, such as manufacturers and other patient organizations, may play in the outreach and education efforts for the Program. Alexion believes that involving more parties who may have contact with enrollees in the outreach and education efforts will help maximize the number of enrollee participation in the Program by increasing enrollee awareness about the Program.

Thus, Alexion urges CMS to encourage manufacturers, charitable organizations, and specialty pharmacies to get involved in outreach efforts and educate enrollees regarding the availability of the Program. We believe that a wider involvement will help CMS better achieve the goal of the Program to make health care more accessible, equitable, and affordable for more enrollees.

- B. Section 60.2.1 – Alexion supports CMS' proposed definition of an enrollee “likely to benefit” from the Program.

The Draft Guidance mentions that Part D sponsors are required to undertake targeted outreach, both prior to and during the plan year, to Part D enrollees “likely to benefit” from the Program.¹⁰ Although section 1860D–2(b)(2)(E)(v)(III) of the Act introduces the term “likely to benefit,” the statute does not provide a definition for the term. As such, in section 60.2.1 of the Draft Guidance, CMS states that enrollees “likely to benefit” from the program are generally those with (1) higher OOP costs that (2) are likely to be incurred earlier in the plan year.

Alexion supports CMS' proposed definition of an individual “likely to benefit” as being an individual with high OOP costs that are likelier to be incurred earlier in the plan year. This definition is particularly relevant to patients with rare diseases since therapy for rare diseases tend to require high OOP costs consistently throughout the year, which would result in costs being incurred earlier in the year.

⁹ Draft Guidance at 19.

¹⁰ Draft Guidance at 19.

Furthermore, Alexion agrees with CMS' proposed requirement that Part D sponsors undertake targeted outreach to enrollees that are “likely to benefit” from participating in the Program, in addition to the general outreach and education required by the Act. We agree with CMS' general understanding that enrollees with higher OOP costs incurred earlier in the plan year are likelier to benefit from the Program.

V. Section 70 – Requirements Related to Part D Enrollee Election

- A. Section 70.3.5 – CMS should require Part D sponsors to process an enrollee's election to participate in the Program immediately at the POS to avoid unnecessary delays, and enforce the use of the same standardized election request forms across all plans to avoid denials due to omission of information.

In the Draft Guidance, CMS proposes to require that Part D sponsors process an enrollee's request to participate in the program within 24 hours. Although we recognize that CMS implemented this requirement to encourage the timely processing of requests, we note that a 24-hour delay in request processing could result in prescription abandonment and cause unnecessary difficulties for enrollees. Moreover, certain patients with rare diseases may not have the luxury of waiting 24 hours for their medication, and their conditions may worsen when faced with unnecessary delays in obtaining their medication. Thus, Alexion recommends that CMS require Part D sponsors to immediately process an enrollee's election to participate in the Program at the POS, rather than allowing plans to unnecessarily delay the process.

We are also concerned that the Draft Guidance allows a Part D sponsor to deny a participation request for “failing to submit the information requested within the timeframe listed on the request.”¹¹ With lack of consistency or proper guidance, enrollees could inadvertently fail to fill out all of the information requested by the individual plan. Especially if a particular Part D plan decided to request a large volume of information from enrollees for participation, it could ultimately increase the rate of denials that derive from incomplete forms.

To avoid widespread denials due to omission of information, Alexion recommends that CMS require the use of the same standardized election request form across all Part D plans, rather than merely encouraging the use of suggested language to be included in the forms. The same requirements should also apply to Third-Party Marketing Organizations (TPMOs). The standardized forms would promote a uniform request for participation and minimize the amount of information that the enrollee must provide to the Part D sponsor to process their request. In most cases, the Part D sponsors will already have the information needed to process the enrollee's request. To the extent additional information may be required, such information should be requested in a standardized form to minimize instances where information may be inadvertently omitted.

Moreover, using the same standardized form across all plans would enhance Program education and outreach by facilitating the use of standardized education materials that are applicable to all

¹¹ Draft Guidance at 33.

Part D plans. In line with this recommendation, we suggest that CMS make the standardized instructions available in multiple languages to ensure all enrollees have access to the information about the Program in format that is most understandable to the individual.

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

A. Section 80.2.2 – CMS should provide examples of what constitutes “good cause” for failure to pay the Program billed amount.

Part D sponsors must reinstate an individual who has been terminated from the Medicare Prescription Payment Plan if the individual demonstrates “good cause” for failure to pay the program billed amount within the grace period and pays all overdue amounts billed. The Draft Guidance further provides that an individual may demonstrate “good cause” through a credible statement that the failure to pay was “due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.”¹²

However, we believe that the definition of “good cause” provided in the Draft Guidance is not sufficiently illustrative. A lack of a clear definition of “good cause” could allow plans to refuse to reinstate individuals at will and may result in inconsistencies of standards across plans. Thus, Alexion recommends that CMS provide examples of what constitute “good cause” to ensure that Part D sponsor adjudication of good cause submissions are fair and consistent across all plans and across each plan's enrollees.

B. Section 80.3 – Alexion supports CMS’ limitation of a Part D plan's ability to preclude an individual from opting into the Program in a subsequent year for non-payment of amounts billed to each individual plan.

A Part D sponsor may preclude an individual from opting into the Medicare Prescription Payment Plan in a subsequent year only if the individual owes an overdue balance to that specific Part D sponsor. If an individual pays off the outstanding balance during the subsequent year, a Part D sponsor must permit them to opt in after that point.

Alexion supports this limitation on the preclusion of enrollees to elect the Program in a subsequent plan year to a specific Part D sponsor. Allowing a new Part D sponsor to preclude an enrollee from participating in the Program because of the enrollee's non-payment under a previous Part D sponsor would not only be difficult to administer, but it would also be susceptible to errors and omissions in the transmission of information between the sponsors. The omissions would in turn potentially lead to enrollees erroneously being denied the option to participate in the Program altogether, which is not aligned with the objective of the Program to allow more enrollees to have access to affordable and equitable health care.

¹² Draft Guidance at 40.

We appreciate your consideration of our comments and for CMS' continued dialogue with Alexion as the agency endeavors to implement the Medicare Prescription Payment Plan. Please contact me at Lisa.Feng@Alexion.com if you have any additional questions about our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa B. Feng". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Lisa B. Feng, DrPH

Senior Director, Health Policy

Alexion AstraZeneca Rare Disease

September 20, 2023

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

Dear Dr. Seshamani,

Thank you for the opportunity for our 61 organizations to provide feedback on CMS's implementation of the Medicare Prescription Payment Plan (MP3). Our organizations supported the passage of provisions to reduce and manage beneficiary out-of-pocket (OOP) costs for enrollees in the Medicare Part D program. We appreciate the opportunity to work with the agency to ensure that implementation allows the greatest number of beneficiaries possible to benefit from the ability to pay their prescription drug costs through monthly zero-interest payment installments.

The successful implementation of the MP3 is critical. For many beneficiaries, the new flexibility will be among the most directly "felt" impacts of the *Inflation Reduction Act*. If successfully implemented, cost smoothing – in conjunction with the new annual OOP cap – will protect beneficiaries from sizeable upfront costs while reducing the OOP burden of prescription drug costs. However, significant work remains to achieve this aim, which is made more complex given the opt-in enrollment dynamic of the program.

Our organizations appreciate CMS's continued engagement with the patient advocacy community on the MP3 and the agency's commitment to an iterative process; we collectively acknowledge and commit to working with the agency to ensure those lessons inform the implementation and education process moving forward.

In the draft guidance, the agency has proposed the implementation of beneficiary protections that are critical to ensure beneficiaries benefit rather than experience unintended harms. **We support CMS's proposed beneficiary protections and ask the agency to finalize these provisions** while providing additional operational detail, where beneficial. In this letter, we also offer feedback on implementation considerations for the MP3 program.

1. Stakeholder Education (Secs. 20; 60.1, 60.2.2)

The MP3 program offers the new flexibility for beneficiaries to pay their OOP costs for prescription drugs in payment installments. However, there are a number of complexities related to the program, including the need for beneficiaries to opt-in, changing monthly maximum costs, and

the need to continue payment for previously incurred costs. As a result, a range of educational efforts will be necessary to ensure smooth introduction and implementation of the MP3, as well as ease of enrollment and use by beneficiaries.

CMS has indicated that further information on education and outreach efforts are forthcoming. We make the following recommendations for your consideration in advance of Part II of this guidance expected in early 2024:

Utilize regular points of contact with beneficiaries

CMS outlines in the guidance the Part D plans will be required to include educational material about the MP3 during Open Enrollment and in promotional materials, as well as a process to notify individuals that are likely to benefit from the program prior to and during the plan year. In addition to these requirements, CMS should outline requirements for the inclusion of information (or, at a minimum, a phone number and web link) about the MP3 on regular plan documents including the evidence of coverage notice and explanation of benefits statements. Information about the MP3 should be included on a recurring basis in the annual notice of change, as maximum potential liability under the program will change in conjunction with increases in the annual Part D beneficiary OOP cap.

In addition to materials provided by plan sponsors, CMS beneficiary and provider-facing materials such as the Medicare & You handbook should contain education about the MP3. CMS may also evaluate whether including a phone number and website for beneficiaries to learn more about the MP3 on enrollee's physical Medicare or Part D plan cards will promote beneficiary awareness.

The role of pharmacies in providing education

Pharmacists and pharmacy technicians have a central role in education, as they are required by statute to provide beneficiaries that are "likely to benefit" notification about the MP3 program. We encourage CMS to evaluate both active prompts and passive educational materials for the MP3 at the point of sale.

We also ask CMS to encourage pharmacies, on a voluntary basis, to provide information about the MP3 in Medicare beneficiary communications, such as an automated call or email when a prescription is ready. These regular communications serve as a recurring avenue to raise awareness of the payment flexibility (i.e., you may be eligible to pay your drug costs through payment installments). Further, notifying a beneficiary about the need to opt-in to the program in advance of their arrival at the pharmacy will be essential if point of sale (POS) enrollment is not mandated to coincide with the introduction of the MP3 in 2025. In the absence of advance notification, beneficiaries that are likely to benefit from the MP3 may face decisions on whether

to pay the full OOP cost of the medication or, alternatively, return to retrieve their prescription after their opt-in request has been approved by their Part D plan.

In conjunction, CMS should review concerns that arose during the implementation of the Part D program, specifically that pharmacies reported a lack of information about the low-income subsidy calculations because neither the plans nor the government provided sufficient information.¹ In advance of pharmacists and pharmacies delivering notification of likely benefit and making available a point of sale mechanism, we urge CMS to ensure that pharmacists and staff are appropriately furnished information and educational materials. This will not only make the transition to providing patient education for MP3 easier for pharmacies, but aid in ensuring patients receive the materials they need to make an informed decision on opting-in to the MP3.

Engaging prescribers in education efforts

Prescribers also have an important role in educational efforts for the MP3. As a result of the Consolidated Appropriations Act of 2021,² Part D plan sponsors are required to offer real-time benefit tools to provide prescribers with information regarding a beneficiary's financial liability for a prescribed medication. This information is valuable as care providers have discussions with their patients about their care plan and affordability.

Similarly, information and education for providers around the MP3 should be prioritized. Prescribers, case managers, and nurse navigators should be included in educational efforts for the program with the goal that providers will include information about the MP3 in their dialogue with Medicare beneficiaries. In addition to conversational prompts, providers could include information about the MP3 for Medicare beneficiaries in standard materials such as visit summaries, and when applicable, physical prescription forms. The role of the prescriber in providing this information will be even more central to beneficiary's awareness of the MP3 if point of sale enrollment is not mandated in 2025, as individuals would need to opt-in prior to reaching the pharmacy counter.

2. Flexibility in First Month Versus Subsequent Monthly Caps (Sec. 30)

CMS issued a technical memorandum³ in July 2023 on the calculation of the maximum monthly caps under the MP3, with additional details on examples included in the August guidance. We appreciate CMS's efforts to provide a direct interpretation of the statute in the IRA regarding the first month versus the calculation for subsequent months; however, we encourage the agency to

¹ Robert Pear, States Intervene After Drug Plan Hits Snags, *The New York Times*, January 8, 2006.

² Consolidated Appropriations Act of 2021. Section 119. <https://www.congress.gov/116/plaws/publ260/PLAW-116publ260.pdf>

³ Centers for Medicare and Medicaid Services. Technical Memorandum on the Calculation of the Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans. 17 July 2023. <https://www.cms.gov/files/document/monthly-cap-cost-sharing-technical-memo-july-2023.pdf>

explore additional flexibility within the statute to permit beneficiaries to spread out their incurred OOP costs as evenly as possible.

Consumers and beneficiaries are used to paying expenses over a fixed period, as in a mortgage, as well as having additional incurred costs added to a previously owed principal amount, as is typical with credit cards. However, the higher maximum monthly cap calculation for the first month is novel and outside the consumer experience for other owed expenses. This complexity may make it overly difficult for beneficiaries to understand the MP3 program and their potential monthly liability.

Additionally, the higher first month cap limits the value of MP3 for beneficiaries that incur a new, relatively large OOP cost later in the year. For example, a beneficiary may start the year taking two prescriptions, each with a monthly fill cost of \$5 that the individual pays for at the time of purchase. However, in October, the same beneficiary is newly diagnosed with a condition, requiring a 90-day course of treatment with a Part D drug with an OOP cost of \$700. Under the methodology discussed in the technical memorandum, if the individual opts into MP3 at the time of their October prescription fill (consisting of \$700 for the new prescription, plus \$10 for filling the existing prescriptions), they would owe \$636.67 the first month, with a balance of \$73.33 spread out over the remaining two months of the year along with any additionally incurred costs. Under the proposed first month methodology, this beneficiary would not greatly benefit from the MP3. However, if CMS provides the flexibility to spread out costs evenly over time (*which would result in the beneficiary's opt-in month cost being less than the first month maximum monthly cap outlined in statute, fulfilling the legal requirement*), the same beneficiary could instead pay \$236.67 in October and the remaining two months of the year (along with any additional incurred costs).

As alluded to in example 1 in the guidance, beneficiaries may circumvent the higher first month cap by opting in the month prior to an incurred expense, at which point their OOP costs can be spread out evenly for months after the opt-in month. However, this may create a misaligned incentive if a beneficiary is prescribed a new costly prescription; the individual may immediately opt-in to the MP3, but delay filling the script until the following month in order to have a lesser first-month liability.

These complexities are avoidable. **We ask CMS to instead exercise regulatory authority to allow beneficiaries the option to spread out their incurred costs evenly for the opt-in month in addition to the subsequent months.** This change will lessen the complexity of determining a beneficiary's monthly liability as well as broaden the number of beneficiaries that may benefit from the MP3.

3. Payment Mechanisms (Sec. 40)

CMS encourages plans to offer a variety of payment options to beneficiaries, including manual and automated electronic fund transfers (EFT) from a financial institution, such as a checking or savings account, as well as a credit or debit card. Offering the ability to pay via manual options, such as cash or check, are also encouraged.

To the extent possible, CMS should require plans to offer the proposed payment options. The EFT options will be broadly beneficial for beneficiaries and plans, as will the ability to minimize the risk of late payment via autopay options. Additionally, manual options of paying by cash and check are important for the Medicare population, as 25% of individuals aged 65 and older report a preference for paying bills via check.⁴ Further, while credit cards should be retained as a payment option, materials should indicate this method is a non-preferred option. The use of credit cards may result in interest expenses on medical debt, thereby undermining the value of the MP3 program.

We also support CMS's direction that no minimum amount be required in order to opt-in to the MP3, as it supports the diversity of beneficiary experience and ability to select additional payment flexibility.

In addition to the included information elements for billing statements noted in the guidance, we also encourage CMS to direct plans to include a payment schedule through the end of the year based on currently invoiced amounts. The inclusion of a schedule will clarify a beneficiary's continued financial liability, as well as assist with financial budgeting and planning. This schedule should be caveated with a note indicating that the payment schedule for future months will change if additional costs are incurred.

CMS should further explore allowing beneficiaries who have opted into the program to choose to pay for selected prescriptions at the point of sale. For example, an individual that takes one medication with a relatively high OOP cost may also take two maintenance medications with a monthly fill cost of \$5 per script. The beneficiary may prefer to pay for the lower cost medications at the point of sale, rather than on a delayed basis. The costs paid for at the POS may then be applied against the maximum monthly cap amount as the plan provides the monthly invoice for costs incurred via the MP3.

We also ask CMS to provide instruction in future guidance regarding the mid-year death of a beneficiary with respect to outstanding financial liabilities under the MP3.

⁴ Federal Reserve Bank of Atlanta. U.S. Consumers' Use of Personal Checks: Evidence from a Diary Survey. January 2021. <https://www.atlantafed.org/-/media/documents/banking/consumer-payments/research-data-reports/2020/02/13/us-consumers-use-of-personal-checks-evidence-from-a-diary-survey/rdr2001.pdf>

4. Notification of Likely Benefit (Sec. 60.2)

As part of the statutory requirements of the IRA, pharmacists are required to notify beneficiaries who are “likely to benefit” about the option to utilize the MP3. However, as CMS notes, the program may not be well-suited for all beneficiaries, especially beneficiaries that only require relatively low-cost, maintenance medications.

In the proposed guidance, CMS presents the findings of a claims analysis that compares the OOP cost of a fill and the associated number of beneficiaries that are likely to benefit from enrolling in the MP3. In the table, the minimum dollar value shown is \$400, where an estimated 91% of 2.2 million beneficiaries notified would benefit. The next dollar value shown, \$500, would result in 95% of 1.1 million beneficiaries notified benefitting from enrolling in the MP3, according to CMS’s definition.

It would have been beneficial to see CMS’s analysis performed at the \$300 and/or \$350 level, as the table shown by CMS makes a clear case that the trigger for the notification should be set no higher than \$400. When the notification amount is set at \$500, by CMS’s own analysis, one million beneficiaries that would otherwise have benefited from the MP3 would not be notified. In our view, this outcome would be unacceptable.

We note that the analysis performed considers Part D costs only. Beneficiaries may have other Medicare expenses that disproportionately occur early in the year, such as deductible payments for Medicare Parts A and B.⁵ As a result, it may be advantageous for beneficiaries in some situations to backload their drug costs. Examples like the above show that CMS should err on the side of notifying more, rather than fewer, beneficiaries they are likely to benefit from the MP3. **As a result, we ask CMS to set the amount triggering notification of likely benefit at \$400 or lower. This amount should also be based on the total OOP of prescription drugs filled in a single day.** More than half of adults aged 64 and older report taking four or more prescription drugs,⁶ and the cumulative amount OOP they pay for prescription drugs is more likely to indicate benefit than their cost for a single drug.

5. Point of Sale Enrollment (Sec. 60.2.3)

Point of sale (POS) enrollment would allow beneficiaries to opt-in to the MP3 at the point they determine payment installments would help them pay for their medications. As such, **it is vital that POS enrollment be made available concurrently with the introduction of the MP3 in 2025, rather than waiting until 2026 or later.**

⁵ Medicare.gov. Costs. Accessed 11 September 2023. <https://www.medicare.gov/basics/costs/medicare-costs>

⁶ Kaiser Family Foundation. Data Note: Prescription Drugs and Older Adults. 9 Aug 2019. <https://www.kff.org/health-reform/issue-brief/data-note-prescription-drugs-and-older-adults/>

The draft guidance asks for feedback on three avenues for beneficiaries to opt-in via near real-time options: telephonic, via phone app, or through a new “opt-in” indicator on the pharmacy’s claims submission. CMS suggests that in the initial year of availability, these options would be mutually exclusive though additional options may be added in the future.

We recommend that CMS utilize a claims-based opt-in for implementation since both the telephonic and app-only approaches create potential barriers for patients. Telephonic and app-based approaches in isolation may create access restrictions for beneficiaries in areas with limited or sporadic phone reception. Specific to the telephonic option, surveys indicate that a significant percentage – 40% in a one recent study performed in the United Kingdom⁷ – of members of the “baby boomer” generation report anxiety related to talking on the telephone. Meanwhile, smartphone use is not universal among older adults. A recent AARP survey showed that 81% of individuals 60 to 69 and 62% of those 70 and older use smartphones,⁸ numbers which have been validated by other studies.⁹ Due to these access barriers, it is not appropriate to rely solely on either of these options for opting into the MP3.

In comparison, a claims-based approach would place minimal burden on the beneficiary. Ultimately, beneficiary ease of use should be the top-tier consideration, as the goal of the MP3 is to improve the ability of beneficiaries to afford their medications, thereby reducing incidence of prescription abandonment and increased risk of adverse outcomes. Such a process would also eliminate potential complexities related to “Urgent MP3 Election” outlined in Sec. 70.8.3 of the proposed guidance.

The claims-based approach is also likely to have fewer pharmacist workflow and practical shortcomings than the other proposed options. For example, pharmacy staff will be required to provide a baseline level of information about the MP3 as part of notifying the beneficiary that they are likely to benefit from the program. At that point, a claims-based approach would permit pharmacy staff to directly indicate a beneficiary would like to enroll, rather than requiring a beneficiary to get out of line and wait to the side to engage in a telephonic or app-based enrollment. Further, since beneficiaries that opt-in to the MP3 have no liability at the point of sale, no additional burden exists for pharmacy staff in terms of calculating a beneficiary’s liability.

We thank CMS for conceptualizing three options that are relatively straightforward to implement; as a result, there is no substantive reason to delay the implementation of POS enrollment to 2026 or beyond. It is important for beneficiaries to be able to opt-in to the MP3 when they need to do

⁷ Russell, Helen. Phone Call Anxiety: Simple Ways to Overcome Your Telephobia, According to Psychology. BBC Science Focus. 17 May 2023. <https://www.sciencefocus.com/the-human-body/telephobia>

⁸ Kakulla, Brittne Nelson. Older Adults Keep Pace on Tech Usage. January 2020.

<https://www.aarp.org/research/topics/technology/info-2019/2020-technology-trends-older-americans.html>

⁹ Faverio, Michelle. Share of those 65 and older who are tech users has grown in the past decade. Pew Research Center. 13 January 2022. <https://www.pewresearch.org/short-reads/2022/01/13/share-of-those-65-and-older-who-are-tech-users-has-grown-in-the-past-decade/>

so; for beneficiaries incurring a new, relatively large OOP expense and completing their first fill, this is likely to occur at the pharmacy counter or via a mail-order service. Delaying implementation until a future year will limit the ability of beneficiaries to utilize this important option, create confusion as enrollment processes change between one year and the next, or enable or further delays in implementation that will limit the impact of the MP3 for beneficiaries.

Based on these factors, we recommend that CMS direct plans and pharmacies offer point of sale enrollment through a claims-based approach starting in 2025. To provide maximum time for implementation, we encourage CMS to issue direction on POS enrollment prior to the issuance of Part II of this guidance through the annual Medicare Advantage rate notice or other appropriate avenues.

6. Enrollee Election and Programmatic Interactions (Sec. 70)

We laud CMS for acknowledging the importance of encouraging eligible Medicare Part D beneficiaries to apply for the Low-Income Subsidy (LIS) program. As noted, the LIS program is more advantageous than MP3 for eligible beneficiaries in that the LIS provides \$0 premiums and low-cost, fixed copayments for covered prescription drugs. It is essential that Part D sponsors inform those interested in opting into MP3 of their potential eligibility for the LIS program and how to apply. By CMS' own estimates,¹⁰ up to three million seniors and people with disabilities could benefit from LIS program but are not currently enrolled. We also support CMS' direction to Part D plan sponsors to reimburse the individual for any excess premium or OOP cost sharing when an MP3 participant is retroactively enrolled in LIS.

7. Beneficiary Protections During Termination of Election, Reinstatement, and Preclusion Processes (Sec. 80)

Our organizations thank CMS for the proposal to include key beneficiary protections in the MP3 program. The statutory language for the MP3 permits beneficiaries to be disqualified from using the payment installment flexibility in the case of a missed payment. However, a beneficiary may be late on a payment for valid reasons, including administrative error by a health plan, a hospitalization or other health event that makes the beneficiary unable to pay on time, or travel or seasonal relocation that delays receipt of an invoice.

CMS's proposals are responsive to these scenarios and provide easily-understandable protections for beneficiaries, based on precedent in the Part D program found in 45 CFR§ 423.44.¹¹ Our organizations support the creation of the proposed two-month grace period after the deadline for a payment balance has passed, the ability to switch between plans without carryover MP3

¹⁰ U.S. Department of Health and Human Services. FACT SHEET: Biden-Harris Administration Announces New Tools to Lower Prescription Drug Costs for Low-Income Seniors and People with Disabilities. 12 June 2023.

<https://www.hhs.gov/about/news/2023/06/12/fact-sheet-biden-harris-administration-announces-new-tools-lower-prescription-drug-costs-low-income-seniors-people-disabilities.html>

¹¹ Code of Federal Regulations. 45 CFR§ 423.44. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423>

eligibility ramifications, and the ability for a disqualified beneficiary to have their eligibility for the MP3 reinstated by their Part D plan once overdue balances have been paid. We ask CMS to finalize these provisions in future guidance. We also ask CMS to establish a standard initial due date (such as 30 or 45 days) following issuance of a bill to beneficiaries participating in the MP3.

We support CMS's proposal for plans to use existing Part D appeals procedures regarding election, billing, and termination-related disputes. However, given that beneficiary disputes around the MP3 may materially impact beneficiaries' ability to pay for prescribed medications – and thus, have impacts on their health – we ask CMS to set forth definitions for “timely” review and adjudication. We also encourage the agency to consider the creation of a process measure in the Star Rating system associated with timely adjudication of beneficiary appeals. Other appeals processes (e.g., the independent dispute resolution process put in place by the No Surprises Act)¹² have faltered due to sheer volume and potential misuse; a process measure would incentivize plans to process appeals in a given timeframe.

Conclusion

We thank CMS for their responsiveness and engagement with beneficiaries on the implementation of the MP3, including through the issuance of this Part I guidance well in advance of the program's January 1, 2025, start date. Our organizations stand ready to continue working with CMS to help ensure have consumer-friendly information needed to make informed decisions about opting into the MP3.

To discuss these recommendations in additional detail, please contact Michael Ward at mward@agingresearch.org.

Sincerely,

ADAP Advocacy
Allergy & Asthma Network
Alliance for Aging Research
Alliance for Patient Access
Alpha-1 Foundation
Alström Syndrome International
American Association on Health and Disability
Arthritis Foundation
Asthma and Allergy Foundation of America
Autistic People of Color Fund
Biomarker Collaborative
Cancer Support Community

Lupus Foundation of America
MET Crusaders
Miles for Migraine
Movement Disorders Policy Coalition
National Association of Nutrition and Aging
Services Programs (NANASP)
National Council on Aging
National Fabry Disease Foundation
National Headache Foundation
National Health Council
National Menopause Foundation
National Organization for Rare Disorders

¹² Ernst & Young. No Surprises Act: What Payers Need to Know. 26 June 2023. https://www.ey.com/en_us/health/payers-and-the-no-surprises-act

CancerCare
CaringKind, The Heart of Alzheimer's Caregiving
CLI Society
Community Access National Network
Davis Phinney Foundation for Parkinson's
Derma Care Access Network
Exon 20 Group
Genetic Alliance
Global Liver Institute
Haystack Project
HD Reach
Headache and Migraine Policy Forum
HealthyWomen
Heart Valve Voice - US
HIV+Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
Inflammatory Breast Cancer Research
Foundation
Lakeshore Foundation
Lupus and Allied Diseases Association, Inc.

National Organization for Tardive Dyskinesia
Neuropathy Action Foundation
Noah Homes, Inc
Organic Acidemia Association
Partnership to Advance Cardiovascular Health
Partnership to Fight Chronic Disease
Patient Access Network (PAN) Foundation
Patients For Affordable Drugs Now
PD-L1 Amplifieds
PXE International
RASopathies Network
StopAfib.org
SYNGAP1 Foundation
The AIDS Institute
The Bonnell Foundation: living with cystic
fibrosis
The Michael J. Fox Foundation for Parkinson's
Research
Triage Cancer
TSC Alliance
U.S. Pain Foundation



September 20, 2023

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

Re: Medicare Prescription Payment Plan Guidance

Dear Administrator Seshamani:

On behalf of the Alliance for Patient Access (AfPA), thank you for the opportunity to provide comment on the Medicare Prescription Payment Plan Guidance. Specifically, AfPA supports robust beneficiary education on the establishment of the program and the benefits of enrolling. CMS should also implement clear requirements for disenrollment, allow for adequate grace periods related to missed payments, and enable swift reinstatement to the program once payment is made.

About AfPA

Founded in 2006, AfPA is a national network of policy-minded health care providers who advocate for patient-centered care. AfPA supports health policies that reinforce clinical decision making, promote personalized care and protect the clinician-patient relationship. Motivated by these principles, AfPA members participate in clinician working groups, advocacy initiatives, stakeholder coalitions and the creation of educational materials.

Medicare Part D Redesign

AfPA advocated for the \$2,000 out-of-pocket cap and monthly payment plan that were instituted in the Inflation Reduction Act and are pleased that CMS is working diligently to implement these provisions to benefit our seniors. This program redesign is vital in ensuring beneficiaries can afford their medicines and will bring Medicare beneficiaries' cost exposure within the Part D program in line with other insurance plans by capping out-of-pocket expenses. Currently, due to high coinsurance requirements, many Medicare beneficiaries have high out-of-pocket medication costs, particularly at the start of a new plan year, making this cap, along with measures that provide consistent costs month-to-month, critical.

Because the out-of-pocket cap and monthly payment plan will be new to beneficiaries in 2025, it is critical CMS takes the opportunity to educate seniors on the new opportunities they have to lower their Part D treatment costs, along with the opportunity to benefit from more consistent monthly medication costs.

Beneficiary Education

It is especially important to ensure that patient education is done in a clear and simple manner and does not confuse or overwhelm beneficiaries with unnecessary or overly technical information. There is real potential for confusion for Part D beneficiaries, and clear educational materials can help avoid much of that confusion.

We encourage CMS to broadly educate Part D beneficiaries. While targeted outreach is important and effective in ensuring those most likely to utilize the program are contacted, we support broadening that outreach as much as possible. When Congress passed the IRA and enacted the payment plan language, their intent was to ensure the program could support as many beneficiaries as possible. Medicare beneficiaries have health care costs outside of the Part D drug spend that factor into their total health care cost exposure, and

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CMS should ensure that beneficiary education is not solely based on a high Part D drug spend. We understand that CMS will be releasing Part 2 of this guidance in the future and encourage CMS to provide a more detailed education strategy in that guidance.

Beneficiary Enrollment

It is also important to ensure that beneficiaries are given ample opportunity to enroll in the program. Statutory limitations make it unfeasible to switch the program from “opt-in” to “opt-out”, making it even more imperative to make it as easy as possible for beneficiaries to enroll in the program. When implementing this program, we encourage CMS to consider multiple avenues of enrollment to ensure that the program is accessible for a wide range of beneficiaries who may not have access to reliable phone service or a smartphone to enroll via an app.

One important avenue for enrollment is at the pharmacy where the beneficiaries receive their medications. Pharmacists are in a unique position to educate beneficiaries on the opportunity to opt into the level payment plan. For this reason, we encourage CMS to implement enrollment at the point-of-sale for 2025 rather than 2026 as proposed. We understand that implementing point-of-sale enrollment is a challenge logistically; however, it presents an important opportunity to expand beneficiary enrollment and should be in place when the program becomes available in 2025.

We also support the proposal to allow beneficiaries to opt into the program at any point in the year. This is crucial in the event that a beneficiary’s medication usage changes, making the program more applicable to their situation. We encourage CMS to require a strict and efficient timeline for processing these changes to enable patients to benefit from the program as quickly as possible.

It is also important for CMS to provide additional guidance if patients switch plans in the middle of the year due to a relocation or a move. In Part 2 of this guidance, we encourage CMS to clarify what security is in place to ensure that out-of-pocket expenses that have already been paid are carried over to the new plan and patients don’t face excessive wait times when plans are switched.

Grace Periods and Notice Requirements

CMS has clarified that beneficiaries can be disenrolled based on a missed payment. However, additional clarity is needed on the length of disenrollment for non-payment, grace periods for payments and ways to remedy non-payment leading to reenrollment in the program.

AfPA strongly supports grace periods being implemented for patients who miss payments, instead of automatic disenrollment from the program. We appreciate CMS’ proposed two-month grace period; however, it is important that CMS ensure beneficiaries receive clear communication during that grace period, in the event that they are not aware of the outstanding balance. This communication is critical because procedural/administrative issues can pose challenges related to timely notification of an outstanding balance.

When considering what disenrollment triggers look like, CMS should examine the current challenges facing the Medicaid redetermination program. Evidence on the Medicaid program has shown that administrative barriers are a leading cause of disenrollment, rather than eligibility. Of all Medicaid patients disenrolled as of September 2023, 72% of those disenrollments were for procedural reasons.¹ AfPA urges CMS to require notification and communication with beneficiaries about outstanding balances to ensure that similar administrative issues do not result in beneficiaries losing access to this program.

¹ <https://www.kff.org/medicaid/issue-brief/medicaid-enrollment-and-unwinding-tracker/>

We also urge CMS to provide more clarity on disenrollment and what that entails. We understand that in the event that a beneficiary has an outstanding balance after the two-month grace period ends, the patient will be disenrolled and potentially barred from participation in the following plan year and in future years. We are concerned that without specific guidance, plans will disallow patients from utilizing the benefits of the payment plan for multiple years. We encourage CMS to release specific guidance to clarify the regulations around excluding patients from the program for outstanding balances and support clear regulations requiring eligibility for re-enrollment after a one-year period of disenrollment. Patients should also be allowed to re-enroll in the program after they have repaid the balance that they owe.

Conclusion

The Medicare Prescription Payment Plan Guidance contains critical provisions implementing the monthly payment plan, a program that will ease the burden of high out-of-pocket costs patients often face at the beginning of a new plan year. We applaud CMS for implementing these provisions codified in the IRA and ask CMS to continue to work to expand seniors' access to affordable health care and ensure the clinician-patient relationship remains strong.

We recognize the complexity of the issues facing CMS and appreciate the opportunity to comment. If you have any questions or would like further information, please contact Charles Husser at (202) 951-7097.

Sincerely,

A handwritten signature in cursive script that reads "Josie Cooper". The signature is written in a dark ink and is positioned below the word "Sincerely,".

Josie Cooper
Executive Director
Alliance for Patient Access



September 20, 2023

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

Dear 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 draft guidance 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” (Draft Part One Guidance) issued on August 21, 2023.

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.

AMCP commends CMS for its continued efforts to reduce out-of-pocket costs for patients. AMCP shares CMS’ commitment to ensuring access to low-cost medication to improve the health outcomes of patients.

Implementation

AMCP and its members are concerned about ensuring timely implementation of the Medicare Prescription Payment Plan (MPPP) given the complexity of the requirements and the short turnaround time before the effective date. While the Draft Part One Guidance notes that it will be finalized by spring 2024 and that a draft part two guidance will be issued in early 2024 and finalized by spring or summer 2024, AMCP is concerned that CMS’ timeline does not give plans enough time to adequately prepare for implementation by January 1, 2025. Plans need to complete a variety of technical changes, including but not limited to creating opt-in, billing, and payment processes; drafting and finalizing communications to MPPP participants (Participants)

and prospective Participants; coordinating with pharmacies regarding claims processing changes; and implementing new data submission requirements. Given the heavy lift needed for this implementation, plans need information and guidance from CMS as soon as possible. AMCP urges CMS to accelerate its timeline for issuing guidance such that all final operations guidance is given to plans with sufficient time to implement all facets of the MPPP by the effective date.

Because of this difficulty with implementing a new program in a short timeframe, AMCP also urges CMS to use its enforcement discretion during the first year of the MPPP for plans that have made good faith efforts to comply with its requirements. AMCP asks for understanding that plans are moving as quickly as possible to implement this complex program with limited resources while awaiting final guidance on important aspects of the MPPP.

Participant Billing Requirements

AMCP applauds CMS for encouraging Part D sponsors to offer multiple payments methods, such as electronic funds transfer (EFT), cash, or check. AMCP encourages CMS to expand on these enumerated options by expressly listing pre-pay and auto pay mechanisms in its final guidance. These options would reduce the likelihood of missed payments. AMCP also encourages CMS to allow Participants to deduct payments from Social Security. AMCP urges that CMS should encourage as many payment options as possible.

The Draft Part One Guidance notes that, while Participants may pay more than the maximum monthly cap, Participants cannot pay more than their total out-of-pocket costs incurred. AMCP encourages CMS to allow Participants the option to pay up to the maximum out-of-pocket (MOOP). The Part D sponsor would then use the financial reconciliation outlined in Section 1860D–2(b)(2)(E)(v)(III)(gg) of the Inflation Reduction Act (IRA) to adjust for any overpayment. This approach would give each Participant the greatest amount of flexibility and control when determining the payment options that work best for their individual circumstances.

Requirements Related to Part D Enrollee Outreach

AMCP supports the development of a uniform, national communication strategy to educate Medicare enrollees and others. The overall approach should incorporate a variety of tools and messengers to ensure the broadest reach. AMCP's members would welcome additional guidance, model documents, and training materials to assist them in their outreach efforts. Standardized communications for insurance plans, pharmacies, pharmacists, and providers would help to ensure consistency and clarity.

AMCP encourages CMS to update the Medicare.gov Plan Finder website to include information about the MPPP and the out-of-pocket cap to help beneficiaries when selecting a plan.

We suggest that CMS provide educational materials and guidance to pharmacies while encouraging pharmacies to provide education programs to alert front-line pharmacy employees about the MPPP. This would help to alleviate the potential for confusion for these employees, Participants, and prospective Participants alike. Front-line pharmacy employees need to understand how the MPPP will work so that they can adequately respond to inquiries from prospective Participants. They also need to learn how to correctly process MPPP claims. If a point of sale (POS) election option is implemented, these employees will also need to

understand any new processes to ensure that patients are able to opt in while interacting with the front-line pharmacy employees.

Prohibition on Part D Enrollee Discrimination

AMCP's mission is to improve Americans' health by ensuring access to high-quality, cost-effective medications and other therapies.¹ For this reason, AMCP supports CMS' prohibition on discriminating against or inhibiting access to the MPPP for any Part D enrollee, including those eligible for the Low-Income Subsidy (LIS). Eligibility for the LIS is based on an enrollee's income and other assets, which must be below specified levels. The goal of the LIS program is to increase access to needed prescription medications and to support medication adherence by lowering the cost barrier. AMCP believes that all Part D members should be able to avail themselves of the potential benefits of the MPPP.

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 or (703) 705-9358.

Sincerely,



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

¹ One of AMCP's strategic priorities is to address health disparities in medication use and access. See <https://www.amcp.org/about/about-amcp/amcp-strategic-priorities> for more information.



September 20, 2023

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Via Email: PartDPaymentPolicy@cms.hhs.gov

Re: Comments on 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

To Whom It May Concern,

On behalf of the Medicare Committee of the American Academy of Actuaries¹ (the committee), we appreciate the opportunity to provide comments on the draft part one guidance for the *Maximum Monthly Cap on Cost-Sharing Payments Program*.²

The committee's comments cover four areas of the Medicare Prescription Payment Plan (MPPP) for Centers for Medicare & Medicaid Services (CMS) consideration, discussed further below.

1. Simplification of the monthly payment formula
2. Consideration of various options for enrollment outreach
3. Creation of a centralized tool for beneficiaries
4. Analysis of the potential downstream impact on health plan operations and incentives

Simplification of the monthly payment formula

While the formula for calculating monthly participant payments is relatively simple, understanding the resulting values can be difficult. Plans and pharmacists may be challenged to explain to participants how their payment amount is set, and participants may be confused by the sometimes significant changes in payment amounts from one month to the next.

An alternate approach might treat each month as a distinct “no-interest loan,” in which the payment is always calculated as [Out-of-Pocket (OOP) Costs] / [# of months remaining in year]. Under this approach, the payment amount for any given loan would never change, but the number of loans provided could increase if the participant has additional OOP costs in future months (resulting in a

¹ The American Academy of Actuaries is a 19,500-member professional association whose mission is to serve the public and the U.S. actuarial profession. For more than 50 years, the Academy has assisted public policymakers on all levels by providing leadership, objective expertise, and actuarial advice on risk and financial security issues. The Academy also sets qualification, practice, and professionalism standards for actuaries in the United States.

² <https://www.cms.gov/files/document/medicare-prescription-payment-plan-part-1-guidance.pdf>

greater total payment owed). Under the current approach, payments are often highest in the first month, lower in the second month, and gradually increase afterward. Under this alternate approach, payments would be the same in all months for a single loan, and total payments would stay the same or gradually increase in subsequent months until the Maximum Out-of-Pocket (MOOP) is met. A calculation like this may make it easier for participants to understand what they owe for each month (leading to better compliance), ease the burden on pharmacists, and result in fewer billing errors.

Consideration of various options for enrollment outreach

The methodology for identifying enrollees who are “likely to benefit” (section 60.2) has several limitations. Because it relies on 2023 expenditures to identify people likely to benefit in 2025, this method will likely miss newly diagnosed patients who will begin treatment in 2024 or 2025. These patients are more likely to face high OOP costs for the first time, and, as a result, they may be important to flag as “likely to benefit.” While the targeted Part D enrollee notification at point-of-service (POS) initiative is likely to alleviate this limitation, it may benefit from an accompanied enrollment option at the POS (possibly via the website application described in section 70.3.1).

Additionally, given how different the benefit design will be in 2025 due to the *Inflation Reduction Act* (IRA), historical OOP costs may not predict future OOP costs well. The proposed methodology will likely overstate the number of people likely to benefit if based on 2023 OOP costs due to the lack of MOOP in 2023. CMS could consider re-adjudicating claims to 2025 defined standard benefits.

A relatively simple improvement to CMS’ proposed methodology could include identifying and publishing the top 20 drugs most likely to trigger OOP costs in excess of the monthly cap based on historical data, providing enrollees with additional information for decision-making.

Creation of a centralized tool for beneficiaries

As discussed above, it may be difficult for a participant to understand and plan for the amounts owed each month, which makes it critical to have accurate and easy-to-understand tools for enrollees to decide whether the program is right for them. An interactive online tool in which enrollees can input their expected claims by month could be beneficial. Rather than duplicating resources by having each plan sponsor develop its own tool—which could result in inconsistent beneficiary experiences—we suggest that CMS develop a tool used by all plans and to which pharmacists could direct enrollees. One possibility would be to build the tool or provide a link directly within Medicare Plan Finder (MPF) on medicare.gov. To the extent MPF already has functionality for enrollees to input their expected drug claims and calculate their estimated OOP costs, it would be a natural extension to use the same data to also show what monthly participant payments would be under MPPP. This could encourage more proactive decisions by enrollees to opt in to MPPP, which will help prevent any delays in treatment or operational complications associated with real-time enrollment.

With regard to real-time enrollment, we note that the guidance suggests plan sponsors develop a mobile or web-based application. However, as noted above, this may be less efficient and more prone to inconsistent beneficiary experiences and/or calculation errors than if CMS coordinated the development of a single application to be used by all plan sponsors.

We note the following additional considerations which would help make a decision tool successful:

- While many enrollees may appreciate the ability to input their own costs, such as through MPF as discussed above, others may benefit from a few default examples, such as a \$500 OOP cost and a \$2,000 OOP cost, in January versus June, for example, to illustrate what could be typical payment amounts or the pattern of change in payments throughout the year. This could be illustrated in a flyer sent to enrollees and available at the pharmacy counter.
- For user-input costs, the tool could allow for input of a drug name and automatically look up the expected OOP costs, as many enrollees may not know the cost of their drug or understand what their OOP costs will be as they move through the benefit phases.
- Similarly, a tool could account for prior OOP costs to inform enrollees that participation may not be as beneficial if they are already near their MOOP for the year.
- To the extent CMS encourages plans to provide information on the Low Income Subsidy (LIS) program, the tool could also directly compare OOP costs under the LIS program to demonstrate the incremental value of the program and include a link to information on LIS eligibility and the application process.
- It will be important for enrollees to understand how MOOP accumulation is affected by the program, given accumulation will be based on costs incurred rather than actual monthly payments under MPPP.

Analysis of the potential downstream impact on health plan operations and incentives

The following are some additional considerations as CMS implements this important new program:

- **Medicare Stars Rating Impact**—We encourage CMS to monitor any Stars impacts from implementing this program. Members could be confused about certain elements of the program (e.g., varying payment amounts over time, or conflicting information from member tools), which could drive a negative perception of the program and member complaints.
- **Adherence**—We encourage CMS to continue to explore ways to encourage higher levels of adherence for stand-alone Prescription Drug Plan (PDP) members. While Medicare Advantage plans benefit financially from adherence through the Stars bonus program and potential medical cost offsets, PDPs do not benefit financially and incur additional prescription costs. This program could further increase adherence, a desired outcome, but we recommend aligning PDP incentives with that goal.
- **Bad Debt**—There will be higher levels of uncertainty (particularly in the first year) with regard to projected bad debt levels. Bad debt is likely to impact plan financials and may cause premiums to increase. We encourage CMS tracking of the bad debt filed in bids before and after implementation to monitor if there is any material impact from the program's implementation. Bad debt impacts could be larger for plans with higher morbidity populations, such as special needs plans.
- **Low-Income Membership**—Section 70.2 of the draft part one guidance states the importance of informing individuals interested in the Payment Plan of potential eligibility in the LIS program. This section also states that the draft part two guidance will provide “additional requirements” about “Part D sponsor responsibilities related to Part D enrollees participating in the LIS program.” Other interested parties have estimated that 2 million to 3 million LIS-eligibles have not enrolled.³ With potentially millions of enrollees being affected, we would ask that CMS

³ [“Take-Up Rates in Medicare Savings Programs and Extra Help”](#); National Council on Aging; Sept. 9, 2022.

consider how such requirements might affect Part D LIS/non-LIS market segmentation, such as described in recent MedPAC work or other Part D plan dynamics.⁴ In addition, we would ask for clarification on whether or how CMS intends to measure or reward/penalize a plan's enrollment in the Payment Plan by LIS-eligibles. Finally, we recommend that CMS ensures the payment plan is beneficial to a given LIS member, as examples like B7 may be worse for the member than not smoothing.

- **POS Election**—Even if unachievable for the 2025 plan year, we believe the opportunity for participants to elect into the program at the POS could be valuable for increasing program elections. We encourage thoughtful consideration of implementing POS election in the near future and consideration of ways to engage other stakeholders (e.g., retail pharmacies) to assist. Historically, providers have struggled with having accurate and reliable benefit plan information at the POS, which will be important for this program.

The committee appreciates the opportunity to provide comments on the draft part one guidance on the *Maximum Monthly Cap on Cost-Sharing Payments Program* and welcomes the opportunity to speak with you in more detail and answer any questions you have regarding these comments. If you have any questions or would like to discuss this further, please contact Matthew Williams, the American Academy of Actuaries' senior health policy analyst, at williams@actuary.org.

Sincerely,

Rina C. Vertes, MAAA, FSA
Chairperson, Medicare Committee
American Academy of Actuaries

Derek Skoog, MAAA, FSA
Vice Chairperson, Medicare Committee
American Academy of Actuaries

⁴ “[Segmentation in the stand-alone Part D plan market](#)”; *MedPAC Report to Congress*, chapter 7; June 2022.



September 19, 2023

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

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

Dear Administrator Brooks-LaSure:

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

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

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

Participant Billing Requirements (Section 40)

Clear and simple billing practices will minimize the administrative burden on patients as well as the risk of missed payments. CMS should encourage plans to align MPPP billing with Part D premium billing, as well as offer autopay options and the ability to automatically deduct MPPP payments from Social Security checks. Regarding the required information for billing statements, the Lung Association encourages CMS to prioritize clear, actionable information for patients on the first page of each statement, as well as notify patients once they have reached the \$2,000 OOP cap and provide a breakdown of their monthly payments for the rest of the year. Additionally, if patients enrolled in the MPPP switch Part D plans mid-year, plans must notify consumers that they will continue to receive monthly bills from their previous plan to avoid confusion.

The Lung Association appreciates the request for comment on practices related to debt collection. As we recently outlined in comments on a request for information regarding medical payment products, millions of patients experience medical debt with devastating

consequences.² The Lung Association encourages you to use all available authorities to restrict egregious debt collection practices related to the MPPP.

Requirements Related to Part D Enrollee Outreach (Section 60)

A robust education and awareness strategy will help patients and other stakeholders understand the OOP cap and their ability to spread payments out over a calendar year. Recent polling suggests that only one third of seniors are aware of the upcoming annual OOP prescription drug limits for people with Medicare coverage.³

The Lung Association looks forward to reviewing and commenting on part two of this guidance, which will include additional information on outreach and education. We specifically urge 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. All materials must be in plain language and accessible to individuals with limited English proficiency and individuals with disabilities.

One educational tool that will be especially important to patients is a simple online calculator that allows them to input expected prescription drug costs and determine whether opting into the MPPP makes sense for them. We urge you to prioritize development of this resource so it is ready before open enrollment in fall 2024 and would be happy to provide feedback during the development process.

Finally, the guidance discusses the process for notifying enrollees who are likely to benefit from the MPPP about the program at the point of sale. We urge you to set the threshold for notifying patients no higher than \$400 and to consider setting a lower threshold. Especially in the first year of the program, notifying as many patients as possible about the program is important to ensure successful uptake.

Requirements Related to Part D Enrollee Election, Including a Request for Information on Real Time POS Election (Section 70)

Point of sale enrollment is an essential feature of successful MPPP implementation. Many patients will not decide to enroll until they are faced with a high OOP cost for a prescription. Again, this is especially true in the first of year of the program, as fewer patients will likely be aware of and understand how the program will impact their OOP costs during the first open enrollment period. 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. For these reasons, the Lung Association strongly urges CMS to implement point of sale enrollment in 2025 and not further delay it.

In general, we believe that point of sale enrollment via a clarification code entered by the pharmacist would provide the smoothest experience for patients. If this not possible for 2025, CMS should specify what technical or other barriers are blocking implementation, how and why the final timeframe was chosen, and a clear process to address the specified barriers no later than 2026. CMS should provide both telephonic and online point of sale enrollment options for 2025.

Finally, once patients affirmatively opt into the MPPP, we encourage CMS to require plans to automatically reenroll patients who remain with an existing plan. Many patients with lung

disease and other chronic conditions who benefit from the MPPP are on regular maintenance medications and will likely continue to benefit from enrollment. Auto reenrollment will help to streamline this process.

Procedures for Termination of Election, Reinstatement, and Preclusion (section 80)

The Lung Association supports the consumer protections in the procedures for termination from the MPPP, including comprehensive notice requirements, a two-month grace period for late payments, a good cause exemption, and the ability for patients to enroll in the MPPP in subsequent years after paying off outstanding balances. We urge CMS to include all of these protections in the final guidance. Additionally, CMS should provide additional detail on the good cause exemption process, including the types of reasons plans should consider for granting an exemption and clear standards for how plans inform patients about the availability of this exemption.

Other Implementation Issues

Strong monitoring and oversight will be important during this period of significant change for Medicare Part D. For example, especially for patients with moderate spending who do not reach the OOP cap, any changes in cost-sharing or utilization management like moving drugs from copay to coinsurance or moving drugs to higher tiers could actually increase OOP costs. CMS should closely monitor the impact of the MPPP and other parts of the Part D redesign in these areas to address potential unintended consequences and ensure that patients do not experience problems accessing the medications they need to treat lung diseases. Additionally, CMS should monitor uptake of the program, including collecting and releasing data on the demographics of those using the program, late payment and disenrollment rates, and other key information.

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 Wimmer
President and CEO

¹ KFF, Public Opinion on Prescription Drugs and Their Prices. Updated August 21, 2023. Available at: <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>

² Partnership to Protect Coverage, Comments on Medical Payment Products RFI, September 11, 2023. Available at: <https://www.lung.org/getmedia/1aec961e-3df8-4273-b5de-e85098ca6b23/091123-PPC-Medical-Debt-RFI-FINAL.pdf>.

³ 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/>.



September 20, 2023

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

Submitted via email: PartDPaymentPolicy@cms.hhs.gov

Re: Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments

Dear Dr. Seshamani:

The American Pharmacists Association is pleased to submit comments on draft part one guidance for the Maximum Monthly Cap on Cost-Sharing Payments Program (MPPP), established by section 11202 of the Inflation Reduction Act (IRA).

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.

APhA thanks HHS for meeting with APhA in July to discuss educating consumers about the Inflation Reduction Act (IRA) and your ongoing work to implement the IRA provisions to provide relief for millions of Medicare beneficiaries by improving their access to affordable prescription medications.

APhA also appreciates the [draft guidance](#) and [Fact Sheet](#) clarifying that “[p]harmacies will be paid in full by the Part D sponsor, in accordance with Part D prompt payment requirements.” To help ensure a seamless approach for beneficiaries, APhA urges CMS

to develop and/or require Part D plans to develop clear, consumer-friendly, standardized educational materials for beneficiaries to help provide the intended affordable relief to enrollees. APhA also urges CMS to update the Medicare.gov Plan Finder website to include information about the MPPP and the out-of-pocket cap to help beneficiaries when selecting a plan.

The draft guidance notes that it will be finalized by spring 2024 and that a draft part two guidance will be issued in early 2024 and finalized by spring or summer 2024. The implementation deadline of January 1, 2025, may not be adequate. APhA recommends CMS accelerate its timeline for issuing guidance to Part D plans to ensure that all final operations guidance is given with sufficient time to implement all facets of the MPPP by the effective date, or APhA recommends extending the implementation date.

§50. Pharmacy Payment Obligations and Claims Processing

50.1 Pharmacy Claims Processing Requirements

APhA appreciates the draft guidance stating that “consistent with section 1860D-12(b)(4) of the Act and 42 CFR § 423.520, Part D sponsors must reimburse a network pharmacy the total of a participant’s OOP amount and the Part D sponsor portion of the payment for a covered Part D drug no later than 14 days after the date on which the claim is received for an electronic claim or no later than 30 days after the date on which the claim is received for any other claim.”

The draft guidance states “[a]t this time, CMS is encouraging the adoption of an electronic claims processing methodology such as the one currently used for real-time COB billing transactions using NCPDP standards.”

Most pharmacy transaction systems do not have an exception process to support actions for messages on paid claim responses and would incur technology costs, maintenance, and training of pharmacy personnel. Accordingly, APhA urges CMS to require Part D plans to pay pharmacies adequate dispensing fees to pay for any incurred pharmacy expenses if CMS elects to use the COB standard.

In addition, the draft guidance states, “Part D sponsors would utilize an additional Bank Identification Number (BIN) and/or Processor Control Number (PCN) unique to the Medicare Prescription Payment Plan to facilitate electronic processing of supplemental COB transactions for program participants.”

APhA supports NCPDP’s comments recommending each Part D Sponsor establish a unique BIN/PCN for this program and requests CMS require the PCN begin with “MPPP” to assist with claim billing orders so that pharmacy practice management systems can identify and process these claim responses.

APhA also supports the following NCPDP requests for guidance from CMS on how to manage the following scenarios:

- Patient has Supplemental Medicaid coverage and it is unknown to the pharmacy or plan:
 - Not returned with COB-OHI information.
 - When the pharmacy has not performed an E1 transaction to know if the beneficiary has Medicaid coverage.
- Beneficiary has more than two other payers:
 - In Version D.0, the standard is limited to providing three payers in the response.
 - In Version F6, the standard is limited to providing four payers in the response.
- Processing out-of-cycle reversals and adjustments.
- A claim is adjusted after the last invoice is received by the beneficiary at the end of the calendar year.

APhA also supports NCPDP’s request for CMS to include a statement in the final guidance indicating there will be no impact to Automated TrOOP Balance Transfer (ATBT) processes and Financial Information Reporting (FIR) transactions will continue to reflect the TrOOP and Drug Spend by month using the original claim accumulators, as they currently do.

CMS may want to consider permitting participants the option to pay up to the maximum out-of-pocket (MOOP). The Part D plan would then use the financial

reconciliation outlined in Section 1860D–2(b)(2)(E)(v)(III)(gg) of the Inflation Reduction Act (IRA) to adjust for any overpayment.

50.2 Pharmacy Transaction Costs

The proposed guidance states that “[a]ny additional transaction fees or other costs pharmacies incur from processing claims under the Medicare Prescription Payment Plan or otherwise related to such program are considered allowable pharmacy costs associated with the dispensing of a covered Part D drug that may be paid through applicable dispensing fees.”

APhA recommends CMS add a requirement for Part D plans, in addition to the term “allowable,” as pharmacists’ ongoing experiences with Part D plans and their pharmacy benefit manager (PBMs) is that they are often unlikely to reimburse pharmacies for costs that are “allowed.” Accordingly, CMS must make it clear to Part D plans and PBMs that MPPP-related pharmacy costs for the COB methodology approach are required to be reimbursed to pharmacies through sufficient dispensing fees.

50.3 Requirements for Different Pharmacy Types

CMS is seeking feedback on “unique scenarios that may arise related to different pharmacy types participating in the program that may require alternative payment or claims processing standards.”

APhA supports NCPDP’s request for additional information on the following long-term care (LTC) scenarios:

- How should the process work when the patient pay amount is billed to the facility rather than directly to the beneficiary?
 - The pharmacy expects payment from the facility rather than the patient. Should the pharmacy submit the COB Medicare Prescription Payment Plan claim?
 - How would this be identified to the pharmacy?
 - Will the beneficiary or the legal representative of the beneficiary also receive the claim billing invoice?

- If the beneficiary is not in a facility in January but enters a facility later in the year (while enrolled in the program), would the beneficiary continue to be billed for their monthly program payment amount?
- Will Low-Income Cost-Sharing Subsidy (LICS) retrospective eligibility be handled differently for LTC beneficiaries?
- When it would be beneficial for LTC patients to enroll in the program.

§60. General Part D Enrollee Outreach Requirements

CMS notes that “if a Part D enrollee has not already opted into the program, the Part D sponsor will notify the pharmacy to inform the individual about the program if their cost-sharing for covered Part D drugs exceeds a dollar threshold based on either an individual prescription or all prescriptions filled on a single day.” CMS also states it will provide additional guidance on the contents of notifications and model language for education materials.

APhA reiterates the message from our August 8th joint letter that the text of the statute does not require pharmacies to enroll or register a beneficiary into the Smoothing Program or to document the encounter and that Part D and MA-PD plan sponsors, not pharmacies, are best suited to enroll patients into the program. Congress went as far as to title subclause (III) under Section 11202 as “PDP Sponsor and MA Organization Responsibilities.” There is a clear line of demarcation from Congress on the responsibilities of Part D and MA-PD plans under the IRA. Where election into the MPPP occurs at the point of sale (POS) (i.e., opt-in) without delay, potential participants will likely require the assistance of pharmacy personnel to educate and inform them about the details of the MPPP and assist with the communication to the Part D sponsor. CMS should ensure that any actions at the pharmacy counter by pharmacy team members (i.e., how to correctly process MPPP claims, etc.) are reimbursed in full through an administrative fee to pharmacies that cover all of the costs for performing any services and any transaction fees that result (e.g., claim reversals and resubmissions).

60.2.4 POS Notification Requirements

APhA supports the language under §60.2.4 which states that if a prescription is picked up by another person who is not the Part D enrollee, then the pharmacy would be required to provide the person who is picking up the prescription with the relevant information, as the pharmacy will not be able to easily track down and notify the Part D enrollee directly.

§70. Requirements Related to Part D Enrollee Election

70.3.7 Retroactive Election in the Event the Part D Sponsor Fails to Process an Election within 24 Hours

The proposed guidance states “if a Part D enrollee has fulfilled all program election requirements, but the Part D sponsor is unable to process the election into the program in the required amount of time due to no fault of the individual, the Part D sponsor must process a retroactive election back to the original date” “when the individual should have been admitted into the Medicare Prescription Payment Plan (i.e., within 24 hours of the individual providing the requisite information for election into the program). In addition, the Part D sponsor must reimburse the participant for any OOP cost sharing paid on or after that date and include those amounts, as appropriate, in a monthly bill under the program within 45 days.”

APhA requests CMS clarify that Part D plans are the only party responsible for the retroactive election and reimbursement to the participant and that the Part D plan, or its PBM, will not pass this administrative burden onto the pharmacy. For example, a patient who picks up their medication and pays the full copay, and later is retroactively enrolled in the program should not be permitted to return to the pharmacy for a refund as pharmacies lack the ability, reimbursement, and resources to provide any remedy.

APhA also supports NCPDP’s comments requesting clarification from CMS on the reprocessing and reimbursement/billing of retroactive claims when a beneficiary participates in the program. Guidance is needed on how the reimbursement/billing process will work.

70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs

CMS is also seeking comments on different options (telephone only, mobile or web-based application, clarification code) to process elections into the MPPP in “real-time and near-real-time,” at the POS beginning in 2026 or later.

Under all three options, if pharmacy personnel are required to educate and inform patients about the details of the MPPP and assist with the communication of the Part D plans, then pharmacies should be reimbursed for these costs and any transaction fees that result, such as for the claim reversal and resubmissions mentioned in the draft guidance.

Thank you for the opportunity to provide comments on the draft guidance. If you have any questions or require additional information, please contact APhA at mbaxter@aphanet.org.

Sincerely,



Michael Baxter
Vice President, Federal Government Affairs



September 20, 2023

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 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 August 21, 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*

Arnold Ventures (AV) is a philanthropy dedicated to investing in evidence-based policy solutions that maximize opportunity and minimize injustice. Our work within the health care sector is driven by the recognition that the system costs too much and fails to adequately care for the people it serves. Our work spans a range of issues including commercial-sector prices, provider payment incentives, prescription drug prices, clinical trials, Medicare sustainability, and complex care.

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, this letter provides comments on the following sections:

- 60.1 General Part D Enrollee Outreach Requirements
- 60.2.3 Targeted Part D Enrollee Notification at the Point of Service (POS)
- 70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and other POS Needs
- 80.2.1 Involuntary Terminations—Notice Requirement
- 80.5 Disenrollment

Summary of the Medicare Prescription Payment Program (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 opting into 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. The MPPP program primarily benefits beneficiaries with high OOP costs incurred early in the calendar year.¹

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 as well as any OOP costs to the pharmacy for any prescriptions that they obtain in the future. 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.

60.1 General Part D Enrollee Outreach Requirements

Part D sponsors must provide informational materials about the MPPP through communication and marketing materials during open enrollment as well as in educational materials to their beneficiaries. Model language and templates for these materials will be forthcoming in future CMS guidance.

Clear educational materials provided to Part D beneficiaries will be critical to the success of the MPPP program. It is critical that beneficiaries understand the implications of joining this program because while some beneficiaries will benefit, others may be worse off. Top line messages that need to be communicated include the following:

- The MPPP is administered by an individual's Part D plan but is an entirely separate program. If for any reason a beneficiary is dropped from the MPPP program by their Part D plan that does not affect their Part D coverage.
- Beneficiaries need to prioritize Part D premium payments over monthly installment payments. The beneficiary can lose Part D coverage by failing to pay their premium. This is not the case if they fail to make their monthly MPPP installment payments.
- The MPPP primarily benefits those with high OOP costs early in the calendar year. Beneficiaries that have high OOP costs at the end of the year or who incur monthly OOP costs at the pharmacy counter that do not vary much over time are unlikely to benefit from the MPPP. It is important to provide example calculations in educational materials that describe scenarios in which beneficiaries would benefit from opting into the MPPP as well as scenarios where they would not benefit (as discussed in section 70.3.3).

With respect to the last bullet, it is important to note that a beneficiary enrolled in the MPPP that already has consistent coinsurance or copayments each month will initially benefit by paying very low monthly installment payments. But they will receive high monthly installment bills at the end of the year that could be as much as 3 times their normal monthly copayments and coinsurance payments. Without effective communication, a beneficiary in this scenario may not have joined the MPPP because of those balloon payments at the end of the year. The statutory formula in the

¹ This is because those high OOP costs are smoothed over many monthly installment payments. Most beneficiaries with high OOP costs at the end of the year, or those that already have relatively "smooth" monthly OOP payments (such as \$200 per month) do not benefit from this program.



IRA for repaying OOP costs to the Part D plan under the MPPP does the opposite of smoothing payments over time for these beneficiaries.

In addition to providing information to beneficiaries about the MPPP in their promotional materials and in their communications with beneficiaries, Part D sponsors are also required to provide information to beneficiaries *after* they opt into the MPPP. This includes examples of how monthly installment payments are calculated. Importantly, the guidance specifies that these examples would cover cases that illustrate when opting into the program would be beneficial as well as cases where it would not be beneficial. (See Sections 70.3.3, 70.3.4 and 70.3.5 on Processing Election Requests). It is also important to consider how beneficiaries might receive direct technical assistance from their Part D plan about the MPPP when making the decision about whether it would benefit them under their individual circumstances.

60.2.3 Targeted Part D Enrollee Notification at POS

The pharmacy will notify beneficiaries with OOP costs above a threshold amount in a single visit that they are likely to benefit from opting into the MPPP. CMS is seeking comments on the threshold amount to use for such notifications. Based on an analysis of claims data, CMS has found that a threshold of somewhere between \$400 to \$700 in OOP costs in a single visit is likely to identify beneficiaries that will benefit from the MPPP program.

Arnold Ventures recommends that CMS also consider the month of the year in which those high OOP costs are incurred. If the threshold is set at the low end of this range, such as at \$400, then a subset of beneficiaries is more likely to face ballooning installment payments at the end of the year after joining this program. To help mitigate this problem, the threshold could be lower for beneficiaries who join in the first half of the year and higher for those who join in the second half of the year.²

Other factors CMS could consider when targeting the program to beneficiaries who will benefit most from the MPPP are the following, which affect the pattern of OOP costs over time:

- Whether the drug treats a chronic or acute condition (OOP costs are more likely to recur in future months if the drug treats a chronic condition).
- Days supplied of the prescription (e.g., 30 days versus 90) which affects the amount of OOP costs and how frequently they recur.

These factors could help to predict monthly OOP costs and whether a particular beneficiary would face ballooning installment payments at the end of the year if they were to join the MPPP.

70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and other POS Needs

CMS is considering how to implement real time POS election into the MPPP program starting in 2026 or later. The ability to have POS election is critical, but it will be important to target POS election to the subset of beneficiaries who are likely to benefit from the program.

² For example, a beneficiary with \$400 per month in OOP costs will not face ballooning installment payments if they join the MPPP early in the year. However, if their OOP costs of \$400 month do not begin until August, then they would face escalating monthly installment payments including a very high monthly installment payment at the end of the year.



80.2.1 Involuntary Terminations—Notice Requirement

Arnold Ventures strongly recommends that Part D plans be required to include in their notices that beneficiaries should prioritize premium payments over MPPP installment payments to ensure that they do not lose their Part D coverage.

80.5 Disenrollment

Section 80.5 outlines that all beneficiaries are permitted to switch to a new Part D plan during special and open enrollment periods and enroll in that new plan's MPPP. This includes those who do not pay their MPPP monthly installment payments and were involuntarily disenrolled from the MPPP prior to switching plans. In turn, there may be instances where beneficiaries rejoin the MPPP through new Part D plans even when their outstanding MPPP balances are being actively pursued by the plans in which these beneficiaries were previously enrolled.

Allowing beneficiaries to switch Part D plans and opt back into the MPPP without repaying past due balances to the previous Part D plan could increase the likelihood that Part D plans will have to assume unpaid MPPP balances and offset these new liabilities through higher premiums.

Arnold Ventures supports guardrails that maintain the integrity of the Part D program by mitigating upward pressure on Part D premiums and premium subsidies paid by Part D beneficiaries and taxpayers. These could include limitations placed by the Secretary on the ability of beneficiaries to opt back into the MPPP after switching plans if they have a significant outstanding balance with another Part D plan under the MPPP.

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 or Mark E. Miller, Ph.D. at 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



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September 20, 2023

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 Guidance

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 Guidance that was released on August 21, 2023.

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.^{1,2} Even for insured 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

¹ 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

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

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 \$16,551.³ 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*.⁴

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. 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.

40. Participant Billing Requirements

Multiple forms of payment, such as an electronic fund transfer mechanism (including automatic charges of an account at a financial institution or credit or debit card account) and payment by cash or check will likely be necessary to accommodate all beneficiary preferences and needs. Offering only one payment option may prevent beneficiary ability to participate in the program.

ASCO supports inclusion of language stating that Part D sponsors (and any third parties Part D sponsors contract with) may not bill a participant more than the maximum monthly cap. Like CMS, we believe that late fees, interest payments, or other fees, such as for different payment mechanisms are not to be permitted in the program. Program participants should not receive financial penalties and increased costs for entering a program designed to ease financial burden.

60.1 General Part D Enrollee Outreach Requirements

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, CMS should ensure that all communication materials are culturally appropriate and

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

⁴ 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.

address the specific communication assistance and language needs of all beneficiaries enrolled in a Part D plan.

In the 2024 Medicare Advantage/Part D final rule, CMS finalized a requirement that Part D sponsors must provide communication materials to enrollees on a standing basis in any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area. For other non-English beneficiaries, Part D sponsors must provide materials in a format or language upon beneficiary request.⁵ CMS should consider this requirement as it develops program communications, regardless of format, to assist in enrolling participants into the program. In addition to addressing beneficiary communication needs, this will align with CMS's efforts to provide culturally and linguistically appropriate services and help advance health equity and eliminate disparities.

Medicare beneficiaries need accurate information about this program, and they need to know where to find up-to-date and accurate information. Enrollees should understand monthly financial obligations and how payments will change if they enroll in the program. Beneficiaries should also understand the financial implications for timing of their enrollment, including awareness that earlier enrollment in the plan year may be more beneficial.

CMS should monitor Part D plan marketing and communication materials to protect Medicare beneficiaries from misleading and confusing marketing. All materials should be concise, clear, and free from distracting content to ensure individuals have accurate and necessary information to make choices that best meet their needs.

ASCO supports CMS' proposal to include communication and marketing materials about the availability of the LIS program under Part D in the next phase of guidance. Part D beneficiaries should be aware that under new law, an additional subset of individuals may qualify for LIS subsidies. Section 11404 of the Inflation Reduction Act (IRA) expands eligibility to individuals with incomes up to 150 percent of the federal poverty line. Beginning January 1, 2024, this change will provide a full subsidy to those who currently qualify for the partial subsidy, improving affordability of prescription drug coverage for a new subset of Medicare enrollees.

Finally, CMS should also develop communication materials for providers to share with their patients. Individuals with cancer often face enormous economic burdens and will approach their physicians for information about patient resources to assist with these burdens.

70.1 Part D Enrollee Eligibility

We appreciate CMS stating clearly in the guidance that Part D sponsors cannot set a minimum out of pocket (OOP) cost sharing amount that Part D enrollees must incur to participate. We also agree with CMS that Part D sponsors may not restrict the application of the MPPP benefit to specific Part D covered

⁵ <https://www.federalregister.gov/documents/2023/04/12/2023-07115/medicare-program-contract-year-2024-policy-and-technical-changes-to-the-medicare-advantage-program>

drugs. CMS states that once an individual has opted into the program, OOP cost sharing for all covered Part D drugs must be included. We agree with CMS that this could minimize potential confusion and operational challenges, in addition to improving access to all Part D drugs.

70.3.3 Processing Election Request at the Time of Enrollment in a New Plan

ASCO supports the requirement that Part D sponsors must allow Part D enrollees to opt into the MPPP during annual enrollment periods, initial enrollment periods, and special Part D enrollment periods and that MPPP information must be integrated into the materials and procedures for the Part D plan enrollment. If MPPP materials are not included in standard Part D plan enrollment materials another touch point is needed and could potentially create a barrier to entry into the program.

70.3.5 Processing Election Request During a Plan Year

When a Part D enrollee is already enrolled in a Part D plan and requests to opt into the MPPP during the plan year, Part D sponsors must process the election request within 24 hours to prevent delays in dispensing drugs to individuals when they opt into the program. ASCO believes patients should have immediate access to their prescriptions at \$0 out of pocket while waiting for their election into the program to process, and we do not believe they should have to wait 24 hours to access medications. We urge CMS to work with Part D plan sponsors to implement a process for dispensing medication to the beneficiary at \$0 out of pocket during the enrollment process.

70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs

CMS is also considering options to effectuate election into the MPPP at the POS without any delay or with only a nominal delay between the election request and effectuation beginning in 2026 or later.

As stated above, ASCO believes it is imperative individuals with cancer have immediate access to life-saving therapies. Moving forward with this proposal would allow individuals to opt into the program at the pharmacy and collect their prescription in the same pharmacy transaction. This has implications for beneficiaries with social determinants of health-related needs such as lack of transportation. Facilitating enrollment at the POS will ease burden on patients.

70.3.10 Prohibition on Part D Enrollee Discrimination

ASCO commends CMS for including language stating that Part D sponsors are not allowed to design their MPPP to discriminate against any person based on race, color, national origin, disability, sex, or age in admission to or participation in the program, whether carried out directly by the Part D sponsor or through a contractor. Inequalities endure within and across multiple cancer diagnoses and population groups. Variations in cancer outcomes continue to be associated with factors such as race/ethnicity, sexual orientation and gender identity, age, geography (e.g., rural v. urban), socioeconomic status, and

health literacy, among many others.⁶ ASCO strongly supports efforts that prevent discrimination based on age, health conditions, and sociodemographic factors within all programs.

70.4 Mid-Year Plan Election Changes

CMS is requiring plans to process midyear elections within 24 hours. We encourage CMS to articulate what communication should occur between the old and new Part D plan sponsors to prevent any lapse in prescription fills or other unexpected patient burdens. We also ask the agency to require clear communications from the old Part D plan sponsor to the beneficiary regarding outstanding monthly payments even though the patient is no longer insured by that plan.

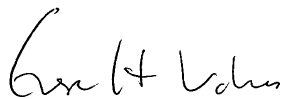
80.4 Prohibition on Part D Plan Enrollment Penalties for Failure to Pay Medicare Prescription Payment Plan Amount Billed

ASCO strongly supports CMS' statement that a Part D sponsor cannot decline future enrollment into a Part D plan based on an individual's failure to pay a monthly amount billed under the MPPP. ASCO is committed to supporting policies that allow individuals to access affordable insurance without interruption⁷. Enrollment restrictions result in disruptions in care, unanticipated treatment delay, and delays in screening and care, all of which are linked to worse cancer care outcomes.⁸ ASCO urges the Agency to monitor Part D plan compliance with this requirement.

* * * * *

We appreciate the opportunity to comment on the Medicare Prescription Payment Plan Guidance. Please contact Gina Hoxie (gina.hoxie@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,



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

⁶ NCI: Understanding Cancer Disparities, 2018. <https://www.cancer.gov/about-cancer/understanding/disparities>

⁷ <https://www.asco.org/sites/new-www.asco.org/files/content-files/2017-ASCO-Principles-Healthcare-Reform.pdf>

⁸ <https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/>



BY ELECTRONIC SUBMISSION VIA PartDPaymentPolicy@cms.hhs.gov

September 20, 2023

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: Solicitation for Comments on Draft Part One Guidance on Maximum Monthly
Cap on Cost-Sharing Payments Program**

Dear Deputy Administrator Seshamani:

AstraZeneca PLC (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 four therapy areas – Oncology, Vaccine & Immune Therapies, Cardiovascular, Renal & Metabolism (CVRM), and Respiratory & Immunology. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

We appreciate the opportunity to respond to the Centers for Medicare & Medicaid Services (CMS) solicitation for comments regarding the part one draft guidance on the Maximum Monthly Cap on Cost-Sharing Payments Program (“Medicare Prescription Payment Plan” or the “Program”). AstraZeneca commends CMS for its proposed implementation of the Medicare Prescription Payment Plan, which has been established by section 11202 of the Inflation Reduction Act of 2022 (IRA).¹

AstraZeneca supports CMS’ goal of making access to lifesaving medications more accessible, equitable, and affordable. Our commitment to patients is demonstrated through our groundbreaking research and development, as well as through significant investments in our AZ&Me Prescription Savings Program. We support the goals of the Medicare Prescription Payment Plan that will allow seniors to spread the costs of their medication throughout the plan year, working to support affordability and reducing barriers to access. We recognize that each patient has unique circumstances that can affect their ability to access and afford their medications. We support efforts to recognize these issues and meet individual patient needs.

¹ Pub. Law 117-169 (Aug. 16, 2022).

The Medicare Prescription Payment Plan will be pivotal in enhancing patient access to innovative medicines. However, CMS could improve the implementation of the Program through the recommendations described in detail below.

Our comments may be summarized as follows:

- Overall, the implementation of the Program should place emphasis on improving affordability for enrollees while minimizing the administrative burden placed on patients.
- The Program should also use a variety of communication methods that are tailored to enrollee needs and presented using clear language that is fully comprehensive to the enrollees. Given the diversity of the Medicare patient population, outreach should be done in a way that is accessible and employ multiple touch points and forms of communication.
- Under section 20, CMS should expand on education and outreach efforts to enrollees and ensure they are delivered in a standardized, understandable, and timely manner.
- Under section 30, CMS should clarify whether charitable assistance from bona fide charitable organizations would count towards “incurred costs,” and provide clarifications on the term “out-of-pocket (OOP) costs incurred by the participant.”
- Under section 40, CMS should require, rather than only encourage, the Part D sponsors to offer multiple means of payment and to prioritize applying the participant’s monthly payments to their Part D premium amounts.
- Under section 60, CMS should encourage manufacturers and other entities to also educate and reach out to enrollees about the Program. Though AstraZeneca agrees with CMS' proposed definition of “likely to benefit,” we recommend that CMS set the point-of-sale (POS) notification threshold amount based on a recognized benchmark that reflects the average senior's income.
- Under section 70, CMS should require all Part D sponsors to use the same standardized election request forms to minimize unnecessary denials. CMS should also require Part D sponsors process an enrollee's election to participate in the Program at the point-of-sale. CMS should further consider requiring a passive opt-in approach to enrollment.
- Under section 80, CMS should provide examples of what enrollees could use to demonstrate “good cause” for the failure to pay. AstraZeneca believes CMS should continue to limit a Part D sponsor’s ability to preclude an individual from opting into the Program in a subsequent year for non-payment of amounts billed to each individual plan.

I. CMS Should Implement the Program with a Focus on Improving Affordability for Enrollees, Minimizing Administrative Burdens, and Meeting Enrollees Where They Are.

AstraZeneca makes recommendations led by three core principles. First, CMS’s implementation of the Medicare Prescription Payment Plan should be focused on improving affordability for enrollees. We support CMS's implementation of the Program as an enrollee-centric option intended to address the uneven financial exposure of the Part D benefit that could adversely affect access to needed medications.

Second, CMS should implement the Program with the aim of minimizing administrative burdens on enrollees. Part D sponsors are in the best position to streamline and simplify an enrollee's choice to participate in the Medicare Prescription Payment Plan. Enrollment should be available immediately, at the point-of-sale, with no delays that could ultimately lead to abandonment.

Third, CMS should implement the Program in a way that meets enrollees where they are, using the outreach method that works best for the individual enrollee. To achieve this, Part D sponsors should use standardized and easy-to-understand communication methods of multiple modalities (e.g., text, email, and paper notices) and flexible payment framework (e.g., electronic fund transfer, cash, check, etc.) that maximize an enrollee's ease of access and use of the Program. Specifically, the outreach should be presented to enrollees using clear and simple language that takes into consideration the reading comprehension level of the enrollee.

II. Section 20 – Overview

A. Section 20 – CMS should expand on education and outreach efforts to enrollees and ensure they are delivered in a standardized, understandable, and timely manner.

In section 20 of the draft guidance, CMS requests feedback specifically on the best ways to educate Part D enrollees about the Medicare Prescription Payment Plan.² An important goal of the Program is to maximize the number of enrollees who are aware of the Program by educating and reaching out to the enrollees in a standardized, understandable, and timely manner.

CMS should ensure that all enrollees understand how the new Program works. Specifically, CMS should encourage all Part D sponsors to use the same standardized educational materials and make them available in multiple languages and multiple formats. Rather than sending the educational materials using the same, single communication method for all enrollees, we believe CMS should encourage the Part D sponsors to use a combination of communication methods that would best reach the enrollee. For example, this would involve a mix of text, email, or paper notices.

Furthermore, the education materials should also be communicated in a way that is easy to understand and provide enrollees with all the necessary information about the Program, including what their monthly payment is likely to be, based on expected spending and the therapies that they are prescribed. CMS should consider implementing tools, such as a new integration feature in Medicare Plan Finder, to ensure the enrollees have access to individualized monthly cost estimates based on plan selection. This would help in implementing the Program in an enrollee-centric manner and lessen the administrative burden placed on enrollees to determine their individualized exposure. Dynamic estimates of out-of-pocket costs are particularly important for patients taking specialty therapies as these costs often represent a greater share of patient OOP expense, relative to other primary care products. It is also important that the education and outreach be completed

² CMS, *Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance* (Aug. 21, 2023), p. 5.

in a timely manner to allow that enrollees sufficient time to consider their options and apply for the Program.

AstraZeneca also suggests that the Part D sponsors be required to provide the educational materials to enrollees throughout the year, including as enrollees progress through the benefit and detailed, step-by-step instructions on enrolling in the program for upcoming Part D plan year elections. By providing multiple options for enrollment throughout the plan year, enrollees will have an opportunity to understand the impact of the program on their out-of-pocket spending as their spending changes.

III. Section 30 – Program Calculations and Examples

A. Section 30.1 – CMS should clarify whether charitable assistance from bona fide charitable organizations would count towards “incurred costs.”

In section 30.1 of the draft guidance, CMS defines “incurred costs” broadly as “any costs incurred or treated as incurred under section 1860D-2(b)(4)(C)” of the Social Security Act (the “Act”).³ The IRA significantly revised the definition of “incurred costs” such that the term could arguably apply to third party payments, such as payments by bona fide charitable organizations, that are made on behalf of enrollees. Specifically, section 1860D-2(b)(4)(C)(iii)(II) of the Act provides that “costs shall be treated as incurred ... if such costs ... for 2025 and subsequent years, are reimbursed through insurance, a group health plan, *or certain other third party payment arrangements...*”

CMS has not specified how the existing definition for “incurred cost” differs from definition of the term as revised by the IRA. AstraZeneca suggests that CMS clarify whether charitable assistance from bona fide charitable organizations will count towards an enrollee's “incurred costs,” to minimize confusion about the term “incurred costs” and its applicability.

B. Section 30.2 – CMS should explain how the term “OOP costs incurred by the participant” differs from “incurred costs” and provide mathematical examples to demonstrate the difference.

The draft guidance suggests that “OOP cost incurred by the participant,” which is used for the calculation of the “subsequent month” maximum monthly OOP cap, differs from “incurred costs” as defined in the statute and as applied to the “first month” maximum monthly OOP cap. Specifically, the draft guidance states that:

“OOP costs incurred by the participant” refers only to the patient pay portion for covered Part D drugs that a program participant would have paid at the POS if they had not opted into the Medicare

³ Draft Part One Guidance, p. 7.

Prescription Payment Plan, not to all incurred costs as defined under section 1860D–2(b)(4)(C) of the Act.⁴

Moreover, CMS states throughout the draft guidance that the maximum monthly OOP cap is not intended to affect how an enrollee progresses through the benefit, but the cap is merely intended as a mechanism to spread the costs incurred by the enrollee across the plan year.

However, CMS does not sufficiently clarify how the “OOP costs incurred by the participant” differs from the general “incurred costs” definition as defined in the statute. We interpret CMS’ “OOP costs incurred” variable as a mathematical tool to calculate the enrollee’s OOP costs. AstraZeneca requests that CMS clearly state that the “OOP costs incurred by the participant” should only be used as a variable for calculating the “subsequent month maximum cap.” Also, we recommend that CMS provide mathematical examples to demonstrate that the “OOP costs incurred by the participant” has no impact on the individual enrollee’s general “incurred costs.”

IV. Section 40 – Participant Billing Requirements

A. Section 40 – Part D sponsors should be required to offer enrollees multiple means of payment.

In the draft guidance, CMS does not require, but “encourages” Part D sponsors to offer enrollees with multiple means of payment, such as an electronic fund transfer mechanism and payment by cash or check.⁵ However, “encouraging” the Part D sponsors to offer the flexibility allows the plans to omit the flexibility altogether. This may result in many enrollees having no option to pay via the only method of payment that may be available to them.

Thus, only offering limited payment methods may discourage or prevent enrollees from participating in the Program. For example, a Medicare beneficiary without a bank account may be unable to take advantage of an electronic fund transfer mechanism. We believe the implementation of the Program should be focused on providing enrollees with enrollee-centric options and present them with accessible payment participation options. Offering enrollees more flexibility in choosing differing payment approaches is consistent with the statute and CMS’ goal of making the Program available to eligible patients. For this reason, AstraZeneca recommends that CMS mandate, rather than “encourage,” sponsors to offer multiple methods of payment to ensure enrollees are not deterred from participating in the Program due to variations in access to payment methods and to streamline the enrollment process.

B. Section 40.1 – Part D sponsors should be required to prioritize applying a participant’s monthly payments to their Part D premium amounts.

The draft guidance states that Part D sponsors are only “encouraged,” not required, to prioritize payments towards Part D plan premiums to avoid a Part D enrollee losing their Part D coverage.⁶

⁴ Draft Part One Guidance, pp. 7-8 (emphasis added).

⁵ Draft Part One Guidance, p. 13 (emphasis added).

⁶ Draft Part One Guidance, p. 14.

This permits the Part D sponsors to choose whether to apply the participant's payments towards the Part D plan premiums or other outstanding balance.

We note that Part D sponsors have an incentive to mitigate their liability to pharmacies for the balance due under the Program. By making the prioritization of payment optional for Part D sponsors, while incentivizing them to prioritize payments to pharmacies, CMS effectively calls for situations where participants may lose their Part D coverage despite paying the premium amount. As a result, many enrollees may be discouraged from opting into the Program.

To remedy this issue, AstraZeneca recommends Part D sponsors be required to apply payments received from enrollees first towards their Part D plan premiums before other outstanding balances, as this would help preserve continuity of coverage for the enrollees.

V. Section 60 – Requirements Related to Part D Enrollee Outreach

A. Section 60.1 – CMS should encourage manufacturers and other parties to also educate enrollees on the Medicare Prescription Payment Plan.

In the draft guidance, CMS states that it intends to “develop tools (e.g., model documents and training materials) to help Part D enrollees decide whether the program is right for them.”⁷ Further, the draft guidance states that Part D sponsors are required to educate enrollees prior to and during the plan year regarding the availability of the Program. Yet, CMS does not mention whether other entities that could contact enrollees, such as manufacturers, charitable organizations, and retail and specialty pharmacies, should also be involved in the outreach and education efforts.

To ensure the Program reaches as many enrollees as possible and to promote enrollee awareness about the Program, it would be helpful to have more entities involved in the outreach process. Thus, AstraZeneca urges CMS to engage a comprehensive set of stakeholders and encourage other relevant entities, including manufacturers, charitable organizations, and pharmacies, to participate in reaching out and educating enrollees about the Program. This may include the development of model materials for distribution, as well as clear guidance for manufacturers on permissible forms of beneficiary contact and, as applicable, a clear safe harbor for such communication. Furthermore, CMS should incentivize other relevant entities to actively distribute comprehensive education materials about the Program, including example calculations, to enrollees. Involvement from more entities would help with achieving the goal of the Program to make health care more accessible, equitable, and affordable for more enrollees.

B. Section 60.2.1 – AstraZeneca agrees with CMS' proposed definition of an enrollee “likely to benefit” from the Program.

CMS requires Part D sponsors to direct targeted outreach to enrollees “likely to benefit” from participating in the Medicare Prescription Payment Plan.⁸ In the draft guidance, CMS defines enrollees “likely to benefit” from the Program as enrollees with (1) higher OOP costs that (2) are

⁷ Draft Part One Guidance, p. 19.

⁸ *Id.*

likely to be incurred earlier in the plan year. This may include patients taking oncology therapies or other specialty therapies.

AstraZeneca agrees with the definition of “likely to benefit” proposed in the draft guidance as we also believe that enrollees with higher OOP costs incurred earlier in the plan year are more likely to benefit from the Program. To the extent that outreach is made to all Part D beneficiaries, AstraZeneca supports CMS’ proposal to require Part D sponsors to direct targeted outreach to enrollees that CMS determines are more “likely to benefit” from the Program, in addition to the general outreach and education required by the Act.

C. Section 60.2.3 – CMS should establish a POS notification threshold that accurately takes into account average senior's income based on a recognized benchmark.

The draft guidance proposes to establish a POS notification threshold, which CMS will use to determine whether an enrollee is “likely to benefit” from the Program. CMS would require notification of the enrollees if the enrollee incurs OOP costs that equal or exceed the designated POS notification threshold. CMS has not specified the amount for the threshold yet. To establish an accurate POS notification threshold, CMS seeks comments regarding the potential threshold amount, ranging from \$400 to \$700, and specific factors that CMS should consider when determining the threshold for 2025.⁹

AstraZeneca recommends that CMS compare the threshold amount to a recognized benchmark that would accurately reflect the amount of an average senior’s income when CMS determines the potential POS notification threshold. This recommended threshold-setting method would allow the POS notification threshold to more accurately locate the enrollees who are most likely to benefit from participating in the Program by accounting for the cost of living. This would allow the Program to reach out to the enrollees likely to benefit from the Program earlier on in the process, thereby helping achieve the goal of balancing the “desire to identify individuals with potential cash-flow concerns at the pharmacy and provide them key information about a program that may benefit them while ensuring precision in the notification.”¹⁰ CMS should choose the approach that maximizes in capturing the number of enrollees who are “likely to benefit” from the Program.

VI. Section 70 – Requirements Related to Part D Enrollee Election

A. Section 70.3.5 – CMS should require Part D sponsors process an enrollee's election to participate in the Program at the point-of-sale.

CMS is proposing to establish a 24-hour requirement for processing election requests during the plan year. As CMS notes in the draft guidance, the Program should be structured in such a way as to ensure patients do not face unnecessary barriers to accessing their prescriptions. Given the overarching goals of the Program, AstraZeneca believes that Part D sponsors, depending on the

⁹ Draft Part One Guidance, p. 25.

¹⁰ *Id.*

needs of the individual enrollee, should be required to process elections to participate in the Program at the point-of-sale, or otherwise provide \$0 access to beneficiaries pending election into the program. For enrollees accessing their Part D drugs from a specialty or mail-order pharmacy, the approach may differ slightly given the need for the pharmacy to verify certain information from the patient.

AstraZeneca is also concerned that the draft guidance also allows a Part D sponsor to deny an enrollee's request to opt into the Program if the enrollee fails "to submit the information requested within the timeframe listed on the request."¹¹ We urge CMS to consider whether this creates room for wide denials of enrollee's requests based on omission of information. CMS should introduce appropriate patient safeguards or processes to accommodate patient needs and ensure that election to participate in the Program is protected. We further recommend CMS consider implementing a passive opt-in to the Program to ensure Medicare beneficiaries have full opportunity to participate in the Program as a default.

To minimize potential error that may result from discrepancy in election request forms, AstraZeneca recommends that CMS require all Part D sponsors and other agents, such as Third-Party Marketing Organizations (TPMOs), to use the same standardized election request form. Using the same standardized forms across all plans would decrease discrepancies and the amount of information that the enrollee must provide to the Part D sponsor to process their request for participation in the Program. The forms could then be offered in multiple languages to ensure enrollees have access to the format that is easiest for them to understand.

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

A. Section 80.2.2 – CMS should provide examples of what enrollees could use to demonstrate "good cause" for the failure to pay.

CMS requires that Part D sponsors reinstate enrollees who were previously terminated from the Program if the enrollees show "good cause" for why they could not pay their dues on time and pay off all overdue bills under the Program. According to the draft guidance, "good cause" can be proven with a credible statement indicating that the enrollee's circumstances were beyond the individual's control or "individual could not reasonably have been expected to foresee."¹²

AstraZeneca is concerned that the definition of "good cause" as proposed by the draft guidance is unclear. Due to the ambiguity on what constitutes a "good cause," Part D sponsors will have wide latitude to deny enrollees from reinstating their participation. Moreover, such a policy will allow Part D sponsors to apply the standards inconsistently across plans. AstraZeneca recommends that CMS provide examples for "good cause" and specify the type of documents or methods enrollees may use to demonstrate "good cause." We believe further clarifications would help ensure "good cause" determinations are applied consistently and equally across all plans and for each enrollee.

¹¹ Draft Part One Guidance, p. 33.

¹² Draft Part One Guidance, p. 40.

B. Section 80.3 – AstraZeneca supports CMS' limitation of a Part D plan's ability to preclude an individual from opting into the Program in a subsequent year for non-payment of amounts billed to each individual plan.

The draft guidance only allows Part D sponsors to preclude an enrollee from opting into the Medicare Prescription Payment Plan in a subsequent year if the enrollee owes an overdue balance to that specific Part D sponsor. If an enrollee pays off the outstanding balance during the subsequent year, a Part D sponsor must permit the enrollee to opt in after that point.

AstraZeneca supports this limitation on the preclusion of enrollees to elect the program in a subsequent plan year to a specific Part D sponsor. Allowing a new Part D sponsor to preclude an enrollee from participating in their program because of the enrollee's non-payment under a previous Part D sponsor would not only be difficult to administer, but it would also be susceptible to errors and omissions in the transmission of information between the sponsors. The omissions would in turn potentially lead to enrollees erroneously being denied the option to participate in the Program altogether, which is not aligned with the objective of the Program to allow more enrollees to have access to affordable and equitable health care. Particularly for oncology patients, such preclusions from the Program could result in life-threatening consequences for enrollees. As a broader principle, we believe that safeguards are needed that would prohibit plans from prospectively denying patient enrollment in the Program based on status and standing from a previous plan year.

AstraZeneca thanks CMS for the opportunity to submit comment regarding the draft guidance on the Medicare Prescription Payment Plan. We look forward to continuing to engage with CMS as it implements the Program. I can be reached at sarah.arbes@astrazeneca.com to address any questions about our comments.

Sincerely,

A handwritten signature in dark ink, appearing to read "Sarah Arbes", written in a cursive style.

Sarah Arbes

Head of U.S. Federal Government Affairs & Policy

September 20, 2023

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016
Re: Medicare Prescription Payment Plan Guidance

Submitted via email to PartDPaymentPolicy@cms.hhs.gov

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 guidance on the Medicare Prescription Payment Plan (MPPP) issued on August 21, 2023.

BCBSA is a national federation of 34 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 is eager to work with CMS on the implementation of the Medicare Prescription Payment Plan program for 2025 as set forth by the Inflation Reduction Act of 2022 (IRA). We recognize success for this program is highly 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:

- **CMS should lead communication and standards setting:** BCBSA supports CMS providing messaging that communicates the benefits of MPPP election. All stakeholders need to speak with one voice to educate enrollees about the program and how it may or may not benefit enrollees. Second, CMS should outline clear program standards that apply across the industry. Program requirements from targeting enrollees who are “likely to benefit” to debt collection efforts should apply to all Part D sponsors. Similarly, CMS should educate enrollees and other stakeholders of the program requirements to set common expectations of the new program.
- **CMS should release Part II guidance as soon as possible:** CMS stated this is “Part I” of the guidance to support implementation of the MPPP program. We urge CMS to

release Part II of the guidance before the proposed “early 2024” target. There is a strong case to release Part II in Q4 of 2023, if possible, to allow for public comment and revised guidance in advance of the CY2025 bid deadline. CMS noted in the accompanying Fact Sheet the Part II guidance will include “Part D plan bid information” and “monitoring and compliance requirements,” all of which are critical for Part D sponsors to design and price for the MPPP. Additionally, we request in Part II of the guidance for CMS to explore mechanisms at its disposal (e.g., risk corridors, risk adjustment, demonstration authority) to stabilize the program given the unknown financial risks of implementing the MPPP. This will provide more certainty for pricing the MPPP benefit under Part D as plan sponsors work to maintain affordable premiums for enrollees given the major benefit redesigns in CY2025.

- **CMS should 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 CY2025 given the need to make operational adjustments in response to additional CMS guidance (Part II) 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 I)

Section 10. Introduction

- *Application to Employer Group Waiver Plan (EGWP):* BCBSA supports waiving the MPPP program for EGWPs, or initially delaying application to EGWPs in 2025, to focus Part D plan efforts on identifying enrollees with the highest need of election to the MPPP. Enrollees covered by EGWPs generally face low out-of-pocket (OOP) cost-sharing and are not ‘likely to benefit’ from the MPPP. By exempting EGWPs, Part D plans will have additional resources to target enrollees, as noted in section 60, with a high-cost claim and a higher likelihood of benefit from the program. If CMS does not approve a waiver or delay, BCBSA suggests CMS indicate which aspects of the program would apply to EGWPs.

Section 30. Program Calculations and Examples

- *30.1 Calculation of Maximum Monthly Cap in First Month:* BCBSA supports CMS’ proposal attributing OOP costs for extended day prescriptions (e.g., 90 days) to the month the prescription was filled. This will align with claims processing and is the best and simplest operational approach rather than pro-rating the OOP costs over the length

of the extended supply.

- *30.2 Calculation of Maximum Monthly Cap in Subsequent Months:* BCBSA supports CMS conducting a coordinated communication approach in sharing information with all stakeholders. This is a critical component to beneficiaries understanding the program. Specifically, BCBSA supports CMS publishing model communication materials that clarify when the bills to enrollees may exceed the monthly maximum cap if participants do not pay monthly bills in full.

BCBSA also supports CMS' interpretation of "costs incurred" by the program participant. As outlined in the guidance, amounts paid by drug manufacturer patient assistance programs and State Pharmaceutical Assistance Programs (SPAPs) are excluded from TrOOP and are not considered "costs incurred" under the MPPP, which aligns with other Part D program elements. We recommend CMS further define "third parties" for which payment amounts would not be included in OOP costs incurred by the participant.

- *30.3 Example Calculations:* BCBSA urges CMS to include additional examples calculating the maximum monthly cap for situations where an enrollee: (1) receives support from a State Pharmaceutical Assistance Programs (SPAP); (2) is covered by an employer group waiver plan (EGWP); (3) is covered under an enhanced alternative plan with and without supplemental drug benefits (building off Example B2); and (4) is also an LIS beneficiary, including partial and full. We appreciate the examples in this section and Appendix B to demonstrate how the MPPP program will function in various scenarios. These additional examples will support Part D plan understanding of how the MPPP will accumulate based on the standard benefit but applied to a different benefit such as an enhanced plan or EGWP.

Section 40. Participant Billing and Examples

- *Debt Collection:* BCBSA requests specific guidance regarding the actions that Part D sponsors will be required to take regarding debt collection for amounts due under the program. CMS should outline clear program standards that apply across the industry as it pertains to debt collection so each Part D sponsor is engaging in appropriate debt collection efforts. Such requirements should supersede other federal and state laws and requirements that may conflict with and undermine the implementation of the MPPP.
- *Flexibility in MPPP Payments:* CMS should align MPPP payment options with current premium payment options, particularly for the early years of implementation. For example, payment options should include e-funds, deduction from Social Security checks, cash and checks.
- *Encouraging Auto Payments:* BCBSA recommends CMS explore ways for patients to be encouraged to use auto payments. For example, Part D plans should be able to use rewards and incentives to encourage beneficiaries to sign up for auto payments.

- *40.1 Prioritization of Premium Payments:* BCBSA requests clarification regarding how Part D sponsors should handle payments that are clearly intended to go toward a participant's MPPP balance, but the participant has premium payments outstanding. Since CMS is proposing to require a separate bill for MPPP, Part D plans should have the flexibility to move payments between a members MPPP balance and their premium balance.
- *40.2 Financial Reconciliation Process:* BCBSA requests clarification that Part D sponsors have discretion in how they implement a financial reconciliation process used to correct inaccuracies in billing and/or payments.

Section 50. Pharmacy Payment Obligations and Claims Processing

- *50.1 Pharmacy Claims Processing Requirements:* BCBSA believes the coordination of benefits (COB) billing transactions is the most optimal methodology presented in the guidance to implement the MPPP at the pharmacy counter and enable \$0 cost-sharing for enrollees. We recognize this presents a challenge to NCPDP establishing standards and stakeholders to test supplemental COB transactions in advance of 2025 to ensure operability. BCBSA believes the supplemental COB transaction approach is a better long-term platform as CMS expands the MPPP program to include real-time election at the pharmacy counter.
- *50.3 Requirements for Different Pharmacy Types:* BCBSA requests CMS allow Part D plans to exclude prescription drug claims that are processed via "post-consumption" billing. This billing can occur in long-term care (LTC) pharmacies and allows for accurate billing for drugs consumed by the patient, thereby reducing waste and overall costs. It is appropriate to exclude these claims from the MPPP and monthly payment amount as these claims can be filed weeks after the drug is dispensed. Additionally, we ask CMS to clarify whether plan sponsors would bill the enrollee, caregiver, or the facility in the case of LTC pharmacies.
- *50.4 Paper Claims:* BCBSA agrees with CMS' proposal to not require Part D plans to retrospectively include paper claims in the MPPP program. Claims submitted for direct member reimbursement (DMR) have already been paid by the enrollee and would not be appropriate for inclusion in the monthly payment amount.

Section 60. Requirements Related to Part D Enrollee Outreach

- *60.2.1 Identification of Part D Enrollees Who Are Likely to Benefit:* BCBSA offers the following suggestions on targeting individuals:
 - BCBSA supports CMS publishing model materials communicating that not all Part D enrollees will benefit from participation in the MPPP and include information about the circumstances that may make an enrollee likely and unlikely to benefit from the MPPP. These standards should be clearly and widely communicated with all stakeholders impacted by this program.

- 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.
- Part D plans should be directed to cease enrollee notifications under the likely to benefit notification standard at some point in Q4 in the calendar year. This will reduce the number of enrollees electing into MPPP where the benefit is minimal and the financial risk is high.
- While BCBSA recommends CMS waive the MPPP requirement for EGWPs, should CMS include such plans, we urge EGWP enrollees be excluded from targeted outreach as this population faces lower OOP costs than the non-EGWP population.
- *60.2.2 Targeted Part D Enrollee Notification Prior to POS:* BCBSA recommends CMS define standards for required Part D sponsors' outreach to individuals prior to POS. We strongly encourage CMS and Part D plans to prioritize MPPP election prior to the start of CY2025. Given the potential for operational challenges for mid-year elections, this approach will drive enrollees to opt-in to the program prior to the start of the benefit year and provide a better member experience.
- *60.2.3 Targeted Part D Enrollee Notification at POS:* BCBSA recommends CMS use a single claim threshold for scripts that are equal to or exceed the specialty tier cost threshold for CY2025. This provides a clear signal to enrollees that specialty drug prescriptions are a high indicator of likely benefit from the MPPP program, and it provides CMS with the ability to alter the threshold in future years and expand the target population as needed.
BCBSA agrees with CMS' statement that POS enrollment is unlikely to be an option in 2025. We urge delay of POS enrollment until CMS, Part D sponsors and pharmacies can demonstrate successful POS election after a thorough testing period.
- *60.2.4 Notification Requirements:* BCBSA requests CMS to clarify how Part D sponsors should require pharmacies to provide required POS notifications and how CMS intends to validate compliance with this requirement. In Part II of the guidance, it will be helpful to know if such requirements necessitate changes to PBM-pharmacy contracts to ensure compliance. We recommend that CMS provide standardized language to pharmacies communicating that an enrollee meets the likely to benefit criteria and how to elect into the MPPP.

Section 70. Requirements Related to Part D Enrollee Election

- *70.1 Part D Enrollee Eligibility:* BCBSA recommends CMS revisits its proposal prohibiting Part D sponsors from setting a minimum OOP amount for election into the MPPP and instead set a de minimis amount of drug claims to be eligible. This will limit enrollees who have low dollar generic prescriptions from electing into the MPPP and being billed single dollar amounts throughout the year – clearly not a benefit to the enrollee.

- *70.2 Interactions Between Low Income Subsidy (LIS) and Medicare Prescription Payment Plan:* BCBSA requests CMS provide clear guidance through any forthcoming model materials regarding the requirement for Part D sponsors to provide individuals with information about both the MPPP and LIS program: (1) prior to the plan year, (2) upon opting into the program, (3) when there is an LIS status change, and (4) when a participant has failed to pay the billed amount. Model materials should clearly communicate that there are limited circumstances in which an LIS enrollee would benefit from the MPPP and that LIS enrollment for qualifying individuals is more advantageous than participation in the MPPP. We also recommend that interested LIS enrollees be required to first speak with the Part D plan before enrolling in MPPP. This will ensure that enrollees understand the benefits and risks and it will protect beneficiaries from large payments at the end of the year.

In order to provide full understanding and clarity for beneficiaries, CMS should provide clear communication through model materials or related guidance on the limited scenarios in which an enrollee would receive greater benefit from the MPPP as opposed to LIS. CMS also should require plans to do outreach to members that lose LIS coverage to alert them that MPPP is an option. We believe it is critically important to ensure that beneficiaries are fully equipped with all the information necessary to make informed decisions about their care and strive to avoid any circumstances of potential confusion. CMS' intention to include a calculator to model prospective MPPP payments is especially important for the LIS population.

- *70.3 Election Procedures*
 - *70.3.3 Processing Election Request at the Time of Enrollment in a New Plan:* BCBSA recommends CMS provide its model communication and calculator to stakeholders who support enrollees applying for coverage under a Part D plan. Enrollees may not understand how their OOP costs differ from plan premium and the details of how the MPPP will work, and CMS communication to these stakeholders will support appropriate elections.
 - *70.3.5 Processing Election Request During a Plan Year:* BCBSA requests that CMS not implement a 24-hour requirement for processing MPPP elections during the plan year. Given the operational limitations of many smaller, regional plans, the proposed requirement would be a challenge to make reasonable efforts to collect information and process the election request in 24 hours. We urge CMS to extend this timeframe to allow Part D plans to pass eligibility files to PBMs, which occur on a regular cadence. A 24-hour turn-around would be aggressive and does not account for weekends and holidays when eligibility transmissions may be delayed. We further note our recommendation to prioritize MPPP election prior to the start of CY2025 given the potential challenges of mid-year elections.
 - *70.3.7 Retroactive Election in the Event the Part D Sponsor Fails to Process an Election within 24 Hours:* BCBSA recommends CMS make retroactive elections optional in the first year due to operational challenges.

- *70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs:* BCBSA encourages CMS to collaborate with pharmacies and NCPDP in the implementation of this process given their importance in successful real-time election.

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

- *Review of Election and Nonpayment Trends:* BCBSA recommends CMS to track trends on enrollee elections and non-payments. CMS should adjust its election and termination eligibility criteria to address trends that indicate fraud, waste, and abuse is occurring.
- *80.2 Involuntary Terminations*
 - *80.2.2 Required Grace Period and Reinstatement:* BCBSA requests CMS further define the timing of the reinstatement for good cause, which would be particularly important if an enrollee tries to be reinstated in the MPPP in December. BCBSA also requests CMS to provide clarity on good cause for reinstatement and how it differs or is similar to the good cause provision for non-payment of premiums.

Section 90. Participant Disputes

- BCBSA supports the reliance on established Part D appeals procedures about amounts owed under the MPPP and established Part D grievance procedures for all other disputes. We believe it is appropriate to leverage existing policies and procedures to handle disputes under the MPPP and not create new ones. While BCBSA does not have specific recommended changes to section 30 and section 40 of existing grievance and appeals guidance, we support CMS incorporating any MPPP-specific elements as appropriate.

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.

Sincerely,

Kris Haltmeyer

Vice President, Policy Analysis

Office of Policy & Advocacy



Biotechnology Innovation Organization
1201 New York Ave., NW
Suite 1300
Washington, DC, 20005
202-962-9200

VIA ELECTRONIC DELIVERY

September 20, 2023

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

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

Dear 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) 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.

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 timely implementation of the Medicare Prescription Payment Plan (MPPP) which will provide much-needed cost sharing relief to many beneficiaries by allowing them to spread high-cost sharing expenses over the benefit year. The implementation of the MPPP is critical since beneficiaries have continued to face significant out-of-pocket (OOP) costs and may struggle with their budgets, incurring a significant amount of these OOP costs in a short period of time. A



2019 Avalere report found that beneficiaries who reached the Part D catastrophic phase in January incurred an average of more than \$3,100 in OOP costs in a single month.¹

In addition to posing financial burden on beneficiaries, high-cost sharing has also been linked to negative health outcomes. Studies have shown that high OOP costs affect medication adherence since beneficiaries with high cost-sharing may delay prescription refills or abandon them at the pharmacy.^{2 3} As CMS implements provisions of the MPPP, the Agency should prioritize enrollment mechanisms that make the program more widely accessible and easy for beneficiaries to participate. The increased flexibility to spread out cost sharing payments will help many beneficiaries afford their prescriptions and subsequently increase medication adherence and improve medical outcomes.

While BIO supports the development of the MPPP, we also recognize the complexities of CMS's calculations for determining which beneficiaries will benefit from participation, in which beneficiaries with higher monthly OOP expenses in later months will not gain the same utility as those beneficiaries with high monthly OOP expenses in earlier months. In order to mitigate the potential for beneficiary confusion around enrollment and OOP expenses, BIO encourages CMS to develop ways to enhance the beneficiary experience, including the development of calculator tools for beneficiaries to understand their OOP costs, real-time enrollment at pharmacy POS, and auto-enrollment for beneficiaries to continue to participate in later years. BIO appreciates CMS enacting this critical payment option and looks forward to partnering with CMS to drive patient access and implement this proposal.

70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs, p.34-36

CMS proposes various options to allow for real-time or near-real-time beneficiary election into the Payment Plan at pharmacy point-of-sale (POS), with a proposed implementation timeline of 2026 or later. CMS provides three potential POS methods; 1) Telephone-only; 2) Mobile or Web Based; and 3) Development of a Clarification Code.

BIO urges CMS to create real-time election into the MPPP at pharmacy point of sale (POS) by 2025 rather than 2026 or later. An earlier timeline for pharmacy POS elections is critical to drive beneficiary enrollment and encourage uptake in the program. In order to implement real-time election, BIO supports a combination of all three proposed methods in order to provide greater flexibility for beneficiaries and encourage enrollment. While all three methods may require some operational changes for Part D plans and PBMs, it is still feasible to implement real-time POS elections on a 2025 timeline. Today, Part D plans and PBMs already track enrollee OOP spending so they can administer the current Part D individual reinsurance program and target those individuals for potential enrollment in the plan's medication therapy management (MTM) programs.

Administering this real-time election would build upon existing systems used to track enrollee spending and cost share and thus should not be technically difficult to administer. BIO encourages CMS to implement the real-time POS election requirement sooner than later since any delays would put program participation at risk.

In addition, BIO suggests that individuals who opt-in to the MPPP should be automatically re-enrolled at the start of each plan year. Allowing auto-enrollment would encourage participation into

¹ "Out-of-Pocket Costs Among Medicare Part D Enrollees Reaching the Catastrophic Threshold." Avalere. Oct 2019.

² Doshi, Jalpa A., Pengxiang Li, Hairong Huo, Amy R. Pettit, and Katrina A. Armstrong, Association of Patient Out-of-Pocket Costs With Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents. *Journal of Clinical Oncology*. 2017. doi: 10.1200/JCO.2017.74.5091.

³ Eaddy, Michael T., Christopher L. Cook, Ken O'Day, Steven P. Burch, and C.Ron Cantrell. How Patient Cost-Sharing Trends Affect Adherence and Outcomes. *Pharmacy and Therapeutics*. 2012;37(1):45-55.



the program and ease beneficiary burdens associated with enrollment. The auto-enrollment process for the MPPP could follow a similar process currently used for those who are auto-enrolled into Medicare or Qualified Health Plans, in which enrollees receive an Auto-Enrollment Notice and may review their plan details and opt out of coverage if they choose. BIO encourages CMS to offer an auto-enrollment option to simplify the potentially challenging and overwhelming process of enrollment and protect those who may forget to renew the benefit by providing the consistent guarantee of affordable payments spread throughout the year.

80.2.2 Required Grace Period and Reinstatement, p.39

CMS proposes a two-month grace period for individuals who do not pay the monthly billed amount. For individuals who do not pay the overdue balance during the grace period, Part D sponsors are required to terminate the individual from the MPPP by sending a termination notice. If an individual who have been terminated from the MPPP pays all overdue amounts billed and demonstrates good cause for failure to pay, Part D sponsors must reinstate that individual into the MPPP.

BIO supports a grace period and good cause policy which will protect beneficiaries who experience temporary hardship due to unforeseen circumstances from being terminated from the program if they miss a single payment. At a minimum, a two-month grace period will greatly help beneficiaries maintain the affordability of monthly payments by providing beneficiaries with more time to gather funds and reducing immediate financial strain. CMS could also consider a longer three-month grace period, which would align with the three-month grace period given in Marketplace plans under the Affordable Care Act. A longer grace period would allow for more flexibility in the event of communication delays or life events outside of beneficiaries' control.

BIO also applauds CMS for requiring the reinstatement of beneficiaries who pay all overdue amounts and demonstrate good cause for failure to pay. For beneficiaries experiencing challenges meeting monthly payments, it will be even more difficult for them to make a lump-sum immediate payment at the pharmacy. Therefore, it is critical that beneficiaries who experience temporary financial challenges be given the opportunity to continue to participate in the MPPP to avoid the heightened financial strain of paying all their OOP costs at once.

In order to effectively operationalize the reinstatement policy, BIO requests further guidance from CMS as to how reinstatement procedures will be implemented. For example, it is unclear how an individual terminated from the program can be reinstated into the program if they switch to a different Part D plan, or how long Part D sponsors may continue to refuse an individual from opting-in to the MPPP again if they had been previously terminated. As CMS develops further guidance in these areas, BIO urges CMS to consider greater protections for beneficiaries by prohibiting practices by Part D sponsors, pharmacies, or other parties that could disincentivize beneficiaries from enrolling or being reinstated into the MPPP.

In addition, BIO requests that termination notices be sent through electronic and physical mail, as well as any other application that beneficiaries use to receive communication on Medicare coverage and benefits. Sending termination notices through multiple avenues will better accommodate beneficiaries of their preferred mode of communication and reduce the risk of beneficiaries missing the notice.



60. Requirements Related to Part D Enrollee Outreach, p.19-26

CMS states that it will cover specifics around enrollee outreach and education in its Part Two Guidance, including guidance on marketing and communication procedures, sample model language, tools, and standardized communication materials.

BIO appreciates CMS's willingness to provide additional guidance on communication and marketing tools, procedures, and materials, which will be instrumental in encouraging participation into the program and helping beneficiaries understand their payment responsibilities. As CMS develops its Part Two Guidance, we encourage the Agency to establish standardized notification language and easy-to-use analytical tools so that enrollees will understand if they benefit from participating in the MPPP. It is imperative that communication on the MPPP is initiated early and often. Communication and outreach on the MPPP is not only critical to encourage participation into the program, but will also help enhance health literacy among those at risk for health disparities. Studies have shown that there is a significant overlap in demographic populations for those at risk of health disparities and low health literacy.⁴ Ensuring that beneficiaries understand the program's benefits is fundamental to improve health literacy and reduce disparities, particularly for disadvantaged and vulnerable populations.

For effective outreach, BIO recommends that the education and information on the MPPP be included into routine communication throughout the plan year. For example, all Monthly/Quarterly Explanation of Benefits (EOB) could include a projection of patient's cost sharing obligations, both with and without participation into the MPPP. BIO also supports the creation of a scenario-planning calculator tool that would allow patients proactively to compare their cost sharing obligations, both with and without participation. These tools would greatly help beneficiaries decide whether they may benefit from the MPPP and allow existing participants to plan out their payment obligations. In addition to the initial enrollment notice, it is also critical that participants receive reoccurring reminders of their installment payment obligations. For instance, individuals who discontinue their Part D prescriptions mid-way through the plan year should be reminded of the need to pay off their monthly obligations. BIO requests that all communication and educational materials be sent through both physical and electronic mail, including mobile applications if available, to encourage accessibility for beneficiaries who may prefer one form of communication over another.

60.2 Targeted Part D Enrollee Outreach Requirements, p.19-26

CMS proposes various methodologies that could trigger the POS notification to enrollees, such as using a single prescription amount versus a single day accumulation amount, as well as a range of POS notification thresholds from \$400 to \$700.

BIO believes that proactive notification and outreach for a wider range of beneficiaries is critical so that beneficiaries themselves can make an informed decision about whether they will benefit from participating. The applicability of spreading out OOP expenses over a benefit year is greatly valuable to many beneficiaries, therefore CMS should encourage broader participation into the program. Accordingly, BIO encourages CMS to determine the notification thresholds based on an examination of data and evidence on dollar amounts of OOP expenses that cause patient financial hardship and trigger prescription abandonment. We encourage CMS to continue to evaluate if a threshold lower than \$400 might be helpful for more beneficiaries who could benefit from the program.

⁴ Fleary SA, Ettienne R. Social Disparities in Health Literacy in the United States. *Health Lit Res Pract.* 2019 Mar 8;3(1):e47-e52. doi: 10.3928/24748307-20190131-01. PMID: 31294307; PMCID: PMC6608915.



BIO also suggests that CMS apply the notification threshold to a wide range of unit measurements instead of only a single prescription amount or daily accumulation amount. Some beneficiaries may find that a majority of their OOP expenses are with a single prescription, whereas others may have multiple large OOP expenses in a day. In addition, those on a fixed income often budget for the entire month rather than on a single transaction. Due to the different situations of different beneficiaries, it is important to notify many beneficiaries who may benefit from the MPPP. Therefore, BIO recommends that the notification could be triggered by all unit measurements, including, but not limited to, a per day, per month, or per prescription amount. By having the notification triggered by either a per day, per prescription, or per-month amount, more individuals who will benefit from the MPPP will be informed and empowered to participate.

Appendix A- Definitions for Medicare Prescription Payment Plan, p.43

CMS states that Part D sponsors must include all “covered Part D drugs” in the MPPP program.

BIO therefore requests clarification from CMS on the interpretation of “covered Part D drug” in relation to the MPPP. Specifically, BIO encourages CMS to confirm that the MPPP also applies to drugs that are treated as being included in a Part D plan’s formulary as a result of a coverage determination or appeal. 42 C.F.R. 423.100 states that a covered Part D drug includes drugs “in a Part D plan’s formulary as a result of a coverage determination or appeal...and obtained at a network pharmacy or out-of-network-pharmacy...” Therefore, we believe these drugs would be incorporated and processed within the MPPP. Further clarification from CMS would provide certainty to stakeholders on this point.

70.3.5 Processing Election Request During a Plan Year, p.32

CMS proposes that when a Part D sponsor receives an opt-in request during Part D plan enrollment, the Part D sponsor must process the request within 10 calendar days of receipt or the number of calendar days before the plan enrollment starts, whichever shorter.

BIO requests that CMS consider ways in which opt-in requests could be granted upfront while pending approval with the Part D sponsor. One possible approach could involve allowing enrollees to pay \$0 at POS for the prescription while the Part D sponsor processes the request. CMS could evaluate the feasibility of this upfront option and assess how enrollees who may be rejected could pay back their usual OOP cost sharing obligations. We encourage CMS to assess the benefits and risks of such an approach and ensure that all enrollees are effectively informed about their cost sharing obligations.

40. Participant Billing Requirements, p. 12

The guidance addresses billing and payment methodologies to ensure timely, uniform, and seamless implementation of the MPPP.

In the interest of simplifying and improving the enrollee experience, BIO recommends that CMS utilize patient navigators for various billing processing issues as well as other enrollment and scenario-planning services. Patient navigators, such as those established through the Affordable Care Act to assist consumers with the Health Insurance Marketplace, have the infrastructure and expertise to assist with a wide range of services. The Agency may consider equipping navigators with education information, resources, and scenario-planning tools related to the MPPP to better serve enrollees and enable information sharing. As trusted partners, navigators may be able to assist enrollees with many tasks including understanding their OOP payment options, grievance and



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appeals, debt repayment, and other tasks to help enrollees navigate the MPPP. Navigators may also help to provide specialized assistance to meet the needs of dual eligible and LIS enrollees. Enrollees who are able to utilize patient navigators will be better equipped to understand basic concepts related to their bills and their cost sharing obligations.

100. Data Submission Requirements, p.42-43

CMS states that Part D sponsors will be required to report information related to the MPPP on Prescription Drug Event (PDE) records and through new annual reporting requirements.

As CMS develops details around data collection requirements, BIO encourages the Agency to 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. Information around terminations will greatly enhance accountability and transparency to ensure that enrollees are not unjustly terminated or prevented from participating. We look forward to the opportunity to provide feedback on the data submission requirements through the requisite public comment periods.

Conclusion

BIO appreciates the opportunity to provide feedback to CMS through this draft guidance. We look forward to continuing to work with the Agency to ensure Part D enrollees can access this payment option in an efficient and timely manner. Should you have any questions, please contact us at 202-962-9200.

Sincerely,

/s/

Crystal Kuntz
Senior Vice President
Healthcare Policy & Research
Biotechnology Innovation Organization

Good afternoon,

Bright Health and our PBM, ESI, is providing the following comments and questions with regards to the draft Medicare Prescription Payment Plan guidance:

- Beneficiaries will move quickly from MPP to MOOP if enhanced benefits are part of the highlighted statutory text. In this case, they may hit MOOP before they actually get to \$2000.
- Guidance indicates that MPP is calculated on the Basic Standard Design but refers to incurred and non-incurred expense to be included? Please provide clarification.
- How a “dynamic MOOP” will interact with smoothing (i.e. Retro-LICS)?
 - How will plans know that a member has moved to MOOP and no longer is in MPP?
 - How will beneficiaries know that they are no longer MPP?
 - How will plans get member to pay for MPP applied prior to MOOP once they reach MOOP?
 - If a member changes plans midyear and was previously enrolled in MPP, how will the new plan manage MPP and MOOP calculations? Who manages the payments?
- How will CMS have plans communicate to members how variable the MOOP actually is in model documents?
- How will MOOP affect plan design? Will enhanced benefits be reduced? (With the Coverage Gap discount, many plans eliminated brand drug cost-sharing reductions given the financial downside of offering any coverage.) What are the potential unintended consequences of MPP?
- How does getting to MOOP faster or slower affect manufacturer behavior?
- What happens if members stop making MPP payments?
- How will members enroll in MPP? Will it be at POS? Use of a file like dTRR? Nx Transactions?
- How should the plan handle claim adjustments/reversals? Should the member be refunded if they’ve already paid a monthly payment, or should any refund amounts be credited towards their monthly payments?

- Upon disenrollment from the plan, the plan can bill the individual for any outstanding MPP owed. What if the individual does not pay their outstanding balance owed to the plan? In this case why should they be allowed to enroll in MPP with their new Medicare plan?
- How should plans handle transition fills where the drug being filled is not covered on the plan's formulary? Would these costs be excluded from MPP as outlined in Section 30 of the guidance referencing non-covered drugs, or would the plan have to include the costs incurred from the transition fill in MPP?
- If a member receives a transition fill where the drug being filled is covered on the plan's formulary but has a clinical utilization management edit attached, and the member ultimately receives a denial for lacking medical necessity. How should the plan handle? Should the costs incurred from the transition fill be included in the MPP amount?

Thanks!

William Yee | Senior Compliance Manager

e: wyee@brighthousehealthcare.com

Good afternoon,

Below are comments we ask to be considered as part of the final Medicare Prescription Payment Plan Guidance. We appreciate the opportunity to provide you with feedback and your consideration of said feedback.

Comment #1 – P15, section 50.1 Pharmacy Claims Processing Requirements, the use of a separate and unique BIN/PCN to facilitate COB payments under the Medicare Prescription Payment Plan complicates claim adjudication and downstream processes further than they currently are. Capital Rx, a PBM, has the functionality to adjudicate claims in a single transaction for all the documented CMS scenarios and to bucket dollar amounts in their appropriate financial categories. This approach also eliminates the need for Pharmacies to send multiple transactions and minimizes confusion. Instead of requiring Plan Sponsors/PBM's to use a unique BIN/PCN combination, we are asking CMS to allow an option for Sponsors/PBMs to use a single transaction solution for those that have this capability.

Comment #2 – P34-36, section 70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs, CMS's proposal to use a submission clarification code (SCC) may potentially address beneficiaries concern at POS in the short term, but it will create operational challenges for Plan Sponsors. Pharmacies may incorrectly use the SCC during claims transmission and not obtain beneficiary consent to participate in the Medicare Prescription Payment Plan. This will create discrepancies between Plan Sponsors and PBM's data exchange processes requiring the use of additional resources to reconcile the misinformation originally submitted by the Pharmacy at POS. Plan Sponsors will have to reach out beneficiaries to verify program enrollment and may lead to beneficiary confusion about the program and frustration about repayments; ultimately leading to unwanted grievances at no fault of the Plan Sponsor. Instead of requiring the use of an SCC by the Pharmacy, Capital Rx recommends having the Pharmacy contact the Plan Sponsors/PBM's helpdesk to trigger the beneficiaries real-time POS election into the Medicare Prescription Payment Plan.

Thank you,

Jason Barretto

Vice President of Government Program Operations

Capital Rx

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David Schwartz
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September 20, 2023

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

RE: Medicare Prescription Payment Plan Guidance

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 I draft guidance. CareFirst supports your pledge to strengthen protections 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 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 and look forward to future collaboration on IRA implementation.

As the largest health insurer in the Mid-Atlantic region, CareFirst believes 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 or the agency) finalizes guidance to implement the MPPP in advance of it becoming effective in 2025, our detailed comments below underscore the need for timely communication, collaboration, and accountability to ensure the program works as intended.

General Comments

CareFirst generally supports the concept of the MPPP and appreciates CMS soliciting feedback but encourages the agency to reconsider its outlined guidance release timeline. We strongly recommend the agency finalizes Part I guidance before the end of this year and releases draft Part II guidance as soon as possible, ideally in Q4 2023. This will provide plan sponsors with the time needed to appropriately account for potential losses and other bid information included in the Part II guidance. Releasing the draft part II guidance sooner ensures plans have time to consider these provisions prior to the release of the 2025 Advance Notice and Proposed 2025 Medicare Advantage Technical Rule, which will likely also incorporate provisions of the IRA related to Part D redesign that must be reflected in plan bid submissions. Furthermore, Part II guidance should be finalized no later than April 1, 2024, to provide ample time to price these provisions in advance of 2025 bid submission by June 3, 2024. CMS should also issue a recalibrated risk adjustment model that accounts for Part D redesign for public comment as soon as possible and finalize the model prior to the end of 2023.

CareFirst believes it is important for the MPPP to consider variation in plan capabilities and leverage model enrollee education materials wherever possible to promote uniformity. Not only will this promote consistency in messaging to beneficiaries across the country, but it will help ensure a level playing field between larger and smaller carriers to encourage robust competition. We encourage CMS to outline clear expectations and standards for Part D sponsors and appreciate the agency's plans to provide direct education to Medicare beneficiaries about the benefits of this program. This education should reference individuals' obligations to timely repay Part D sponsors on a monthly basis despite not incurring any costs at the point of sale (POS) and the needed communication and collaboration between CMS, beneficiaries, pharmacies, and plan sponsors to ensure program success.

Section 10 – Introduction

CareFirst encourages waiving applicability of the MPPP for EGWPs given these enrollees generally face stable, low out-of-pocket costs and are not likely to benefit from the MPPP. Not applying the MPPP to EGWPs will allow Part D sponsors to dedicate more resources and targeted outreach to those most likely to benefit from this new and complex program as referenced throughout the guidance, particularly in section 60.

Section 30 – Program Calculations and Examples

CareFirst supports the outlined calculations of the maximum monthly cap in the first month and subsequent months, including the treatment of extended day supplies. In the event the agency continues to apply the MPPP to EGWPs, we encourage CMS to provide additional examples for a beneficiary enrolled in an EGWP.

Section 40 – Participant Billing Requirements

Regarding debt collection, CareFirst urges CMS to provide specific guidance regarding the process Part D sponsors must undertake to seek collection of unpaid amounts under the MPPP. We request CMS provide clear standards that account for other related federal and state laws and regulations (e.g., Fair Debt Collection Practices Act, Public Law 95-109), to promote uniformity across the industry. Additionally, we request clarification if Part D sponsors are allowed to attribute payments intended to go towards the MPPP to the MPPP if the beneficiary also has an outstanding premium balance. Further, we encourage CMS to clarify that Part D sponsors have flexibility to implement a financial reconciliation process of their choice so long as it meets program guidance requirements.

Section 50 – Pharmacy Payment Obligations and Claims Processing

CareFirst supports CMS encouraging the use of an electronic claims processing methodology and not requiring Part D plans to retrospectively include paper claims in the MPPP program. We request clarification if the proposed additional bank identification number and/or processor control numbers must be included on member identification cards.

Section 60 – Requirements Related to Part D Enrollee Outreach

CareFirst reiterates the need to provide Part II guidance as soon as possible given it will include “guidance on communications at the pharmacy, model language, and standardized materials” in addition to targeted Part D enrollee outreach. We strongly encourage CMS to provide model language for all required communications to current and prospective enrollees about the availability and benefits of the MPPP that must be included in promotional materials prior to the plan year, during the plan year, and at the POS by April 1, 2024. Additionally, Part D sponsors should have clear guidance on how to target enrollees likely to benefit from the program to ensure the use of consistent standards and guardrails across the industry. This will be particularly helpful in developing assumptions for bid calculations.

CareFirst appreciates CMS acknowledging “a POS enrollment option is not likely for 2025” and encourages the agency to focus on educating enrollees likely to benefit from the MPPP about the value of enrolling in advance of the plan year starting. We urge CMS to delay the option for POS enrollment until there is sufficient evidence pharmacies, Part D sponsors, and CMS have the necessary systems

infrastructure in place to adequately support this process. CareFirst would appreciate clarity from CMS regarding how pharmacies must notify Part D sponsors about a POS election, including any required documentation. It will be important to ensure pharmacies understand their role in this process and for CMS to outline clear expectations, including any pharmacy compliance obligations, to ensure there is accountability for all stakeholders.

Section 70 – Requirements Related to Part D Enrollee Election

CareFirst appreciates CMS acknowledging low-income subsidy (LIS) enrollees are not likely to benefit from the MPPP and encourage CMS to clearly so state in any forthcoming program materials. It would also be helpful for CMS to identify the limited circumstances in which an LIS eligible individual might benefit from enrolling in the MPPP.

While recognizing the value of having a legal representative opt into the MPPP on an enrollee's behalf, CareFirst has some concerns this option could potentially be ripe for fraud. We urge CMS to provide clear guidance regarding what documentation (e.g., appointment of representative or designation of personal representative form) must be provided by the legal representative to identify themselves as having this authority at the time of election.

For processing election requests during the plan year, CareFirst encourages CMS to reconsider the proposed 24-hour turnaround timeframe. At minimum, this 24-hour timeframe should be limited to electronic election requests that have all the necessary information provided at the time the request is made. Election requests during the plan year should be processed within the lesser of 2 business days or 72-hours unless the request is deemed urgent and the enrollee's "life, health, or ability to regain maximum function" is jeopardized as noted in section 70.3.8. Lastly, we urge CMS to provide additional guidance around Part D sponsors obligations to process retroactive elections. For urgent elections, we request CMS institute some guardrails and clearly define "reasonably believes" to ensure individuals who are likely to benefit from the MPPP are not waiting until a markedly high cost sharing amount to opt into the program. This underscores the need to prioritize elections prior to the plan year starting.

For mid-year plan election changes, CareFirst strongly urges CMS to allow Part D sponsors to prevent individuals who have switched plans from opting into the MPPP due to previous termination from the program from another Part D sponsor due to non-payment. This is critical to minimizing the potential for individuals to intentionally switch from plan to plan to avoid repayment and ensure long term sustainability of the MPPP as well as of the underlying Part D benefit. Not allowing Part D sponsors to preclude enrollment of individuals who have a history of unpaid balances places unfair burden on plans that would inevitably be contemplated in bid assumptions in future years.

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

CareFirst supports CMS's outlined process for voluntary and involuntary terminations. We again encourage CMS to provide specific guidance and identify allowable actions by plans in seeking unpaid balances, including after processing an involuntary termination. CareFirst strongly supports allowing Part D sponsors to preclude future elections into the MPPP for individuals with unpaid balances to that sponsor from a previous year and encourage CMS to extend this policy to any Part D sponsor (i.e., individuals who switch plans during open enrollment with an unpaid balance should still be precluded from the MPPP). CMS maintaining a list of all individuals that were involuntary terminated and those with unpaid balances over two months (i.e., beyond the outlined grace period) should help facilitate this process.

Thank you again for the opportunity to provide our input. We look forward to continually working with you to implement the IRA.

Sincerely,

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

David Schwartz



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September 20, 2023

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: PartDPaymentPolicy@cms.hhs.gov
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Prescription Payment Plan Guidance

To Whom It May Concern:

Cigna welcomes the opportunity to respond to the Centers for Medicare & Medicaid Services (CMS) Draft Part One Guidance for the Maximum Monthly Cap on Cost-Sharing Payment Program (Draft Part One Guidance), also known as the Medicare Prescription Payment Plan (MPPP).

The Cigna Group is a global health company committed to improving health and vitality. Our subsidiaries are major providers of medical, pharmacy, dental, and related products and services, with over 190 million customer relationships in the more than 30 countries and jurisdictions in which we operate. Within the United States, Cigna provides medical coverage to approximately 14 million Americans in the commercial group health plan market, predominantly in the self-insured segment. We also provide coverage in the individual Affordable Care Act insurance segment in several states, both on- and off-Exchange, to about 235,000 people. Additionally, we serve more than 4.5 million people through our MA, Medicare Prescription Drug Program and Medicare Supplemental products. In all of the segments we serve, Cigna is focused on creating products and services that support a quality, affordable, equitable, and sustainable health care system for all Americans.

Overall, Cigna thanks CMS for the overall approach to the Draft Part One Guidance, including allowing for flexibility in key areas of program implementation. However, we have concerns with the impact of the program on 2025 bids and premiums, the overall implementation timelines, as well as operational challenges associated with identifying beneficiaries likely to benefit from the program, processing program elections within a 24-hour period, and lack of ability to hold member accountable for MPPP payments.

Consistent with these concerns, Cigna offers CMS the following key recommendations:

- Finalize all program guidance at least one year prior to the start of the program on January 1, 2025;
- Allow for the collection of monthly MPPP payments from enrollees through deductions from Social Security;
- Clarify what information can be provided on MPPP payment invoices;
- Set the "likely to benefit" pharmacy POS notification threshold for 2025 at \$700 for a single prescription drug;
- Enable MPPP enrollee outreach through support and training to pharmacies, including rural pharmacies;
- Allow 72 hours for non-urgent MPPP election requests;

- Shorten the non-payment grace period from two months to one month; and
- Create a modified process to address MPPP participant disputes.

Cigna's detailed feedback is provided below.

Financial Considerations for 2025 Bids

Cigna appreciates the IRA's goal of making health care more accessible, equitable and affordable for consumers. However, Cigna is concerned that it will be extremely difficult for plans to estimate beneficiary behavioral response to the MPPP when calculating 2025 bids.

CMS has previously stated that plans should account for predicted debt due to the MPPP in their bid submissions, which is intended to provide a level of compensation for unpaid debt. However, we are concerned about the high level of uncertainty and lack of historical experience to accurately predict this risk, and the potential impact to plan premiums resulting from this uncertainty. Although the Draft Part One Guidance states that new data reporting would be created for uncollected balances, the bids for 2025 will not be based on any experience.

Cigna urges CMS recognize the high degree of uncertainty and difficulty in accurately predicting the level of financial risk associated with the MPPP, especially for the first two years of the program. CMS should explore what additional mitigation mechanisms might be available to help provide stability to the program as it gains the necessary experience to manage this risk.

Additionally, we ask CMS to consider waiver flexibility for Employer Group Waiver Plans (EGWPs). Today, EGWP plan sponsors provide Medicare Part D coverage for over 7 million members across the Medicare benefit. The ability of employers to provide coverage for their retirees is incumbent upon members' payment towards their premiums as well as applicable cost share for their medications. Many of these employer plans will not have adequate funding to front the cost of these medications to the pharmacies under the MPPP without assurance of member payment. We ask CMS to consider the inherent differences between EGWP plans and populations and the individual Part D program. Employers should have the discretion to manage their plans as they do today, including maintaining the ability to remove members who fail to make payment for the employer sponsored benefit. In these instances, beneficiaries would then have access to a special enrollment period to enroll in an individual Part D plan, as they do today. Because of this, we believe beneficiaries are sufficiently protected to afford EGWP employers the ability to closely manage their benefit as they do today.

Section 10. Introduction: Overall Timeline

CMS guidance:

This Draft Part One Guidance will be finalized by spring 2024 after consideration of all comments received on the draft. CMS will issue a draft part two guidance, as well as model language and supporting materials, covering additional topics, such as outreach and education, by early 2024. CMS will follow the same procedures for comment solicitation before finalizing the additional guidance in spring or early summer 2024.

Cigna comment:

According to the timeline as proposed by CMS, the part two guidance may not be finalized until after the bids for CY 2025 are due. Plans and their partners will need all final guidance

to inform their bids and achieve the goals of the MPPP. Cigna strongly urges CMS to finalize all guidance for the Medicare Prescription Payment Plan by the end of CY 2023 in order to allow Part D plans adequate time to fully operationalize the program as intended by January 1, 2025. Alternatively, we ask CMS to consider phasing in certain components and requirements proposed in the guidance, to afford Part D plans sufficient time for implementation following issuance of all final MPPP guidance.

Section 40. Participant Billing Requirements

CMS guidance:

The Draft Part One Guidance requires Part D sponsors to bill participants who are in the Medicare Prescription Payment Plan and incur OOP costs in an amount for each month that cannot exceed the applicable maximum monthly cap. Each billing period will be a calendar month. CMS notes that past due balances from prior monthly bills may also be included in a billing statement, which could result in the total amount on the billing statement exceeding the maximum monthly cap. However, the amount billed for the month for which the maximum monthly cap is being calculated cannot be higher than the cap for that month. Because of this, CMS states that late fees, interest payments, or other fees, such as for different payment mechanisms, are not permitted under the program. CMS also encourages Part D sponsors to offer multiple means of payment, such as an electronic fund transfer mechanism and payment by cash or check.

For the first month, in scenarios where OOP costs are incurred in the first month, Part D sponsors must bill the participant the lesser of the participant's actual OOP costs or the first month's maximum monthly cap. For subsequent months, the maximum monthly cap is determined by calculating the sum of any remaining OOP costs owed by the participant from a previous month that have not yet been billed and any additional OOP costs incurred by the participant in the subsequent month, divided by the number of months remaining in the plan year.

Cigna comment:

Cigna appreciates CMS's flexibility in encouraging multiple means for payment and seeks additional clarity on information that can be included on MPPP invoices regarding amounts owed and implications for different payment amounts. We provide the following specific recommendations.

- **Payment Mechanisms:** Cigna appreciates CMS encouraging multiple means for payments and we recommend allowing for the collection of monthly payments through deductions from Social Security, at the option of the member, as is permissible for Part C and D premiums. In addition, members should not be encouraged to make cash payments through the mail, nor should plans be required to accept cash as payment, as this practice encourages mail theft.
- **Financial Reconciliation Process:** Cigna recommends that CMS allow participants to pre-pay above the monthly cap, even if the amounts are more than the total OOP costs incurred to date. Part D sponsors would be able to conduct a financial reconciliation at year-end or upon member request.
- **First Month MPPP Payment Calculation:** Cigna recommends that a beneficiary's minimum payment for the first month enrolled in the plan should not be calculated by using a "lesser of" logic. This approach to calculation will help to eliminate larger payments for beneficiaries at the end of the calendar year.

- **MPPP Invoice Information Clarification:** CMS should clarify what information can be included in the MPPP invoice to beneficiaries. In addition to the maximum monthly payment amount on the MPPP billing invoice, Cigna also recommends that CMS clarify which information is permitted to be included on the invoice. In particular, we believe that plans should have the ability to include information regarding the implications of different billing amounts and how various payments made at different points during the year will have an impact toward the end of the year.

Additionally, as CMS currently requires plan sponsors to attempt recovery on previous years, we recommend allowing the MPPP invoice to include prior year balances and netting balances year over year. Finally, Cigna also recommends allowing plan sponsors to include MPPP owed balance information in the monthly premium billing statements.

- **Mid-year Enrollment:** Cigna recommends that all member costs incurred prior to election but processed after the election date be applicable to the MPPP if the member enrolls mid-year. In addition, costs from claims that are adjusted prior to the election should also be included.

Sec. 50.1 Electronic Claims Processing Methodology

CMS guidance:

CMS encourages adoption of an electronic claims processing methodology such as the one currently used for real time COB billing transactions using NCPDP standards. Part D Sponsors would use an additional Bank Identification Number (BIN) and/or Processor Control Number (PCN) unique to the MPPP to facilitate electronic processing.

Cigna comment:

Cigna supports the use of a BIN/PCN approach as opposed to the use of a pre-funded payment card. However, we are concerned about the expectation of the plan sponsor or PBM to retroactively process claims if the pharmacy does not submit under the BIN/PCN approach. Cigna would like CMS to clarify such expectations. We agree that paper claims should be excluded such that the amounts in such claims would not be subject to the MPPP. In addition, out-of-network claims should be excluded from the MPPP.

Section 60. Requirements Related to Part D Enrollee Outreach

CMS guidance:

CMS states that 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. To implement this, CMS developed a standardized framework for assessing "likely to benefit," which will be used to inform targeted outreach both prior to and during the plan year. Overall, CMS asserts that those with high OOP drug costs early in the year (including recurring costs) are likely to benefit from the Medicare Prescription Payment Plan. CMS also seeks comment on potential point-of-sale (POS) notification thresholds from \$400 to \$700, as well as whether it would be preferable to use a value based on the OOP costs for all prescription filled in a single day.

For the pharmacy notification requirement, CMS is proposing to base the determination of whether an enrollee is likely to benefit from participating in the program based on when they incur OOP costs for a single prescription that equals or exceeds the POS threshold. CMS will provide additional guidance on the contents of notifications, as well as model language for educational materials in the next phase of guidance, and welcomes input on these topics.

Regarding different pharmacy scenarios, CMS notes that it is aware that claims processing and billing practices may differ for certain unique pharmacy scenarios and seeks comment on whether and what alternative notification processes or standards should be established for different types of pharmacies (for example, requiring notification via a phone call as opposed to a paper notice).

CMS details that because a Part D enrollee is unlikely to benefit from opting into the MPPP in December, enrollees should not be notified that they are likely to benefit in the last month of the plan year. CMS notes that if a prescription is picked up by another person who is not the Part D enrollee, the Part D sponsor must require the pharmacy to provide the person who is picking up the prescription with information about the MPPP.

In addition to notifying all prospective Part D enrollees about the ability to opt into the Medicare Prescription Payment Plan, Part D sponsors must also conduct outreach directly to individuals who are likely to benefit from the program, both prior to and during the plan year.

Cigna comment:

Cigna believes that the POS notification for members likely to benefit and other proactive outreach will present considerable challenges for pharmacies and Part D sponsors, particularly during the first year of the MPPP. To facilitate a least burdensome implementation process, Cigna recommends the following:

- **“Likely to Benefit” POS Notification Threshold:** Cigna recommends that CMS set the “likely to benefit” POS notification threshold for 2025 at \$700 for a single prescription drug because of the lack of real-time enrollment at the POS. Furthermore, the \$700 threshold should be updated annually thereafter by applying an appropriate index to inflation. We have concerns that if the notification were set lower, too many beneficiaries notified at the POS would leave the pharmacy without their prescription in order to enroll in the MPPP. Cigna supports targeted enrollee outreach only for pre-plan year election during the first year to avoid such instances.
- **Notification of Likely to Benefit:** While CMS notes that as enrollees are not likely to benefit from the MPPP if they enroll in December, no notification should be provided. Cigna would like to recommend that notifications not be provided in November or December, as enrollees are provided a 2-month grace period on MPPP payments. Moreover, enrollees are not likely to benefit from enrollment in November given that enrolling at this time of year will only shift the total cost to December.
- **Outreach Prior to and During the Plan Year:** As mentioned above, Cigna is concerned about the challenges presented by POS notification and we believe that any POS outreach will be difficult to conduct during the first year of the MPPP without posing issues for beneficiaries. To this end, we recommend that CMS exercise enforcement discretion for this requirement during the first year of the program.
- **Marketing, Communications and Training Materials for Stakeholders, Including Pharmacies:** CMS’s notification, marketing and educational information

and initiatives will be critical for MPPP implementation. In particular, guidance on communications at the pharmacy, model language, and standardized materials are needed to achieve effective enrollee outreach. Cigna urges CMS to work with plans, PBMs and pharmacies to develop and roll out such communications and materials, including use of CMS standardized and/or model template forms, documents and resources such as pamphlets and information in the Medicare Plan Finder tool. In addition, online educational videos and webinars about the MPPP, featuring examples of enrollees of who would benefit (and not benefit) from participating, would be helpful. Information provided to pharmacies—especially rural pharmacies—and provider offices would also be useful to reach Part D enrollees where they are likely to visit. CMS's support and training for individuals and stakeholders notifying Part D enrollees about the MPPP, such as pharmacies and their employees, will be particularly important. In particular, we ask that CMS offer focused support and training to rural pharmacies and providers as they face unique challenges and limited resources.

- **Pharmacy Notification Processes:** Cigna believes that regardless of the type of pharmacy, all pharmacies should be able to send email, text or paper notifications, but should not be required to make notifications by phone.

Section. 70.3 Election Procedures

CMS guidance:

CMS details that Part D sponsors must provide beneficiaries the ability to opt into the MPPP through the plan enrollment process, and such options must include a paper option that can be faxed or mailed, or a toll-free telephone number and a website application that provides the individual with evidence that the election request was received. Additionally, Part D sponsors may be required to process retroactive claims under the Program to protect enrollees from delays of Part D sponsors in processing election requests.

When a Part D enrollee is already enrolled in a Part D plan and requests to opt into the Medicare Prescription Payment Plan during the plan year, Part D sponsors must process the election request within 24 hours to prevent delays in dispensing drugs to individuals when they opt into the program. Upon receiving a Medicare Prescription Payment Plan election request, a Part D sponsor must communicate within 24 hours:

- An approval of the request and effective date when the individual starts in the Medicare Prescription Payment Plan;
- A request for additional information; or
- A denial of the request through a written notice of denial.

CMS also solicits comment on whether there is an interim solution that Part D sponsors could implement to prevent Part D enrollees from waiting 24-hours to receive their prescription at \$0 out of pocket while waiting for their election into the program to process.

For LIS beneficiaries, CMS states that Part D sponsors must process retroactive claims and premium adjustments for LIS-eligible individuals and make any resulting refunds and recoveries within 45 days of the Part D sponsor's receipt of complete information regarding these adjustments.

Regarding plan switching, Part D sponsors are not required to automatically sign up an enrollee who switches plans mid-year, but the enrollee may elect to continue participating in the program with the new plan. Part D sponsors are not required to automatically sign up an

enrollee who switches plans mid-year, but the enrollee may elect to continue participating in the program with the new plan and the enrollee's monthly OOP cap is calculated using the statutory formula for the new plan.

Cigna comment:

Cigna is concerned about several of the timelines to process election requests and retroactive claims and offers comments in the following areas related to election procedures.

- **24-Hour Election Processing Timeframe:** Cigna recommends allowing more than 24 hours for non-urgent MPPP election requests. Currently, most Coverage Requirements Discovery (CRD) requests are not processed within 24 hours. CMS should establish a process to allow for non-urgent MPPP election requests to be processed within 72 hours after receiving a complete request.
- **LIS Beneficiaries and Retroactive Claims:** If Part D sponsors are to provide refunds within 45 days, Cigna recommends that any refund be reduced by the amount owed on the next MPPP billing invoice so that members are not required to immediately make a MPPP payment. Additionally, we suggest allowing members to have the option to have the refund credited to their entire bill to reduce future payments.
- **MPPP Election Options:** Given the multiple avenues plans must offer for election and the operational complexity of making all avenues available by January 1, 2025, Cigna requests that CMS consider phasing in MPPP election options over the course of the first year. In addition, Cigna recommends that plans be encouraged, but not required to offer a fax option for beneficiaries, as the vast majority of beneficiaries do not use this functionality.

Section 70.3.9. Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs

CMS guidance:

CMS is also considering options to effectuate election into the Medicare Prescription Payment Plan at the POS without any delay or with only a nominal delay between the election request and effectuation beginning in 2026 or later. These options are potential alternatives or additions for a future year to CMS's proposed 24-hour effectuation requirement and would allow individuals to opt into the program at the pharmacy and collect their prescription in the same pharmacy transaction. The methods for real-time or near-real-time elections include telephone only, mobile or web-based application, and clarification code.

Cigna comment:

Cigna agrees with CMS that POS enrollment is not feasible for CY 2025. It cannot be accomplished until the minimum data elements are available to capture a beneficiary or legal representative's request to elect into the MPPP and provide the appropriate documentation to ensure that beneficiaries have the appropriate education to determine whether the MPPP will benefit them. In addition, pharmacies must have the ability to reverse/reprocess or process MPPP COB claims subsequent to the election.

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

CMS Guidance:

CMS explains that Part D sponsors must provide individuals with a grace period of at least 2 months when an individual has failed to pay the bill amount by the payment due date. CMS states that the grace period must begin the first day of the month for which the balance is unpaid or the first day of the month following the date on which the payment is requested, whichever is later. Part D sponsors must also reinstate an individual who has been terminated from the MPPP if the individual demonstrates good cause for failure to pay the program billed amount within the grace period and pays all overdue amounts billed.

CMS also details that a Part D sponsor may only preclude an individual from opting into the MPPP in a subsequent year if the individual owes an overdue balance to that Part D sponsor and that new sponsors may not prohibit an individual from opting into the program even if the individual was terminated from the program for non-payment by a different Part D sponsor.

Cigna Comment:

Cigna has significant concerns regarding the length of the grace period provided to MPPP members, as well as the available remedies for pursuing non-payment. Our full comments in following areas are below.

- **Grace Period:** Cigna is concerned that providing members with a two-month grace period before termination in the program is too long. CMS should consider a one-month grace period. We would also be supportive of allowing pharmacies to start collecting cost sharing amounts at the point of sale when members fail to make MPPP monthly payments. If CMS maintains this two-month grace period, we recommend that requests from beneficiaries to elect into MPPP be processed for the next calendar year during November and December.

Cigna also seeks additional clarity on how “credible statements for failure to pay” and “circumstances for which the individual has no control” will be defined. It would be helpful to understand if these terms will be interpreted to correspond to similar processes in place when beneficiaries fail to pay premiums.

- **Remedies for Non-Payment:** While the Draft Part One Guidance states that plans will continue to bill terminated enrollees for monthly payments, Cigna recommends allowing plans to pursue other remedies for non-payment.

Section 90. Participant Disputes

CMS Guidance:

CMS details that each Part D sponsor must have appeals procedures for making timely coverage determinations regarding the prescription drug benefits an individual is entitled to under the Part D plan. Part D sponsors must apply their established Part D appeals procedures to any dispute made by a Medicare Prescription Payment Plan participant about the amount of Part D cost sharing owed by that participant for a covered Part D drug.

Cigna Comment:

We agree that there needs to be a process for members to submit MPPP disputes with their plan sponsor. Cigna recommends that there be clear processes outlined for this, similar to processes that plans must follow for other financial interactions with members for premium billing, good cause and LEP disputes. As the beneficiary has already received their drugs, the MPPP is not related to a coverage review, so the appeals process related to coverage reviews per se may not be appropriate to the type of disputes related to the MPPP. MPPP disputes most likely would center on the ability to elect into the program, timing of the election or the specific calculation of payment amounts. Ideally, MPPP participant dispute processes should be separate and distinct from existing Part C and D grievance and appeals processes. However, whether addressed through modifications to the Part C & D grievance and appeals guidance or through separate guidance, CMS should provide clarity on how MPPP-specific disputes should be addressed.

In addition, plans should be held harmless as it relates to complaint tracking module complaints (CTMs) and grievances related to the MPPP if the CTM or grievance is not due to plan error.

* * *

Thank you for your consideration of these comments. Cigna would welcome the opportunity to discuss these issues with you in more detail at your convenience.

Respectfully,

A handwritten signature in blue ink that reads "Kristin Julason Damato".

Kristin Julason Damato

Good morning,

After reviewing the Medicare Prescription Payment Plan, Clear Spring Health has a lot of concerns over the proposed guidance. We have a large PDP plan made up of mostly low income members. Since these members already have a reduced cost share at the POS we don't believe this guidance should apply to these members. In addition, these members are likelier to change plans several times during the year and trying to manage payment requirements between Payors would be too difficult to apply and take too many resources from a Plan perspective. Also these members are very hard to contact as we have less than half of their phone numbers and a lot of incorrect demographic information when they're auto assigned to us. The burden will fall on the plan if these members elect to sign up for payment plan as they're unlikely to pay their copays. Please let us know if you have any questions or comments.

Thank you,

Eddy Lopez, PharmD

VP of Pharmacy Operations

Clear Spring Health

Ph: 754-208-5867

Fax: 312-284-2042

Dear. Dr. Seshamani:

We appreciate the opportunity to provide the following comments on the draft Medicare Prescription Payment Plan (Program) Guidance issued by the Centers for Medicare & Medicaid Services (CMS) on August 21, 2023.

Listed below are our main comments and recommendations:

- CMS should lead in educating beneficiaries about the program so there is understanding on how it works and the value that it may provide to beneficiaries. CMS needs to implement the Medicare Prescription Payment Plan via a simplified method so all stakeholders (beneficiaries, pharmacies, part d health plans and pbms) can effectively implement and receive benefit from it.
- Because of the complexities in operationalizing such a program, we feel that CMS should not include any complaints or grievances about the Medicare Prescription Payment Plan against Star measures/ratings for at least several years. This will allow both CMS and Part D health plans to address issues from initial implementation of the Medicare Prescription Payment Plan program. Part D health plans and PBMs also require guidance and ample time to test prescription drug events (PDEs) to ensure meeting requirements.
- CMS should exercise enforcement discretion for at least the first full year of the Medicare Prescription Payment Plan Program to allow Part D health plans and CMS to work out operational issues and prioritize beneficiary outreach and education.
- It is important that the Medicare Prescription Payment Plan program be evaluated by CMS for its effectiveness during its first year and allow part d health plans to make improvement to both lower costs of administering program and providing optimal beneficiary experience.

Specific Comments on draft Medicare Prescription Payment Plan Program Guidance

Section 10. Introduction:

- CMS should issue final guidance no later than the last quarter of 2023 so as to allow Plans sufficient time to have systems and operations in place, and allows

development/distribution of communication materials about the Program, including instructions to beneficiaries on how to enroll into the program.

Section 20. Overview

- CMS should create separate communications for the sole purposes of describing the Program to beneficiaries and explain the program to them as simply as possible.

Section 30. Program Calculations and Examples

- CMS should provide beneficiary education to address complex situations where the prescription claim transactions are later edited or reversed.

Section 40. Participant Billing Requirements

- CMS to confirm if beneficiaries can pay more than their monthly installment if they choose to do so, and share any reporting with Part D health plans regarding beneficiaries payment history with other other/previous Part D health plans.

Section 50. Pharmacy Payment Obligations and Claims Processing

- CMS should consider the numerous difficulties associated with the proposed POS COB claim approach and provide additional guidance.

Section 60. Requirements Related to Part D Enrollee Outreach

- Plans should be permitted to include information in their Program materials and content about beneficiaries who are not likely to benefit from participation. Additionally, Annual Notice of Change (ANOC)/Evidence of Coverage (EOC)/LIS Rider materials should be updated to include high level information about the Program, including LIS applicability.

Section 70. Requirements Related to Part D Enrollee Election

- Recommending that the timeframe to process an enrollment request should be 10 days and enrollment into the program would apply to future claims.

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

- CMS should allow Part D health plans to limit enrollment and disenrollment to one time per year into the Program and part d health plans should be able to exclude any beneficiaries from opting into the Program in subsequent years if they owe an overdue balance to any Part D sponsor.

Section 90. Participant Disputes

- Recommend that CMS institutes a process for Medicare Prescription Payment Plan Program-related billing disputes are tracked/reported separate from the traditional Coverage Determination and Appeals (CDA)/DMR process.

Section 100. Data Submission Requirements

- Indicators on EOB & PDE communicating if beneficiary is enrolled or not enrolled into the Medicare Prescription Payment Plan Program.

Thank you for considering our comments.

Michael Pica, RPh

Vice President, Pharmacy Operations

P: 718-873-5606

[30 Montgomery St., 15th Floor, Jersey City, NJ 07302](mailto:mike.pica@cloverhealth.com)

mike.pica@cloverhealth.com

Our plan has a question related to the Medicare Prescription Payment Plan Guidance issued by CMS on 8/21/23. We do not see any references in the guidance in relation to the Financial Information Reporting (FIR) process or the Transaction Facilitator, which is required under the Medicare Part D program.

By CMS definition, FIR transactions are designed to facilitate the real-time transfer of beneficiary information and TrOOP and Drugs Spend dollars accumulated between all Part D plans the beneficiary may have had during a calendar year. In regards to “the OOP Smoothing Program”, how would the FIR transactions reflect instances where cost share smoothing has occurred? What about situations where the participant has not paid for their prescriptions while using cost share smoothing and chooses to leave the plan to avoid paying for their prescriptions? We understand that per section 80.5 of the guidance, nothing in the Act or in this guidance prohibits Part D sponsors from billing an individual for an outstanding Medicare Prescription Payment Plan amount owed. But how does the new plan of record determine the TrOOP amount without knowing whether or not the beneficiary was a participant in a previous plan’s OOP Smoothing Program?

Thank you for your consideration.

Thank you,

Charles Perez, MHSA, BS, CPhT

Manager, Pharmacy Services

CMS Contracts: H3755, H4198, H4277

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Congress of the United States
House of Representatives
Washington, D.C. 20515

Anna G. Eshoo
Sixteenth District
California

September 13, 2023

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

Dear Administrator Brooks-LaSure,

I appreciate your continuing efforts to implement provisions from the Inflation Reduction Act (IRA) (Public Law 117-169) that will lower prescription drug costs for Medicare beneficiaries. As the Centers for Medicare & Medicaid Services (CMS) finalizes the draft guidance released on August 21, 2023, entitled “Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans,” and prepares to issue additional guidance for the Medicare Prescription Payment Plan early next year, I respectfully ask you to ensure that beneficiaries are able to enroll in the Medicare Prescription Payment Plan at the point of sale at the pharmacy counter as soon as practicable. Thank you for including critical patient protections in the draft guidance. As a Member of Congress who created the monthly cap provision of the Inflation Reduction Act, it was my intent for the legislation to provide significant new protections and cost savings to Medicare beneficiaries in a clear and simple process.

To ensure the Medicare Prescription Payment Plan meets the goal of the IRA, which is to lower prescription drug costs for Medicare beneficiaries, CMS should model the opt-in process for the Medicare Prescription Payment Plan after the Medicare Part D Low-income Subsidy (LIS) process for enrolling beneficiaries. I appreciate that CMS has acknowledged it is considering this as an option and I urge you to include a similar process in any final guidance to ensure the Medicare Prescription Payment Plan reaches all the beneficiaries that need it.

I also commend CMS for including important patient protections in the draft guidance and strongly urge CMS to retain those protections in any final guidance. Specifically, I support:

- Offering beneficiaries a grace period to make overdue payments without being threatened with disenrollment;

- A process that allows beneficiaries to be reinstated after paying overdue or past bills;
- Requiring Part D sponsors to have a mechanism in place to notify pharmacies when a beneficiary incurs high out-of-pocket costs related to Part D that makes the beneficiary likely to benefit from the Medicare Prescription Payment Plan;
- Using the thresholds outlined by CMS to ensure Part D sponsors and pharmacies can proactively ensure beneficiaries most in need of the Medicare Prescription Payment Plan can opt in before they arrive at the point of sale;
- Making the Medicare Prescription Payment Plan effective immediately upon opt-in; and
- Requiring Part D sponsors to send targeted promotional materials to beneficiaries help those who struggle to afford their high cost medications.

Finally, CMS should prioritize standing up the Medicare Prescription Payment Plan in 2025 to coincide with the \$2,000 annual cap on out-of-pocket costs taking effect. While CMS is working actively to implement many provisions of the IRA, few are as directly meaningful to beneficiaries as a cap on out-of-pocket costs. CMS should work to ensure processes for the Medicare Prescription Payment Plan are in place as soon as practicable.

I appreciate your work on this important topic and look forward to seeing the Medicare Prescription Payment Plan become a reality. I stand ready to work with you to ensure that one of the ultimate goals of the IRA is realized: lower costs for Medicare beneficiaries.

Most gratefully,

Anna G. Eshoo

Member of Congress

September 20, 2023

The Honorable Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: [Medicare Prescription Payment Plan Guidance]
7500 Security Boulevard
Baltimore, MD 21244-1850

Via Electronic Submission

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

Priority Health appreciates the opportunity to provide comments on behalf of Corewell Health in response to the recent CMS guidance regarding the Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans. Corewell Health is a Michigan-based not-for-profit integrated health system with a team of 60,000+ dedicated people including more than 11,500 physicians and advanced practice providers and more than 15,000 nurses providing care and services in 22 hospitals, 300+ outpatient locations, and several post-acute facilities. In addition, as an integrated health system, Corewell Health includes Priority Health, a health plan that insures more than 1.2 million lives. Corewell Health is not only Michigan's largest health system, but also Michigan's largest private employer. Through experience and collaboration, we are reimagining a better, more equitable model of health and wellness.

Participant Billing Requirements (Section 40)

Priority Health appreciates the guidance detailing the operational requirements of the Medicare Prescription Payment Plan ("the program"). We have identified a number of questions that still remain and hope to see them addressed in part two of the guidance. First, under Medicare Part D, members are allowed to deduct premiums from their railroad retirement or Social Security benefits. Will they be allowed to deduct monthly payments for the new Medicare Prescription Payment Plan from their checks as well? CMS has outlined in this guidance that participants cannot pay more than their total out of pocket costs incurred for the month; how should plans handle overpayments in the program? Regarding the program not permitting fees, we feel that consideration must be given to fees that are outside the plan's control, including non-sufficient funds fees, credit card fees, and other costs that are a result of third-party institutions adding a charge that impacts costs. We would seek clarity on those fees and how they should be applied to a member's bill.

Requirements Related to Part D Enrollee Outreach (Section 60)

We ask that CMS provide templates for inserts which should be included in the pre-enrollment packet during open enrollment. Additionally, templates for required documents which must be provided to members or prospective members would be helpful to ensure compliance and consistency similar to other IRA model documents and language.

As we engage in the process of informing members about the Medicare Prescription Payment Plan, we ask for latitude for our sales agents to ensure we can help educate members on not only the benefits of the program but also the potential impacts if they are not a member who is likely to benefit from enrolling in the program. Ensuring plans, and more specifically sales agents, have the authority to inform members who may not benefit from enrolling in the Medicare Prescription Payment Plan, from our perspective, is as important as enrolling members who will benefit. We are concerned the billing process may lead to surprise billing for members enrolled, but not well-suited to the program as members may not be aware at the point of sale. CMS should also be aware of the potential for Fraud, Waste, and Abuse when costs to a member may not be presented or known at the point of sale and the Pharmacy provider will receive reimbursement.

Requirements Related to Part D Enrollee Election (Section 70)

In seeking to better understand the distinction between the Part D enrollment process and election into the Medicare Prescription Payment Plan, we ask for clear guidance on how to administer enrollments into a Part D plan, which include an election into the Medicare Prescription Payment Plan when the plan determines there are deficiencies in an election request. Are plans able to separate the election request from the rest of the application so we can enroll the applicant into the Part D plan and send back the election request as outlined in the guidance?

The 24-hour turnaround for election requests is highly unusual, and we are concerned that this does not allow for adequate time to ensure that beneficiaries receive the correct benefit and that we are compliant with the program's requirements. We feel the program and beneficiaries would be better served if plans were allowed a seven-day period to administer election requests. We believe this extension would help ensure accuracy and compliance with the standards outlined by CMS in the guidance.

Thank you for the opportunity to share our comments on this initial guidance. We look forward to continuing our collaborative relationship with CMS and the ongoing implementation of the Inflation Reduction Act.

Regards,



Scott Norman
VP, Medicare
Priority Health

September 20, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21241

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

Dear Administrator Brooks-LaSure:

The Crohn's & Colitis Foundation appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed guidance for the newly created Medicare Prescription Payment Plan (MPPP). The guidance begins to put in place provisions of the Inflation Reduction Act (IRA) that are of critical importance to Medicare beneficiaries -- the ability to spread payment for prescription drug costs up to the new \$2,000 annual cap throughout a calendar year.

The Crohn's & Colitis Foundation is a non-profit, volunteer-fueled organization dedicated to finding cures for Crohn's disease and ulcerative colitis and improving the quality of life of children and adults affected by these diseases. Crohn's disease and ulcerative colitis are chronic, degenerative autoimmune diseases collectively known as inflammatory bowel disease (IBD). 1 in 100 Americans suffer from IBD. If not properly treated, IBD causes pain and a diminished quality of life, and can eventually lead to malnutrition, cognitive impairment, repeated hospitalizations, multiple surgeries, or even death.

The Foundation Commends CMS for its continued efforts to reduce out-of-pocket costs and financial burdens on patients. While implementing this new program, it will be critical that CMS work with patients and their representatives to support choice and access to clear, understandable, and actionable information. This is particularly true for people with chronic diseases and disabilities such as IBD who are most likely to avail themselves of this option.

Participant Outreach and Education

CMS is requesting input on the most effective tools and messengers for educating beneficiaries about the program as well as how the new program will interact with existing programs designed to assist beneficiaries. In our experience, there is no single mode of communication that is most effective. It is important that patients are reached through multiple channels and hear about options repeatedly and from different messengers. This should include, but not be limited to the following: television and radio announcements; a dedicated website with videos, factsheets, and

instructions in multiple languages; direct mail; and, materials made available to healthcare providers, pharmacies, and other retailers.

We encourage CMS to partner with patients and patient groups from the outset to develop these materials and the methods to disseminate them. It will be important that CMS devote critical time and resources to this effort. Regardless of the messenger or tool, there are three key times when beneficiaries should be informed of their options. These are the points of prescription, pharmacy fill, and plan election or change.

Participant Billing Requirements

Beneficiaries should have the option to autopay costs they opt to spread out over the year. This will reduce the burden on beneficiaries and reduce the likelihood of missed payments. We appreciate that the guidance includes the option to do an electronic fund transfer as well as credit card and check options. Part D beneficiaries are also able to deduct their premiums from Social Security benefits, and we recommend that MPPP payments should be eligible for this option as well. In general, CMS should encourage sponsors to offer as many payment options as possible and align billing with premium billing, timing, and payment methods.

The Foundation also appreciates the clarity in the guidance on protections from debt collection and feels strongly these protections must remain in place to assure beneficiaries are not subject to inappropriate debt collection activities. Finally, we recommend that plans be required to notify beneficiaries when they have reached their \$2,000 cap and advise them what their payments will be for the rest of the year. At this point, the payments should remain stable and predictable, so beneficiaries will appreciate this actionable information. This will also address concerns about people who choose smoothing but are unaware of the annual out-of-pocket (OOP) cap.

Requirements Related to Part D Enrollee Outreach

We encourage CMS to update the Medicare.gov Plan Finder to include information about the MPPP and the OOP cap to help guide beneficiaries when selecting a plan. One of the most important outreach tools will be a reliable, accessible monthly cost calculator that tells beneficiaries what their monthly obligation will be if they opt into the program. By making this tool available at each decision point, CMS will offer beneficiaries the most basic information they need when they need it.

CMS also requests information about targeted notification at the point of sale (POS). We recommend that this notification be accompanied by an efficient, seamless way for beneficiaries to opt-in at POS. It will negatively impact uptake and medication adherence if a patient needs to step away from the pharmacy counter, contact their plan to enroll, and then return to the pharmacy.

As POS election is a critical component of meeting the underlying goals of this program and minimizing the burden on beneficiaries, we urge CMS to achieve POS election as swiftly as possible. We urge CMS to make every effort to implement POS election when the program begins in 2025. CMS should not wait until 2026 as proposed, and certainly not until after 2026 to achieve POS real-time election.

Additional Issues

As with any new initiative, particularly one directly impacting beneficiaries, ongoing monitoring and oversight is necessary. We encourage CMS to put in place efforts to monitor the uptake and use of the program. In addition, CMS should monitor the unintended consequences on access, such as increased utilization management, of this and other parts of the Part D redesign during implementation.

Conclusion

The Crohn's & Colitis Foundation appreciates the opportunity to provide input into the MPPP. Please do not hesitate to contact Erin McKeon, Associate Director, Federal Advocacy if you or your staff would like to discuss these issues in greater detail. She is reachable via e-mail at emckeon@crohnscolitisfoundation.org.

Sincerely,



Laura Wingate
Executive Vice President, Education, Support, & Advocacy
Crohn's & Colitis Foundation

From: [CMS PartDPaymentPolicy](#)
To: [OOP Smoothing Comments](#)
Subject: FW: Medicare Prescription Payment Plan Guidance
Date: Tuesday, September 19, 2023 11:45:11 AM

From: Curtis Skane <curtis.skane@sscinc.com>
Sent: Tuesday, September 19, 2023 11:44 AM
To: CMS PartDPaymentPolicy <PartDPaymentPolicy@cms.hhs.gov>
Subject: Medicare Prescription Payment Plan Guidance

Below are comments in response to the August 21, 2023 memorandum, *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*. Thank you for your consideration.

Medicare Prescription Payment Plan Guidance

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Section 20. Overview

How will CMS identify participants (e.g., MARx file)?

Will CMS track voluntary and involuntary terminations and share this data across plan sponsors?

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Section 30. Program Calculations and Examples

- We are requesting guidance on processing out of cycle reversals and adjustments. Additionally, how should member billing reflect these reversals and adjustments?
- We are requesting guidance and additional claim examples if different plan types affect claim processing.
- We agree with CMS that paper claims should not be processed for Medicare Prescription Payment Plan participants.

-

50.1 Pharmacy Claims Processing Requirements

- Will CMS provide educational material or guidance for pharmacies regarding proper claim submission ordering?
- We are requesting guidance on supplemental Medicaid coverage:
 - Not returned with COB-OHI information.
 - When the pharmacy has not performed an E1 to know beneficiary has Medicaid coverage.
- At POS, the participant will pay \$0. If the maximum monthly cap is the highest possible, \$167.67, how will the participant know this will be their monthly cost prior to receiving the plan's monthly invoice?
 - Will it be the responsibility of the participant to ask for the prescription cost at the pharmacy?
 - Will pharmacies be required to inform the participant of the prescription cost prior to purchase?
 - How will a participant be given enough information to make informed, financial decisions?
- We are requesting guidance on how participants and their claims will be identified?
- We are requesting additional guidance on adjustments that cross calendar years. For

example, a December 2025 claim adjusted in January 2026.

- Will participants have the choice not to use the payment program and use an alternate payment method (e.g., cash)?
- We are requesting guidance on impacts to Real Time Benefit Tools and e-Prescribing (e.g., responses to participants).
- In the claim example, step 2a indicates the pharmacy receives a message on the paid claim indicating the participant is enrolled in the payment plan and the payment plan BIN/PCN is provided.
- We are requesting guidance on how a participant will be indicated on enrollment records and how that may impact reporting requirements.

Section 50.3 Requirements for Different Pharmacy Types

- We are requesting additional guidance on how should the process work when the patient pay amount is billed to the facility rather than directly to the participant?

50.4 Paper Claims

- We are requesting guidance on handling participant reimbursements at, above, and below the total remaining amount due to the plan. Should plan sponsors reimburse participants directly or apply credits and debits to billing invoices?

60.1 General Part D Enrollee Outreach Requirements

- Guidance related to communications may impact claim setup and should be communicated as early as possible.

60.2.1 Identification of Part D Enrollees Who Are Likely to Benefit

- How should it be determined if a LTC patient will benefit from program enrollment?

Section 70.3.7 Retroactive Election & Retrospective Claims Processing

- We are requesting guidance on a maximum time threshold when a claim may be reprocessed.

Section 70.3.8. Standards for Urgent Medicare Prescription Payment Plan Election

- We are requesting additional guidance and claim examples if an enrollee requests reimbursement based on retroactive enrollment. Varying claim types (COB vs DMR) increase difficulty in financial reconciliation and increase the risk for over- or under-calculating an enrollee's monthly billed amount. There is also an enhanced risk downstream impact to required materials and communications which may cause member abrasion and/or confusion.

70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs - 3. Clarification Code

- We strongly disagree with a proposal that involves a clarification code and do not believe anything related to participant enrollment should be administered by the PBM. Plan Sponsors should remain responsible for all member payment plan elections and education.
- We request CMS consider the following:
 - Not all patients retrieve their prescriptions from the pharmacy
 - Not all people picking up patient prescriptions are legal representatives for the patient
 - Pharmacists do not know who patient's legal representatives are, therefore allowing for POS election is not a feasible option for legal representatives

80.1 Voluntary Terminations

- Once a participant has opted out of the payment plan, how long should a plan sponsor invoice the participant for past due balance?

Appendix B – Additional Medicare Prescription Payment Plan Calculation Examples

- The claim examples included in Appendix are appreciated, however, we are requesting

examples of how the program should work when a participant has multiple supplemental coverages throughout the benefit plan year.

Curtis Skane

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September 20, 2023

Submitted via email to: PartDPaymentPolicy@cms.hhs.gov

Meena Seshamani, M.D., PhD.,
CMS Deputy Administrator & Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Prescription Payment Plan Guidance

Dear. Dr. Seshamani:

CVS Health appreciates the opportunity to provide comments on the draft Medicare Prescription Payment Plan (Program) Guidance (Guidance) issued by the Centers for Medicare & Medicaid Services (CMS) on August 21, 2023.

CVS Health serves millions of people through our local presence, digital channels, and our approximately 300,000 dedicated colleagues – including more than 40,000 physicians, pharmacists, nurses, and nurse practitioners. Our unique health care model gives us an unparalleled perspective on how to better design systems to help consumers navigate the health care system – and their personal health care – by 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.

To successfully implement the Program will be complex and challenging for Part D Sponsors (Plans), pharmacies, and pharmacy benefit managers (PBMs). It will entail significant new costs and accompanying risks. We are concerned that the proposed point of service (POS) coordination of benefits (COB) claim approach could create confusion for enrollees regarding out-of-pocket (OOP) costs and changes in monthly payment amounts, as well as potential financial risk due to the lack of cost transparency at POS.

In light of the above, our overarching comments and recommendations are as follows:

- It is imperative that CMS implement the Program in a way that simplifies the processes as much as possible for enrollees, pharmacies and Plans, and provides ample lead time for all stakeholders to iron out operational issues. CMS should also take the lead in

providing general education and outreach to enrollees about the Program so that they understand what it is, how it works, and what is and is not permissible.

- If CMS proceeds with the POS COB approach, it should evaluate the effectiveness of this approach after the first year, and consider allowing more efficient, streamlined options such as payment cards, in the second year and beyond. It is important that the Program be flexible and evolve over time to allow for innovation and improvements that will provide a better beneficiary experience while lowering the costs of administration.
- Given the prescriptive nature of the Program based on the statutory parameters and the operational complexities, CMS should not include any enrollee complaints or grievances about the Program in Star Rating measures, at least until the Program has been operational for two or more years. This will give Plans and CMS the necessary opportunity to address and resolve anticipated implementation issues. Even then, great care should be taken to ensure Plans are not held accountable in Star Ratings for beneficiary dissatisfaction with aspects of the Program that are outside of the Plan's control or discretion. In addition, Plans and PBMs will also require 2025 Medicare technical redesign guidance and 2025 final Prescription Drug Event (PDE) guidance as early as possible because PDE certification begins in July of 2024, and these changes need to be tested together with the implementation of the Program.
- CMS should exercise its waiver authority to waive the requirement that employer group waiver plans (EGWPs) offer the Program. Not only do EGWP enrollees generally have lower cost sharing so that there is much less need for the program for them, but there are additional complexities in calculating OOP costs for EGWPs. This, and the fact that employers generally do not offer such programs as part of their employee health benefits, will make many employers reluctant to continue offering EGWPs if they have to offer the Program.
- CMS should exercise enforcement discretion for at least the first two years of the Program as CMS, Part D sponsors, PBMs and pharmacies work together to address the many operational, technical, administrative and policy challenges presented by the Program.

Our more specific comments and detailed recommendations to help with the smooth implementation of the Program are included in the attached Appendix.

Thank you for considering our comments. We understand that the smooth and effective implementation of the Program as part of the Part D redesign enacted through the Inflation Reduction Act of 2022 (IRA) is a top priority of CMS and Congress as a means to reduce the

burden of beneficiary out-of-pocket drug costs. We stand ready to help CMS in any way we can to make the Program work and achieve its goals.

We would be happy to respond to any follow-up questions you may have.

Sincerely,

A handwritten signature in black ink, appearing to read "Melissa Schulman".

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

Appendix

Specific Comments on draft Medicare Prescription Payment Plan Program Guidance

Section 10. Introduction

CMS states it will issue 2025 final guidance by spring 2024, and that in the final guidance CMS may amend any policies, including policies on which CMS has not expressly solicited comments. CMS also states it will issue a second round of draft guidance by early 2024 that will be finalized in spring or early summer 2024.

While we understand the statute requires implementing the Program for plan years beginning on or after January 1, 2025, we are concerned that there will not be sufficient time after the issuance of final guidance in spring 2024 and beyond for Plans to put in place the necessary infrastructure and processes to ensure a smooth roll-out of the Program by January 1, 2025.

Not only will Plans need the 2025 Medicare redesign technical guidance so they know how the Part D Program itself will function in order to overlay the Program, but the Program will require extensive system enhancements by Plans, PBMs, and pharmacies. Based on current Program knowledge and proposed guidance, below are some of the system and operational changes stakeholders will need to manage and budget for. Any additional Program policy changes that CMS communicates after December 2023, will create significant implementation risks to an already overly complicated proposed process.

Pharmacies

- Set up and maintain hundreds of new Bank Identification Numbers (BINs)/Processor Control Numbers (PCNs)
- Establish new pharmacy and Point-of-Sale (POS) system workflows and automation processes to:
 - React to new Approved Message Codes
 - Identify which 4RX information returned is associated with the Program
 - Initiate COB claim billing processes based on Program 4RX returned on Paid claim responses
 - Adjust existing claim billing payer order rules
- Manage patient profiles (when Medicare Part D plan changes, Program 4Rx data also needs to change)
- Address POS rejects, prevent prescriber outreach
- Support beneficiary inquiries post prescription dispensing due to the lack of transparency as to incurred costs at POS

- Manage budgets for overlapping system enhancements, e.g., implementation of new HIPAA standards such as NCPDP Telecommunication vF6/F7 and Medicare Part D Redesign changes
- Negotiate new contract terms with Plans and/or their PBMs to address the transaction and labor costs to support the Program COB approach

Plans/PBMs

- Establish new BIN/PCNs (potentially purchase new BIN), create/distribute payer sheets
- Develop eligibility exchange processes to communicate beneficiary enrollment and disenrollment into the Program between the Plan and PBM
- Develop new COB processing method (Other Payer Patient Responsibility Amount versus Other Payer Amount) and associated adjudication logic
- Manage additional Medicare beneficiary Other Health Insurance (OHI) eligibility data
- Determine and return Program 4RX in the appropriate order when other supplemental or primary coverage applies in the claim response
- Manage beneficiary calls/grievances related to the Program
- Conduct pharmacy outreach to address beneficiary inquiries related to the Program
- Manage financial reconciliation processes to address:
 - Situations where supplemental payer patient cost share is greater than Medicare Part D cost share
 - Adjustments to Program statements because of pharmacy claim reversal and reprocessing for claim edits and return to stock cadence
 - Retrospective claims processing
- Implement standardized solutions when Program 4RX results in greater than 3 other health insurance records to return on Medicare Part D claim response
- Manage budgets for overlapping system enhancements, i.e., Telecommunication vF6/F7, 2025 Medicare Part D redesign, 2025 PDE File Layout changes, and potential increase in CMS COB user fees
- Negotiate contract terms with pharmacies to address transaction and labor costs to support the COB approach

Given the complexity of the Program and magnitude of the operational, system, and process changes that will need to be made, we ask that CMS issue the final guidance as far in advance as possible and, at a minimum, no later than the last quarter of 2023, bearing in mind that Plans will need to fully complete implementation by August 2024 as a practical matter in order to be ready for CY 2025 open enrollment. CMS should exercise enforcement discretion for at least two full years, and so until at least January 2027, to allow Plans sufficient time to work out technical and operational issues. This will also allow CMS and Plans to prioritize resources on outreach and education of beneficiaries about the Program.

We also ask CMS not to include in Star Ratings any beneficiary grievances related to aspects of the Program that are outside of the control or discretion of Plans, or that are based on confusion or misunderstanding of how the Program works. There are numerous aspects of the Program that may not be intuitive to beneficiaries and that gives rise to dissatisfaction, such as the fact that the Program does not apply to non-Part D drugs. Because Plans are not responsible for, nor able to change, the parameters of the Program or its many requirements, CMS should not hold them accountable for beneficiary dissatisfaction or complaints related to Program requirements. To ensure that these grievances do not affect Star Ratings, CMS could, for example, allow Plans to separately log grievances related to the Program. Even for those aspects that are under the control of a Plan, we ask CMS to wait until the Program is fully implemented and has been operating smoothly for at least two years before including any aspects in Star Ratings.

CMS states that Program requirements apply to all Plans, including EGWPs. We ask CMS to consider waiving the requirement that EGWPs offer the Program, using its authority under 42 CFR 423.458(c). This authority allows CMS to waive or modify any Part D requirement that hinders the design of the offering of, or enrollment in, an employer-sponsored group prescription drug plan. The Program is clearly such a requirement in that it is not an option usually offered by employer plans, and so will hinder the design of employer coverage, as well as the ability of employers to integrate Part D benefits seamlessly into their existing coverage. Under the IRA Part D redesign provisions, it is our understanding that enhanced employer coverage will count towards an enrollee's incurred costs, which will affect and complicate calculations under the Program. Additionally, the industry will require further CMS guidance on Non-Calendar Year EGWPs. For example, for a non-calendar year EGWP that runs from July 1, 2024 - June 30, 2025, it is not clear whether a beneficiary could enroll in the Program on January 1, 2025, or whether they have to wait until July 1, 2025, of the data that their new plan year starts in 2025 in order to enroll. We also ask that CMS provide examples of how to calculate their monthly maximums.

In light of these additional complexities, employers may consider dropping Part D coverage, which is precisely the reason Congress gave CMS authority to waive such Part D requirements for EGWPs. Not only does the Program hinder the design and offering of employer-sponsored group Part D coverage, but there should be less need for, and fewer enrollees likely to benefit from, the Program in the case of EGWPs. This is because EGWP coverage is more generous than individual Part D coverage, thus cost sharing is usually lower for EGWP enrollees. This makes it less likely that EGWP beneficiaries would need or choose to participate in the Program.

Recommendations:

- **CMS should issue final guidance no later than the last quarter of 2023 so that Plans have sufficient time before open enrollment for the 2025 plan year not only to have systems and operations in place, but also to develop and send out communication**

materials about the Program, including instructions on how to enroll, to beneficiaries.

- **CMS should exclude grievances related to aspects of the Program outside the control of Plans from Star Ratings and should include other aspects of the Program in Star Ratings only after the Program has been operating smoothly for at least two years.**
- **CMS should exercise enforcement discretion for at least the first two full years of the Program to allow Plans and CMS to work out operational issues and prioritize beneficiary outreach and education.**
- **CMS should exercise its waiver authority for EGWPs in 42 CFR 423.458(c) to waive the requirement for EGWPs to implement the Program.**

Section 20. Overview

CMS requests feedback on the best ways to educate Part D enrollees about the Program, in particular seeks input on which model documents or other materials would be helpful to update and develop, ways to conduct outreach and education most effectively, how to leverage existing resources and how to communicate about overlapping Programs.

At a minimum, Plans will need to describe the Program in the Evidence of Coverage (EOC) and Summary of Benefits (SB) documents. We recommend that CMS considers creating separate communications solely to address the Program so that it is not buried in a much longer document and potentially overlooked by beneficiaries. Communication to educate beneficiaries should be initiated early in the enrollment process, including a section in the “2025 Medicare and You” handbook. Since this document is available in September prior to open enrollment, and is always available online for reference, it will be an ideal document for beneficiaries to reference for information. In addition, although it will be challenging to do so given the detailed rules around the Program, CMS should prioritize providing clear, crisp, and concise information about the Program that beneficiaries are likely to read. Important information, such as that the Program does not apply to paper claims, should be emphasized through format and placement. For those interested, they can get to more detailed information, but it is imperative that all beneficiaries at least have awareness and a basic understanding of what the Program is intended to accomplish. If too much information is provided all at once, beneficiaries may skip over it and not learn about the Program at all, which could result in significant beneficiary dissatisfaction later on.

Recommendations:

- **CMS should create separate beneficiary communications solely for purposes of describing the Program.**
- **CMS should explain the Program as simply and concisely as possible to all beneficiaries so they will have a basic understanding of its purpose, and then those beneficiaries who are interested can be provided more detailed information.**

Section 30. Program Calculations and Examples

CMS explains that once an enrollee opts into the Program, they will be billed monthly for all their OOP costs for all covered Part D drugs as long as a participant remains in the Program.

The COB approach for the Program will result in monthly Program calculations inclusive of prescription claims subsequently reversed or edited. It is important to note that a pharmacy's return to stock cadence for prescriptions dispensed but not picked up by the beneficiary will add significant complexity in timing issues related to the monthly invoice and payment process. These amounts reported on the Program invoice will increase beneficiary inquiries to the pharmacy and Plan member service call centers. The pharmacy will not have any visibility to the calculations and related prescriptions reported on the invoice. The plan's member services call center may not yet have visibility to the reversed or edited transaction (e.g.: prescription still in a waiting to pick up status at the pharmacy). These discrepancies are likely to cause significant beneficiary complaints that will require CMS guidance and beneficiary education to try to mitigate.

CMS should provide more complex and challenging monthly calculations and examples for the various situations that can occur after the POS transaction, for example:

- Retro-LICS adjustments where the patient pay increases or decreases, and how those changes will impact the monthly maximums
- Late supplemental payments (through Paper Claims or via latent Nx Transactions)
- Claim reversals made by pharmacies or by other payers and how the monthly calculations could fluctuate due to the ongoing changes that can occur throughout the plan year

Recommendation:

- **CMS should provide Program calculation guidance and beneficiary education to address complex situations where the prescription claim transaction is subsequently edited or reversed.**

Section 40. Participant Billing Requirements

CMS states that it encourages Plans to offer multiple payment options, such as an electronic fund transfer mechanism (including automatic charges of an account at a financial institution or credit or debit card account) and payment by cash or check. It also encourages Plans to offer participants flexibility around requesting a specific day of the month for Program charges and withdrawals from a bank account.

We appreciate the flexibility CMS gives to Plans to determine what means of payment to offer to participants, while encouraging multiple means of payment and allowing participants more choices. We believe it will be in the interests of most Plans to offer participants various means of payment and more choice, but for clarity, ask that CMS confirm that when it “encourages” certain actions, these actions are not mandatory, and Plans will not be penalized in any way if they choose not to take them. For example, CMS also encourages Plans to prioritize payments towards Part D plan premiums so that a Part D enrollee does not lose benefits, although it states that Plans may create their own billing and payment procedures. We appreciate this flexibility, since there may be circumstances where it is in the participant’s interests to have amounts due under the Program paid off first.

CMS states that past due balances from prior monthly bills may be included in a billing statement, as long as amount billed for the month for which the maximum monthly cap is being calculated is not higher than the cap for that month. We ask that CMS confirm that participants may choose to pay more than the maximum monthly amount billed if they choose to do so. Many Part D enrollees are retired and no longer receiving regular pay checks, and so they may prefer to “pay ahead” when they have cash on hand. CMS should permit Plans to accept such payments.

CMS states that it is considering specific requirements related to debt collection for amounts due under the Program and requests comment. CMS should permit Plans to require payment in full of all outstanding balances under the Program when a participant’s participation in the Program is terminated, whether voluntarily or involuntarily. Plans should also be able to collect unpaid debts in accordance with applicable laws, including engaging debt collection agencies consistent with such laws.

CMS states that Plans must have a final reconciliation process in place to correct inaccuracies in billing and/or payments. Any correction of inaccurate billing on the Part D claim means that the COB claim submitted by the pharmacy must also be reversed. This requires that both the Med D claim and the Program claim be processed on the same processing system with a way to ‘connect’ the two claims such that if there is a change to the claim pricing of the Med D claim that affects the Part D patient cost share amount, the Program claim will also be identified and adjusted as needed. In this situation, the pharmacy would only learn of the changes through their remittance advice or X12N 835 files.

Finally, we ask that CMS exercise its authority under the Program to disallow enrollees from enrolling in another Program until they have fully paid any amounts owing under a previous Program, whether with the same or a different Part D sponsor. This will remove the incentive for participants to move from one Part D sponsor to another, which is disruptive to care and not in the best interests of enrollees or the Part D Program. CMS should also make available the

Program payment history of beneficiaries to all Part D sponsors so that they may use this data to estimate the costs of the Program for bid purposes.

Recommendations:

- **CMS should confirm that Plans have the flexibility to determine how to manage billing and payment procedures, including what payment options to offer and how to apply amount paid by a participant when it is not clear what the payment is intended for.**
- **CMS should confirm it permits participants to pay more than their monthly maximum amount if they choose.**
- **CMS should exercise its regulatory authority to disallow a beneficiary from enrolling in another Program of the same Part D sponsor or a different Part D sponsor until the enrollee has paid all outstanding balances under a prior Program.**
- **CMS should use already available reporting to share beneficiary information regarding Program payment history with other Part D sponsors.**

Section 50. Pharmacy Payment Obligations and Claims Processing

CMS states that it is seeking feedback on a claims processing methodology to ensure a timely, uniform, and seamless implementation for all interested parties, to provide a consistent participant experience, and to minimize disruption to existing processes. CMS also states that it has several concerns with the proposal by interested parties to use a Plan-issued prefunded payment card, including less Plan oversight to ensure that payment is made for covered Part D drugs of the participant only, the timeliness of issuing payment cards, the need to present a physical card at the pharmacy counter and greater risk of fraud.

We appreciate CMS' concerns related to payment cards, but we believe these can all be addressed satisfactorily, and that the payment card option offers advantages to participants and pharmacies, as well as solving several operational issues raised by CMS. First, the use of a POS payment card offers the necessary OOP cost transparency to the beneficiary, allowing for COB where necessary. The COB approach recommended by CMS does not offer this transparency, creating sticker price shock within the Program monthly statement. Second, as CMS acknowledges, the use of a payment card would keep the pharmacy whole, allow for COB with other payers, and ensure the Program financial transaction is always last, which are major considerations under the Program. Third, CMS does not explain why it believes the risks of fraud or use for non-participants is greater with payment cards. The industry has considerable experience with payment cards and can put in place safeguards, like POS indicators that identify eligible drugs and eligible enrollees for the Program, to ensure a card is used appropriately. The payment card transaction standard can leverage available transaction space to communicate the

necessary prescription details (e.g., Part D covered drug, cardholder) similar to the way the industry implemented HSA benefits.

As noted above, requiring the use of COB claim transactions, where the Program is expected to always be the final claim, creates problems for pharmacies, Plans, PBMs, and beneficiaries, and requires significant system enhancements. While COB transactions may appear to offer increased CMS oversight to the Program, this will only be the case if it can be successfully implemented by all stakeholders involved. Plans will now need to maintain two lines of eligibility within their systems for the same coverage and maintain oversight through their PBMs for beneficiaries who are in the Program. Plans will need to develop a real time or near real time method to notify their PBMs when beneficiaries have enrolled and have been disenrolled for timely processing to occur at the pharmacy counter. Claims received by the Plan post-POS, such as paper claims, where the beneficiary has already paid cash, should continue to be reimbursed based on plan benefits, and we therefore support CMS' decision to exclude them from the Program. However, should CMS decide to include paper claims, we would recommend the Program would only apply to in network paper claims. We suggest out of network claims be excluded as their adjudication introduces additional complexities since it is not based on the negotiated price of the drug as is the case for network pharmacies, and Plans need to calculate any differential owed by the beneficiary above the plan allowance.

The COB process puts the responsibility on the pharmacy to submit multiple claims for the same prescription to the applicable COB payers, in the proper order, and ensure the Program is the last submission. Since Program benefits are specific to enrolled beneficiaries and drugs/products covered under Part D, and identification of eligible claims is limited to paid claim messaging, there will be situations where the COB claim to the Program may not occur as expected. Once a beneficiary receives a medication, any retrospective inquiries from a Plan to request the pharmacy resubmit the claims, may result in POS claim rejects that a pharmacy will not be able to resolve. As a result, CMS should not mandate that the Program require pharmacies to process Program claims retrospectively. CMS should also consider adding the Program information to the Eligibility Transaction (E1) process so that pharmacies can utilize the eligibility transactions to confirm all lines of coverage for a Medicare Beneficiary.

The NCPDP Telecommunication Version D.0 standard (sections 7.5.1.5.9 and 33.14.2.5.5) limits for the COB Other Health Insurance (OHI) data returned in a response to three other payers. The industry will need guidance on how to message and prioritize COB payer information for when a beneficiary already has three or more supplemental payers, and the Program 4Rx information must also be returned. To provide context, CVS Health reviewed current COB data and identified one Part D plan with a total membership of 193,706, and of those, 22,066 beneficiaries already have three supplemental payers, which is approximately 11.4% of their population. If CMS confirms the Program 4Rx information should overlay existing OHI data, this could cause

the beneficiary to overpay when a supplemental payer could have been billed and further reduced their cost sharing.

CMS should provide detailed guidance for how pharmacies should bill COB claims to the Program so there is clear direction and standardization across the industry. For example, in situations where the beneficiary has supplemental coverage, and the COB claim returns a patient pay greater than the Part D benefit, which can occur with Other Payer Amount Paid COB billing, CMS should provide direction on what COB amount Plans should bill to the Program.

CMS will also need to provide guidance for Plans handling COB for the Program when adjustments or changes occur post POS, including latent Information Reporting (Nx) transactions (i.e., the Nx transaction is received after a subsequent Part D claim is processed and/or adjusted), Long Term Care (LTC) post consumption billing, retro-LICS eligibility changes and associated adjustments, and paper claims submitted by beneficiaries, pharmacies, and other payers seeking recovery from the Medicare Part D plans.

Additionally, because pharmacies have at least 90 days to reverse and reprocess claims online, any retroactivity will present a challenge to adjust the Program amounts accurately and timely. This will require the pharmacy to reverse the primary claim, any supplemental payer COB claims, and the Program claim. CMS will need to provide clear expectations and examples around the reconciliation process requirements for Plans and Pharmacies, and any potential audit criteria that CMS may use to monitor this activity. Specifically, it is not clear whether CMS would require pharmacies to reimburse amounts associated with the reversed or adjusted claims to the beneficiary when a claim and associated payments made towards the Program are reversed or adjusted post-POS.

For pharmacies to implement the necessary system and operational flows to manage the Program COB process, we recommend that CMS guidance at a minimum address the following:

- Distinct Program Claims Processing Information (e.g., 4RX)
 - Require all Programs assign a PCN that starts with “MPPP” Program. This will help pharmacies locate these Plans in their system and recognize the 4RX information in the Medicare D Paid claim response
- Availability of Program 4RX within existing real-time eligibility services
 - CMS to include the Program 4RX information within the Medicare Eligibility (E1) transaction data
- Standardized use of NCPDP Approved Message Code values
 - All Plans need to support all three of the Program Approved Message Codes (AMC) that CMS established (not just the value for “Beneficiary likely to benefit from Medicare Prescription Payment Plan”) as follows:
 1. “Beneficiary likely to benefit from Medicare Prescription Payment Plan”

- Recommend sending AMC for the threshold of \$700 for a single claim, as noted in our recommendations for Section 60, so pharmacies know when to notify beneficiaries about the Program.
- 2. “Beneficiary enrolled in Medicare Prescription Payment Plan”
 - Recommend AMC to be sent for those beneficiaries confirmed enrolled into program, so pharmacies know it is not necessary to discuss the Program with the beneficiary, and to look for the Program 4Rx details.
- 3. “Beneficiary no longer enrolled, elected not to enroll in Medicare Prescription Payment Plan”
 - Recommend this AMC is sent so pharmacies know it is not necessary to discuss the Program with the beneficiary.
- Standardized use of a pharmacy model language maintained by CMS to communicate information about the Program to the beneficiary.

We understand that not all Plans are currently able to offer a payment card approach and that it may be difficult, especially for pharmacies in the first year as the Program is rolled out, if different Plans utilize different processing approaches. In light of this, we recommend that CMS proceed with the COB claims method for the first year of the Program, and then, based on the first year experience, consider allowing plans the option to use a payment card in future years. We believe that allowing the Program the flexibility to evolve in this manner will result in the adoption of more innovative, streamlined, and efficient solutions that will reduce beneficiary confusion and the administrative costs of the Program while not precluding the use of the POS COB claims processing method.

Recommendations:

- **In deciding whether to proceed with the POS COB claim process, CMS should consider the numerous difficulties associated with this approach, most notably beneficiary lack of transparency to true OOP costs, increased risk of implementation inconsistencies, and beneficiary confusion.**
- **If CMS proceeds with the COB claim transaction approach, it will need to provide additional guidance to:**
 - **Ensure standardization in claims processing with the use of specific Program Processor Control Number formats and require use of all three Program Approved Message Code values**
 - **Confirm pharmacies are not expected to retroactively process drug claims through the Program**
- **Until there is a solution to handle 3 other payers and OHI data becomes more streamlined, Plans should not be required to allow enrollees with three or more coverages to enroll in the Program. We request that CMS consider adding the Program information to the Eligibility Transaction (E1) process.**

- **We recommend that CMS provide standardized pharmacy model language to communicate information about the Program to the beneficiary that is likely to enroll, rather than allowing for Plan customization.**

Section 60. Requirements Related to Part D Enrollee Outreach

CMS states that, in addition to notifying all prospective enrollees about opting into the Program, Plans must also reach out directly to individuals who are likely to benefit from the Program, both prior to and during the plan year. CMS seeks comments on the range of potential POS notification thresholds from \$400 to \$700, along with specific factors for CMS to take into consideration when determining the threshold for 2025, including using a single prescription versus single day accumulation to count toward the threshold.

While we understand that CMS will, in the second part of its guidance, provide more information on marketing and communication requirements for the Program, we ask CMS to include in the first part of its final guidance the baseline expectations, so that Plans may begin to plan, prepare, and build in sufficient time, the necessary processes to implement the requirements. For example, with respect to notifications to enrollees who are likely to benefit from participation, we recommend that CMS not require printed notifications, but instead provides brief model language for Plans to send in the claim response. In addition, CMS should clarify that Plans may, but are not required, to provide more than one notification to enrollees who meet the “likely to benefit” threshold. If \$700 is set as the threshold for “likely to benefit,” we recommend setting the \$700 threshold at the claim level i.e., \$700 for a single claim as the trigger for performing pharmacy POS outreach.

CMS provided examples of scenarios where enrollees are not likely to benefit from enrollment in the Program, such as Low-Income Subsidy (LIS) enrollees and those who opt in in December. While not required by the statute, we believe it will be beneficial for Plans to include this type of information in their communications about the Program. This will be helpful to enrollees who might otherwise be confused about how the Program operates, and so opt in when it is not in their best interests, which will result in beneficiary frustration and dissatisfaction.

CMS states that if a prescription is picked up by another person who is not the Part D enrollee, a Plan must require the pharmacy to provide information about the Program to that person if it would have provided that information to the beneficiary, even though only the Part D enrollee or their legal representative may opt into the Program. We support this approach since in most cases, a Plan is unlikely to know whether an enrollee, or someone else on their behalf, picks up a prescription, and so it is appropriate not to require Plans to differentiate between these scenarios for purposes of providing notification to the pharmacy.

Recommendations:

- **The OOP threshold for notifying enrollees likely to benefit should be based on a Patient Pay threshold incurred in a single claim.**
- **CMS should allow Plans to notify enrollees who are likely to benefit by sending Approved Message Codes to the pharmacy, and the pharmacy in turn communicating this to the enrollee via the enrollee's preferred communication method, such as SMS Text, email, standard mail.**
- **To avoid disruption in the pharmacy process flow, pharmacies should not be required to relay the "likely to benefit" notification to enrollees at the time the Approved Message Code is received during the dispensing process, but should instead be allowed to do so at a later stage, such as when a prescription is being picked up or delivered.**
- **Plans should be permitted to include information in their Program materials and content about beneficiaries who are not likely to benefit from participation.**
- **Annual Notice of Change (ANOC)/Evidence of Coverage (EOC)/LIS Rider materials should be updated to include high level information about the Program, including LIS applicability.**
- **We recommend including high level variable language in many of the existing marketing model document related to Program participation rather than creating additional models to convey this information. This would streamline the processes, and avoid multiple separate mailing to beneficiaries, which could cause confusion and dissatisfaction.**

Section 70. Requirements Related to Part D Enrollee Election

CMS states that for Program election requests received before start of a plan year, a Plan must respond within 10 days. However, for election requests received during the plan year, CMS states Plans must process the election request within 24 hours to prevent delays in dispensing drugs to these individuals.

A 24-hour turnaround time to process Program election requests during the plan year will be challenging to implement because pharmacies, including Long-term Care facilities (LTC) and Mail Pharmacies, as well as PBMs, will not have visibility to enrollment outcomes and, if they do not receive timely approvals, that could delay dispensing and lead to access to care issues.

We believe CMS should not require any real-time response to send a "likely to benefit" message (via IVR, SMS Text, email). We recommend that the final guidance instead allows any enrollment into the Program to apply to future prescriptions, and not to a prescription that would trigger a notification to an enrollee that would be likely to benefit from enrolling in the Program. Not only will this avoid the potential for delays in dispensing a prescription, but it will allow Plans enough time to process enrollments correctly and accurately. Because drugs under the Program are already covered in an enrollee's Part D benefit, and the Program simply reduces the

amount of cost sharing due at the time of enrollment into the Program, it much more akin to a reimbursement request (for which Plans have 14 days to respond) than expedited requests for benefits (for which Plans have 24 hours to respond). As such, we recommend that CMS allow 10 days to process any Program enrollment requests, whether made before or during the plan year. If CMS retains the 24-hour period, we ask that CMS confirms it would not apply when an enrollee requests to opt into the Program through a broker and not directly to a Plan.

The draft guidance also provides in Section 70.3.7 that, if a Plan cannot process an election into the Program in the proposed 24-hour time frame due to no fault of an enrollee, a Plan must process a retroactive election back to the original date when the individual should have been enrolled in the Program, and must reimburse the participant for any OOP cost sharing paid on or after that date and include those amounts, as appropriate, in a monthly bill under the Program within 45 days.

Because a main benefit of the Program is one of cash flow, and an enrollee will already have paid their cost share in the above scenario, the benefits of reimbursing them only to then add the amount owed by the enrollee under the Program seem low, particularly when weighed against the costs and complexity of retroactive implementation. As such, and because the statute does not require this process, we urge CMS to reconsider this requirement and not move forward with it at this time.

For plan year 2026, CMS is proposing to expand the Program to include a near real-time enrollment. For reasons already mentioned above, we do not believe a real time solution should be mandatory as this can cause delays in dispensing and access to care. If CMS does move forward with a real time solution, the proposal to use a clarification code that pharmacies can submit will not be feasible. Since the Guidance includes very specific requirements for Plans to follow to enroll beneficiaries, including beneficiary acknowledgement and verbal attestation of enrollment, pharmacies or PBMs will not be able to enroll a beneficiary. For other options with a near real time solution when a pharmacy must reverse and reprocess, rejects may occur with supplemental payers due to their billing and reversal windows and back-end data processing.

Recommendations:

- **CMS should not require retroactive processing, enrollment and processing under the Program, which should operate on a prospective basis only.**
- **The timeframe to process an enrollment request should be 10 days and enrollment into the Program should apply to future claims only.**

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

CMS states a Plan may only preclude an individual from opting into the Medicare Prescription Payment Plan in a subsequent year if they owe an overdue balance to that Plan. If an individual pays off the outstanding balance during a subsequent year a Plan must allow them to opt in after that point. We believe that until a beneficiary has fulfilled their financial obligations under the Program, their overdue balance to any Part D sponsor should be a basis for precluding them from participating, regardless of whether it is the same Part D sponsor or a different Part D sponsor. As discussed above, we do not believe it is in the interests of enrollees or the Program to allow an enrollee that still has an outstanding balance owed to one Part D sponsor under the Program to enroll in the Program of another Part D sponsor, because this encourages enrollees to switch Part D sponsors, which is disruptive to care. It also increases costs to the Program, which will lead to higher premiums to all enrollees. While we understand that the statute does not provide for this, it is within CMS' broad regulatory authority to implement such a rule since nothing in the statute prohibits it and it is in the interests of all enrollees and the Program itself.

CMS should also clarify that beneficiaries are limited to one enrollment and disenrollment in the same Program during the Plan year.

Recommendations:

- **A Part D sponsor should be able to preclude any individual from opting into the Program in subsequent years if that individual still has an outstanding amount due on a Program with another Part D sponsor.**
- **CMS should require that Plans limit enrollment and disenrollment to one time per year into the Program.**

Section 90. Participant Disputes

We understand the importance of, and requirement that, Plans implement an appeals procedure to make timely determinations in any disputes Program enrollees may have about the OOP amounts owed under the Program. We also recognize the need to implement meaningful procedures to hear and resolve grievances between Program enrollees and Plans, including election requests, billing requirements, and termination-related issues other than disputes related to the amount of Part D cost sharing owed by that participant for a drug.

In order to meet these goals and requirements, we believe the best approach would be to manage all aspects of grievances and appeals related to the Program as a distinct process, as is the case with Late Enrollment Penalties (LEP), rather than following existing Part D appeals and grievance procedures. In addition, a new case category for Program disputes would be more

effective than using existing case types that do not address the unique requirements of the Program, including billing and reporting.

Precedent for this exists with the LEP dispute process. We agree enrollees should be allowed to dispute the amount owed and this should be supported as a customer service request/review and not processed as an appeal as defined by existing guidance.

If CMS chooses to make billing disputes part of the coverage determination and appeals (CDA) process as proposed, Plans and PBMs would ask for updates to the CDA guidance to clarify the following:

- Case classification (pre-service vs post-service; expedited vs standard)
- Appeal levels (initial dispute classified as CD or redetermination)
- Adjudication timeframes (strongly recommend 30 days because these disputes will be closely linked to grievances)
- Examples of each type of disposition (favorable, dismissed)
- What action constitutes effectuation of a favorable decision (there will be no override or reimbursement check)
- Who must conduct the reviews
- Who may request a CD or appeal
- Who must be notified of the CD or appeal decision (member/ representative, physician)
- Mechanism for communicating the disposition (will it be a revised Program billing statement, a typical CD letter, or another model letter?)
- Handling of an untimely CD or appeal (i.e., whether and when it would need to be forwarded to the IRE)

While not a part of the CDAG/ODAG guidance chapter, Plans and PBMs would also ask for revisions to the following:

- HPMS and audit universe requirements with respect to these new types of CDs and grievances
- Model letter language (i.e., OMB-approved CD denial notice, model dismissal notice, etc. will need to be updated)
- HPMS and audit universe requirements

Recommendation:

- **CMS should create a process for Program-related billing disputes that is separate from the traditional Coverage Determination and Appeals (CDA)/DMR process**

Section 100. Data Submission Requirements

CMS states there should be no impact to PDE/Cost payment fields and the PDE financials should only reflect the Part D plan amounts. We agree with this approach and, if CMS needs to know when an individual enrolls in the Program, one solution would be to include a new field on the PDE stating a beneficiary enrolled in the Program when the claim was paid.

For consideration, CMS should include in an invoice statement or incorporate it in the premium bill. Because the statute requires disenrollment for non-payment of the Medicare Prescription Payment Plan amounts, this would coincide with existing premium billing processes and requirements. If CMS decides to proceed with including Program information on the explanation of benefits (EOB), we recommend to only include a high-level statement that a beneficiary has elected to enroll in the Program, therefore the costs outlined in the EOB may not accurately reflect what occurred at the POS. CMS should not require inclusion of any Program financial details on a per-claim basis for the reasons outlined above.

Recommendation:

- There should be a PDE and EOB indicator indicating enrolled or not enrolled



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September 20, 2023

VIA ELECTRONIC SUBMISSION – PartDPaymentPolicy@cms.hhs.gov

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RE: Medicare Prescription Payment Plan Guidance

Eli Lilly and Company (Lilly) appreciates the opportunity to share comments on the proposed Medicare Prescription Payment Program (MPPP). 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 is a proud member of the Pharmaceutical Research and Manufacturers Association of America (PhRMA) and supports PhRMA's comments on this proposal generally. Lilly believes that MPPP, in addition to the \$2,000 maximum out-of-pocket (OOP) limit also to be introduced in 2025, has the potential to increase drug adherence and augment health outcomes. Our substantive feedback can be summarized as follows:

- 1. CMS should consider lowering the “likely to benefit” standard to a dollar amount that could potentially help a greater number of patients.**
 - 2. CMS should ensure that beneficiaries have multiple avenues to enroll in MPPP.**
 - 3. CMS should work with stakeholders to prioritize a point-of-sale enrollment option for 2025.**
-
- 1. CMS should consider lowering the “likely to benefit” standard to a dollar amount that could potentially help a greater number of patients.**

The MPPP presents a legitimate opportunity to mitigate one-month and/or early in the year disproportionate cost sharing amounts by billing participants for their prescription drugs in fixed, monthly sums. Section 1860D-2(b)(2)(E)(v)(III)(dd) of the Social Security Act requires that plan sponsors have a mechanism to communicate with pharmacies that a patient is likely to benefit from MPPP. Furthermore, section (b)(2)(E)(v)(III)(ee) requires that plan sponsors ensure

pharmacies educate beneficiaries about their eligibility for smoothing under the MPPP and, ultimately help facilitate the enrollment if the beneficiary so desires. **We applaud CMS's foresight in developing the "likely to benefit" standard, as this provides a consistent, objective measure for beneficiary education.**

Presently, the Agency suggests using a single OOP threshold of \$400, which would benefit 2 million patients. **Lilly urges CMS to consider a potentially lower one-time threshold that would benefit a greater-number of beneficiaries that better accounts for abandonment,** like \$250, where research indicates that 69% may abandon therapy, absent an option like smoothing under the MPPP. While there is potential, at a lower one-time threshold, for a significant number of beneficiaries to experience higher OOP under MPPP than under the traditional benefit design, the calculators, tools and other educational materials being developed by CMS should aid beneficiaries in making an informed decision as to smoothing.

This new benefit, while welcome, could create confusion throughout the ecosystem, given the obligations it creates for beneficiaries, plan sponsors, and pharmacies. Pharmaceutical manufacturers have a unique perspective on care delivery and regularly educate stakeholders on reimbursement norms, product acquisition, formulary coverage and policy developments. Thus, **CMS should consider working with PhRMA or a subset of PhRMA members to develop standardized, non-branded educational materials to be carried by manufacturer sales representatives and field reimbursement managers.** A standardized approach will ensure that stakeholders receive consistent messaging about the MPPP.

2. CMS should ensure that beneficiaries have access to multiple enrollment options when opting into MPPP in 2025.

Though CMS will surely undertake major efforts to attract attention and awareness to the MPPP as an option for beneficiaries, it is imperative that beneficiaries can enroll in the program just as soon as they have a conviction to do so. **Thus, we urge CMS to do the work now to ensure that multiple enrollment options are available for beneficiaries to elect to participate in MPPP.** Lilly acknowledges the complexity and magnitude of MPPP and thus encourages the agency to act and prepare now, versus waiting until closer to CY 2025 open enrollment. Medicare beneficiaries (and, in some cases, their caregivers), span the spectrum of tech-savviness. Therefore, **CMS should be prepared to enforce its stipulation that Part D plan sponsors have options for electronic (internet), paper, phone, and web enrollments.** This approach ensures those with varying levels of tech competency have an enrollment avenue that meets their needs.

3. CMS should work with stakeholders to prioritize a point-of-sale (PoS) enrollment option for 2025.

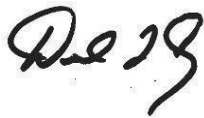
Lilly looks forward to reviewing Part 2 of the MPPP guidance that will focus on the role that pharmacies and other intermediate entities will play in the MPPP ecosystem. Having said that, the pharmacy counter is the key venue for mitigating patient abandonment. Thus, **CMS should prioritize the availability of a PoS enrollment solution in 2025 to capture the maximum number of potential beneficiaries who could benefit from smoothing.** Requiring beneficiaries

to take action somewhere other than the PoS breeds the conditions for patient confusion and leakage.

In its guidance, CMS introduced the idea of using a new clarification code inside existing NCPDP data fields. Upon opt-in, the pharmacist would reverse the claim and resubmit with the addition of the new code. Subsequently, the pharmacist would process a standard COB claim and bill the MPPP BIN/PCN number. This appears to be the most beneficiary-centric proposal for electing to participate in the MPPP in that there would be limited role for the beneficiary to play beyond agreeing to enroll. In its infancy, beneficiaries may be reticent to try the MPPP, given its newness and contrast to lived experiences to that point. **Focusing efforts on this strictly transactional, NCPDP approach to effectuation will allow the Agency to focus on getting its technology to a steady, usable state that will create a positive beneficiary experience.**

Lilly appreciates the opportunity to provide feedback on part one guidance on a select set of topics for the MPPP Program. If you have any questions, please contact Derek Asay at derek.asay@lilly.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Derek 28", written over a faint circular stamp.

Derek L. Asay
Senior Vice President, Government Strategy

Dear. Dr. Seshamani:

Elixir is a pharmacy benefit manager (PBM) that counts among its clients a number of Medicare plan sponsors that provide a prescription drug benefit to people with Medicare. We thank CMS for this important draft guidance and appreciate the opportunity to comment.

Elixir submits the following comments in response to the 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***, released August 21, 2023.

Summary of Recommendations

- We request examples of how the Medicare Prescription Payment Plan operates in EGWP contexts.
- We request clarity around the options CMS will allow and/or suggest for plan sponsors to collect unpaid Medicare Prescription Payment Plan balances, including examples of how the difference among state laws bear on collection efforts when a member moves from one state to another while carrying an uncollected balance.
- We suggest the proposed separate PCN start with “Medicare Prescription Payment Plan” to help with billing order, consistency and simplicity.
- We suggest that preclusion from Medicare Prescription Payment Plan participation be available to plan sponsors other than the plan that is owed an uncollected balance.
- We recommend that CMS gather data about uncollected Medicare Prescription Payment Plan balances and individuals precluded from opting into the Medicare Prescription Payment Plan (in subsequent years) at the beneficiary level and, ideally, use this data to allow other plan sponsors (not just the plan that has not been paid) to preclude Medicare Prescription Payment Plan participation in a subsequent year if the individual fails to pay the amount billed for a month as required under the program.

General comments

The timing of this is extraordinarily rushed, particularly given that MCMG and model document updates are anticipated in February 2024 – these will also require new programming training, etc. Moreover, final guidance is currently expected in the summer of 2024.

More time is needed to gain the required clarity, develop and implement the required system enhancements, coordinate responsibilities and tasks with sponsors and other partners, and execute to the requirement.

Plan sponsors should be given some grace in terms of Star measure impacts from beneficiary complaints related to Medicare Prescription Payment Plan, since the program is new and participants will be instructed to file grievances for Medicare Prescription Payment Plan issues.

The IRA provides that sponsors can account for estimated losses in their plan bids for Medicare Prescription Payment Plan amounts not paid by beneficiaries. However, there is no way for sponsors to estimate these losses for the first year of the program (2025 bids). We request guidance from CMS as to how plans might project for Medicare Prescription Payment Plan delinquencies in their CY 2025 bids. Moreover, given that EGWPs are permitted to waive a formal bid, CMS guidance on ways to project and manage delinquencies would be most welcome.

Section 40 – Participant Billing Requirements

Plan sponsors should be expected to manage billing and enrollment requirements, as opposed to these responsibilities falling to PBMs or pharmacies.

There are administrative challenges if a beneficiary changes plans (moves to a new contract) during a SEP. Examples for various potential scenarios would help stakeholders plan and execute in line with CMS expectations.

In the guidance, if a beneficiary moves from Plan A to Plan B, Plan A balances don't transfer over to Plan B, so Plan A is still responsible to collect for amounts incurred while the beneficiary was with Plan A. What are the opportunities for Plan A to collect from the beneficiary who has left for another plan? It would be optimal to identify a mechanism by which Plan A can effectively recover amounts owed to Plan A by the beneficiary. For example, is use of a debt collection service among the available options that CMS is considering?

The fact that different states have different requirements around debt collection adds complexity. For example, if a beneficiary moves to another state, is the plan expected to account for the new state's law when attempting to collect unpaid amounts, or the old state's law (where the debt was incurred), both, or "other"?

Section 50.1 – Pharmacy Claims Processing Requirements

CMS suggests the use of a separate Part D sponsor BIN/PCN combination for Medicare Prescription Payment Plan claim processing. We support this option and would suggest the PCN start with "MPPP" to help with billing order, consistency and simplicity.

We also support the COB option and agree that a card-based option comes with many complexities that could ultimately have a negative effect on beneficiary access to care.

Even so, the COB option represents a significant challenge, in terms of real-time or near-real-time enrollment data feeds that are not in place or developed, and will require significant system enhancements based on criteria that are not yet fully defined by CMS.

The associated administrative challenges will require significant system enhancements for claim processors. For example, plans do not currently have a way to inform PBMs in real-time when members have enrolled in Medicare Prescription Payment Plan ; eligibility files are often passed daily. One potential solution we are exploring is the use of an eligibility indicator in the adjudicator to denote participation status. This could enable plan sponsor staff to manually update the member eligibility record to activate the participation indicator for a beneficiary who opts-in to the Medicare Prescription Payment Plan at POS. However, this also represents a challenge because the sponsor's eligibility system (the source of truth for eligibility data in the adjudicator) must be updated accordingly at the same time or else the next daily file process will not include the relevant indicator of participation and therefore revert the member back to non-MPP participation status. Even if the plan's eligibility system is updated at the same time as a manual update within the adjudicator, a beneficiary record could still be reverted inappropriately to non-participating status due to the timing of the file versus the time of the manual update.

Section 60.2.3 – Targeted Part D Enrollee Notification at POS

We support a single prescription threshold, as opposed to calculating an accumulated amount over multiple scripts in a single day, as the trigger for POS notification. In addition to this being a simpler solution for POS adjudication purposes, it represents a cleaner solution for billing purposes.

In order to provide the best potential benefit to the beneficiary, we suggest a higher threshold for POS notification. That said, since every beneficiary's financial situation is unique to that beneficiary, a zero-threshold (triggering a POS notification regardless of the cost-share amount) may prove to be in the best interest of beneficiaries, could reduce administrative burden for point of sale adjudication logic, and reduce the risk of beneficiary confusion.

Section 60.2.4 – POS Notification Requirements

Point of sale messaging is the standard for pharmacy communication at the point of sale (for example, ***Medicare and Your Rights***) and we support this as the simplest and most efficient method of notification. Other methods (mail, fax, text) would present difficulties in terms of document approval, notification timeframe requirements and cost.

Section 70.3.5 – Processing Election Request During a Plan Year

The 24-hour waiting period represents a situation where a beneficiary could leave the pharmacy without their script, even while it allows the pharmacy to reprocess once the beneficiary is enrolled in Medicare Prescription Payment Plan . One option to alleviate this obstacle to care would be to allow a short supply, e.g., a 3-day supply, similar to the LTC emergency supply, to minimize POS cost for beneficiaries during the waiting period.

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

We support the requirement to terminate an individual's Medicare Prescription Payment Plan participation if that individual fails to pay their monthly billed amount, and the option for a sponsor to preclude an individual from opting into the Medicare Prescription Payment Plan in a subsequent year if the individual fails to pay the amount billed for a month as required under the program.

We are concerned with the potential for abuse of the two-month grace period before termination, combined with preclusion being specific to the plan that has not been paid. There is no apparent mechanism to prevent individuals from moving to another plan if their participation is terminated for non-payment and they are precluded from opting-in to the Medicare Prescription Payment Plan in the subsequent year. This leaves other plans exposed to the blind risk of enrolling beneficiaries who will not pay their amounts owed for reasons other than financial hardship.

The current data submission requirements (Section 100) do not include uncollected Medicare Prescription Payment Plan balances or preclusions at the beneficiary level. We recommend that CMS collect this data at the beneficiary level and, ideally, use this data to allow other plan sponsors (not just the plan that has not been paid) to preclude Medicare Prescription Payment Plan participation in a subsequent year if the individual fails to pay the amount billed for a month as required under the program.

Appendix A – Definitions for Medicare Prescription Payment Plan

We suggest using the term “Patient Out of Pocket (OOP) Cost” in Appendix A to replace the term “Patient Pay Amount” throughout the guidance. “Patient Pay Amount” has a specific definition, especially related to Prescription Drug Event (PDE) data, so using different terminology here would avoid confusion.

Appendix B – Additional Medicare Prescription Payment Plan Calculation Examples

We request additional examples of how the program should work when a beneficiary has multiple supplemental coverages throughout the benefit plan year.

Again, we thank CMS for the opportunity to comment on this important guidance and look forward to future guidance regarding implementation for the first year of the Medicare Prescription Payment Plan.

Please direct any questions or follow-ups to ComplianceDepartment@elixirsolutions.com.

Best regards,





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September 19, 2023

Comments from Fallon Health (H9001 & H8928) on the CMS draft Medicare Prescription Payment Plan Guidance:

- **Requirements related to Part D enrollee outreach (section 60 – p. 19)**
 - Will CMS consider creating a model script for plan outreach to enrollees?
 - On page 19 of the draft guidance CMS is asking what model documents would benefit from some language included about the Medicare Prescription Payment Plan (MPPP). Our plan suggests that CMS include information on the MPPP in the following document models: Part D EOB; EOC; ANOC; Formulary; and Summary of Benefits
 - Will CMS providing guidance on the frequency of targeted outreach to eligible enrollees?
- **Requirements related to Part D enrollee election, including a request for information on real-time POS election (section 70 – p. 26)**
 - Would CMS consider adding details to the draft guidance to address potential situations where a pharmacy refuses to provide medication at no cost at the point-of-sale and does not accept the plan's MPPP program? Has CMS contemplated any pharmacy resistance to this draft guidance?



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September 20, 2023

VIA ELECTRONIC SUBMISSION — PartDPaymentPolicy@cms.hhs.gov

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RE: Medicare Prescription Payment Plan Draft Part One Guidance

Dear Dr. Seshamani,

We appreciate the opportunity to respond to CMS's Maximum Monthly Cap on Cost-Sharing Payments Program Draft: Part One Guidance.¹ 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 2022 we, under the Roche umbrella, invested \$15 billion globally in research and development – more than any other health care company in the world. In the past ten years, we have delivered to patients 20 new medicines that treat devastating diseases like cancer, multiple sclerosis, and hemophilia. In addition to our over 40 approved medicines, we have 85 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 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. However, access and patient affordability concerns have grown over the years as aggressive utilization management

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

techniques and new entities, such as pharmacy benefit managers (PBMs), have proliferated. These shifts threaten the historically generous coverage beneficiaries have come to enjoy under the program.

As noted in our June 5 comments relating to the CY 2025 Medicare Part D Benefit Redesign, 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 Medicare Prescription Payment Plan (MPPP). Overall, we are pleased with CMS’s thoughtful approach to complex operational details, and appreciate that CMS has incorporated critical feedback from key stakeholders, most importantly patient and patient advocates. Below, we provide more specific feedback around stakeholder outreach, MPPP enrollment, and beneficiary protections.

Stakeholder Outreach

As described in our previous comments, a robust and comprehensive educational campaign is essential to ensure the successful implementation of the MPPP. Such a campaign should be coordinated by CMS and involve collaboration with Part D sponsors and pharmacies, ensuring the broadest possible reach to beneficiaries. Despite statutory requirements for CMS and Part D sponsors to provide information about the MPPP to beneficiaries—particularly those “likely to benefit” from the program—many details are left to the discretion of the Agency.

We appreciate CMS’s alignment on the importance of clear and multi-modal beneficiary education in order to maximize patient benefit, as well as the general approach CMS describes in this draft Guidance. We look forward to the additional direction around marketing and communications procedures and content CMS plans to release in the next phase of Guidance. In that Guidance, we urge CMS to require updates to current education and outreach materials associated with annual Part D open enrollment (e.g., Medicare & You handbook, 1-800-Medicare, CMS websites, and Medicare Plan Finder) as these will, for many beneficiaries, be the first media through which they learn about the program. Additionally, we look forward to additional detail around the beneficiary tools referenced in CMS’s technical memo.² We believe this tool should enable patients to assess their unique situation with respect to their medication and time of enrollment in the MPPP, compare their monthly OOP costs with and without enrolling in the MPPP, and make a self-determination about whether they are likely to benefit from the program.

In addition to this overarching feedback, we offer the following regarding targeted beneficiary outreach and development of educational materials.

- **Targeted outreach**—We maintain that it is of utmost importance that educational materials and tools are readily accessible to beneficiaries prior to the start of each plan year to enable participation in the MPPP at the time of plan enrollment, if the beneficiary so chooses. However, we also acknowledge that not all beneficiaries who may benefit from the program at some point in the plan year will elect to participate upon plan enrollment, either because they are not aware

² 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>.

of the the program (despite a robust campaign) or because their situation at that time is such that they do not expect to benefit from the program. For this reason, proactive notification of a patient's potential benefit from the MPPP will be critical. We look forward to the additional detail CMS plans to release in its forthcoming Guidance, but in the meantime would stress that especially in the early years of the MPPP, CMS should take a more inclusive approach in defining patients "likely to benefit" from the program. While we appreciate the analysis CMS conducted using PDE data, and agree with the need for a clearly defined minimum threshold to identify beneficiaries likely to benefit from the MPPP, we believe an even lower threshold than \$400 in single day OOP cost could be used. In doing so, CMS would be acknowledging that historical analyses may not perfectly reflect the OOP realities of today, and would ensure that patients on the margin of potential benefit from the program are not overlooked. We also believe that the tools CMS proposes to make available to patients, as well as the processes in place to allow patients to easily disenroll from the program strengthen the case for a more inclusive threshold for notification by the Part D sponsor.

- **Development of educational materials**—For the purposes of development of the forthcoming Part Two Guidance, we encourage CMS to proactively engage patient, caregiver, and provider groups—particularly those representing vulnerable patients or those otherwise lacking the requisite health literacy to navigate a new program like MPPP—to solicit specific feedback on the needs of these beneficiaries, both in content and mode of communication. Such engagement should occur prior to the release of the Part Two Guidance and continue throughout the development of the educational materials and tools, as well as throughout the plan year. Aside from direct beneficiary feedback, these groups are best equipped to convey the needs of the patients, and can serve the dual purpose of being ambassadors for the program itself, helping to enroll as many patients likely to benefit as possible.

MPPP Enrollment, Re-enrollment, and Voluntary Termination

In this Guidance, CMS seeks feedback on three options to effectuate real-time or near-real-time election into the MPPP at the point of service (POS) with minimal or no delay in the plan taking effect. We appreciate CMS's solicitation regarding these options—telephone-only, mobile or web-based applications, and a new clarification code submitted on claims—as well as the consideration CMS gives to the benefits and challenges of each option. We believe the most important tenets of the POS enrollment are:

1. that the modes of enrollment are as inclusive as possible, recognizing that not all beneficiaries have access to, or are comfortable, with certain modes;
2. that the enrollment process itself is as straightforward and beneficiary-friendly as possible, minimizing abandonment throughout the process; and
3. that POS enrollment is implemented as quickly as possible, weighing any operational challenges against the high value this represents for beneficiaries who may not know to participate in the program upon plan enrollment or whose situations may have changed in a way such that they now benefit from the program.

We urge CMS to consider these aspects as it develops parameters for POS enrollment.

Regarding re-enrollment and voluntary termination, we reiterate our previous comments around the need for straightforward and accessible processes. Beneficiaries renewing coverage with the same Part D sponsor should be given ample notice of their participation in the smoothing program (or lack thereof) and reminded of the availability of the program and its terms and conditions. We also suggest that upon enrollment in the MPPP, beneficiaries are given the option for their participation to automatically renew in the new year, obviating the need for re-enrollment each year while still maintaining an option for patients (upon their initial enrollment in the program) to re-enroll each year if they so choose. We encourage CMS to provide Part D sponsors additional Guidance regarding the voluntary termination process, to ensure that it is as simple and timely as possible.

Beneficiary Protections

Section 11202 of the IRA requires Part D sponsors to disenroll beneficiaries from the smoothing program for failure to pay the amount billed for a month under the smoothing program, and allows Part D sponsors to prevent these beneficiaries from re-enrolling in the program in subsequent years. However, few other details around disenrollment and “lock-out” are provided in the statute. As such, in our previous comments, we urged CMS to develop strong policies that protect beneficiaries against burdensome administration, harsh penalties, or other restrictions that might weaken the benefit of the program and needlessly expose patients to high and unpredictable monthly costs.

We appreciate the clarity CMS provided in this Guidance, as well as the beneficiary-friendly focus CMS took in defining key aspects of the program. Specifically, we appreciate that in balancing the financial and operational considerations from a Part D sponsor perspective, CMS:

1. establishes a two-month grace period for late payments, and requires Part D sponsors to consider additional factors outside of a beneficiary’s control that may impact their ability to make payments even within this grace period;
2. clarifies that if a patient does not comply with the payment policy, they may only be terminated from the MPPP (i.e., their overall plan enrollment is not affected);
3. establishes that a Part D sponsor may only preclude a beneficiary from opting into the MPPP in a subsequent year if the beneficiary owes an overdue balance to that Part D sponsor (i.e., once an outstanding balance is paid, the Part D sponsor must permit the beneficiary to opt into the MPPP, and a patient’s ineligibility to participate in the MPPP under one Part D sponsor does not preclude them from participating in the MPPP under a different Part D sponsor in a subsequent year);
4. establishes reasonable and consistent invoicing requirements; and
5. requires that each Part D sponsor use established appeals procedures for making timely coverage determinations regarding the prescription drug benefits an individual is entitled to under the Part D plan.

At the same time, we encourage CMS to provide additional Guidance on some of these points. For example, in the Part Two Guidance, we urge CMS to require additional notices within the period of

payment delinquency, beyond the current requirement of 15 days pre-termination and 3 days post-determination. Early and frequent beneficiary reminders can reduce the risk of involuntary termination from the MPPP. Additionally, the established grievance procedures that plans are required to apply for disputes under the MPPP outline both standard (30 days, possibly 44 days) and expedited timelines (24-hour). In this Guidance, CMS does not specify the conditions under which a dispute under the MPPP should be handled within the expedited timeline. Timely resolution of MPPP disputes could greatly influence whether a patient receives needed medication.

* * * * *

We appreciate this opportunity to provide feedback on this draft Guidance, and we look forward to providing our feedback on the Part Two Guidance. Please feel free to contact Dan Neves, Director of Federal Policy at nevesd2@gene.com.

Sincerely,



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

GSK Comment Letter

Response to CMS on Monthly Cap on Cost-Sharing Payments Program Draft: Part One Guidance



September 20, 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
Attn: PO Box 8016

RE: Medicare Prescription Payment Plan Guidance

Dear Dr. Seshamani:

GSK appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS or the Agency) on the Maximum Monthly Cap on Cost-Sharing Payments Program Draft Part One Guidance¹ as outlined in the Inflation Reduction Act (IRA). GSK is a member of and endorses the comments of the Pharmaceutical Research & Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO) on the Medicare Prescription Payment Plan (MPPP).

GSK is a global biopharmaceutical company with the ambition and purpose to unite science, technology, and talent to get ahead of disease together. We seek to prevent and treat disease with vaccines, specialty, and general medicines. Our global specialist HIV company, ViiV Healthcare, is fully dedicated to delivering advances in prevention, treatment, and care for people with HIV. GSK supports policy solutions that transform our U.S. healthcare system to one that rewards innovation, improves patient outcomes, and achieves higher value care.

GSK supports the ability for patients to spread cost-sharing throughout the plan year by enrolling in the Maximum Monthly Cap on Cost-Sharing Payments Program, now known as the MPPP. In addition to our submitted comments in June on CMS' *Calendar Year (CY) 2025 Part D Redesign* guidance,² we respectfully submit the additional comments of policies associated with part one of the MPPP guidance below to highlight issues of paramount interest to GSK and the patients we serve.

¹ CMS, Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments, August 21, 2023.

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

² HPMS Email, "Solicitation for feedback on IRA Part D Redesign," April 11, 2023.



1. Program Calculations and Examples

GSK supports the Agency's approach to calculating and smoothing monthly costs in the MPPP program to make them as low as possible for enrollees. The statutory smoothing formula is a straightforward calculation with a generally consistent payment from month to month for Part D enrollees with high out-of-pocket (OOP) costs, especially those who may hit their maximum OOP early in the year.

However, we acknowledge that the experience of some Part D enrollees may be less straightforward under the MPPP program, specifically, individuals with total OOP costs that fall way short of the \$2,000 annual OOP threshold, or who elect the program late in the year. These enrollees may encounter inconsistent monthly smoothing obligation amounts and higher costs at the end of the year than what they would otherwise pay at the pharmacy, which could result in confusion and unintended affordability challenges. GSK encourages CMS to provide education about these inconsistencies to Part D enrollees through plan sponsors, pharmacies, and CMS in outreach and education materials.

2. Requirements Related to Part D Enrollee Outreach

GSK strongly supports the requirement for Part D sponsors to notify prospective enrollees of the MPPP program during open enrollment through member communications and enrollee educational materials. CMS provides clear guidance regarding the importance of enrollee education and outreach. We urge the agency to further develop and describe its plans and requirements in this regard in its forthcoming "Part Two" MPPP guidance. Since the MPPP program is voluntary, enrollee education and outreach are vital processes in ensuring that participants proactively opt-in. CMS should therefore develop a strong, multi-faceted outreach and notification that involves the Agency, Part D plans and pharmacies. GSK also encourages CMS to consider opportunities to involve other potential stakeholders in outreach and education efforts – such as patient and senior advocates, health care providers, pharmaceutical manufacturers, and patient assistance programs.

General Part D Enrollee Outreach Requirements

CMS' approach to performing enrollee outreach prior to and during the plan year provides a crucial opportunity to ensure that individuals who are likely to benefit can sign up before they reach the pharmacy counter. In addition, the ability to broadly explain the MPPP program enhancements to beneficiaries, prior to the fall 2024 open enrollment for Calendar Year (CY) 2025 will be integral to beneficiary participation in MPPP. Given the variance in Part D enrollee circumstances and plan choices, **GSK recommends that the Agency ensures that consistent and clear outreach and education materials are provided to all Part D enrollees.** We also encourage CMS to update its current education and outreach materials associated with annual Part D open enrollment – including *Medicare & You* handbook, 1-800-Medicare, CMS websites, etc. – so that these materials include a comprehensive and clear explanation of the MPPP program with various illustrative scenarios of what enrollees can expect in terms of OOP costs.

Targeted Part D Enrollee Outreach Requirements

Enrollee election in the MPPP program will also be linked with targeted outreach and education, which will need to include both direct outreach to individuals (and their caregivers or representatives) and a comprehensive pharmacy notification process. While pharmacies are required to notify Part D enrollees at the pharmacy if they are "likely to benefit" from MPPP, GSK believes that the best time for individuals to



be notified is before they reach the pharmacy, especially if CMS is not able to establish a strong POS election requirement for 2025. We therefore encourage CMS to require plan sponsors to conduct more targeted and detailed communications to enrollees who have historically had higher Part D OOP costs. This proactive communication would not only provide important advance notification of MPPP but will also improve the timeframes in which potential MPPP participants will have to opt-in the program and provide more time for plans to process the enrollment.

As CMS develops model communication documents and training materials for enrollee outreach for plans and pharmacies, **GSK encourages the Agency to work with patient and senior advocacy groups to develop outreach and educative materials in plain language easily understood, and to create model language that can be used by third parties that interact directly with persons with Medicare – including health care providers and manufacturers’ patient assistance programs.** In addition, CMS should work with pharmacists and pharmacy groups to identify how MPPP program information can be appropriately communicated to patients during pharmacy encounters.

Proposed standard for enrollees “likely to benefit” from MPPP

In the draft guidance, CMS proposes a range of \$400 - \$700 as the potential “likely to benefit” notification threshold, with estimated numbers of enrollees that would be notified at different dollar thresholds. **GSK urges CMS to maintain a patient-focused position by setting standards for calculations of the “likely to benefit” threshold that would identify larger numbers of Medicare beneficiaries.** Based on CMS’ retrospective modeling of PDE data, the draft guidance notes an additional 200,000 beneficiaries would fall in the “likely to benefit” standard if the threshold were based all prescriptions filled in a single day. The Agency also projected that at a \$400 threshold, just over 2 million Part D beneficiaries are likely to benefit from the MPPP program – only 4 percent based on a total number of 50 million Part D beneficiaries in 2022. **To ensure that a larger pool of potential MPPP program participants is identified, GSK encourages CMS to use a lower threshold for notification at the POS (either \$400 or lower).**

3. Requirements Related to Part D Enrollee Election

Interactions Between LIS and Medicare Prescription Payment Plan

GSK supports CMS’ proposal in the draft guidance to leverage communications about the MPPP program to remind patients in Medicare of the potential to qualify for the low-income subsidy (LIS) program.

Processing Election Request During a Plan Year

CMS also proposes that plans must process election requests within 24 hours for requests made during a plan year and seeks comments on interim solutions that Part D plan sponsors could implement to prevent prospective MPPP participants from waiting 24 hours to receive their prescription at \$0 cost-sharing.

GSK notes that much of the benefit of Congress’ requirement that pharmacies notify individuals that they would be likely to benefit from MPPP will be lost if the individual cannot act on that notification to elect to participate and avoid the high OOP payment that otherwise could prompt them to abandon their prescription(s). **Therefore, we strongly support every effort that moves towards effectuating a POS**



option at the start of the program in 2025. This would eliminate potential enrollee complications and confusion for not having \$0 cost-sharing while program election is being processed.

In the draft guidance, CMS proposes a retroactive election process when plans fail to process a beneficiary's election into the MPPP within required timeframes, due to no fault of the beneficiary. **To prevent enrollees from abandoning urgent and necessary medicines at the pharmacy due to delayed election, GSK urges CMS to include information and model language about the retroactive election option in educational and outreach materials on MPPP.** We also encourage CMS to develop clear standards to ensure that plans cannot deny an urgent MPPP election within the defined standards of the draft guidance.

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

CMS requested input on three proposed options to effectuate real-time or near-real-time election into the MPPP at the POS without any delay or with only a nominal delay between the election request and effectuation: (1) telephone-only, (2) mobile or web-based applications, and (3) a new clarification code submitted on claims. The proposed options are expected to begin in 2026 or later, as CMS states that a POS enrollment option is not likely for 2025.

GSK strongly encourages CMS to enhance the benefits of the MPPP by establishing all three proposed options as multiple mechanisms in which prospective participants can opt into the program, as effectuating more than one proposed election method will reduce barriers to participation and may increase program uptake. CMS should consider the technical and infrastructure limitations faced by some enrollees (such as those requiring accommodations due to a disability, non-English speaking individuals, and rural dwellers without reliable cellular and/or internet services) when considering feasible options for effectuating POS election into the MPPP and to the extent possible, account for the wide range of circumstances representative of all Medicare enrollees.

4. Pharmacy Payment Obligations and Claims Processing

GSK supports CMS' goal of developing claims processing methodologies that do not impact the normal pharmacy workflow, and that results in a timely, uniform, and seamless implementation for all parties. We encourage the Agency to prioritize patient access and affordability by developing processes to ensure that plans and pharmacies effectuate MPPP opt-in at the point of sale (POS). As CMS develops a claims processing methodology, it will be important to ensure that any changes to pharmacy workflows and claims processing can occur seamlessly and in conjunction with the POS election mechanism. We therefore encourage an easy one step enrollment process at POS, to prevent pharmacy workflow disruption and member prescription abandonment.

Additionally, GSK acknowledges that the Agency may not be able to accomplish real time POS election in the first year, but we encourage CMS to consider developing a mechanism that would give enrollees access to the MPPP's benefits in fewer than 24 hours when supported by an election confirmation.

5. Procedures for Termination of Election, Reinstatement, and Preclusion

GSK applauds the proposed patient protections in the draft guidance that ensures that Part D enrollees benefit from the MPPP, balancing beneficiary access and patient protections with plan operational and

GSK Comment Letter

Response to CMS on Monthly Cap on Cost-Sharing Payments Program Draft: Part One Guidance



financial considerations. **To further improve these protections, we encourage CMS to increase the grace period for MPPP participants to voluntarily opt out and pay outstanding amounts over the remaining months of the year, from at least two months, to at least 90 days.**

Additionally, we encourage the Agency to work with patient and senior advocacy groups to ensure that the education and outreach materials on the MPPP clearly explain the participant rights and responsibilities under the program in patient friendly language and is inclusive for all Part D enrollees across diverse backgrounds.

GSK appreciates the opportunity to provide comments on the MPPP Part One Guidance, as outlined in the IRA. We stand ready to engage with CMS on this critical work to ensure the program is implemented without adverse impacts to Medicare patients. Please do not hesitate to contact me at Harmeet.S.Dhillon@gsk.com, should you have any questions or requests for additional information.

Respectfully,

A handwritten signature in black ink, appearing to read "H.Dhillon", is positioned below the "Respectfully," text.

Harmeet Dhillon
Head, Public Policy
GSK



Submitted Electronically to PartDPaymentPolicy@cms.hhs.gov

September 20, 2023

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

RE: Medicare Prescription Payment Plan Guidance

Dear Administrator Brooks-LaSure and Deputy Administrator Seshamani,

Haystack Project appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') draft part one guidance outlining its proposed implementation of 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).

Haystack Project is a 501(c)(3) non-profit organization enabling rare and ultra-rare disease patient advocacy organizations to coordinate and focus efforts that address systemic reimbursement obstacles to patient access and innovation. Our core mission is to evolve health care payment and delivery systems with an eye toward spurring innovation and quality in care toward effective, accessible treatment options for all Americans. We strive to amplify the patient and caregiver voice in these disease states where unmet need is high and treatment delays and inadequacies can be catastrophic.

We are pleased to see that the draft guidance prioritizes the well-being of Medicare beneficiaries. Our feedback aims to offer CMS insights from the standpoint of rare disease patients and suggest improvements that further the Program's goal of ensuring that beneficiaries can afford the treatments they need. 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.

Section 30 – Program Calculations and Examples

Implement an interactive online tool to reduce confusion on monthly payment calculations, and eliminate potential for higher payments in initial month after costs are incurred.

Section 30 of the draft guidance includes examples demonstrating how to calculate a participant's monthly payment. However, these scenarios seem to introduce a level of complexity that could confuse patients and dissuade them from participation. In light of this concern, it would be prudent for CMS to consider augmenting its explanation(s) and simplifying its approach.

One effective strategy could be to provide supplemental resources such as an interactive online tool that would be readily accessible to patients and enable them to input their specific information and receive a clearer, more personalized breakdown of their monthly obligations within the program. The resource should provide essential information, including details on how monthly payments may vary based on prescription fills, offering real-world examples for clarity. Additionally, it should offer guidance on accessing financial assistance for individuals facing challenges in affording their prescription medications, with clear instructions or convenient links for easy access. Lastly, it should reassure users that their annual out-of-pocket expenses will not surpass \$2,000, offering peace of mind and financial predictability. This type of user-friendly resource would not only demystify the process but also empower individuals to make informed decisions about their participation.

Second and most importantly, CMS must understand that while the statute provides for different caps for the first month versus subsequent months, most beneficiaries expect that their expenses will be spread evenly across the remaining plan months. They expect that the Program will remove financial hardships associated with front-loaded out-of-pocket costs; CMS' implementation retains enough potential for high initial-month payments to reduce Program benefits for those needing it the most. Evenly distributed payments would comply with the statutory maximum monthly payment amounts and align with beneficiary expectations. While this approach will not significantly alter the fact that the program's value diminishes for those enrolling later in the year, it does enhance affordability during the initial month for a broader range of potential participants throughout the plan year.

Section 40 – Participant Billing Requirements

Advance warning of upcoming payments, smoothing previously unpaid amounts, and applying undesignated payments to the Program for participants paying Part D premiums through Social Security payment deductions could all improve an already well thought out set of requirements.

Section 40 provides guidance on billing and billing statements. Including the information plans must provide on monthly invoices, prioritization of payments, and the financial reconciliation process. We are grateful that CMS has thoroughly considered the needs of the Medicare

population in this section and provided multiple options for beneficiaries to meet their financial obligations to the program. We offer the following suggestions to further enhance the program and ensure beneficiaries are given appropriate access to payment information and mechanisms.

Access to Payment Information and Payment Options

Given the Medicare population's tendency to be less digitally savvy, bills should be available in paper and electronic form. Similarly, CMS should offer a variety of payment options, including manual and automated electronic fund transfers (EFT) from a checking or savings account, credit card or debit card as well as an option to pay in-person, via check, money order or cash. At a minimum, an address should be provided for individuals who wish to mail in their payments. Finally, beneficiaries should be well informed of the schedule of upcoming payment deadlines, especially as additional prescription drug costs are incurred.

Additional Guidance on Program Implementation

We believe beneficiaries need additional clarity regarding several elements of the Program. 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. This issue is of particular significance within the context of rare disease patients, as the out-of-pocket costs for a single prescription could potentially reach the \$2,000 annual cap. It is unclear whether participants would be issued refunds for returned products or required to continue paying for a drug they have ceased using. The practical implications of these scenarios, especially in the context of a 3-month mail order fill versus a single prescription obtained from a pharmacy, could lead to a lack of uniformity among issuers and leave some beneficiaries with financial obligations they did not expect.

The potential that the Program would offer minimal financial relief for individuals requiring high-cost treatments late in the year is of particular concern to our patient communities. Haystack Project's patient advocacy organizations have emphasized that patients newly prescribed a treatment in the latter part of the year should not suffer financial burdens that patients filling a prescription early in the year can eliminate through Program participation. We urge CMS to enable participants to spread out-of-pocket costs over a 12-month period, rather than the remainder of the calendar year. The primary concern within our communities is that patients receiving a new prescription in, for example, October, would be unable to pay their out-of-pocket costs (with or without Program participation), and have to delay filling their prescription until January. Addressing this concern with a 12-month, rather than calendar year, approach would be an important step toward ensuring that the Program reduces the likelihood that Medicare's most vulnerable beneficiaries suffer compromised outcomes from cost-related treatment delays.

Additionally, beneficiaries express concerns about whether insurance plans can prevent individuals from opting into the payment plan for multiple subsequent years after a prior termination due to nonpayment. Similarly, participants need to understand their options during

a grace period to avoid termination. We 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 up-front payment of past due amounts. Since termination from the Program leaves participants with fewer financial options and plans with a debt that may be difficult to collect, we strongly encourage CMS to specifically grant participants at least one opportunity per plan year to catch up on missed payments by requesting a recalculation that evenly spreads their monthly payments over the remaining months of the plan year.

Lastly, there is a great deal of uncertainty about what constitutes "good cause" for missing a payment. Both plans and participants need guidance on the practical application of this standard. We recommend CMS provide a set of illustrative examples to shed light on the circumstances or scenarios that would qualify as "good cause" for missing one or more payments. This guidance would offer much-needed clarity in navigating the payment program.

Prioritization of Premium Payments

The guidance indicates that CMS encourages Part D sponsors, when in receipt of payments not clearly designated as a payment to either part D plan premiums or Medicare Prescription Payment Plan payments to prioritize payments towards Part D plan premiums. While we support CMS' policy decision to ensure that beneficiaries maintain Part D coverage, we have concerns that this policy may have unintended consequences.

Our understanding is that most Part D enrollees utilize direct deductions from their Social Security payments in order to pay their Part D premiums. Accordingly, these beneficiaries are unlikely to mail additional payment to the plan sponsor for the purposes of paying premiums. While their automatic social security deductions are clearly designated as a Part D premium payment, the methods of payment for Program payments are more likely to be done via personal check or EFT and therefore are much more likely to be left without a clear designation as to which account the funds should be applied. For participants paying their Part D premiums through automatic deductions from their Social Security payments, an undesignated payment would almost certainly be intended as a Program payment. may be received by the plan sponsor before the social security deduction.

In addition, participants may make payments a few days early or a few days late. This could create confusion for participants and plans on how to apply payments, e.g., toward the next month's amount due or to the balance remaining. We urge CMS to require that plans allow participants to designate how they wish to apply any payments that exceed the amount due for a particular month and (1) permit pre-payment of a subsequent month's invoice as well as (2) enable recalculation of monthly payments for participants electing to apply overpayments to the remaining balance.

Section 60 – Requirements Related to Part D Enrollee Outreach

Uniform model notices, forms, and communications from both plans and pharmacies would reduce confusion and enhance consistency and predictability; deploying patient groups like

Haystack Project as well as existing educational tools beneficiaries are familiar with will aid program awareness.

We commend CMS for recognizing the vital role of effective outreach and education in facilitating the Program's success. The creation of model notices, forms, and beneficiary communications would enhance consistency and predictability significantly. We ask that CMS release these resources in draft form, allowing stakeholders the opportunity to offer feedback and input.

In addition, we recommend that CMS utilize existing resources to maximize enrollee education. For instance, CMS could enhance program awareness by utilizing the plan finder tool as it is a critical resource for beneficiaries and their families when making decisions about their Part D plans. By incorporating a calculator tool into Medicare.gov that illustrates how the program can benefit a beneficiary based on their anticipated prescription drug needs, CMS could streamline the process for opting in. Prescribers should also have access to real-time benefit tools that offer information about the financial responsibility tied to specific prescriptions, enabling them to engage in discussions with their patients about the Program.

Similarly, CMS should develop informational materials tailored for use by pharmacies to educate beneficiaries about the program. These materials should offer clear instructions on how to opt into the program, ensuring that Part D enrollees are well-informed and prepared to make decisions regarding their participation well in advance of the 2025 plan year. Additionally, active prompts at pharmacy counters could inform Part D enrollees about the program and provide them with the opportunity to participate. This could involve incorporating statements like "have you considered opting in" within automated pharmacy notifications commonly used to alert patients that their prescription is ready for pick-up.

We also note that the IRA requires pharmacists to proactively engage beneficiaries who are "likely to benefit" from the Program, inform them on how the Program might be helpful and outline mechanisms for opting in. We strongly urge CMS to set the single-fill dollar threshold at or below \$400. This is particularly important in the initial year since beneficiaries may be unaware that they have the option to make monthly payments to their plan and avoid paying at the pharmacy counter.

In addition, 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 should provide FAQs and model PowerPoint presentations that patient advocacy organizations can use to inform their patient and provider communities on the Program, including how each patient can determine whether they should opt in and when/how to do so. We also encourage CMS to update the Medicare & You handbook with pertinent information on the Program and outline a clear set of requirements for plans, including that program information be included with plan documents, including the evidence of coverage notice and explanation of benefits statements.

Section 70 – Requirements Related to Part D Enrollee Election

A POS option is both feasible and critical in Plan Year 2025; Patients, pharmacies, and plans should also consider a 2025 opt-in request as same-day participation.

We believe this Program has tremendous opportunity to help beneficiaries afford and continue to afford their life saving prescriptions. Currently, a dishearteningly high number of individuals and families find themselves burdened by unaffordable out-of-pocket expenses. The prospect of spreading these costs evenly over the course of a year really is a beacon of hope for innumerable Medicare beneficiaries living on a fixed income and their families, sparing them from the agonizing reality that filling a high-cost prescription could mean getting inextricably behind on housing, utility, and transportation bills. It is critical that the first year of this Program is successful. We are concerned that confusion or unnecessary complexity in the enrollment process will either dissuade beneficiaries from participating or simply add to their existing financial stressors.

Because the IRA requires plans to make the Program available to all enrollees and does not provide for any basis upon which a participation request could be denied other than involuntary termination in the previous year, enrollment in the first year of the Program should be the easiest for plans to process. Accordingly, patients, pharmacies, and plans should consider a 2025 opt-in as participation on the day the request is made. This could be operationalized by requiring that requests for participation made via telephone or online through CMS or the plan sponsor's website are acknowledged with a tracking or confirmation number that participants can utilize at the point of sale to confirm that they have opted in.

While we understand plans may need some time to process requests, participation should be retroactively applied to the date the election was made and beneficiaries should be able to take advantage of the payment advantages the moment they elect to enroll. We are concerned that delaying participation due to processing wait times and creating an expediting mechanism for occasions when a plan agrees a prescription is “urgent” will create a burden for clinicians and patients alike. This would be an additional administrative burden in an already unfamiliar and complex Program that providers would have to navigate along with any prior authorization or step therapy hurdles plans have implemented. This issue is critically important to Haystack Project and its members. For many rare disease patients, every prescribed treatment is perceived as potentially reducing disease burden or progression and viewed as urgent. Even introducing a requirement for patients to return within 24-72 hours to access their medications would needlessly impose stress and inconvenience.

In addition, offering a point of sale (POS) opt-in process during the first year of the Program is critical to its success as most Medicare beneficiaries make important decisions about their health and finances at the pharmacy counter. A POS participation mechanism will ensure that individuals facing high out-of-pocket costs when they seek to fill their prescription can elect to participate in the Program and receive their medication without delay. **We strongly urge CMS to adopt the point-of-sale (POS) enrollment approach in the 2025 plan year, recognizing requests as equivalent to participation during the processing period stipulated by plans.**

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 observed in Medicare or Qualified Health Plans. Participants would be reminded of 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.

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

A grace period is critical and should be extended to 3 months in line with other health plans.

We support CMS' policy to implement a grace period and ask that it be three rather than two months. We also support CMS' requirement that Part D plans provide participants with continued information throughout the grace period on the impact of late payments, including that the individual faces involuntary termination from the Program. These communications should make clear that Part D benefits continue as long as premiums are paid and that the grace period for this Program is separate and distinct from enrollment in their Part D plan.

As outlined above, we urge CMS to consider adopting a mechanism that permits participants to have their missed payments spread across the remaining plan months. This measure would enhance the feasibility of ongoing participation and alleviate the necessity for terminated individuals to establish "good cause" for payment lapses. We further request that CMS provide illustrative examples of "circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee."

Conclusion

Haystack Project appreciates the opportunity to submit feedback on CMS' part one guidance on 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 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 or our policy consultant, Kay Scanlan of Consilium Strategies at mkayscanlan@consilstrat.com.

Sincerely,



Chevese Turner
Chief Executive Officer
Haystack Project – *Voices of Rare and Ultra Rare*
Chevese.turner@haystackproject.org



September 18, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
P.O. Box 8013, Baltimore, MD 21244
Mail Stop: C4-26-05

RE: Medicare Prescription Payment Plan Guidance

Dear Administrator Brooks-LaSure:

The Healthcare Leadership Council (HLC) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) Medicare Prescription Payment Plan draft part one 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 a popular and successful program since its inception. In a recent Morning Consult survey, 91 percent of seniors report being pleased with their Part D plan and 86 percent say it provides good value.¹

We strongly support the objective of the new Medicare Prescription Payment Plan program to help those seniors with high upfront prescription costs smooth payments out over the course of the plan year to better afford their medications. We also recognize that the substantial burden of implementing this new program falls largely on Part D sponsors and hope CMS will work closely with stakeholders to reduce implementation barriers to ensure the success of the program.

Two ways to reduce these implementation barriers are to move away from relying on the point of sale to identify enrollees who may benefit from the program, allowing plans more certainty in administering the program, and to delay the program implementation one calendar year to take effect January 1, 2026. This adjustment would allow plans time to invest in the significant

¹ 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.

payment infrastructure required and to incorporate requirements in the part two guidance CMS anticipates releasing in 2024. Plan design for 2025 is already underway, and it will be difficult to incorporate the guidance on this program in time.

Thank you for the opportunity to provide feedback on the draft part one guidance of the Medicare Prescription Payment Plan that will build on the success of the Part D program. HLC looks forward to continuing to engage with CMS on this important issue. If you have any questions, please do not hesitate to contact Debbie Witchey at dwitchey@hlc.org or 202-449-3435.

Sincerely,

A handwritten signature in black ink, reading "Mary R. Grealy". The signature is fluid and cursive, with the first name "Mary" and last name "Grealy" clearly legible.

Mary R. Grealy
President



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8170 33rd Avenue South
Bloomington, MN 55425
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Mailing Address:
P.O. Box 1309
Minneapolis, MN 55440-1309

September 20, 2023

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

Filed Electronically: PartDPaymentPolicy@cms.hhs.gov | Email subject line "Medicare Prescription Payment Plan Guidance."

Dear Sir/Madam:

Thank you for this opportunity to offer our comments on the Medicare Prescription Payment Plan Guidance (MPPP) draft part one guidance.

HealthPartners holds five contracts with the Centers for Medicare & Medicaid Services (CMS): H2422 (MA FIDE SNP), H2462 (1876 Cost), H3416 (MA-PD PPO), H4882 (MA-PD PPO), and S1822 (Employer Group-only PDP), and we offer Medicare plans in Minnesota, Wisconsin, Iowa, Illinois, North Dakota, and South Dakota. Our long history of participating in the Medicare program and serving Medicare beneficiaries goes back to 1985. Our comments are based upon our experience and learnings serving Medicare beneficiaries and applying CMS guidance. We appreciate the opportunity to offer comments and engage with CMS on the MPPP.

HealthPartners is a member of America's Health Insurance Plans (AHIP), the Alliance of Community Health Plans (ACHP), and the SNP Alliance. We participated in the development of and support their comments submitted under separate cover.

1. Section 10 - Introduction and timeline. HealthPartners appreciates CMS' work to develop draft guidance and the timeline for future draft guidance and issuance of final guidance. However, we are concerned that the timelines are not aggressive enough to ensure uniform and consistent information to Medicare beneficiaries and support plans and other stakeholders in standing up the MPPP for Jan. 2025.

Recommendation: CMS modify its timeline as follows:

- Issue final part one guidance by Dec. 31, 2023
- Issue draft part two guidance with comment period by Dec. 31, 2023
- Issue final part two guidance and draft model materials by April 1, 2024
- Develop a uniform, national communications strategy by April 1, 2024
- Issue final model materials by June 1, 2024

2. Section 10 - Introduction and plan types in scope. CMS applies the guidance to plan types that include Employer Group Waiver Plans (EGWPs) and demonstration plans. Regarding EGWPs, they generally offer rich Part D coverage with low Part D cost sharing and most retirees enrolled in EGWPs will not benefit from MPPP. In addition, MA-PDs that participate in CMS demonstrations such as the VBID model and eliminate Part D cost sharing will not benefit from MPPP.

Recommendation: CMS use its waiver authority to exclude EGWPs from MPPP for the initial years of the program. In addition, CMS exclude from MPPP any MA-PD plans participating in VBID or other demonstrations that result in no Part D cost sharing.

3. Section 20 - Overview. Education on what is the MPPP, how it works and who would value from it most is critical, and a number of stakeholders will need to be involved.

Recommendation: CMS develop and finalize a uniform, national communications campaign by April 1, 2024. A comprehensive approach that includes consistent key messages and accurate and clear information and model documents will help minimize confusion for beneficiaries, plans, advocacy groups, and other stakeholders. There are number of plan documents that CMS needs to revise to include information about the MPP and these documents include the ANOC, EOC, and EOB and those need to be finalized by June 1 to ensure timely distribution to enrollees and plan set up. In addition, CMS needs to include information in the Medicare & You Handbook and the Medicare Plan Finder tool, resources that must be final for distribution in Sept. 2024 and available online Oct. 1, 2024.

4. Section 30 - Program calculations and examples. HealthPartners appreciates the example calculations and encourages CMS to continue to share examples as additional situations are identified.

Recommendation: CMS continue to develop and share examples including scenarios with claims reprocessing or adjustments. Furthermore, we encourage CMS to make available an online calculator for beneficiaries and others to use to determine if a person would benefit from participation in MPPP. Illustrative examples in the Medicare & You Handbook and the Medicare Plan Finder tool would be helpful too.

5. Section 40 – Participant billing requirements. CMS lists the required elements to be included in the monthly billing statement including LIS program information. CMS encourages plans to provide participants flexibility with monthly payment dates and requests input on financial reconciliation standards.

Recommendation:

- For exclusive D-SNPs, CMS should not require that LIS program information be included in the billing statement. All enrollees have LIS by nature of being eligible for the exclusive D-SNP. The information is unnecessary and confusing.
- CMS clarify how reprocessed claims and adjustments are to be reflected in the billing statement.
- CMS keep it optional that plans allow MPPP participants to choose which day of the month their program payments would be due. This adds to much variation and complexity to the billing cycle. Plans need flexibility to use systems already in use for payment of premiums and other financial obligations.
- CMS provide additional information regarding collecting amounts owed under the program and clarify that plans may continue to bill participants monthly amounts due (including any past due amounts) following the end of the plan year, and a participant's obligation to pay amounts owed under the MPPP remain when the individual disenrolls from the program or the plan.
- CMS allow plans to bill an individual in full or provide them with payment plan options that extend over a shorter period of time when the participant chooses to disenroll from MPPP.

6. Section 50 - Pharmacy payment obligations and claims processing. HealthPartners supports CMS' proposal for an electronic claims processing methodology (two transactions) to facilitate the processing of claims for MPPP participants. We strongly support the exclusion of OON pharmacy claims from MPPP, to enable plans to implement and operationalize the requirements of the program.

Recommendation: CMS clarify that by not requiring plans to retroactively include paper claims submitted that out-of-network pharmacy claims are excluded under MPPP.

7. Section 60 – Requirements related to Part D enrollee outreach. CMS outlines the requirements for general and targeted outreach as well as proposals for the POS notification threshold.

Recommendation:

- CMS issue final guidance by April 1, 2024, and final models by June 1, 2024, to ensure that plans have sufficient lead time to operationalize revisions to existing beneficiary materials, and develop new materials as needed. In addition, before the end of 2023, CMS should develop a uniform, national communication strategy to educate Medicare enrollees and others about the MPPP.
- CMS allow for flexibility on how plans identify enrollees likely to benefit in advance of a plan year, especially at the start of MPPP.
- CMS provide flexibility on how plans identify enrollees likely to benefit in advance of a plan year, especially in the early years of MPPP implementation. We urge CMS to exclude exclusive D-SNP enrollees from the targeted outreach.
- CMS set the POS notification threshold at \$700, to address implementation and operational complexities associated with the POS notification for both the plan and pharmacies.

8. Section 70 - Requirements related to Part D enrollee election. CMS provides guidance on program eligibility.

Recommendation:

- Model language and other communication materials developed by CMS explain the differences between the MPPP and LIS program and reasons that LIS enrollees are not likely to benefit from the MPPP.
- CMS apply enforcement discretion for good faith efforts made by plans to meet processing deadlines under the program for plan year 2025.
- CMS extend the timeframe for processing election requests to at least 72 hours for plan year 2025. CMS apply enforcement discretion for good faith efforts made by plans to meet processing deadlines under the program for plan year 2025.
- CMS extend the timeframe for processing election requests to 3 business days for plan year 2025. We are concerned about the operational feasibility for processing of election requests made by an enrollee during the plan year within 24 hours. Also, a turn-around-time of based on hours is difficult to administer.
- CMS' communication materials should educate enrollees who may be eligible for the LIS program that participation in the MPPP is unlikely to benefit them.
- Exclusive D-SNPs should not be required to educate on LIS program.
- Given the operational complexity involved with retroactive elections, CMS make this requirement optional for the first year of the program. Alternatively, if CMS finalizes its requirement on retroactive elections, CMS apply enforcement discretion for good faith efforts made by plans to meet the processing deadlines for retroactive elections for plan year 2025.
- Given the operational complexity involved with retroactive elections, CMS make this requirement optional for the first year of the program. Alternatively, if CMS finalizes its requirement on retroactive elections, CMS apply enforcement discretion for good faith efforts made by plans to meet the processing deadlines for retroactive elections for plan year 2025.

9. Section 80 – Procedures for Termination of Election, Reinstatement, and Preclusion. CMS outlines when a participant can voluntarily opt-out of the program and when the plan can involuntarily term participation.

Recommendation:

- CMS provide plans with the model notice to acknowledge receipt of voluntary terminations from an individual who notifies their plan about their intention to opt out of the MPPP.

- If an enrollee switches their plan during the plan year to a plan offered by the same carrier, that the MPPP election can continue to be honored in the new plan.
- CMS consider allowing plans to require a single final MPPP payment, rather than continued monthly billing after termination, particularly if the enrollee has completely left the carrier.
- CMS provide plans with the model notices associated with involuntary terminations addressed under Sections 80.2 and 80.2.
- CMS not allow an MPPP participant with unpaid past due invoices under their previous plan to enroll in the MPPP under a new plan until the enrollee has paid off their past due invoices with their previous plan.

10. Section 90 – Participant disputes. CMS states that plans must apply the appeals and grievances guidance and processes.

Recommendation:

- CMS issue the revised appeals and grievances guidance that addresses MPPP disputes in draft form for public comment before finalizing.
- CMS consider applying a hold harmless policy to ensure that summary and overall star ratings do not go down if lower performance results are likely due to MPPP impacts.

Thank you for the consideration of our comments. If you have any questions regarding our comments, please feel free to contact me at Amy.L.Schultz@healthpartners.com.

Sincerely,

Amy L. Schultz
Director, Medicare Programs and Shared Services
HealthPartners

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September 20, 2023

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

Re: Medicare Prescription Payment Plan Guidance

Dear Dr. Seshamani,

Humana appreciates the opportunity to provide feedback and recommendations to CMS on the Medicare Prescription Payment Plan established by the Inflation Reduction Act (IRA). We offer these comments in response to the CMS guidance dated August 21, 2023, 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."* Humana currently serves approximately 5.1 million beneficiaries enrolled in our Medicare Advantage (MA) plans and 2.8 million beneficiaries enrolled in our Medicare Part D Prescription Drug Plans (PDPs). As a long-time Part D plan sponsor, we hope that you find our feedback and recommendations constructive in developing an approach to cost-sharing flexibility in 2025 and beyond.

Humana supports the policy goal of establishing the Medicare Prescription Payment Plan 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:

- **Finalize this guidance and release Part Two of the payment plan guidance by the end of 2023.** The technical specifications are needed as soon as possible so that plan sponsors can begin to develop the infrastructure necessary to support this program with ample development time.
- **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.
- **Finalize the proposal to use the BIN/PCN approach at the pharmacy counter** as it will provide the beneficiary the most streamlined user experience with the payment plan.
- **Create additional accountability mechanisms for beneficiaries** that will incentivize them to make their cost-sharing payments to the plan sponsor under the payment plan.

- **Allow for maximum flexibility for plan sponsors** in the first several years of the program to build and develop election and billing processes that can best support the immediate needs of beneficiaries while balancing the operational complexities of the payment plan.
- **Commit to studying the implications and the trends associated with the payment plan** to understand beneficiaries uses and needs to inform future communication and operational requirements.

We value this opportunity to provide recommendations related to the Medicare Prescription Payment Plan under the IRA 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", written in a cursive style.

Michael Hoak
Vice President, Public Policy

Section 10 and 20. Introduction and Overview

CMS summarizes key components of the statutory requirements relating to the Medicare Prescription Payment Plan. CMS has chosen to provide guidance on the payment plan in two stages while voluntarily soliciting feedback from stakeholders on various aspects of payment plan design and operation. CMS proposes to formally refer to Medicare beneficiary out-of-pocket smoothing as the “Medicare Prescription Payment Plan” and refer to those who elect to participate in the payment plan as “participants”.

Humana Comment: Humana supports the policy goal of establishing the Medicare Prescription Payment Plan (*otherwise referred to as “payment plan” or “program” in our comments*) as a mechanism to allow Part D enrollees to spread significant costs over time in lieu of a single larger expense. **We share the belief that payment plan participation benefits a relatively small portion of the larger Part D population and believe that it is essential to identify those members to ensure elections into the payment plan prior to the start of the coverage year.**

We appreciate CMS’s approach to providing guidance in two parts. 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. As such, we recommend that CMS provide final guidance on the following timeline:

- ***Final Part One Payment Plan Guidance is needed by end of 2023:*** Final guidance outlined in Part One of the payment plan guidance will be needed by end of 2023. Plan sponsors will need at least one year to build the infrastructure necessary to support beneficiaries in the payment plan.
- ***Final Part Two Payment Plan Guidance is needed by April 1, 2024:*** Likewise, we recommend that CMS release the proposed Part Two guidance on the Medicare Prescription Payment Plan as soon as possible. That guidance should be finalized no later than April 1, 2024 to ensure that those communications can be developed by plan sponsors well in advance of the 2025 Annual Election Period (AEP).

Section 30. Program Calculations and Examples

CMS reiterates the methodology and calculations included in the July 17th memo on what is now referred to as the “Medicare Prescription Payment Plan.” CMS provides several examples to reflect that calculation of the maximum monthly cap is different in the initial month of payment plan participation than in subsequent months.

Humana Comment: We thank CMS for providing additional examples of how to calculate the maximum monthly cap for program participants, both through this guidance and the guidance dated July 17, 2023, titled “*Technical Memorandum on the Calculation of the Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans.*” In addition to the examples outlined by CMS in Part One of the guidance, it would also be helpful to understand other scenarios including:

- ***Retroactive changes:*** It is not uncommon to have retroactive changes to a claim or retroactive changes in member eligibility. We recommend that CMS also provide examples about how to process re-adjudicated claims or changes to a member’s eligibility status such as retroactive eligibility.

- **Variation by plan types:** CMS should provide additional examples as to how the payment plan would work for enhanced plans or Employer-Group Wavier Program (EGWP) plans.

Additionally, **we recommend that CMS develop an interactive and dynamic cost calculation tool for use by individuals interested in payment plan participation.** Rather than encouraging each plan sponsor to develop a unique calculator tool, we feel that a standardized tool associated with this novel program would represent a more enrollee-centric approach to presenting information on the payment plan. We envision a consumer-friendly tool that would allow Part D enrollees to estimate their monthly out-of-pocket (OOP) expenses with and without electing the payment plan. Importantly, this should include examples of what the beneficiary's cost-share amount could be based on their previous or anticipated utilization. Potential program participants should be given the opportunity to make fully informed decisions regarding participation. 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.

Such a calculator would allow potential participants to see how significantly the monthly payments can vary under the program, even for those with relatively consistent OOP spending, such as the hypothetical member described on the bottom of page 21 and top of page 22 of the Draft Part One Guidance. This member has OOP spending of \$500 per month beginning in September, but the monthly payments if this member opts into the program range from \$166.67 to \$916.66. **In addition, if the statutory language permits, we would recommend participants in the program in subsequent months after the first month of participation in the payment plan pay the greater of the calculated maximum monthly cap amount as defined for that month and that of the prior month, but capped such that the participant never pays more than the total year-to-date OOP spending amount.** While we understand it is possible the statutory language would not permit such an adjustment, we believe it would produce more stable month-to-month payments for participants and result in a better participant experience.

Section 40. Participant Billing Requirements

CMS outlines information that must be included on a program participant's monthly bill. CMS notes that plan sponsors must send a bill for payment plan participation that is separate from any invoice for Medicare Advantage or Medicare Part D premiums and that payments received for premiums must be prioritized. Billing statements under the payment plan must contain certain information including amounts due, past payment history, progress towards the OOP cap, and information on addressing past due payment and opting out of the payment plan. CMS also proposes to prohibit the application of any late fees, interest payments, or other fees to amounts due for payment under the payment plan.

Humana Comment: Humana appreciates the clarification on the participant billing requirements and concurs with CMS that program participants will need detailed billing information to understand their financial responsibilities under the payment plan. Although plan sponsors are accustomed to billing member premiums, those amounts are largely consistent across similarly situated members in the plan and remain consistent through the year, while the payment plan

will result in each beneficiary having a bill that is unique to their incurred cost and will vary from month to month. Therefore, **Humana recommends that CMS provide as much flexibility in billing operations as possible for beneficiaries and plan sponsors, especially during the first year of the program.**

In that spirit, **Humana believes plan sponsors should be able to provide participants with options when it comes to payment plan billing.** This includes providing participants with the option to combine premium billing statements with payment plan statements. We suspect that many program participants would prefer to receive a single itemized statement, including plan premiums and payment plan balances, from their plan sponsor. This may be difficult for plan sponsors to operationalize in the first year of the payment plan – but by offering additional flexibility, plan sponsors may be able to generate more member-centric payment offerings. Additionally, members should have the option to modify their cost-share billing, including paying more than the monthly cap, when appropriate, to ensure that cost-share bills are more predictable and avoid instances in which a disproportionate amount of cost-sharing payments are due at the end of the year. As part of the guidance, CMS notes that participants will be allowed to pay more than their maximum monthly cap under the payment plan if they choose to do so. We applaud CMS for this clarification. Importantly, such flexibility provides both participants and plan sponsors with the opportunity to avoid situations in which a significant portion of a participant’s OOP costs are deferred until late in the coverage year. However, we have some concern with CMS’s assertion that plan sponsors should offer participants full flexibility as to the form in which payments are made. While plan sponsors generally have the ability to accept payments made via electronic funds transfers and checks, they do not have a mechanism to accept cash payments. We encourage CMS to clarify this piece of the guidance to indicate that participants must have multiple mechanisms to make monthly payments while also giving plan sponsors flexibility to set some limitations on which payment mechanisms will be accepted.

Furthermore, **plan sponsors should be able determine the billing timeline for the payment plan and establish incentives to ensure that participants pay their payment plan bills.** As previously stated, this will be a new function for plan sponsors who will need to send unique bills to each program participant. As such, plan sponsors should have some discretion as to when cost-share payments under the payment plan are due as the retrospective nature of the payment plan will require bills to be generated and distributed after the end of the month. Many plan sponsors carefully consider how member mailings, like the payment plan bill, will impact call center volumes and stage the distribution of the mailings to ensure that incoming inquiries can be appropriately managed. Additionally, plan sponsors should be permitted to establish incentives for timely payment of cost-sharing bills for program participants who have authorized payment mechanisms on file. We have found that recoveries from enrollees are typically very difficult to collect. At present, there are limited incentives for Part D enrollees to pay amounts due in instances when a claim is reprocessed or re-adjudicated, resulting in an unpaid balance.

Moreover, CMS’s contention that plan sponsors cannot impose any late fees or interest on outstanding amounts due under the payment plan may increase abuse of payment plan benefits. While we agree that the participant should be given some flexibility in satisfying amounts due under the payment plan, **we also encourage CMS to include design features that will incentivize responsible use of the payment plan, including allowing late fees or interest**

payments on cost-share bills that are in arrears. We are concerned that unpaid balances accrued under the payment plan could have a broader impact to the entire Part D population in future coverage years. We also note that monthly amounts due under the payment plan have the potential to far exceed member premiums amounts under the Part D program. Plan sponsors may be forced to assume high rates of non-payment in forthcoming Part D bids – potentially driving up costs for all enrollees and the Medicare program itself through higher premiums and direct subsidy payments. While the imposition of financial penalties to participants should not be a primary response to nonpayment of amounts due under the payment plan, we feel that a blanket prohibition on such penalties could limit the ability of plan sponsors to encourage participant compliance with payment parameters.

Lastly, CMS notes that 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 an individual has disenrolled from the Part D plan or terminated their election of the payment plan either voluntarily or involuntarily. **Humana is concerned that this model – in which the member continues to be billed monthly after disenrollment or termination– could become extremely confusing for participants.** In this scenario, members who have left one plan and joined another could receive three distinct bills in a month including one from their previous plan sponsor for the payment plan, a second from their current plan sponsor for their premium, and a third from their current plan sponsor for their new payment plan. **We recommend that plans be allowed to bill the member in full upon disenrollment or establish a payment plan that is shorter in duration (i.e., two to three months, or an estimated bill in December to avoid going into the next plan year).**

Section 50. Pharmacy Payment Obligations and Claims Processing

In keeping with IRA requirements, CMS seeks to ensure that the establishment of the payment plan does not impact amounts paid to pharmacies. CMS is encouraging the adoption of an electronic claims processing methodology such as the one currently used for real-time coordination of benefits (COB) billing transactions using National Council for Prescription Drug Programs (NCPDP) standards. Part D sponsors would utilize an additional Bank Identification Number (BIN) and/or Processor Control Number (PCN) unique to the payment plan to facilitate electronic processing of supplemental COB transactions for program participants. CMS further stipulates that all payment plan policies will apply across all pharmacy types, including specialty and mail-order.

Humana Comment: Humana strongly supports CMS’s proposal to use the BIN/PCN approach as it will be a more streamlined experience for participants. As noted in the guidance, CMS is encouraging the adoption of a two-transaction approach to processing prescriptions filled on behalf of program participants that would rely on two different BIN/PCN combinations for claims adjudication. While this approach will require a greater number of total claims transactions, it closely mirrors the process used today for COB and will ensure that cost-spreading under the payment plan includes ONLY Part D covered drugs. We also believe that this approach to processing participant claims will minimize the potential for errors in the enrollee cost-sharing amount that is reported to CMS via the Prescription Drug Events (PDE) file, which could also limit the need for retroactive claims reprocessing. Accordingly, Humana supports the proposed approach to claim adjudication under the payment plan. As CMS considers the additional technical guidance that is needed related to the BIN/PCN process,

examples on how to process multiple supplemental coverages, reversals and adjustments and plan reconciliation of two BIN/PCNs are needed.

CMS has expressed a willingness to consider alternative mechanisms to facilitate claims processing under the payment plan, such as a plan sponsor-issued pre-funded payment card. **We share CMS's concerns regarding the pre-funded payment card mechanism** as it will create new complexities for both the member and the plan sponsor. A payment card approach would require plan sponsors to align formulary coverage under distinct plans with allowable expenses that may accrue to the payment card. Each plan sponsor would need to ensure that the card would permit *only* payments in accordance with their unique formulary of covered Part D drugs. In other words, the card could not be used more broadly to pay for nonformulary drugs, over-the-counter products, or any other health care expense. Moreover, plan formularies change and evolve – sometimes during the coverage year – adding an additional layer of complexity. Establishing the parameters around use of such a card could present significant challenges for plan sponsors and confusion for participants.

As CMS considers unique scenarios across pharmacies and claims types, we'd encourage the agency to exclude incurred costs from the program during the first year to limit the complexities in the program. We support CMS's proposal to exclude paper claims from the payment plan which should include instances in which a participant files for direct member reimbursement. Additionally, we believe products dispensed to patients in long-term care facilities should also be excluded.

Section 60: Requirements Related to Part D Outreach Requirements

CMS reiterates that both the agency and plan sponsors are required to provide informational materials on the payment plan to Part D enrollees, including multiple forms of targeted outreach. In order to identify which Part D enrollees will “likely benefit” from payment plan participation, CMS is proposing to set a single OOP threshold on a single claim basis. CMS reasons that individuals having a single claim amount in excess of the maximum monthly cap that would apply under the payment plan stand to benefit from participation.

Humana Comment: We commend CMS for offering additional details on how the agency envisions the efforts necessary by plan sponsors to target Part D enrollees who will “likely benefit” from participation in the payment plan. **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 continue to encourage CMS to develop as much model language and standardized communication materials as possible to allow for similar participation elections to occur across plan sponsors during the 2025 AEP.

As CMS considers the tools needed for enrollee outreach, we encourage the agency to focus on the robust communication needs that will be necessary to support this program. We recommend that CMS to establish a standardized set of key terms relating to the payment plan along with model language that can be employed by Medicare plan sponsors, pharmacies,

patient advocates, and other stakeholders charged with facilitating use of the payment plan. The model language should include information on when enrollees would benefit, when enrollees would not benefit, how to opt into the program, the expected experience at the pharmacy counter, how program participation impacts the Part D benefit, and financial implications of payment plan participation. From an enrollee communications perspective, it will be critical for CMS to develop payment plan materials that include the following:

- **Examples of who may and may not benefit from payment plan participation:** As discussed in Part one of the guidance, there are some enrollee populations who will not benefit from participation – and in many ways cost-share smoothing for those enrollees could even be detrimental. Therefore, CMS should create clear examples of who may benefit from payment plan participation (i.e., those who hit the maximum out-of-pocket cap, or MOOP, in the first half of the year) and those who may not benefit (i.e., those with already predictable costs).
- **Materials on how and when to opt into the payment plan:** CMS should develop educational materials on the program that emphasize the importance of opting into the payment plan prior to the coverage year. We believe that mid-year and mid-month opt-ins will create increasingly complex experiences for participants; therefore, participation elections prior to the start of the coverage year will minimize potential issues before the enrollee goes to the pharmacy counter or receives a bill from a plan sponsor.
- **Anticipated experiences at the pharmacy and payment plan bills from plan sponsors:** Program participants will have a new experience at the pharmacy counter (i.e., cost-sharing is not collected by the pharmacy, inclusion of only covered Part D drugs) and will now receive new bills in the mail from their plan sponsor. There needs to be clear communications, with examples provided, about how the experience for enrollees is likely to play out – so they know what to expect if they choose to opt into this new benefit.
- **Clear explanations of financial implications for enrollees:** Enrollees will need very clear communications about the financial implications of payment plan participation and their responsibilities should they opt in. We are particularly concerned about cost-share bills at the end of the year that could put additional financial pressure on participants.
- **Model Materials:** We recommend that CMS develop targeted model language for inclusion across the following resources:
 - Evidence of Coverage documents;
 - Explanation of Benefits;
 - Plan Annual Notice of Change;
 - Examples of billing statements under the Medicare Prescription Payment Plan including information on how the bills may fluctuate over the course of the year;
 - Notices provided to members at point-of-sale who are “likely to benefit” from participation;
 - Explanation of the Medicare Payment Plan and the Low-Income Subsidy program including who is most likely to benefit from each program; and
 - Notice of approval/denial for payment plan participation.

In addition to the more general enrollee communication needs, targeted outreach will also be essential in ensuring that enrollees who are likely to have a high OOP claim are aware of the payment plan. Pursuant to relevant sections of the IRA, plan 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 participation in the payment plan. CMS

has 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 payment plan participation and a dollar threshold in this range should thus be the trigger for a plan sponsor to notify a pharmacy of the potential payment plan benefit to an enrollee. **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 recommends using a \$700 threshold for the first year of the program.** In advance of the 2025 AEP, Part D enrollees will receive multiple communications informing them of the new payment plan option and highlighting their opportunities to enroll.

Additionally, CMS should take into account specific nuances with mail-order pharmacies and other closed-door pharmacies as it relates to education on the payment plan. The pharmacy should not be required to educate the member on the payment plan 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 payment plan in the packaging when the member hits the threshold.

While we believe a point-of-sale notification to pharmacies can rightly supplement the direct communications to enrollees, establishment of the notification protocol requires meaningful changes to the pharmacy workflow. CMS has indicated that additional details on the pharmacy notification process are forthcoming in Part Two of the guidance on the payment plan. We are concerned that these details are anticipated for release less than 12 months before the point-of-sale notification process must be in place and we would encourage the agency to share more information as soon as possible.

Section 70. Requirements Related to Part D Enrollee Election

CMS sets parameters on enrollee elections for payment plan participation, including at the time of plan selection and throughout the plan year. Part D enrollees must be given a paper form option, a toll-free phone number, and a web-based process. Part D plan sponsors must also have a process to effectuate a retroactive election into the payment plan when an enrollee has certain urgent prescription fill(s) for which they paid the associated cost sharing before the enrollee's payment plan election was received and processed.

Humana Comment: At the macro level, Humana agrees with CMS that low-income subsidy (LIS) enrollees are unlikely to benefit from participation in the payment plan. We appreciate that CMS is trying to consider how to appropriately educate enrollees on both the payment plan and the LIS program. However, we are concerned that communications about these two programs in parallel could be confusing to beneficiaries and could lead them to confuse elements of the two programs. Considering that complexity, we believe it is important to have standardized language explaining the two programs and request that CMS provide specific model language on how plan sponsors should communicate such information to enrollees. Additionally, we think it would be beneficial for CMS to develop a survey tool that could be included as part of enrollee tools like Medicare Plan Finder to help members determine whether the LIS, payment plan, or normal cost-sharing is the best fit for them.

Humana supports CMS's proposal to provide beneficiaries with multiple options for electing into the payment plan including through the enrollment process, on the plan's website, via phone, and through a paper application. As we have shared previously, we believe that it is

imperative to identify the beneficiaries who are most likely to benefit from the payment plan in advance of the coverage year. Humana also encourages CMS to update the associated plan enrollment forms to ensure that enrollees are required to submit their payment information as part of opting into the payment plan. We also appreciate CMS's efforts to align the requirement for the payment plan with the current requirements for enrollment in a Part D plan. This will help in streamlining new operational complexities.

Additionally, **Humana believes that the 24-hour processing timeline proposed by CMS for mid-year participation elections is feasible. Despite that, we are concerned about the potential volume of such elections and therefore would recommend that this timeline is reserved only for specific scenarios.** This could include scenarios in which the enrollee hits the MOOP on first fill, where they exceed the \$700 claim limit and are therefore "likely to benefit" from the payment plan, or other unique scenarios that would warrant a mid-year and mid-month election that is effective within 24 hours. In all other instances, plan sponsors should be able to give enrollees an option as to when the payment plan participation takes effect. We suspect some enrollees may benefit from an immediate election, such as those who are seeking to fill a prescription with high OOP costs. On the other hand, others may not have an urgent need and will prefer a program start date and associated billing that aligns with the beginning of the next calendar month. Furthermore, CMS should ensure that there are exceptions to this timeline for participation requests that are not processed electronically or telephonically as we foresee situations in which it will not be possible to process a paper-based election received via fax transmission within the proposed 24-hour timeline.

Humana appreciates that CMS wants to offer some limited subset of beneficiaries the option to retroactively elect in the program. **However, we do not believe that retroactive elections can be supported in the first year of the payment plan.** We are concerned that the payment plan already presents an overwhelming number of operational complexities and retroactive elections would only exacerbate those challenges. Given that, we urge CMS to study the trends in the payment plan through the initial year and determine if there is a need for retroactive elections starting in 2027, after the agency has been able to collect at least a year's worth of data on the program, before establishing retroactive processing requirements for plan sponsors. If CMS believes that it is essential to offer retroactive elections in 2025, the agency should provide details as to when plan sponsors would be required to retroactively activate participation in the program, including examples as to how the agency expects the plan sponsors to provide refunds for any incurred costs and how the cost-share bills should be generated.

Furthermore, Humana supports CMS's decision to exclude a point-of-sale election in the payment plan in 2025. We understand that the agency would like to explore the opportunities to establish a point-of-sale election process in 2026 and beyond. Once again, we believe it is important to collect data on the uses and trends in the payment plan for at least one full year before establishing additional requirements. Further, we believe any development of a point-of-sale solution should be done with robust stakeholder engagement and advice from the third-party standard setting organizations, like NCPDP, as part of that process.

Finally, **Humana supports CMS's policy that a member must opt into the payment plan with each plan sponsor if the member changes plans mid-year. We also believe that it is appropriate for a member to be required to opt into the payment plan annually especially during the first several years of the program.** Each plan is likely to have different billing policies

and operational requirements and the beneficiary should be given the opportunity to fully review the terms of the payment plan prior to opting into it.

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

Part D sponsors must have a process to allow a participant who has opted into the payment plan to opt out during the plan year. Sponsors must continue to bill amounts owed under the payment plan in monthly amounts not to exceed the maximum monthly cap according to the statutory formula for the duration of the plan year after an individual has been terminated. The Part D sponsor may also offer the participant the option to repay the full outstanding amount in a lump sum but may not require full immediate repayment.

CMS sets standards for necessary communications associated with involuntary terminations and establishes a minimum grace period before which involuntary terminations will not be allowed. CMS also stipulates that plan sponsors may only preclude an individual from participating in the payment plan in a subsequent year if that individual has outstanding payment plan balances that are unpaid.

Humana Comment: We concur with CMS that program participants should have the ability to opt out of the program during the plan year. Although we recognize that there are limited scenarios in which an enrollee may elect payment plan participation and then later wish to voluntarily termination participation, it will be important to set limits on the ability of enrollees to change their elections during the coverage year. Because the payment plan program represents a substantial operational hurdle for plan sponsors, we suggest CMS limit the number of affirmative elections on payment plan participation in each year to one. In other words, an enrollee who elects to participate but then terminates participation would not be permitted to make another election to participate later in the year.

We also 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 comments, we recognize that 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. For example, **CMS should preclude participants who do not submit their monthly payment or are terminated from the payment plan for non-payment from making future payment plan elections with other plan sponsors.** This would require CMS to allow for data sharing between plan sponsors on those enrollees who have been termination from the program due to non-payment of their monthly billed amount to ensure that plans are made aware of newly-electing members who have been termed from the payment plans for non-payment to other plan sponsors. This is not unlike data that CMS shares between plan sponsors today on the Late Enrollment Penalty (LEP). At a minimum, CMS should establish a process for the agency to collect data on non-payment in the payment plan as it relates to participant behavior and unpaid cost-sharing bills in order to identify potential changes in the future that would incentivize participants to pay billed amounts.

In this vein, we are likewise concerned about the proposed two-month grace period when an individual has failed to pay the billed amount by the payment due date. **We believe it is more appropriate to have a grace period that does not exceed 30 days.** The proposed two-month standard could result in plan sponsors holding the full balance of a participant's incurred costs for three months or longer. We encourage CMS to revisit the proposed standard in such a way that protects a participant's participation status while also incentivizing timely payment of billed amounts.

Lastly, **Humana encourages CMS to explore opportunities to support plan sponsors financially should the uptake and unpaid cost-sharing bills from the payment plan be greater than expected.** Prior to the first year of the payment plan in 2025, plan sponsors will not have any experience with this type of program to reflect in their bids. As experience builds over time, plans will be able to more appropriately estimate expected costs associated with non-payment. We believe that establishing a transitional financial support program could limit significant outliers in the bidding process that would increase the overall cost for beneficiaries through higher premiums, and the Medicare program, through increases in the direct subsidy.

Section 90. Participant Disputes

CMS proposes to require plan sponsors to apply their established Part D appeals procedures to any dispute made by a program participant about the amount of Part D cost sharing owed by that participant for a covered drug. Likewise, CMS indicates that Part D sponsors must apply their established Part D grievance procedures to any dispute made by a program participant related to any aspect of the payment plan, including election requests, billing requirements, and termination-related issues other than disputes related to the amount of Part D cost sharing owed by that participant for a drug.

Humana Comment: We appreciate CMS's effort to provide an initial indication on how participant grievances and appeals should be handled by plan sponsors under the payment plan program. However, there remains a need for additional details on how CMS expects plan sponsors to classify and respond to disputes made by program participants and potential participants.

For example, Sections 70.3.4 and 70.3.5 of this proposed guidance sets standards on how plan sponsors must consider participation requests and parameters on approving and denying participation requests. CMS indicates that participation denials must be accompanied by a description of the grievance process available to the individual but is silent as to whether such a denial may be subject to an appeals process. **We encourage CMS to provide a more comprehensive set of standards on participant disputes to be used by all plan sponsors. Absent such standards, there is the potential for inconsistent application of grievance and appeals rights across plan sponsors.**

What are the guidelines if a participant should expire while taking part in this program?

My input as a Medicare senior is as follows:

1. If you truly want feedback, write these documents in much simpler to read and understand language.

I want to know in simple language “what will this mean for me?”

Get the people who write the annual Medicare guidebook to write the language. They understand the need for language simplicity for us seniors and they’re good at it!

2. Spreading out part d costs throughout the year is nice, but not the real help we need! We need lower prescription costs, and not just a few drugs to be lowered every year starting in a few years. We need bold moves to be made to get overall prices down now!!! Like President Biden campaigned on! We need Medicare seniors to be able to use manufacturer’s discount cards!!!! Why is this denied to the people who need it most????? This is just morally wrong.

3. Spreading out costs doesn’t really help us afford our meds. It just kicks the can down the road. We can’t afford them now, we can’t afford them later. THAT is what you need to understand.

Sincerely,

[REDACTED]

Good afternoon. Would it be possible for the monthly payments to be automatically taken from their Social Security or Railroad retirement benefits. I believe that the monthly payments are going to be an issue. Also will there be a trial run with a few beneficiaries to see if it works?

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

People over 65 with disabilities should not have to pay for medicine to benefit their health and to help them continue living a normal life period!!!

Good morning,

After reading the recent publication on the Medicare Prescription Payment Plan details, I wanted to add some feedback that didn't seem to be addressed. Has thought been given to Medicare Advantage Members that may change plans mid year for the case of a special enrollment period such as out of service area or moving to a 5 star rated plan? Will they continue to be billed by the former insurance sponsor and also the new insurance sponsor if they elect the Medicare Prescription Payment Plan, or would the former payment plan transfer to the new insurance sponsor to keep numbers accurate? I realize 2025 is still over 16months away, but I like to stay up to date with changes early to be able to effectively explain to my members clearly.

Thank you,



I personally think that giving Medicare beneficiaries the opportunity to pay a monthly billed amount rather than the full cost at one time is a good idea.

Would it be possible for any Medicare beneficiary to set up something like a Flexible Spending Account with a variable allocation from their monthly Social Security check up to an annual limit? CMS could create a calculator that would help the beneficiary determine the appropriate amount based on prior pharmacy utilization. Any amounts unused could roll over toward the next year's expenses.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Hello,

Thank you for considering my comments in response to the Medicare Prescription Payment Plan Guidance draft. I am a pharmacist at [REDACTED] and oversee a large team (pharmacists and technicians) that assist patients with medication access and financial assistance. In addition I teach the 1st year pharmacy students about Medicare Part D and assist over 100 patients each open enrollment season to ensure they are in the best plan for the year.

I am a part of [REDACTED] who recently provided an excellent representation of thoughts for this program. I would like to provide a few more key points as a pharmacist working with Medicare Part D patients on drug cost each day.

1. Pharmacies recommended to Provide education to patients at point of sale on options for the MPPP - most pharmacists in retail barely have enough time to take a lunch break. In addition these conversations will be very indepth. Today, a Part D outreach is typically 30 min – 1hr long depending on the patient. If this is a requirement for pharmacists we should be reimbursed for our services and improve staffing models to provide such service (along with MTM).
2. Patients do not start medications at the same time so there will be ongoing bills which will lead to confusion in a population that already has a difficult time navigating the health system. Many of our patients are also on 10+ medication which also adds to the confusion of monthly bills. Patients may also get confused when switching plans at the end of they year and getting bills from multiple health plans the following year.
3. Patients often feel meds "don't work", had a reaction and stop, provider discontinued med or a patient passes away. Given my experience with patients trying to get reimbursed for these situations today (pharmacy unable to take back after medication is sold), I suspect patients will refuse to continue paying. I understand there is guidance to protect the patient and provide grace periods but there seems to be no incentive to pay (future participation in the program doesn't seem that harsh) we have many oncology

patient family members who request reimbursement when their loved one pass away due to the steep price of medications.

Thank you for considering my concerns. I believe there is still a long way to go to make this program realistic but look forward to helping our patients afford their medications in a manner that does not put further stress on the patients/providers/pharmacists. Please reach of for further questions or if you would like to watch a part D visit this open enrollment season.

Best,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1. Include messaging on ANOCs and MSNs. Send easy short instructions and messaging for providers to use with beneficiaries.
2. See above. Create and provide a short and long version for provider use. We believe that the POS guidance and ease of use is crucial. SHIPS add to any outreach on Medicare topics. Create and provide fact sheets for SHIPS to use.
3. States add to existing outreach materials. Add link to Medicare.gov website on the topic. SHIPs add message to their local websites and social media.
4. SHIPs add messaging to all approved outreach materials: power point presentations, handouts, etc.
5. Request that SHIPs be kept in the loop as the plan proposal progresses.

From: [CMS PartDPaymentPolicy](#)
To: [OOP Smoothing Comments](#)
Subject: FW: New format response
Date: Tuesday, September 19, 2023 10:03:20 AM
Importance: High

-----Original Message-----

From: [REDACTED]
Sent: Tuesday, September 19, 2023 9:59 AM
To: CMS PartDPaymentPolicy <PartDPaymentPolicy@cms.hhs.gov>
Subject: New format response
Importance: High

This is the most confusing and ridiculous payment policy I have ever seen. You should send information to consumers that can easily be read and understood. Just as everything you create it is mind boggling.
I've had enough!

[REDACTED]

My name is [REDACTED]. For the purpose of this comment, I have two roles. I am a citizen advocate, I am also employed as an Independent Living Specialist and represent [REDACTED]. [REDACTED] is a center for independent living that serves north central Montanans with disabilities. The best comment I can offer CMS and ACL is to keep offering those things sessions that you're about to embark upon. I think the comment for this request on part D Medicare and drug pricing CMS would have served Americans with disabilities and those with chronic conditions to have opened this RFI until after the listening sessions were complete.

My center for independent living works with citizens that are on Medicaid, Medicare, and or dual eligible. I find that having them go to SHIP is a better opportunity than what I can give them at the cils but it doesn't mean that cils don't have a role to play in helping citizens navigate these services. Oftentimes, in north central Montana as [REDACTED] and our local [REDACTED] County Area on Aging tried to form aging and disability resource

centers and network partnerships it was really hard to break down silos for both drug pricing and services.

As this policy change will those help dual eligibility who are both on Medicare and Medicaid and particularly Medicare. [REDACTED] advocates that all drugs go through this process because it is hard for people with disabilities to get access to the newest drugs and trials to see if their co occurring or other health conditions that they may be facing as Americans with disabilities can be worked on. [REDACTED] is hoping that those who are only on Medicaid and private insurance will benefit from this future policy. As a citizen advocate, [REDACTED] also worries that Qualys or Quality Adjusted Life Years dealing with people with disabilities particularly IDD in the medical community when dealing with prescription drugs. policies with negative impacts or potentially discriminatory impacts regarding medical care could come in to play when dealing with prescription drugs and services. Thank you for allowing me to submit these comments and [REDACTED] does hope to participate in future town halls regarding prescription drug pricing and citizens with disabilities.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Good Day,

Which model documents or other materials CMS should develop or update: Post cards with clear explanations of the program that can be handed out or mailed, flyers, radio advertisement, social media and Power point presentations.

How to most effectively conduct outreach and education about the program: Outreach to Adult communities with an emphases on the underserved and vulnerable populations, educating community based organizations and use resources that are already available.

How to leverage existing resources, including the SHIP: Execute training programs for SHIP counselors to provide the information to beneficiaries through counseling, publications, outreach, health fairs and online platforms.

How to communicate about overlapping programs: Continue to screen Medicare beneficiaries for LIS and Medicare Savings, PAAD/Senior Gold adding the new program seamlessly by detailing the requirements and parameters of the Medicare Prescription Payment Program.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Based on review of August 21, 2023 publication from Meena Seshamani regarding monthly cap and cost sharing payments.

Medicare Prescription Payment Plan

1. Section 30 talks about monthly payment calculations. Is deductible calculated into this monthly cost and does the deductible accumulate towards the 2000.00 max OOP? Paragraph 2 addressed deductible phase cost but does not go far enough to identify how deductible fits into the 2000.00 max OOP. I am thinking deductible is separate but if so, how is it calculated in the 2000.00 cap?
2. I work with a lot of clients that utilize the PAN or HealthWell Foundations, which are 501C independent non-profit organizations providing financial assistance. Currently when these grants are utilized the pharmacy first bills the Medicare prescription plan and then the grant is billed to pick up the remaining cost for a 0.00 co pay to the patient. How will this new system work in calculating cost and then in billing? Page 15 indicates the transaction to Medicare Prescription payment plan would be billed last. Currently, patients utilizing the above noted foundations must have the transaction billed first to Medicare prescription plan to determine Medicare cost that is then billed over to the foundations. How will this work in the new system? I think page 17 may clarify this.
3. How will the Medicare Prescription Payment Plan work with those obtaining medication from a 340 B program? How is initial payment plan determined and how would it be billed?

Current thoughts and concerns:

1. Having all the details in the simplest of terms for our Medicare patients is of utmost importance.
2. I would anticipate that drug formularies will tighten up in order to save money on the payor side. This will result in the need for more prior approvals, denials and appeals on the outpatient side.

3. This is a lot of reading and I apologize if I missed something that might have answered the above questions.

4.

[REDACTED]

From: [CMS PartDPaymentPolicy](#)
To: [OOP Smoothing Comments](#)
Subject: FW: Medicare Prescription Payment Plan Guidance
Date: Wednesday, September 20, 2023 9:56:50 AM

From: Adam Pavek <Adam.Pavek@co.itasca.mn.us>
Sent: Wednesday, September 20, 2023 9:57 AM
To: CMS PartDPaymentPolicy <PartDPaymentPolicy@cms.hhs.gov>
Subject: Medicare Prescription Payment Plan Guidance

Please see Itasca Medical Care's comments regarding the Medicare Prescription Payment Plan Guidance.

- CMS should provide guidance and scenarios for POS COB method and consider the COB transaction and costs at the POS. The current complexity of implementing this change will likely cause significant provider and beneficiary confusion and potential delay in services.
- The LIS member example (B7) in the new guidance illustrates how the current smoothing methodology makes it more challenging for the LIS population to benefit under this rule. While we understand the Act states smoothing must be offered to all members, some members could actually be hurt rather than helped by the rule. If the member in the example did not opt into the program, the member would have had a consistent payment of \$18 per month. However, if the member opted in, they would end up owing \$54 in December. For the low-income population, this is a substantial increase in their monthly payment and could make it harder on this population. We would ask CMS to consider excluding the LIS population from this program given the unintended consequences of the program.
- We ask CMS to consider excluding the D-SNP populations from the Out-of-Pocket smoothing program. In some instances, a member could lose their LIS status for a short period of time but then retro-actively return to their LIS status. A change in status would create significant administrative complexity and potential confusion for the members under this program. We recommend CMS excludes all D-SNP members from this program.
- If CMS is not able to exclude the DSNP population, we highly recommend that CMS expand the VBIID program to allow plans to cover all D-SNP copayments rather than limit the flexibility to the LIS population or specific disease states. This would allow all the cost sharing to be covered for the D-SNP populations and the need for the Out-of-Pocket smoothing program would be eliminated for the population.

To Whom It May Concern:

Please find the questions/suggestion per your request:

- 1) How will unpaid participant bills be handled during participation in the Cost Sharing Payment Program? Specifically, if a participant fails to pay their bill and the participant is terminated from the program, who bares the risk of the unpaid bill, the Sponsor or the dispensing pharmacy?
- 2) Guidance should be provided to Sponsors such that they cannot perform any direct or indirect recoupment/claw back from the dispensing pharmacy for any unpaid Participant charges generated through claims adjudicated while Participant is in the Program.
- 3) The Participant non-payment grace period should be at least 3 months
- 4) Provide guidance, tools and literature to all Part D enrollees (and Sponsors/brokers) regarding LIS in order to identify if enrollees are eligible prior to enrollment for the new benefit year. Ideally, a system to auto-enroll Part D participants in LIS would be the best option.

Regards,

Tom Wells

CFO

twells@ivsolutionsrx.com | ivsolutionsrx.com

P:844.650.5802 | F:844.277.0049

JUSTICE IN AGING

FIGHTING SENIOR POVERTY THROUGH LAW

September 20, 2023

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

Re: Medicare Prescription Payment Plan Guidance

Justice in Aging appreciates the opportunity to provide feedback on the Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans (or Medicare Prescription Payment Plan): Draft Part One Guidance (MPPP Guidance).

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.

20. Overview

- *Which model documents or other materials CMS should develop or update*

We recommend that CMS develop model language that can be incorporated into other Part D materials to explain the MPPP in very simple terms. As discussed below, we commend CMS for requiring messaging around LIS to people interested in the MPPP. Initial outreach should focus on “help with prescription drug costs” where both MPPP and LIS can be advertised together.

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 someone with Medicare Part D. 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.

- *How to most effectively conduct outreach and education about the program*

We appreciate the proposals throughout the guidance to use multiple existing opportunities to conduct outreach and education on both the MPPP and LIS. 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. As discussed elsewhere in these comments, we recommend using as simple of messaging as possible about getting help with prescription drug costs and avoid leading with names of programs that people likely

Washington, DC



Los Angeles, CA



Oakland, CA

don't know or identify themselves as needing or qualifying for. Messaging should also make clear that there is no additional cost for using the MPPP and that the \$2,000 OOP cap applies.

It is critical that CMS test messaging and outreach strategies among diverse populations and ensure there is tailored messaging for underserved communities, people from various racial and ethnic communities, and people with limited English proficiency (LEP). Too often we see disparities in who enrolls in programs like these due to inadequate outreach and lack of translated information. **We strongly urge CMS to translate consumer-facing educational materials into languages beyond English and Spanish.** Community based organizations (CBOs) are the trusted messengers for many people with LEP, and often the only source of in-language assistance. The CBOs do not have the resources to translate these materials themselves. CMS should also proactively reach out to CBOs serving people with Medicare to make them aware of the MPPP and other new Inflation Reduction Act provisions so they are equipped to do outreach in their communities.

- *How to leverage existing resources, including the State Health Insurance Assistance Program (SHIP)*

SHIP counselors, Medicare Patrol, Area Agencies on Aging, care coordinators, social workers, legal aid attorneys, CBOs and others who interact directly with Medicare enrollees will play a very important role helping people learn about the MPPP and make the decision whether to enroll. Materials should be developed to help these individuals explain the MPPP and how it interacts with LIS and other assistance programs to Medicare enrollees. 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.

- *How to communicate about overlapping programs (such as the Low-Income Subsidy and Medicare Savings Programs)*

We recommend CMS pursue an outreach and education strategy that always includes both LIS and MPPP under the single umbrella of help with prescription drug costs. An individual should not have to choose which program to learn more about at the outset but rather should be able to explain their needs and be directed to LIS and/or MPPP accordingly. Educational materials should also direct individuals to find out more information about the Medicare Savings Programs as well. The [Medicare.gov “Get help with costs” page](#) provides a good example of how to group information about various programs together.

70.2 Interactions Between LIS and Medicare Prescription Payment Plan

We commend CMS for using the MPPP as an opportunity to educate on and increase enrollment in LIS. The LIS provides significant financial benefit to people with low-incomes and, as CMS notes, LIS enrollment is more advantageous than MPPP alone. **We strongly support CMS's proposals to require Part D sponsors to inform individuals who are either interested or enrolled in the MPPP about LIS and how to enroll.** We also recommend that people who lose LIS eligibility receive targeted outreach about the MPPP.

We agree with CMS that the circumstances in which MPPP enrollment will benefit LIS enrollees are limited. However, many people with limited income have multiple chronic conditions that may require

multiple prescriptions. The MPPP may benefit these individuals when they experience an acute illness and are prescribed additional drugs or are changing drug regimens mid-year. Even when cost-sharing for an individual drug is low, adding yet another co-pay or two in a month can be a financial burden for someone living on a fixed income. The MPPP may help spread those additional few dollars out over a few months. Therefore, we urge that CMS not discourage outreach and education on the MPPP to people eligible for LIS. Rather, the focus should be on creating educational tools such as worksheets and examples that help individuals understand how the program would impact their costs.

We realize that education around the implications of joining the MPPP may be difficult to explain to someone enrolled in or potentially eligible for LIS. We foresee value in tools that clarify the LIS benefits first and then explain MPPP in terms of how it would or would not provide additional benefit. We recommend using simple examples to illustrate how the MPPP would impact OOP costs for a person with LIS. Seeing Examples B7 and B8 in the appendix, the educational tools should emphasize to LIS enrollees interested in the MPPP that OOP costs could go down and then rise again in the following months to above what they would pay without enrolling in the MPPP.

80.2.1 Notice Requirement

We recommend that CMS require the MPPP termination notice to include information about applying for LIS. We support this requirement in the initial notice and believe it is important to reiterate in the termination notice as individuals may not have read the initial notice. If they are terminated for nonpayment, they may be experiencing financial hardship and be eligible for LIS.

80.2.2 Required Grace Period and Reinstatement

We strongly support requiring a grace period of at least two months before termination and requiring reinstatement after a showing of good cause for nonpayment. We recommend CMS provide examples to illustrate good cause, such as not receiving the required notices.

100. Data Submission 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.

Conclusion

Thank you for the opportunity to provide feedback . If any questions arise concerning this submission, please contact Natalie Kean, Director of Federal Health Advocacy, at nkean@justiceinaging.org.

Sincerely,



Amber Christ
Managing Director of Health Advocacy

September 20, 2023

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

Submitted electronically to: PartDPaymentPolicy@cms.hhs.gov

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

Dear Dr. Seshamani:

Kaiser Permanente appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on draft guidance related to implementation of the Medicare Prescription Payment Plan (MPPP), released for public comment on August 21, 2023. The Kaiser Permanente Medical Care Program¹ is the largest private integrated health care delivery system in the United States, with more than 12.7 million members in eight states and the District of Columbia. Kaiser Foundation Health Plan, Inc., one of the nation's largest not-for-profit health plans, and all our health plan subsidiaries are Part D plans, serving a total of more than 1.8 million Medicare beneficiaries. Kaiser Permanente's mission is to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve.

We strongly support the comments submitted to CMS by America's Health Insurance Plans (AHIP) in response to this solicitation, which offer a series of recommendations to better operationalize the MPPP. In particular, we wish to highlight the following:

- **Timeliness of guidance.** We recommend that CMS provide final part one guidance and draft guidance on bids and potential plans losses as soon as possible, but no later than December 31, 2023. Additionally, we recommend that CMS issue the draft part two guidance with a comment period by no later than December 31, 2023, and issue the final part two guidance and all related model materials by April 1, 2024 to ensure plans have sufficient lead time to operationalize revisions to existing beneficiary materials.
- **National communications strategy.** We recommend that CMS develop and launch a uniform, national communication strategy to educate Medicare enrollees and relevant stakeholders (e.g., pharmacies, providers, State Health Insurance Plan counselors, agents and brokers) about the MPPP. This strategy should include updated model materials (e.g.,

¹ Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc. and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 39 hospitals and more than 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.

Annual Notice of Change, Evidence of Coverage, Explanation of Benefits) with standardized language and consistent terminology across documents to reduce beneficiary confusion around the MPPP.

- **Streamlined enrollment.** We recommend that CMS allow Part D plans to incorporate MPPP election into existing Part D enrollment forms, as collecting this information through the initial enrollment application will improve efficiency and shorten turnaround times for processing via automated enrollment systems already in place. We also recommend that CMS clarify that a beneficiary's election into the MPPP can continue to the following year—allowing beneficiaries to carry over their election into the next year, rather than making a new election each year, would further reduce administrative burden. In addition, we recommend that CMS extend the timeframe for processing election requests to at least 72 hours for plan year 2025.
- **Plan flexibility.** We strongly encourage CMS to provide Part D plans with flexibility to operationalize the MPPP where possible, such as in identifying members likely to benefit from the MPPP in advance of the plan year, choosing whether to issue their members a consolidated billing statement with monthly premiums vs. two separate billing statements for monthly premiums and amounts owed under the MPPP, or billing a member in full vs. providing them with payment plan options if leaving the MPPP during the year with an outstanding balance. We also strongly support CMS in excluding paper claims from the MPPP.
- **Employer group waiver plans (EGWPs).** We recommend that CMS use its waiver authority to exclude EGWPs for the initial years of the MPPP, as EGWPs generally offer a lower overall out-of-pocket cost including for prescription drugs. Individuals enrolled in EGWPs are therefore not likely to benefit from the MPPP, and the costs for operationalizing the MPPP for these plans could have adverse impacts on benefits and/or premiums for beneficiaries.
- **Enforcement.** Given the complexity of this new program, we recommend that CMS apply enforcement discretion in plan year 2025 for good faith efforts made by plans to meet election processing deadlines and address participant disputes. CMS should also 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.

* * *

Kaiser Permanente appreciates CMS' consideration of these comments. Please contact Greg Berger at gregory.b.berger@kp.org if we may provide additional information or answer any questions.

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

Lumeris appreciates the opportunity to respond to the Centers for Medicare & Medicaid Service's (CMS) *Medicare Monthly Payment Program Draft Guidance – Part 1*. Lumeris supports CMS' strategic vision and its core principles of person-centered care through its operation of Essence Healthcare's plans and as a leader in value-based care solutions for provider systems. As an organization, Lumeris is dedicated to the idea that radical change in health outcomes and performance occurs by placing patients at the center of care and decisioning, support by committed provider, payers, and technologies moving synergistically toward the goal of improving and maintaining a patient's health. Our commitment to our Essence members is the same – high quality care can be accessible and affordable to all beneficiaries when supported by value-based agreements that drive both quality outcome measures and cost management.

We applaud CMS for their continued dedication to reduce barriers in accessing care and creating approaches to make the costs of care more manageable for the populations we serve. We welcome the agency's openness to stakeholder input and ongoing commitment to improving health care for all Medicare beneficiaries. Below is feedback from Lumeris team members and key stakeholders regarding various provisions of the rule.

While we appreciate the intention behind separating the invoicing of monthly plan premiums from payments due as a part of the monthly payment program (hereafter referred to as the "program"), we believe that sending multiple invoices to enrollees could result in confusion, increase probability of failure to pay due to that confusion, as well as unnecessary administrative costs for payers. Sending a singular, itemized bill to the enrollee that encompasses all amounts due to their health plan would provide a seamless experience that aligns with billing practices they are familiar with. Since CMS has already stipulated in the draft guidance that monies received should apply first to the Part D premium (especially in instances where plans opt to disenroll members from the health plan for failure to pay the premium), there does not appear to be a strong or compelling reason to separate the billing. We are also concerned a member could interpret the bill as a duplicate, potentially resulting in failure to pay either the amount due on their premium or their monthly program invoice. **We recommend that CMS consider allowing payers the option to consolidate the bills would improve the member experience as well as cut down on unnecessary print, mail, and administrative costs.**

In the draft guidance, "CMS reminds Part D sponsors that actions to collect unpaid debt related to the program may be subject to other applicable federal and state laws and requirements. Additionally, CMS is considering specific requirements related to debt collection for amounts due under the program and requests comment." **We believe that CMS should clearly outline in the final guidance whether the use of collections is an appropriate remedy for non-payment and if there are any specific guidelines associated with using collections.** While the program represents an important step to making the cost of prescription drugs more manageable, the risk is also transferred to the payer who is assuming the upfront costs of Part D payments. Collections should be a last resort; however, it is essential that the option remain available given that payers have no other recourse to recoup dollars other than continued billing, which may not result in repayment. **We believe that payers should be afforded reasonable and appropriate recourse to ensure repayment of any outstanding amounts owed as a result of the program in an effort to protect the Medicare trust fund dollars entrusted to Medicare Advantage and Part D plans.** Effective stewardship will be essential to ensuring that the program is managed in a manner that will promote longevity.

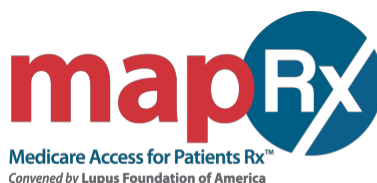
We understand the intent behind the differentiation in the draft guidance with failure to pay program payments versus failure to pay plan premiums. Many payers may elect not to disenroll enrollees for failure to pay plan premiums, especially given the relatively affordable premiums offered by many Part D plans. The financial risks assumed by payers as a part of the program may represent significantly greater costs compared to the risks from non-payment of plan premiums. A single fill of a high-cost drug may vastly exceed the cost of a single month's unpaid premium. With the minimum proposed grace period of three months, the total cost incurred before a payer could involuntarily remove an enrollee from the program could be significant, depending on the cost of that enrollee's medications. **We would encourage CMS to take this into consideration when finalizing policies around non-payment to ensure that payers are provided reasonable protections, or that such non-payment is accounted for through CMS' payments to MA payers.** With respect to reinstatement, we appreciate the goal of offering payers the ability to preclude an individual from the program in instances of non-payment; however, we believe permanent preclusion from the program should be available when a pattern of non-payment has been identified. Such recourse would strike a balance between instances where there is a one-off payment issue and instances where a program participant routinely fails to pay their outstanding balance.

In response to CMS' request for comment on model documents and continuing with the theme of potential member confusion, we are concerned that current Part D Explanation of Benefits (EOB) models do not account for deferred payment and could present confusion to enrollees trying to interpret their costs. The EOB reflects Part D enrollee benefit cost-share and accumulators, whereas the invoice for the program will reflect the amount owed monthly through the program. **We suggest that CMS consider adding new verbiage to the Part D EOB** to advise members that the EOB will reflect the total amounts of their cost-share associated with the dispensed drug, but that if they are enrolled in the program, they will receive a separate invoice that reflects their payments owed as a part of the program. CMS should clearly state that those amounts will differ from the amount shown on the EOB due to splitting the cost over the entire plan year. An alternative approach would be for CMS to develop a methodology that would connect the amounts displayed on the EOB with the monthly amounts associated with the program payments.

We request that future guidance released by CMS address how payers should handle retroactive adjustments to member cost-sharing and Low-Income Subsidy (LIS). Given that adjustments may occur at various points throughout the year, we recommend that CMS provide clear guidelines on how plans should approach those scenarios to ensure all payers apply the same logic to all enrollees. For example, if an adjustment is made early in the year that could result in a refund to the member, should a payer credit that amount against future Part D claims or should they issue a refund payable to the member? We believe addressing such questions proactively will reduce enrollee confusion and mitigate differential treatment of enrollees across payers.

With respect to point-of-sale (POS) enrollment mechanisms and eligibility file changes that will be required to support the program, **we would encourage CMS to finalize guidance as promptly as possible to ensure that payers, pharmacy benefit managers (PBMs), and pharmacies have adequate time to build out the technological capabilities necessary to support the program.** Less than a year is already a rather short timeframe to conduct an implementation, ensure appropriate testing to prevent issues, while also focusing on educational efforts to ensure enrollees know how to leverage the program. While some of the infrastructure is in place, until guidance is finalized, these parties may not be able to dedicate the necessary resources to development. Additionally, any places where CMS can provide standardization in formats would mitigate confusion and difficulty in implementing across PBMs, payers, and pharmacies. **It is essential that CMS,**

payers, PBMs, and pharmacies are all moving synergistically towards the same goal to ensure a positive experience for enrollees who opt into the program January 1, 2025.



September 20, 2023

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
200 Independence Avenue SW
Washington, DC

Submitted via PartDPaymentPolicy@cms.hhs.gov

RE: Medicare Prescription Payment Plan Guidance

Dear Dr. Seshamani:

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 ***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***, published on August 21, 2023.

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 Maximum Monthly Cap on Cost-Sharing Payments Program.

MAPRx appreciates the opportunity to comment on how CMS intends to implement the Medicare Prescription Payment Plan, 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 it is effective in smoothing payments and that CMS is effective in its outreach to beneficiaries who could benefit from the program. Specifically, MAPRx would like to address the following issues CMS raised in this first round of guidance:

- **Program Calculations**
- **Participant Billing and Billing Statement**
- **Claims Processing and Coordination of Benefits**
- **Enrollee Outreach**
- **Program Eligibility and Enrollment**
- **Voluntary and Involuntary Disenrollments**
- **Grace Periods and Notice Requirements**
- **Participant Disputes**

Program Calculations

MAPRx appreciates CMS offering detailed scenarios for the calculations to facilitate deeper understanding of the mechanics of the program. We concur that participants starting the program later in the year could have higher monthly bills, especially compared to those starting earlier in the year. Furthermore, we are concerned that beneficiaries starting later in the year (eg., October) may experience an increase in costs for December, which could be a surprising shock for them. Based on this possible challenge, we urge CMS to explore methodologies to prevent this scenario.

Additionally, given the complexity related to the calculations, MAPRx strongly supports educating beneficiaries at a high level regarding the program calculations, rather than overwhelming them with this the complicated approach contained in the guidance. Specifically, when educating beneficiaries on how the calculations work, we request that CMS offer language stating that the OOP costs may vary slightly from month to month, but that participant costs will never exceed \$2,000 OOP (or your actual OOP prescription costs). We also think it will be helpful to provide guidance to prospective and current participants that the higher your OOP cost, the higher your monthly cost. If CMS is considering providing program participants with detailed charts showing the remaining costs for the rest of the plan year, we recommend displaying only a column for patient OOP costs incurred and monthly OOP costs—thereby removing the maximum monthly cap amount in the draft guidance—to minimize confusion.

Participant Billing and Billing Statement

Overall, MAPRx appreciates CMS' commitment to afford flexibility for participants regarding payment options and to provide transparency for participants through the monthly billing statement. While we appreciate CMS encouraging plans to offer certain payment options, we urge CMS to **require** several different options (eg., electronic funds transfer, automated payments, paper bills, etc.). According to the 2023 ACI Speedpay Pulse Report, older Americans within the baby boomer generation prefer a wide range of payment options for bill payments, including automated clearing house (ACH) automated debit, paper check by mail, debit/credit card, website, or over the phone.¹ Given the diversity of preferences among the Medicare population, we believe requiring plans to offer a multitude of options will facilitate

¹ 2023 ACI Speedpay® Pulse Report: Billing and Payment Trends and Behaviors. ACI Worldwide.
<https://www.aciworldwide.com/wp-content/uploads/2023/08/2023-ACI-Speedpay-Pulse-Annual-Report.pdf>. Accessed September 13, 2023.

greater beneficiary participation in the program.

MAPRx also applauds CMS for requiring Part D plans to provide robust information within the billing statement. We especially appreciate CMS building awareness around financial assistance by including the language about the possible eligibility for the low-income subsidy (LIS). While we generally approve of including the information in the proposed billing statement, we respectfully offer several modifications. The first page of the statement should be reserved for only critically important information so beneficiaries can easily understand their OOP obligation and monthly responsibilities for the remainder of the plan year. We want to ensure the language/information is clear and actionable, therefore, below is the most crucial information we believe should be highlighted on the first page:

- Total, non-itemized OOP costs
- OOP costs expected on a monthly basis for the remainder of the plan year
- Statement reiterating that there will be changes to the monthly OOP costs if a beneficiary has a new prescription or discontinues an existing prescription

Additionally, while the proposed billing statement is robust, there may be some important information missing from it. To that end, MAPRx requests the following additions to the billing statement:

- Information on State Health Insurance Assistance Program (SHIP) counselors as we believe it is important for beneficiaries to have access to an impartial stakeholder to help prepare them for the program (ie., explaining the dynamic of making monthly payments) and answering questions
- Highly visible note/language focused on the impact of noncompliance
 - While beneficiaries may take different approaches regarding medical billing in other healthcare programs, there are consequences for late payments. We request that CMS highlight the imperative for beneficiaries to pay and pay on time
- Language that the beneficiary will not pay more than \$2,000 and informing the patient when that cap has been met, including the standard monthly payments through the end of the year after the cap has been met

Finally, we appreciate CMS' assurance that Part D sponsors and plans cannot seek debt collections against program participants.

Claims Processing and Coordination of Benefits

MAPRx appreciates the detail the agency has provided for the processing of claims and coordination of benefits. We do not have any additional feedback on this section, with the exception that we believe it is important to ensure that assistance provided by patient assistance programs, such as those offered by independent charitable foundations, be properly identified and continue to be included in the patient OOP calculation. Additionally, MAPRx seeks clarification from CMS on this dynamic. Specifically, we ask the agency to clarify whether the two-transaction pharmacy claims process allows for independent charitable assistance to be billed for the patient responsibility as a component of "Other Health Insurance" prior to application of any Medicare Prescription Payment Plan.

Enrollee Outreach

As the Medicare Prescription Payment Plan program will be new in 2025, MAPRx strongly supports a robust effort to educate via beneficiary outreach on this new program. Given the complexities and possible confusion among prospective beneficiaries, effective outreach and education are critical for the success of this program.

The targeted outreach will be a critical step in educating beneficiaries about the possible benefits of enrolling into the Maximum Monthly Cap on Cost-Sharing Payments Program. We strongly encourage CMS to move away from certain thresholds for conducting targeted beneficiary outreach. We caution the agency not to make assumptions about what is beneficial for beneficiaries. Specifically, beneficiaries may face deductibles or other OOP costs in other Medicare programs or have other expenses to consider and this maximum monthly cap could be beneficial even if they do not have a perceived high-cost medication in Part D. We respectfully request that CMS recall that the congressional intent for this specific benefit was to be widely applicable and open to all beneficiaries in Part D. Establishing thresholds for proactive outreach runs counter to that intent. To that end, we strongly advocate for not implementing a threshold for conducting targeted outreach.

As engagement with patient groups is critical for informing CMS's outreach strategy and tactics, we look forward to the opportunity in Part 2 of the guidance to comment on model language for beneficiary communications and plan marketing materials. As stakeholders continue to explore the best education and outreach efforts, we encourage CMS to include information on the program both in plan marketing materials and in materials created by the agency (eg., the Medicare & You handbook and the Medicare website). We specifically wanted to raise a widely utilized platform: the Medicare Plan Finder tool. The Medicare Plan Finder is an important tool for educating beneficiaries on important plan information, including this new program. Many beneficiaries and their caregivers use this tool when making enrollment decisions, and as such, it will be critically important to highlight this new program on Plan Finder. While CMS may offer more details on how it will provide information on Plan Finder in Part 2 of the guidance, we strongly support the development of a customizable analytical tool that could help enrollees determine if the new program would be beneficial.

In addition to our thoughts on educating beneficiaries directly, we also encourage CMS to educate other stakeholders who play a part in educating beneficiaries. As pharmacies will have a significant role at the point of sale (POS) in notifying beneficiaries who may benefit from the program, we hope that CMS will offer specific educational materials to be deployed by pharmacies for review in Part 2. We also believe strongly that educating healthcare providers and prescribers will be another important step to help beneficiaries understand the benefits of the program and how to enroll. We encourage CMS to educate providers and prescribers so they, in turn, can help educate beneficiaries.

MAPRx believes in consistently evaluating the effectiveness of the program outreach, especially by gaining feedback and insights from the stakeholders using and managing the program. We encourage CMS to explicitly provide additional opportunities for stakeholder, particularly patient and caregiver, input in the future. Additionally, collecting demographic data (eg., ethnicity, geography) could also help refine and better target outreach efforts in future plan years.

Program Eligibility and Enrollment

MAPRx appreciates CMS exploring various enrollment options into the program. While we generally agree with CMS' proposed eligibility requirements and election options before and

during the plan year, we have several concerns about the guidance related to enrollment at the point-of-sale (POS). Frankly, we are concerned that CMS is already conceding this as too challenging to implement for 2025, despite this specific enrollment option being critical for catching in real time the patients who may benefit from the program. Therefore, we strongly recommend the agency consider requiring plans and pharmacies to offer real-time or POS enrollment for 2025 as the agency already has reviewed a few feasible ideas. Our organizations are committed to working with CMS and other stakeholders to identify ways in which enrollment options at the POS can be implemented in 2025.

We also strongly support CMS requiring plans to process midyear elections within 24 hours. We fervently believe if there is a mechanism for plans to facilitate midyear elections within 24 hours, then there feasibly could be a mechanism for POS enrollment.

MAPRx also seeks clarification regarding a scenario in which a current participant changes Part D plans midyear (ie., due to a relocation or move). We ask the agency to explain what safeguards and processes will be in place to ensure the effective carryover from the program from one Part D plan to another without “waiting period” delays or loss of OOP “credit” towards the cap.

Voluntary and Involuntary Disenrollments

MAPRx appreciates CMS clearly stating that Part D sponsors may preclude an individual from opting into the plan in a subsequent year if the individual fails to pay the amount billed. However, the guidance is unclear if a plan may preclude enrollment for more than one year. Based on the statutory language, we respectfully recommend that CMS allow Part D plans to preclude affected individuals for only one year and not multiple years. We also recommend halting the preclusion once the beneficiary has made the outstanding payment.

MAPRx also seeks clarification in the event of the death of the beneficiary. If a patient dies, we are unaware of no other instance where CMS has a claim against a beneficiary’s estate. Based on this, we would assume that the Part D plan and/or CMS would absorb the cost. Otherwise, this may discourage beneficiaries from participating in the program.

Grace Periods and Notice Requirements

During consideration of the Inflation Reduction Act, MAPRx strongly supported a generous grace period for any type of smoothing benefit to prevent plans from disenrolling participants immediately following a late payment. We recommend CMS establish a 3-month grace period for late payments. We also strongly support CMS requiring Part D plans to communicate with beneficiaries within this time frame about the consequences of late payments and possible involuntary termination. Specifically, we recommend standardizing plan communications during this time frame. We look forward to providing our feedback on this model language in Part 2 of the guidance.

Participant Disputes

It is important for participants to have a mechanism to resolve disputes with Part D plans. Therefore, we appreciate CMS requiring Part D sponsors to apply their established Part D appeals procedures to any dispute made by a Medicare Prescription Payment Plan participant

about the amount of Part D cost-sharing owed by that participant for a covered Part D drug. However, we are concerned that there are no clear requirements regarding the timeframes associated with disputes. We strongly recommend that CMS require sponsors to resolve disputes within a 24-hour period, leveraging the expedited review process under the current appeals program.

Conclusion

Thank you for your consideration of comments on the Part 1 guidance of the implementation of the Maximum Monthly Cap on Cost-Sharing Payments Program. 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.

- 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
- GO2 for Lung Cancer
- HealthyWomen
- Infusion Access Foundation
- Lakeshore Foundation
- LUNGevery Foundation
- Lupus and Allied Diseases Association, Inc.
- Lupus Foundation of America
- Muscular Dystrophy Association
- National Council on Aging
- National Health Council
- National Infusion Center Association (NICA)
- National Kidney Foundation
- National Multiple Sclerosis Society
- Patient Access Network (PAN) Foundation
- The AIDS Institute
- The Assistance Fund
- The Leukemia & Lymphoma Society
- The Leukemia & Lymphoma Society
- Tourette Association of America
- Triage Cancer

CMS Medicare Prescription Payment Plan Guidance Comment

This document is submitted by the Massachusetts Health Data Consortium (MHDC) and its Data Governance Collaborative (DGC) in response to the CMS Medicare Prescription Payment Plan Guidance Part 1 posted on the CMS website on August 21, 2023 and found here: <https://www.cms.gov/files/document/medicare-prescription-payment-plan-part-1-guidance.pdf>

About MHDC

Founded in 1978, MHDC, a not-for-profit corporation, convenes the Massachusetts's health information community in advancing multi-stakeholder health data collaborations. MHDC's members include payers, providers, industry associations, state and federal agencies, technology and services companies, and consumers. The Consortium is the oldest organization of its kind in the country.

MHDC provides a variety of services to its members including educational and networking opportunities, analytics services on both the administrative and clinical side (Spotlight), and data governance and standardization efforts for both clinical and administrative data (the Data Governance Collaborative/DGC and the New England Healthcare Exchange Network, respectively).

About DGC

The DGC is a collaboration between payer and provider organizations convened to discuss, design, and implement data sharing and interoperability among payers, providers, patients/members, and other interested parties who need health data. It is a one stop interoperability resource. The DGC primarily focuses on three areas:

1. Collaboration: Development of common understanding of and specifications for data standards, exchange mechanisms, and what it means to participate in the modern health IT ecosystem
2. Education: helping members understand their regulatory obligations, the data and exchange standards they're expected to use, and modern technology and related processes
3. Innovation: Identification and development of projects and services needed to make modern health data practices and exchange a reality

General Comments

This section includes general comments about the guidance document.

Price Transparency and Consistency

Our initial expectations were that a payment plan would be designed with 12 equal monthly payments to provide price transparency and predictability/consistency to enrollees. We realize this would either require everyone paying \$166.67/\$166.66 payments to reach \$2000.00 and a potential refund if the \$2000 threshold is not reached or some lower estimated total cost split evenly across the year with the potential to owe additional money if the total amount used ends up being higher than that paid via the payment plan, but this has several advantages to the enrollee:

1. Transparency/no surprise bills. It lets enrollees know what their payments will be ahead of time so they are not surprised by the amount they're asked to pay. The current scheme affords no insight into the expected payment ahead of time unless the enrollee sits down and calculates the payments themselves based on what they've actually filled at their pharmacy. Having transparency is important, especially since the price

at the pharmacy will be \$0 so they will be accepting the medication without knowing how they will be paying for it unless they know they'll go over the OOP maximum early on – even those enrollees who are certain they will eventually meet the OOP maximum and thus know their actual annual responsibility will not know how much they are signing up to pay each month, especially for individuals who expect most of their costs to come from maintenance drugs with a standard cost each month. This may dissuade some individuals who could otherwise benefit from the program from using it as it will make monthly budgeting difficult.

2. **Consistency.** For many people it is easier to absorb a standard monthly payment amount into their budgets as so many other payments are structured that way. This is especially true for seniors who may be living on standard monthly payments like Social Security payments and pension distributions. Having a standard amount to set aside for medications makes other purchasing decisions easier; knowing how much their drugs will cost will inform how much money they have available for other purchases.

Given the priority CMS has been giving to price transparency and eliminating surprise billing, the current plan seems a bit misaligned with other agency activity.

Also, if any of the educational or outreach materials discuss spreading the payments out across the year without going into detail, some people are going to assume that the payments are the same every month. An explicit note that for some participants the payments will probably go up as the year progresses may be appropriate and help them better understand if the program is right for them.

Notice of Likely Disadvantage for Participation

The draft guidance provides instructions for identifying Medicare Part D/Medicare Advantage enrollees who are likely to benefit from the payment plan, but because all enrollees are eligible and certain enrollee usage profiles would result in payment schedules likely less desirable than the default pay-as-you-go until you hit the OOP maximum scenario, participants in our Data Governance Collaborative felt that it was just as important to inform such patients that electing the program might be disadvantageous as it is to notify those patients likely to benefit from it so they can enroll.

For example, an enrollee with \$100 of maintenance drugs every month will not meet their out of pocket maximum during the year and will have even payments across the year in the default POS payment model. If they elect the payment plan this would no longer be true and their payments would get larger toward the end of the year, right at a time when many people have more expenses than at some other times of the year and are most likely to want lower drug costs. While they have the right to elect the plan (and perhaps even some have unusual financial circumstances that would make it a good choice for them), doing so has no obvious benefits and has potential negative consequences. This enrollee should be discouraged from electing the payment plan, or at least efforts should be made to ensure that any such choice is made only after being fully informed about the consequences.

There are many possible ways to do this. One option might be to estimate the enrollee's anticipated purchases based on their medication fills from the previous year if the data is available (with or without acute fills – we suggest that without might make more sense, although this may vary from enrollee to enrollee) and send them a personalized estimated payment plan for the year as part of their enrollment paperwork.

This type of estimate would likely be helpful to all enrollees – those most likely to benefit from the payment plan, those for whom it won't make too much difference, and those who might find it disadvantageous – and we recommend making it a standard part of the program for all enrollees regardless of their anticipated status.

These estimates should be clear that they are based on the previous year's purchases and are not guaranteed to be accurate, and also that unexpected additional medication purchases of any significant amount may greatly alter the payment schedule. It may be appropriate to indicate that the earlier in the year such events happen, the more likely it is that the payment plan would benefit the enrollee.

Real Time Election at Point of Sale

We believe that supporting real time election at the point of sale is important and should be adopted as soon as possible. Guidelines for recommending election at the point of sale based on current purchase amounts

should be developed alongside this feature, perhaps based on making a single purchase of at least \$X amount (perhaps variable by month) or reaching a total OOP maximum of \$Y (varying by month). We are not sure simple “one purchase of \$K” or “one day with \$J in total purchases” is nuanced enough to be effective for individual selection, especially as the timeframe of the purchase can make a huge difference (see below).

Threshold for Identifying Enrollees Who Might Benefit

Participants in our Data Governance Collaborative agree that a payment plan where all of the monthly payments are lower than the anticipated monthly payments for maintenance medications paid for at the time of sale is a reasonable loose threshold for determining in advance of a plan year whether an enrollee is likely to benefit from the payment plan program.

It is less clear how to consider any unexpected, acute prescriptions as they are, by definition, not predictable in advance. We are inclined either to disregard such charges in the pre-plan year recommendation process or possibly average the acute payments accrued throughout the previous 2-3 years if such data is available, perhaps adding it to a middle of year month in the calculations.

We acknowledge the discussion in the guidance document around looking at either the cost of a single drug or a single day's cumulative purchase for determining a threshold for recommending election after the start of a plan year. As noted in a previous comment, we are not certain it is nuanced enough to be effective, particularly if the same thresholds are used throughout the plan year. At a minimum, we suggest that any plan using this mechanism differentiate between 30 day and 90 day supply purchases and evaluate when 90 day supplies are purchased throughout the year. Whether there are refills/it's a drug that patients typically use on an ongoing basis vs for a short period of time may also make a big difference in that they can help estimate whether a one time charge is likely to be repeated in the future.

For example, going on a payment plan for a \$400 purchase for a 90 day supply of a maintenance drug may or may not make sense if that's the only purchase made throughout the year. The exact months during which the purchases are made make a difference. As noted in the table below, someone incurring \$400 for a 90 day supply in January, April, July, and October will likely benefit from the plan under most reasonable criteria (although some people might prefer to pay the four \$400 fees so they don't owe any money in November and December when expenses tend to be higher for many people). Someone incurring \$400 for a 90 day supply in February, May, August, and November may benefit somewhat in that none of their payments will exceed \$400, but will have more than 75% of their annual costs in the last five months of the year and nearly half of their annual costs in the last two months of the year when expenses tend to be higher so it may not be a good fit for everyone. Someone incurring \$400 for a 90 day supply in March, June, September, and December would pay almost the entire bill in the second half of the year and have an almost \$600 payment in December - likely an unfavorable outcome.

Month	New charges/payment	New charges/payment	New charges/payment
January	\$400/\$166.67	\$0/\$0	\$0/\$0
February	\$0/\$21.21	\$400/\$36.36	\$0/\$0
March	\$0/\$21.21	\$0/\$36.36	\$400/\$40
April	\$400/\$65.66	\$0/\$36.36	\$0/\$40
May	\$0/\$65.66	\$400/\$86.37	\$0/\$40
June	\$0/\$65.66	\$0/\$86.36	\$400/\$97.14
July	\$400/\$132.32	\$0/\$86.37	\$0/\$97.14
August	\$0/\$132.32	\$400/\$166.37	\$0/\$97.14
September	\$0/\$132.32	\$0/\$166.37	\$400/\$197.15
October	\$400/\$265.66	\$0/\$166.36	\$0/\$197.14
November	\$0/\$265.66	\$400/\$366.36	\$0/\$197.15
December	\$0/\$265.65	\$0/\$366.36	\$400/\$597.14
Total Paid	\$1600	\$1600	\$1600

Thus, recommending enlisting in the payment plan based on a \$400 purchase in March (and perhaps even February) could lead to an unfavorable outcome for the enrollee.

Prefunded Pharmacy Cards

Participants in our Data Governance Collaborative universally agree that offering a prefunded pharmacy card is the best way to handle ensuring that pharmacies are properly and promptly paid for the patient component of drug purchase price. We recognize the various potential difficulties outlined by CMS in the draft guidance document, but note that nearly all of them also apply to HSA and 125 Cafeteria Plans where such cards are commonplace. We will address a few of them directly:

1. Card used for unauthorized purchases – enrollees are responsible for ensuring that they only use the card for the approved purpose and to purchase the covered prescription drugs. Any purchases that do not fall under this category must be reimbursed by the enrollee. This could be added to the next bill as an additional charge that is outside of the maximum allowed payment, go to collections if necessary, etc. They are also responsible for reporting lost or stolen cards in a timely manner. All of this should be pretty standard for any type of payment card.
2. Participant may forget a physical card – most retail pharmacies allow their customers to put a credit or debit card on file for use without the physical card. This option could be used to limit the effects of forgetting to bring the card to the pharmacy. A secondary billing option equivalent to the current plan could be also be used as a backup or plans could be required to reimburse enrollees (perhaps limited to no more than twice a year?) using the same process outlined in the current guidance for required reimbursements.
3. Participant cannot use the program until a card is received. Participants could be given a temporary number that's good for 14 days that they could put on file at their pharmacy on a temporary basis and replace with their permanent information once it's available. A secondary billing option equivalent to the current plan could be also be used until such time as the card is received or the plans could be required to reimburse enrollees for charges incurred in the first up to N days using a process like the current emergency reimbursement or payer fault reimbursements outlined in the current guidance.
4. Organizational readiness – there are vendor programs and existing banks that manage these sorts of programs that could easily be adopted to the Medicare payment plan program if desired. This would limit the need for new institutional knowledge around the use of these cards inside payer organizations.

September 19, 2023

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: Comment on Maximum Monthly Cap on Cost-Sharing Payments Program Draft Part One Guidance

Dear Dr. Seshamani:

The Massachusetts Biotechnology Council (MassBio) appreciates the opportunity to submit these comments to the Centers for Medicare & Medicaid Services (CMS) in response to the Draft Part One Guidance (the “Draft Guidance”) on the “Maximum Monthly Cap on Cost-Sharing Payments Program” established by section 11202 of the Inflation Reduction Act (IRA)¹ (the “Medicare Prescription Payment Plan” or the “Program”).²

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.

MassBio supports the proposed implementation of the Medicare Prescription Payment Plan. In particular, we appreciate that CMS is proposing to implement the Program in a manner designed to facilitate enrollees’ timely access to needed therapies. In accordance with these goals, MassBio submits the following recommendations to ensure CMS: (1) supports a patient-friendly approach; (2) effectuates the smoothing of patient cost-sharing at the pharmacy point of sale (POS); and (3) ensures adherence to Program requirements by plans. We also outline priorities for beneficiary outreach materials to aid CMS in drafting Part Two of the Program guidance.

¹ Pub. L. No. 117-169.

² 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 (Aug. 21, 2023), available at: <https://www.cms.gov/files/document/medicare-prescription-payment-plan-part-1-guidance.pdf> (“Draft Guidance”).

I. MassBio Appreciates that CMS is Proposing to Implement the Program in a Manner Designed to Facilitate Enrollees’ Timely Access to Needed Therapies.

A. CMS Should Support a Patient-Friendly Approach.

MassBio encourages CMS to use a patient-friendly approach to address enrollees’ cashflow problems and, thereby, improve access to needed medications. Because the Program centers on improving enrollee access to critical therapies, implementation should minimize burdens placed on enrollees. For example, MassBio supports CMS’s proposed patient-friendly approach that offers enrollees increased flexibility in choice of payment method. Implementing a patient-friendly approach will allow enrollees, who may not have access to specific methods of payment, to successfully comply with the Program’s payment requirements.

We are concerned, however, that CMS merely “encourages Part D sponsors to offer multiple means of payment, such as an electronic fund transfer mechanism (including automatic charges of an account at a financial institution or credit or debit card account) and payment by cash or check.”³ We encourage CMS to reframe this policy as an obligation on Part D sponsors. Otherwise, Part D sponsors that strictly offer limited payment options may end up discouraging enrollees from participating in the Program if the limited payment options are not available to them.

B. CMS Should Effectuate Smoothing at the Pharmacy Point of Sale (POS).

To best ensure enrollees have timely access to their medications, an election to participate in the Program at the POS must be processed immediately such that enrollees can opt into the Program at the pharmacy and collect their prescriptions in the same pharmacy transaction. Otherwise the enrollee, who may be suddenly facing high out-of-pocket costs for a new therapy, may elect to leave the pharmacy empty handed. Notably, patients battling complex diseases may not be able to wait 24 hours for their medications. Unnecessary delays in obtaining life-saving medications may exacerbate a patient’s medical condition.

We are therefore concerned that CMS’ Draft Guidance would not require Part D sponsors to process an enrollee’s request to participate in the Program immediately until 2026, giving Part D sponsors 24 hours to process such requests during 2025. While MassBio acknowledges that CMS instituted this requirement to promote the timely processing of requests, we urge CMS to avoid permitting a 24-hour waiting period. Such a policy can result in unnecessary delays and, ultimately prescription abandonment. For these reasons, MassBio urges CMS to work with Part D sponsors to identify a means for processing an enrollee’s election at the POS beginning in 2025.

C. CMS Should Recommend Ensuring Plans Adhere to Draft Guidance via Oversight.

MassBio encourages CMS to implement oversight strategies to closely supervise Part D sponsors and ensure their adherence to all provisions in the Draft Guidance. To operationalize this initiative, CMS

³ Draft Guidance at 13 (emphasis added).

should institute reporting requirements and develop reporting templates while collaboratively engaging with Part D sponsors. CMS plays an integral role in ensuring Part D sponsors adhere to the requirements of the Program. CMS monitoring and oversight will facilitate Program compliance, ensuring that enrollees can continue to enjoy timely access to needed therapies.

II. CMS Should Outline Priorities for Beneficiary Outreach Materials for Part Two of the Guidance.

In response to CMS' request for specific feedback on how to best educate Part D enrollees about the Program⁴, MassBio believes that CMS should outline key priorities for Draft Part Two Guidance's beneficiary outreach materials. Specifically, CMS should offer more detailed guidance that outlines how it will effectively educate Part D enrollees about the Program. In this effort, MassBio supports implementing the program in a manner that facilitates a method of outreach that best meets enrollees' needs. Beneficiary outreach materials should be standardized, clear, and tailored to the circumstance. One way to achieve this objective is by requiring the Program to use various communication methods (e.g., text, email, or paper notices) to effectively reach the enrollees and maximize their use of the Program. Standardized, clear, and tailored outreach materials will help ensure all enrollees understand the Program.

MassBio thanks CMS for consideration of our comments and remains available to meet with CMS to discuss these comments and other related issues of interest to our members. We would be more than happy to answer any questions you may have regarding these comments or to provide any additional information.

Sincerely,



Kendalle Burlin O'Connell, Esq.
CEO & President
MassBio

⁴ CMS, Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance (Aug. 21, 2023), p. 5.

September 20, 2023

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

Sent electronically to PartDPaymentPolicy@cms.hhs.gov

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

Dear Dr. Seshamani:

McKesson Corporation ("McKesson") is pleased to provide comments to the Centers for Medicare & Medicaid Services' (CMS) draft Medicare Prescription Payment Plan Guidance.

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. Its public policy platform is driven by the core belief that the **Patient Comes First**.

General Comments

McKesson appreciates CMS' effort to ensure the new Medicare Prescription Payment Plan is implemented in a "timely, uniform, and seamless" manner while minimizing disruption and creating a "consistent patient experience." We recognize this guidance focuses on a subset of topics but have outlined key recommendations we believe are critical to ensuring the program does not increase pharmacy or patient challenges. This includes encouraging cost transparency and enrollment conversations at the point of prescribing, standardization in patient engagement parameters and streamlining pharmacy operations and financial burdens.

At a time when financial and benefit complexities are increasing, all patients should have a better understanding of the cost of medicines and their cost-sharing burdens. CMS recognized the value

of real-time benefit tools (RTBTs) when requiring Part D sponsors to implement a beneficiary RTBT by January 1, 2023. McKesson recommends CMS use RTBTs as a key mechanism for proactive patient engagement. When used effectively, these tools should enable enrollees to understand their cost-sharing requirements, benefits of enrolling in the Medicare Prescription Payment Plan, and options to enroll in such program before standing at the pharmacy counter. When used at the point of prescribing, these tools allow prescribers and patients to have more effective discussions about their plan benefits, treatment options, and benefits of the payment plan.

We further encourage CMS to make patient benefit, eligibility, and cost-sharing information available in real-time to patients and third parties of their choosing. Standardizing the exchange of this information (e.g., through APIs) will ensure patients and their partners are able to access this data outside of the Part D plan portal and solutions can be tailored to meet the unique needs of individual patients.

Enrollments prior to POS will not be optimized if Part D sponsors provide only education and targeted outreach, without also providing patient navigation and standardized communication. To assist Part D sponsors with defining “likely to benefit” patients, CMS should define “per prescription notification.”¹ Additionally, **CMS needs to set standard thresholds of their expectations of enrollment prior to POS to ensure that Part D sponsors do not rely on frontline pharmacists to explain program intricacies at the POS.**

Finally, for any technology development that would be necessary for pharmacy system vendors, electronic medical records (EMRs), or other vendors, CMS should consider providing funding to these entities (e.g., similar to Navigator programs offered through the Affordable Care Act) so that enrollment processes can be standardized and ensure a seamless patient experience.

Pharmacy Operational Burden

The POS enrollment option described throughout the guidance will be disruptive to pharmacy business operations and ultimately patients, due to the patient education and consultation that would be necessary to facilitate and process enrollment. If CMS determines that the Medicare Prescription Payment Plan cannot operationally move forward without the capacity to enroll patients at POS, we strongly encourage CMS guidance to include:

- **Standardized POS election procedures, as well as provide pharmacies with a single enrollment mobile/web-based app or single 1-800 number to refer the patient to.**²
This would ensure consistent information and processes to execute enrollment, which will support equitable access to the Medicare Prescription Payment Plan. McKesson further recommends that option 3 (clarification code) be eliminated as an avenue to perform enrollment at the POS. Using the code does not provide all the information to the Part D sponsor and does not ensure patient consent into the program. Additionally, with the increase in reversals and resubmits, there is an increased risk of triggering fraud, waste, and abuse audits.

¹ In reference to Section 60.1 General Part D Enrollee Outreach Requirements

² In reference to Section 70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs

- **Require Part D sponsors to utilize RTBTs as a supplemental notification method to process enrollment prior to POS, to help enable a seamless patient experience.**
- **Provide standardized education guidelines to Part D sponsors to inform conduct around patient education of the Medicare Prescription Payment Plan provisions and the various methods for enrollment to minimize the need for pharmacies to counsel and enroll patients.**
- **Exclude by a waiver process those pharmacy types where real-time POS elections are not possible, (such as mail order and LTC pharmacies) or the POS enrollment will not be timely, uniform, or seamless, and participant experiences will be inconsistent across pharmacy types.**
- **Develop strict guidelines for retroactive election to help minimize the burden on pharmacies.**³ If a retroactive election is processed the Part D sponsor should assume responsibility for any effect to the reimbursement/billing process.
- **McKesson recommends that CMS have strict guidelines for retroactive election to reduce as much burden as possible to the pharmacy.**⁴ If a retroactive election is processed, the Part D sponsor should assume responsibility for any effect to the reimbursement/billing process.

In future program years, the coordination of benefits (COB) process can be updated but major changes would drastically increase pharmacy operational burden.⁵ McKesson recommends the following provisions be included in the final guidance:

- **Guidance as outlined in the National Council for Prescription Drug Programs' (NCPDP) comments in regard to the Telecommunication standard Version D.0 Other Payer Response Segment, Version F6 Other Payer ID Count (355-NT),** processing out of cycle reversals and adjustments, and what should occur if a claim is adjusted subsequent to the last invoice received by the beneficiary at the end of the calendar year.
- **Include a statement in final guidance that there will be no impact to Automated TrOOP Balance Transfer (ATBT) processes** and that Financial Information Reporting (FIR) transactions will continue to reflect the True Out-of-Pocket (TrOOP) and Drug Spend by month using the original claim accumulators, as they currently do.
- **Require structured messaging be returned to the pharmacy with member out-of-pocket (OOP) amount applied to the balance** to better inform the patient about their benefit.
- **Clarify the COB methodology for pharmacy types such as long-term care (LTC) scenarios that would require alternative payment and claims processing standards.** LTC pharmacies would not be able to operationalize the current proposed COB methodology and LTC patients who are in and out of LTC facilities may not benefit from the program because LTC patients receive medications from the facility level, and not the retail pharmacy.

³ In reference to Section 70.3.7 Retroactive Election in the Event the Part D Sponsor Fails to Process an Election within 24 Hours

⁴ In reference to Section 70.3.7 Retroactive Election in the Event the Part D Sponsor Fails to Process an Election within 24 Hours

⁵ In reference to Section 50.1 Pharmacy Claims Processing Requirements

- **McKesson agrees with NCPDP’s recommendation to utilize the term “Patient Out of Pocket (OOP) Cost”** in Appendix A to replace the term “Patient Pay Amount” throughout the guidance.⁶

Potential Impact to Patients

While we applaud the spirit of reducing prices for medications within the Inflation Reduction Act, we are concerned that the operations of the Medicare Prescription Payment Plan have heightened avoidable patient burden. **To reduce patient burden, McKesson recommends the following:**

- CMS should **exclude paper claims** from the Medicare Prescription Payment Plan.
- Along with the other standardization needed to operationalize and keep patient burden at a minimum, CMS should **also standardize patient outreach** across Part D sponsors and the Medicare Prescription Payment Plan educational content shared with the member **to create an equitable experience amongst patients enrolled.**⁷
- CMS should create guidance that requires **Part D sponsors to provide navigation services to patients** that enables greater understanding of which option and program is best for them.⁸ Requiring a combination of patient navigation services and enrollment outside of the POS will better support patients and reduce unintended burdens.

Pharmacy Financial Burden

Without additional clarifications and safeguards, the Medicare Prescription Payment Plan may increase both financial and operational burdens for pharmacies, especially independent community pharmacies serving our most vulnerable patients.

CMS must provide the necessary guardrails to protect pharmacies from unanticipated expenses related to the Medicare Prescription Payment Plan implementation:

- Ensure that all fees and costs related to operationalizing the Medicare Prescription Payment Plan are not passed through to pharmacies. These should be reflected in Part D plan bids and should not be transferred to pharmacies due to an increase in transaction volumes, or fees, including retroactive fees which may act similarly to DIR clawbacks.⁹
- Align the bid preparation for Prescription Drug and Medicare Advantage Plans with the Medicare Prescription Payment Plan so that pharmacies can adequately prepare for any operational and reimbursement differences.¹⁰
- Separately recognize and require pharmacy reimbursement for services performed on behalf of the Part D sponsor and prohibit bundling these services within other Part D payments.
- Engage with pharmacies and seek their input throughout the implementation of the Medicare Prescription Payment Plan to avoid unintended consequences that could further exacerbate pharmacy cash flow.

⁶ In reference to Appendix A: Definitions for Medicare Prescription Payment Plan

⁷ In reference to Section 60.2 Targeted Part D Enrollee Outreach Requirements

⁸ In reference to Section 70.2 Interactions Between LIS and Medicare Prescription Payment Plan

⁹ In reference to Section 50.2 Pharmacy Transaction Costs

¹⁰ In reference to Section 40.2 Financial Reconciliation Process.

www.McKesson.com

Other Comments

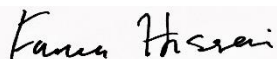
CMS should provide all possible scenarios for pharmacists' if they are expected to enroll at the POS. McKesson supports NCPDP's request for additional examples of how the program should work when a beneficiary has multiple supplemental coverages throughout the benefit plan year. McKesson also supports NCPDP's recommendation for CMS' inclusion of a specific example of a situation where the secondary coverage for the beneficiary returns a higher Patient OOP than what was on the original Medicare Part D claim.¹¹

Leading up to implementation of the Medicare Prescription Payment Plan, CMS needs to continue working with Pharmacies and Part D sponsors for an optimal patient experience.

Conclusion

McKesson appreciates the opportunity to comment on the Medicare Prescription Payment Plan Guidance. If you have questions or need further information, please contact Fauzea Hussain, Vice President of Public Policy, at Fauzea.Hussain@McKesson.com.

Sincerely,



Fauzea Hussain

¹¹ In reference to Appendix B: Additional Medicare Prescription Payment Plan Calculation Examples

September 20, 2023

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

Re: Medicare Prescription Payment Plan Guidance

Dear Meena Seshamani:

This communication is in response to the Centers for Medicare & Medicaid Services (CMS) soliciting comments on the draft part one guidance of the Medicare Prescription Payment Plan issued on August 21, 2023. MCS Advantage, Inc appreciates the opportunity to provide feedback on the Medicare Prescription Payment Plan Guidance.

Section 30

Clearer guidance is needed toward feasibility of the patient to perform partial payments of their copay/co-insurance at the POS. In the event that the member opts into the program late in the year, after reaching their responsibility, should the request be declined to avoid confusion? How will Plan Sponsors manage uncollected dollars? Members can be confused by the changes between first month max cap and subsequent month cap bills generating overload of call and grievances.

How will plans calculate accurately monthly caps when patients disenroll from the plan and enroll in a new one?

If a member opt-in to the Program on November, the Number of Months Remaining in the Plan Year will be 2, this means that the Payment Plan will only be for two months?

Section 40

CMS encourage Part D sponsors to offer participants flexibility around requesting a specific day of the month for program charges and withdrawals from a bank account. This makes the program extremely difficult to manage, different from EOB which are mailed the same date of the month, for example. Meaning there will be no consistency between the EOB and what member really paid. This may cause to provide misleading information.

CMS encourages Part D sponsors to offer multiple means of payment, such as an electronic fund transfer mechanism (including automatic charges of an account at a financial institution or credit or debit card account) and payment by cash or check. This will be a burden to the sponsor's financial department at the time of reconciliation.

Billing Statement information needs to be detailed. The experience is that members don't read.

In the case of a beneficiary enrolled in an Employer Group Waiver Plans (EGWP), is the sponsor expected to collect from that beneficiary? CMS examples would help clarify this requirement.

What are the challenges if a beneficiary changes plans during a SEP?

Section 100 of the Draft One Guidance describes data submission requirements, which includes uncollected Medicare Prescription Payment Plan balances, number of participants with uncollected balances, and number of participants precluded from future Medicare Prescription Payment Plan enrollment.

Disenrollment from Medicare Prescription Payment Plan and preclusion from future enrollment is forward-looking and is welcome. However, what is CMS' intent regarding plans being made whole? Are plan sponsors expected to absorb these liabilities?

Section 50

Will CMS consider no collected dollars in the Part D settlement to protect plans sponsors? How unpaid amounts by members will be handle in the Part D Settlement?

Please provide guidance toward the described disruption scenarios that Part D Sponsors may face and impact of pharmacy dispensing fees related to the program and impact of the PDE.

Section 50.1 mentions that sponsors would use an additional Bank Identification Number (BIN) and/or Processor Control Number (PCN) unique to the Medicare Prescription Payment Plan for these transactions. This is going to confuse the pharmacies because there will be two transactions with two different BIN/PCN.

CMS is encouraging the adoption of an electronic claims processing methodology such as the one currently used for real-time COB billing transactions using NCPDP standards. Do the real-time benefit tools (RTBT) will have to display the monthly payments if opted into the program? Section 50.1 states that the claims processing solution must include no impact to prescriber or participant RTBT but also encourages plan sponsor to consider providing patient cost that reflect the program, as long as total expected OOP liability is clearly communicated to the member.

How will the OOP be displayed in the PDE, as a Patient pay amount or as Other troop amount? Are there going to be fields in the PDE layout for Monthly Participant Payment and for Applicable Maximum Monthly Cap? The patient pay amount is going to be \$0, does this have an impact in COB transactions, at the same time in the PDE and EOB data reporting or does we use the OOP cost?

Regarding the claims processing methodology, we support the COB option and agree that the card option comes with many complexities that could ultimately have a negative effect on beneficiary access to care. However, more guidance regarding how to handle the COB claims should be provided. Also, the COB option represents a significant challenge, in terms of real-time or near-real-time enrollment data feeds that are not in place or developed and will require significant system enhancements based on criteria that are not yet defined by CMS. MCS suggest that when beneficiary enrolls in the Medicare Prescription Payment Plan at point of sale, that the beneficiary still be responsible for a first payment at that time. (This may be a 2026 consideration)

CMS suggests the use of a separate Part D sponsor BIN/PCN combination for Medicare Prescription Payment Plan claim processing. The associated administrative challenges will require system enhancements. For example, plans do not currently have a way to inform PBMs in real-time when members have enrolled in Medicare Prescription Payment Plan. Specific to our PBM, we are exploring the use of a member Eligibility flag in the adjudicator. This could enable plan sponsor staff to manually update the member eligibility record to activate Medicare Prescription Payment Plan for a beneficiary who opts-in at POS. However, this also represents a challenge because the sponsor's eligibility system (the source of truth for PBM's eligibility data in the adjudicator) must be updated accordingly at the same time or else the next daily file process will revert the member back to non-Medicare Prescription Payment Plan participation status. Even if the plan's eligibility system is updated at the same time as a manual update within the adjudicator, a member record could still be reverted inappropriately due to the timing of the file versus the time of the manual update.

If CMS' final decision is to require a unique new BIN/PCN for Medicare Prescription Payment Plan claims, we suggest the PCN start with "MPPP" to help with billing order, consistency and simplicity.

Section 60

POS notification threshold of \$500 driven by a single prescription for member understanding easiness. How plan sponsors notify pharmacies when a Part D enrollee OOP cost meet criterion? There should be a specific OOP cost threshold and specific timeframe to offer the program. How can a member opt in or opt out at the POS? "Single prescription trigger for POS notification vs all prescriptions filled in a day; Threshold for "likely to benefit".

We support a single prescription threshold, as opposed to calculating an accumulated amount over multiple scripts in a single day, as the trigger for POS notification. In addition to this being a simpler solution for POS adjudication purposes, it represents a cleaner solution for billing purposes. In order to provide the best potential benefit to the beneficiary, we suggest a higher threshold for POS notification. That said, since every beneficiary's financial situation is unique to that beneficiary, a zero-threshold (triggering a POS notification regardless of the cost-share amount) may prove to be in the best interest of beneficiaries, could reduce administrative burden for point-of-sale adjudication logic, and reduce the risk of beneficiary confusion.

POS notification through pharmacies is going to be confusing to members because claims processing and billing practices may differ from certain unique pharmacies scenarios. Point of sale messaging is the standard for pharmacy communication at the point of sale (for example, Medicare and Your Rights) and would make for the simplest and most efficient method of notification. Other methods (mail, fax, text) would present difficulties in terms of document approval, notification timeframe requirements and cost.

Section 70

According to Section 70.3.5, when a Part D enrollee is already enrolled in a Part D plan and requests to opt into the Medicare Prescription Payment Plan during the plan year, Part D sponsors must process the election request within 24 hours to prevent delays in dispensing drugs to individuals when they opt into the program. Considering the scenario of the member enrollment on the program at the POS, it may be an operational challenge to complete the process within 24 hours. Retroactive Elections may be very confusing for the participant, in the event they are billed for costs before enrollment. The 24-hour waiting period represents a situation where a beneficiary could leave the pharmacy without their prescription, even while it allows the pharmacy to reprocess once the beneficiary is enrolled in the

Medicare Prescription Payment Plan. One option would be to allow a short supply, e.g., a 3-day supply, similar to the LTC emergency supply, so the participant can receive their prescription while waiting for their election into the program to process.

Section 70.4 establishes that if an individual who opted into the Medicare Prescription Payment Plan switches plans during the plan year or is reassigned by CMS, the new plan sponsor will not be required to automatically sign up the individual for the Medicare Prescription Payment Plan under the individual's new plan. However, if members change plans, what will be the debt collection process? Will there be penalties for late payments, since interest on late payments is not allowed?

Section 80

According to Section 80.5 of the guidance, nothing in the Act or in this guidance prohibits Part D sponsors from billing an individual for an outstanding Medicare Prescription Payment Plan amount owed. However, what will happen if a Plan Sponsor is not able to collect the amount owed? If a beneficiary moves from Plan A to Plan B, Plan A balances don't transfer over to Plan B, so Plan A is still responsible to collect for amounts incurred while the beneficiary was with Plan A. What are the opportunities for Plan A to collect from the beneficiary who has left for another plan? It would be convenient to identify a mechanism by which Plan A can effectively recover amounts owed to it by the beneficiary. Is the use of a debt collection service among the available options that CMS is considering?

How long can a Plan Sponsor collect a debt, even after the plan year has ended?

Can the plan sponsor collect the money owed by the beneficiary from their social security?

The fact that each state has different requirements around debt collection adds complexity. For example, if a beneficiary moves to another state, is the plan expected to account for the new state's law when attempting to collect unpaid amounts, or the old state's law (where the debt was incurred), both, or "other"?

Are CMS considering a way to track beneficiaries who fail to pay due to reasons other than financial hardship? Would such activity be the basis for preclusion from the Medicare Prescription Payment Plan? If so, how will sponsors know if a beneficiary is precluded?

Additional guidance is needed regarding termination of the member from the program if the participant fails to pay the amount billed (time that needs to be elapsed, notices contents and frequency). Although Part D enrollment will not be terminated, this may be stressful and confusing for the member.

Section 90

Members can be confused by the changes between first month max cap and subsequent month cap bills generating overload of calls and grievances.

This program may cause members to disenroll due to dissatisfaction upon receipt of debt statements. This will impact the STARs Rating. Therefore, program implementation factors out of the Part D Sponsor control should not impact STARs Rating.

Additional general comments:

- Pharmacies had different contracted rates for drugs at the POS, therefore beneficiaries will need to understand why they pay different copays when they attend different pharmacies.
- Plan Sponsors do not control drug cost which continues to change constantly. Therefore, the monthly calculation will be impacted by increases in drug cost or patient filling prescriptions at different locations.
- Monthly payments may be perceived by beneficiaries as equal amounts every month. This is dependent on the prescription costs and therefore could vary every month causing beneficiary confusion and lack of transparency.
- Patients may be discouraged from the program when they received a low-cost prescription within a month but later receive a bill for a high amount because they forgot that they had previously filled a high-cost drug for which the plan did not charge a copayment.
- This program could potentially decrease medication adherence because they will not understand for which particular drugs, they are paying monthly payments.
- This program may promote members to disenroll because of dissatisfaction on receiving statements of debts. This will impact STARs rating.
- For elderly members it's easier to communicate with pharmacist at POS, clarify their doubts about plan cost, patients costs or deductibles and in which part D phase they are. Although the Medicare Prescription Plan can as well be explained that dynamic of not paying at the POS but to receive a bill later at home may be not fully understood.
- PBMs will incur in programming their system in order to calculate for each part D qualify claim the OOP cost incurred, Maximum monthly CAP and the monthly participant payments. All of these costs will be passed on to the plan sponsor.
- Additionally, Plan Sponsors will be incurring in costs for creating a participant collection area for billing patients a monthly statement and doing outreach for collection.
- There are a lot of caveats and consideration such as lesser logics or billing the lower amount of a calculation that cannot be easy to be configured in the payment system. The scenarios on this to happen are very high because patients take several drugs in a month (generics, brands , high cost) etc.
- Will the EOB include the amount of the debt, or will it only be indicated in the billing statements? Because both documents will not match and will create confusion.
- Are Dual Eligible Special Needs Plans members excluded from this program? How special need plans transactions will be handled?
- How tier exception will be worked within the program?
- How is the process of collecting debt and/or reimburse debt in case of a claim reprocessing?
- Based on the complexity of this program, system configuration requirements/developments, systems interfaces, providers education, process interactions, etc., a minimum implementation timeframe of 18 months should be provided once the guidance is finalized.
- Please provide guidance toward month-by-month cumulative debt to members, so they could understand the program and avoid confusion.
- How will this process impact CMS retroactive processes notifications to Plan Sponsors? For example: Hospice and ESRD.
- For the project to be financially sustainable, the participant should have a cash fund to prospectively cover OOP.
- Will there be an EOB for the participant to know the status of OOP costs incurred, Maximum Monthly cap and Monthly participant agent?

- Penalties if the patient has debt balance? This situation could interrupt treatment? Could this Maximum Monthly Cap on Cost-Sharing Payments be only for a specific coverage stage, specific patients and/or specific drugs?

We hope that you consider our comments as constructive feedback. Should you have any questions about our comments, please contact us.

Sincerely,

Elizabeth Roman Juarbe

Elizabeth Román Juarbe
Compliance Affairs Advisor
Medical Card System, Inc.



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New York, NY 10018
212.869.3850/Fax: 212.869.3532

September 20, 2023

VIA ELECTRONIC SUBMISSION

Dr. Meena Seshamani
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments

Dear Dr. Seshamani:

The Medicare Rights Center (Medicare Rights) appreciates this opportunity to comment on the **Medicare Prescription Payment Plan (MPPP)** draft guidance. Medicare Rights is a national, nonprofit organization that works to ensure access to affordable and equitable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Each year, Medicare Rights provides services and resources to over three million people with Medicare, family caregivers, and professionals.

Based on this experience, we know people with Medicare are uniquely impacted by high and rising drug prices. This is partly due to utilization and health status. Over two-thirds of Medicare beneficiaries have multiple chronic conditions,¹ and Part D enrollees take 4 to 5 prescriptions per month, on average.² Many live on fixed or limited incomes that cannot keep pace with rapidly escalating drug prices. Half of all beneficiaries, nearly 30 million people, live on \$29,650 or less per year, and one quarter have less

¹ Centers for Medicare & Medicaid Services, "Multiple Chronic Conditions" https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/MCC_Main.

² Leigh Purvis, *et al.*, "Rx Price Watch Report: Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2020" AARP Public Policy Institute (September 28, 2021) <http://www.aarp.org/rxpricewatch>.

than \$8,500 in savings.³ Health care costs comprise a large and disproportionate share of beneficiaries' limited budgets: nearly 30% of Medicare households spend 20% or more of their income on health care, compared to only 6% of non-Medicare households.⁴ Out-of-pocket costs for prescription drugs represent a significant share of this amount, accounting for nearly one out of every five beneficiary health care dollars.⁵ Most people with Medicare cannot afford to pay more for care.

Callers to our national helpline regularly report struggling to afford the prescription medications they need to maintain their health and well-being. And they are not alone. In 2021, over 5 million people with Medicare are estimated to have had difficulty paying for their prescriptions, with Black and Latino beneficiaries being disproportionately affected.⁶ That same year, nearly twenty percent of older adults said they had not filled a prescription in the past two years, most due to affordability concerns.⁷ Yet, drug costs continue to climb—price hikes on brand name medications have exceeded the rate of inflation every year since at least 2006.⁸

The Inflation Reduction Act's Medicare reforms, including the MPPP, will provide much-needed relief: lowering prices, increasing medication adherence, and improving outcomes. In combination with the law's other changes, this "smoothing" program could help more Medicare beneficiaries afford needed care, improving financial and physical well-being. Accordingly, we applaud your efforts to responsibly implement the MPPP, including this initial guidance. The outlined policies take important first steps to address critical issues, such as how drug plans should communicate with enrollees and establish program infrastructure.

We appreciate the opportunity to offer responsive comments which are informed by our work assisting older adults and people with disabilities navigate the Medicare program, including both existing and new enrollees. As discussed in more detail below, although we are optimistic the MPPP will fulfill its potential, we are concerned the program's complexity may hinder its efficacy. By design, its impacts will vary from one beneficiary to another, and even from month to month. These fluctuations may prove confusing for many, tempering active engagement. And for some, the effects may be more pernicious. In certain circumstances, the MPPP's interactions with existing rules and systems may yield undesirable and unanticipated results, causing greater financial harm than the problem it is trying to solve.

³ Wyatt Koma, *et al.*, "Medicare Beneficiaries' Financial Security Before the Coronavirus Pandemic" Kaiser Family Foundation (April 24, 2020) <https://www.kff.org/medicare/issue-brief/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic/>.

⁴ Juliette Cubanski, *et al.*, "The Financial Burden on Health Care Spending: Larger for Medicare Households than for Non-Medicare Households" Kaiser Family Foundation (March 1, 2018) <https://www.kff.org/medicare/issue-brief/the-financial-burden-of-health-care-spending-larger-for-medicare-households-than-for-non-medicare-households/>.

⁵ Kaiser Family Foundation, "10 Essential Facts about Medicare and Prescription Drug Spending" (January 29, 2019) <https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/>.

⁶ U.S. Department of Health and Human Services, Assistant Secretary for Planning and Evaluation "Prescription Drug Affordability among Medicare Beneficiaries" (January 19, 2022), <https://aspe.hhs.gov/reports/medicare-prescription-drugs>.

⁷ AARP, "Consumer Views on Prescription Drugs Survey" (July 2021) https://www.aarp.org/content/dam/aarp/research/surveys_statistics/health/2021/drug-prices-older-americans-concerns.doi.10.26419-2Fres.00476.001.pdf.

⁸ Leigh Purvis, *et al.*, "Rx Price Watch Report: Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2020" AARP Public Policy Institute (September 28, 2021) <http://www.aarp.org/rxpricewatch>.

30. Program Calculations and Examples

We appreciate the inclusion of these examples while noting that they are necessarily complex and may not be immediately understood by all beneficiaries. In addition, we urge CMS to provide straightforward educational materials to enrollees regarding program calculations and request focus group testing of different ways of presenting this information to ensure maximum understanding.

We also request that CMS include language in current consumer-facing Medicare materials, such as the Medicare & You Handbook and Medicare Plan Finder, as well as email and other outreach, as appropriate. We also urge the creation of template language for plans to communicate with enrollees, including in existing materials such as the Annual Notice of Coverage (ANOC) and Evidence of Coverage (EOC) documents. Such language should state, in part, that although their out-of-pocket (OOP) costs may vary from month to month, their OOP costs should never exceed \$2,000 for the year.

CMS states that once a “participant incurs an OOP Part D drug cost, all their OOP costs for all covered Part D drugs will be billed on a monthly basis as long as the participant remains in the program.” This could be read to suggest that participants who leave the program owe a lump sum payment. We encourage CMS to clarify this language, which appears to conflict with 80.1, 80.2, and other sections of the guidance which note the temporary continuation of the maximum monthly cap post-termination, as and notes that plans “...may also offer the participant the option to repay the full outstanding amount in a lump sum but may not require full immediate repayment.”⁹

Additionally, we support the proposed provisions that ensure that progress toward the OOP max is not affected by MPPP participation and payments are allocated toward the OOP max when the prescription is filled—including 90-day prescriptions. We support these clarifications of how MPPP participation does not result in prorated or otherwise spreading out progress toward the OOP max.

40. Participant Billing Requirements

CMS requests comment about specific requirements related to debt collection for amounts due under the program. We urge CMS to discourage aggressive debt collection and/or reporting to credit agencies in addition to the proposed notice under 80.2.1 that would include information about and encouragement to apply for the Part D Low Income Subsidy (LIS) for those who have fallen behind in payments.

We also urge, as with all consumer-facing materials explaining or addressing the MPPP, that the language be tested with Medicare beneficiaries to ensure the intended recipients have the best chance of understanding the billing statements and all other communications regarding this program.

⁹ Centers for Medicare & Medicaid Services, “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,” p. 38 (August 2023), <https://www.cms.gov/files/document/medicare-prescription-payment-plan-part-1-guidance.pdf>.

40.1 Prioritization of Premium Payments

CMS proposes encouraging Part D plans to prioritize premium payments over MPPP payments in cases where there is ambiguity about received payments. This would help prevent Part D enrollees from losing their coverage – jeopardizing access to needed medications and triggering gaps and penalties. We urge CMS to strengthen this language and to expressly prevent plans from applying ambiguous payments to the MPPP plans if there are outstanding Part D premiums. The consequences for losing a Part D plan are significant and greater than the consequences for falling behind in MPPP payments.

50.1 Pharmacy Claims Processing Requirements

We share CMS’s concerns that a pre-funded card may lead to problems for Part D enrollees. Plan communications to enrollees at the pharmacy counter are already too limited and too confusing, and we hesitate to endorse any additional complexity. Further, plan variability in offering such cards could make the plan selection process more complex and otherwise increase beneficiary confusion.

We urge CMS to rule out pre-funded cards, at least for the initial MPPP year. And we urge very careful explanation of any plan differences on claims processing in Medicare Plan Finder and other tools to ensure that enrollees understand the full scope of a particular plan’s specific processes and features.

60.1 General Part D Enrollee Outreach Requirements

CMS proposes to provide additional guidance on marketing and communications procedures and content in the next phase of guidance, including guidance on communications at the pharmacy, model language, standardized materials, and language about the availability of the LIS program under Part D. We strongly support this plan.

CMS requests feedback on which Part D enrollee communication materials would benefit from CMS templates, samples, or model language. We suggest initially targeting planned communications, such as the Medicare & You Handbook, Medicare Plan Finder, Medicare.gov emails sent to people with Medicare, the Annual Notice of Coverage (ANOC), and the Evidence of Coverage (EOC).

Tested model language describing the program, including who might benefit, as well as examples of situations where the program might not fit someone's needs should be developed by CMS and distributed to plans. CMS should also consider reviewing all plan communications regarding the smoothing program to ensure accuracy. In addition, CMS proposes to develop tools (e.g., model documents and training materials) to help Part D enrollees decide whether the program is right for them. We strongly support this plan and urge CMS to use focus groups where possible to ensure maximum efficacy, readability, and comprehensibility.

We urge strong oversight of all communications as well as investigation into patterns of unusually low or high participation that may point to missing, inaccurate, or incomplete education about the MPPP or improper steering or discriminatory design.

60.2.1 Identification of Part D Enrollees Who Are Likely to Benefit

Because this program does not reduce enrollee OOP costs, whether or not reallocation of those costs across the remainder of the calendar year is a “benefit” will be a necessarily personal decision based on expected prescription needs, potential income changes, and other anticipated expenses, both health-related and otherwise. In addition to identifying individuals with large one-drug, one-day, or one-month expenses, CMS should engage in outreach to individuals who reached the catastrophic limit in previous years, those whose expected drug costs in the coverage phase are significantly lower than in the deductible phase, and those who fill expensive prescriptions that are unlikely to be recurrent.

We suggest integration of the smoothing program into the Medicare Plan Finder tool so that, when evaluating plans, beneficiaries can compare their expected monthly costs under the program with their costs if they do not elect smoothing. This self-identification can better account for the beneficiary's knowledge of their unique medical and economic situation, as well as enhance awareness and understanding of the MPPP. Information targeted for people who are “likely to benefit” should clearly explain how they were so identified and how the program would work for them. It is especially important that these, and all materials regarding the smoothing program are extremely clear that this program only shifts incurred costs throughout the year and does not reduce out of pocket expenses or eliminate cost sharing.

Information about programs that can actually reduce expenses, like LIS and SPAPs should be included in all communications. Beneficiaries who have LIS, should rarely (if ever) be identified as likely to benefit from this program.

60.2.2 Targeted Part D Enrollee Notification Prior to POS

CMS proposes that Part D sponsors must also conduct outreach directly to individuals who are likely to benefit from the program, both prior to and during the plan year. We support this intention. Part D enrollees might face a change of circumstance at any point during the year and may have forgotten about the MPPP option if not reminded.

We appreciate the agency's plans to specify the parameters for identification of enrollees prior to the plan year who are likely to benefit, and the goal of alignment with the concepts outlined in section 60.2.1. We reiterate that such targeting must identify people who are likely to benefit from smoothing as well as identify those whose prescription patterns suggest that the smoothing program might have the opposite effect – as where someone who will not reach the catastrophic coverage phase has consistent monthly out-of-pocket expenses. For this reason, the likelihood of recurrence and total annual out of pocket costs is more important than whether the threshold cost is incurred due to a single medication or daily or weekly accumulation.

60.2.3 Targeted Part D Enrollee Notification at POS

CMS seeks comment on a range of potential single day out-of-pocket cost thresholds at the point of sale that would identify a Part D enrollee as “likely to benefit” from the MPPP. We reiterate our thoughts from above that the likely to benefit category should be less about a particular threshold and more about a pattern of prescription costs that are likely to predict that the individual will reach the out-of-pocket cap.

60.2.4 POS Notification Requirements

CMS notes that “Part D sponsors must notify pharmacies when a Part D enrollee’s OOP costs meet these criteria at the POS and require the pharmacy to inform the Part D enrollee that they may benefit from the program and how to opt in if the Part D enrollee would like to participate in the program.” We appreciate that CMS plans to provide additional guidance on the contents of notifications as well as model language for educational materials in the next phase of guidance. We encourage CMS to consider creating a generally applicable point of sale notice with standardized language and tested, complete, information about the program.

We support the proposal that Part D enrollees should not be notified that they are likely to benefit from the MPPP in the last month of the plan year and that participants who have already opted in should not be notified about opting again while their participation is in effect.

We appreciate that “Nothing in this guidance precludes a pharmacy from educating a Part D enrollee about this program, regardless of whether the enrollee’s cost-sharing reaches the POS threshold for required notification.” To ensure such pharmacy communications are accurate, actionable, and clearly understood, we urge CMS to develop template communications and training materials specifically for pharmacies.

70.2 Interactions Between LIS and Medicare Prescription Payment Plan

Throughout the guidance, CMS is requiring Part D sponsors to provide individuals with information about both the MPPP and LIS prior to the plan year and upon opting into the MPPP. We applaud this effort and urge CMS to require screening for LIS prior to enrollment in the MPPP. We also support directing plans to extend LIS eligibility outreach and enrollment assistance to all members, regardless of their MPPP status.

CMS seeks comment on additional ways to conduct outreach to Part D enrollees who may be eligible for the LIS program or are already in the LIS program to educate them about the implications of participating in each of the programs to “help individuals determine which program(s) will be most suitable for their unique circumstances.” We cannot think of a single instance in which a Part D enrollee should choose the MPPP over LIS and we urge caution that a presentation of the programs as a choice between potentially equal options is likely to confuse enrollees. Generally, LIS copayments are consistent month to month except for one-time drug fills. Therefore, we reiterate that CMS should seek to limit any confusion or conflation of these two programs.

70.3.1 Format of Election Requests

We support the format and recordkeeping requirements outlined in this section.

70.3.3 Processing Election Request at the Time of Enrollment in a New Plan

CMS proposes that if a Part D sponsor receives an election request that does not have all necessary elements required to consider it complete, the sponsor must not immediately deny the request. The Part D sponsor must contact the individual to request the additional documentation necessary to process the request within 10 calendar days of receipt of the incomplete election request. We support this requirement.

70.3.8 Standards for Urgent Medicare Prescription Payment Plan Election

CMS proposes that plans must provide retroactive election if the enrollee reasonably believes that any delay in filling the prescription may jeopardize their health. We urge CMS to allow oral attestation by the enrollee to demonstrate or document such need.

70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs

CMS is considering options to effectuate election into the MPPP at the POS without any delay or with only a nominal delay between the election request and effectuation beginning in 2026 or later. We strongly encourage the development of accessible real-time options to better ensure people are able to opt in to the MPPP and gain access to their medications without delays.

70.3.10 Prohibition on Part D Enrollee Discrimination

We support this clear restatement of the ongoing requirement that plans may not design their MPPP (or any part of their plan) to discriminate against any person based on race, color, national origin, disability, sex, or age in admission to or participation in the program, whether carried out directly by the Part D sponsor or through a contractor.

70.4 Mid-Year Plan Election Changes

CMS flags that a prior Part D sponsor may offer the participant the option to repay the full outstanding amount in a lump sum but may not require full immediate repayment. In addition, CMS flags that Part D sponsors may not prevent an individual who has switched plans from opting into the Medicare Prescription Payment Plan because the individual was terminated from the program for non-payment by a different Part D sponsor or had voluntarily opted out of the program under the original plan. We support these clarifications.

Smoothing payments will be made directly to the enrollee's Part D plan, outside of the pharmacy-based clinical data management system. Therefore, when an enrollee changes Part D plans midyear, the information underpinning these payments may stay with the plan and may not be seamlessly accessible

to the enrollee, the pharmacy system or a new plan. Any payment lapses that result could jeopardize the enrollee's immediate and future access to a smoothing program, as well as their health and financial well-being.

We urge CMS to ensure that enrollee out-of-pocket cost tracking and payment obligations transfer with them, along with any clinical data required for managing prescriptions. We also ask CMS to develop guidance for plans on both sides of all enrollment changes, including those that occur midyear, to ensure the request to participate in the smoothing program as well as payment history and future obligations transfer between plans without beneficiary involvement.

In addition, there must be a way for beneficiaries to track their spending relative to out-of-pocket caps and any smoothing mechanisms, in general and across midyear plan changes, and for this information to be reflected in Medicare Plan Finder.

80.1 Voluntary Terminations

CMS flags that a Part D sponsor may offer a former participant who has opted out the option to repay the full outstanding amount in a lump sum but may not require full immediate repayment. We support this clarification.

80.2 Involuntary Terminations

CMS flags that a Part D sponsor may offer a former participant who has been terminated from the MPPP the option to repay the full outstanding amount in a lump sum but may not require full immediate repayment. We support this clarification.

80.2.1 Notice Requirement

We urge CMS to monitor the provided notices to ensure they are sent in a timely manner and contain the required information, including actionable steps.

It is especially vital that the notices make clear that the individual has not been and will not be disenrolled from the Part D plan. We urge CMS to design a template to demonstrate the appropriate language and placement of this information.

80.2.2 Required Grace Period and Reinstatement

CMS proposes that the plan must provide individuals with a grace period of at least 2 months when an individual has failed to pay the billed amount by the payment due date. We support a grace period and recommend that it be at least 3 months to allow beneficiaries time to correct non-payment errors as well as a dedicated, streamlined appeals mechanism. Such an approach largely mirrors Health Insurance

Marketplace rules.¹⁰ Marketplace enrollees who miss a monthly premium have 90 days to make a payment before losing coverage as well as the ability to appeal any subsequent terminations. At a minimum, we strongly support establishing similar protections for smoothing program participants.

CMS also proposes that plans must reinstate an individual who has been terminated from the MPPP if the individual demonstrates good cause for failure to pay. We urge CMS to allow enrollee attestation satisfy the good cause requirement.

Further, we urge CMS to limit any enrollment preclusions to the subsequent year and exact plan the enrollee had previously. We also ask CMS to encourage plans not to use enrollee preclusion at all and to instead work closely with beneficiaries to resolve payment issues, particularly those that may arise out of confusion or misunderstanding about the program.

Additionally, CMS proposes that plans may reinstate participants who have been terminated from the MPPP for failure to pay if they pay all overdue amounts. CMS leaves this to the plan's discretion. We strongly urge CMS to require plans to reinstate participants who pay all overdue amounts.

80.3 Preclusion of Election in a Subsequent Plan Year

CMS flags that plans may not preclude election into the MPPP if the participant has paid all past-due balances. We support this provision.

80.4 Prohibition on Part D Plan Enrollment Penalties for Failure to Pay Medicare Prescription Payment Plan Amount Billed

We also appreciate the policy prohibiting disenrollment from the Part D plan due to failure to pay any amount billed under the MPPP.

90. Participant Disputes

CMS requests public comments on whether sections 30 and 40 should be further amended to accommodate this new program. Because the current Part D appeals process is so onerous, we request the establishment of a streamlined separate appeals process for the MPPP or, at minimum, a dedicated grievance form or dispute resolution process to ensure those trying to opt in or resolve MPPP issues, including termination and exclusion from the program, are not trapped in the unwieldy Part D appeals process. We also urge clear communication from CMS that any appeals or grievances that are filed as MPPP disputes but are actually Part D disputes are redirected to the appropriate channels in a timely manner.

Conclusion

¹⁰ Healthcare.gov, "How to apply & enroll" (last accessed September 20, 2023), <https://www.healthcare.gov/apply-and-enroll/health-insurance-grace-period/>.

Thank you again for the opportunity to provide comment. For additional information, please contact Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Julie Carter, Counsel for Federal Policy at JCarter@medicarerights.org or 202-637-0962.

Sincerely,

A handwritten signature in black ink that reads "Fred Riccardi". The script is cursive and fluid, with the first name "Fred" and last name "Riccardi" clearly legible.

Fred Riccardi
President
Medicare Rights Center

4500 E. Cotton Center Blvd.
Phoenix, AZ 85040



September 20, 2023

Submitted via email to: PartDPaymentPolicy@cms.hhs.gov

Meena Seshamani, M.D., PhD.,
CMS Deputy Administrator & Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Prescription Payment Plan Guidance

Dear. Dr. Seshamani:

Mercy Care appreciates the opportunity to provide comments on the draft Medicare Prescription Payment Plan Program Guidance issued by the Centers for Medicare & Medicaid Services (CMS) on August 21, 2023.

Mercy Care is a not-for-profit health plan offering integrated care to children, adults, and seniors eligible for Medicaid benefits offered through the Arizona Health Care Cost Containment System which is the state agency that administers Arizona's Medicaid program. Mercy Care offers services and supports for members with:

- Physical, general mental health and substance use concerns (Complete Care)
- Serious mental illness (RBHA)
- Children and youth in the foster care system (DCS Comprehensive Health Plan)
- Long Term Care/ elderly, physically disabled (ALTCS/EPD)
- Developmental/cognitive disabilities/ long term care (DDD/ALTCS)
- Medicare and Medicaid (d/b/a Mercy Care Advantage)

Our Mercy Care Advantage (MCA) plan is our Dual Eligible Special Needs Plan serving over 13,000 enrollees in the state of Arizona. All our MCA enrollees qualify for Low-Income Subsidy (LIS) assistance providing them with the lowest cost sharing available for their Part D prescription drug coverage.

The Inflation Reduction Act changes going into effect on January 1, 2024, further benefit dual eligible beneficiaries receiving LIS assistance by expanding the full LIS benefit, allowing all beneficiaries previously eligible for Category 4 to receive LIS Category 1 benefits and the elimination of the beneficiary cost-sharing in Part D catastrophic phase.

In the draft guidance issued, CMS states enrollees eligible for Low-Income Subsidy (LIS) assistance are not likely to benefit from enrollment in Medicare Prescription Payment Plan Program and Mercy Care agrees with CMS. We are concerned the dual eligible population we serve will be confused about how about how the Program

operates and may elect to opt in when it is not in their best interest, which will result in beneficiary frustration and dissatisfaction.

Mercy Care would appreciate CMS to consider excluding Medicare beneficiaries who are dual eligible and qualify for Low-Income Subsidy (LIS) assistance from this Program. If a Medicare beneficiary later loses their Medicaid coverage and no longer qualifies for Low-Income Subsidy (LIS) assistance, then they can receive information about the Medicare Prescription Payment Plan Program for participation consideration.

Mercy Care utilizes CVS Health as our Pharmacy Benefits Manager (PBM). CVS Health shared a copy of their comments submitted to CMS for this Program and agrees with their concerns, comments, and recommendations made to CMS. Additionally

Section 40. Participant Billing Requirements: Our Mercy Care Medicaid plans do not require any type of member billing. Our Mercy Care Advantage Dual Eligible Special Needs plan's do not include plan premiums, our dual eligible enrollees have their Medicare cost sharing amounts covered under their AHCCCS Medicaid plan coverage, and they are not subject to Late Enrollment Penalties (LEP). For the reasons explained, Mercy Care does not have experience billing our membership and does not have a current infrastructure established to conduct member billing and reconciliation activities. It will be extremely challenging for our organization to develop and implement a billing system and processes required to support this Program by January 1, 2025.

Section 80. Procedures for Termination of Election, Reinstatement, and Preclusion: Under current Medicare regulations dual eligible beneficiaries continue to qualify for Medicare Special Election Periods which allow for plan changes throughout the calendar year. Dual eligible enrollees frequently change plans more than once in a calendar year. An enrollee that still has an outstanding balance owed to one Part D sponsor under the Program, should not be permitted to enroll in the Program of another Part D sponsor except in limited circumstances, such as a permanent move outside of their current Part D sponsor plan service area. Allowing enrollees to switch plans when they have an outstanding balance owed will encourage enrollees to switch Part D sponsors and this creates disruption in care. We recommend CMS apply its regulatory authority to limit plan changes under the Program.

Receiving the finalized two-part guidance for this Program in 2024, will not allow sufficient time for proper implementation by January 1, 2025. The Program presents multiple complexities for plans, pharmacies, and pharmacy benefit managers (PBMs) and will require significant process changes, system enhancements, testing, and operational processes to be developed for proper implementation.

Sincerely,

A handwritten signature in black ink, appearing to read "Christina Macias".

Christina Macias
Medicare Compliance Officer
Mercy Care Advantage



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



September 18, 2023

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

Submitted via email: PartDPaymentPolicy@cms.hhs.gov

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

Dear Dr. Seshamani:

The National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the draft part one guidance for the *Maximum Monthly Cap on Cost-Sharing Payments Program* ("MPPP"), established by section 11202 of the Inflation Reduction Act (IRA).

Summary of Recommendations:

- To help ensure that CMS' goals are met of participants' having timely, uniform, seamless and consistent experiences, CMS should *require* that MPPP-related pharmacy costs for the coordination of benefits (COB) methodology approach are reimbursed through adequate and appropriate dispensing fees.
- We agree that there must be a unique nomenclature so that pharmacies may easily identify the relevant claim responses for the COB transactions. Specifically, the Processor Control Number (PCN) should begin with the letters "MPPP" so that pharmacy practice management systems can easily and properly identify and process these claim responses.
- With respect to enrollee notification, there is no requirement that the pharmacy provide counseling or consultation on the matter, nor for the pharmacy to document that the pharmacy has made such notification. We believe that CMS' adopting any of these actions as requirements would be unduly and unnecessarily burdensome on pharmacies, and that enrollee notification, counseling and consultation are the responsibilities of plan sponsors and their pharmacy benefit managers (PBMs). Moreover, if such actions were requirements of pharmacies, they could provide plan sponsors and their PBMs with new opportunities to audit pharmacies and subsequently claw back reimbursement.
- 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. It is very difficult to conceive of how pharmacists and pharmacies could take on the additional

burden of beneficiary enrollment without fair and adequate reimbursement to help facilitate that service.

- As stated in our previous meetings with HHS, we request CMS ensure pharmacies' reimbursements are protected as PDP and MA-PD plan sponsors may decide to recoup the costs of implementing the MPPP through retroactive fees, similar to DIR claw backs. Again, CMS' failure to take such steps likely would be devastating to pharmacists, pharmacies, and the patients we serve.**
- While administratively burdensome, and a requirement for plans and PBMs, pharmacists and pharmacies may be notifying enrollees of their eligibility for the MPPP. To do this, pharmacists and pharmacies will need clear, standardized educational materials provided by CMS or by Part D plans well ahead of 2025. To help ensure a seamless approach for beneficiaries, we urge CMS to develop or require plans to develop clear, consumer-friendly, standardized educational materials for beneficiaries to help provide the intended affordable relief to enrollees. 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.**
- The burdens of any retroactive actions and reimbursements should be carried by the responsible party, i.e., the Part D sponsor, and that responsible party should not be able to shirk its responsibilities by passing the burdens on to pharmacies.**
- In any scenario where election into the MPPP occurs at the point of sale (POS) without delay, potential participants will require the assistance of pharmacy personnel to educate and inform them about the details of the MPPP and assist with the communication to the Part D sponsor. In other words, pharmacy personnel essentially would be recruited to function as agents of the Part D sponsors; thus, pharmacies should be adequately reimbursed an administrative fee for performing these services. In addition, pharmacies should be reimbursed for the technology development costs to facilitate the election at POS and should be compensated for any transaction fees that result, such as for the claim reversal and resubmissions.**

§50. Pharmacy Payment Obligations and Claims Processing

We appreciate CMS' recognition that Part D sponsors must pay the pharmacy the participant's cost-sharing amount in addition to the Part D sponsor's portion of the payment no later than 14 days after the date on which the claim is received for an electronic claim or no later than 30 days for any other claim. In other words, to ensure that the MPPP has no effect on the amount paid to pharmacies, the Part D sponsor must pay the pharmacy for the amount the participant would have otherwise paid at the POS in addition to the sponsor's contracted portion of the payment.

We support CMS' policy of not having an impact on the amount paid to pharmacies. Moreover, we support CMS' policies that the MPPP's claims processing methodology ensures a timely, uniform, and seamless experience for all, provides a consistent participant experience, and minimizes disruptions to existing processes.

Under §50.1, CMS is encouraging the use of an electronic claims processing methodology similar to the one currently used for real-time COB billing transactions using the National Council for Prescription Drug Programs (NCPDP) standards. We support CMS' goals for a timely, uniform, seamless and consistent experience for participants, as well as for an approach that minimizes disruptions to existing processes. However, we believe

that if not implemented with specific elements and assurances, then CMS' proposed approach would not minimize disruptions to existing processes, and consequently could obfuscate CMS' goals for a timely, uniform, seamless and consistent experience for participants.

Generally, pharmacy transaction systems do not have an exception process to support actions for messages on paid claim responses. Pharmacies would have to engage in technology systems development to allow for this type of methodology. In addition to technology systems development time and costs, pharmacies would also have to engage in pharmacy personnel education and training—plus maintenance and similar ongoing resources and costs.

Should CMS opt to choose the COB methodology approach to meet CMS oversight and enforcement goals and purposes, as CMS mentions in its dismissal of the proposal for a method using a Part-D sponsored pre-funded payment card (similar to a Health Savings Account (HSA) card), then CMS should provide or require the necessary funding to ensure pharmacies are paid a dispensing fee to support the COB approach. We appreciate CMS' recognition of this under §50.2. However, the language of this section does not go far enough, as it merely recognizes that MPPP-related pharmacy costs are "allowable pharmacy costs." From our experience, we are confident that plan sponsors are highly unlikely to reimburse pharmacies for costs that are merely "allowed." As CMS is aware, pharmacies have been burdened with exorbitant retroactive fees, i.e., DIR fees, imposed by plan sponsors and their PBMs. In an environment where plans sponsors and their PBMs were free to impose DIR fees that grow exponentially every year, it is practically inconceivable that they would provide pharmacies with dispensing fees that cover costs that are "allowed." **Rather, to help ensure that CMS' goals are met of participants' having timely, uniform, seamless and consistent experiences, CMS should require that MPPP-related pharmacy costs for the COB methodology approach are reimbursed through adequate and appropriate dispensing fees.**

In addition, under CMS' proposal, Part D sponsors would utilize an additional Bank Identification Number (BIN) and/or Processor Control Number (PCN) unique to the MPPP to facilitate electronic processing of the COB transactions. **We agree that there must be a unique nomenclature so that pharmacies may easily identify these transactions. However, we believe that CMS' proposal does not go far enough in this requirement. There is likely a great deal of noise in paid claim responses, and it would be very burdensome and ineffective to rely on manual processes to identify these specific transactions. Specifically, the PCN should begin with the letters "MPPP" so that pharmacy practice management systems can easily and properly identify and process these claim responses.**

§60. General Part D Enrollee Outreach Requirements

Enrollee Notification

As CMS recognizes in the draft guidance, if a Part D enrollee who has not already opted into the MPPP incurs out of pocket (OOP) costs and they are likely to benefit from the new program, Part D sponsors are required to establish a mechanism to notify a pharmacy so that the pharmacy can notify the enrollee that they may benefit from the program and how to opt in if the enrollee would like to participate. CMS is proposing to base the notification determination on whether the enrollees equal or exceed a POS threshold regardless of whether the enrollee receives their medications through a retail pharmacy, mail order, long-term care pharmacy, specialty or home infusion.

CMS indicates that it will provide additional guidance on the contents of notifications and model language for education materials in a second guidance and welcomes further input on this matter.

We appreciate that CMS is developing additional guidance for notifications and education materials. As CMS develops this second guidance, we would like to remind CMS that the statutory language requires pharmacies to notify the potential participant. **There is no requirement that the pharmacy provide counseling or consultation on the matter, nor for the pharmacy to document that the pharmacy has made such notification. We believe that CMS' adopting any of these actions as requirements would be unduly and unnecessarily burdensome on pharmacies, and that enrollee notification, counseling and consultation are the responsibilities of plan sponsors and their PBMs. Moreover, if such actions were requirements of pharmacies, they could provide plan sponsors and their PBMs with new opportunities to audit pharmacies and subsequently claw back reimbursement.**

Under §60.2.4, CMS states that if a prescription is picked up by another person who is not the Part D enrollee, then the pharmacy would be required to provide the person who is picking up the prescription with the relevant information in the appropriate circumstances. We appreciate CMS' recognition that in these situations it would likely be impossible for the pharmacy to track down and notify the Part D enrollee directly.

Enrollee Registration

We support the intent of the IRA and CMS' draft guidance to provide enrollees with new options to manage their OOP costs. The IRA requires pharmacies to notify an enrollee of notification from a plan sponsor that the enrollee has incurred OOP costs that the enrollee may benefit from making an election into the MPPP. However, the IRA does not require pharmacies to enroll or register an enrollee into the MPPP—this is evidenced by the title for subclause (III) under Section 11202 that Congress chose: “PDP Sponsor and MA Organization Responsibilities.” There is a clear line of demarcation from Congress as to Congressional intent with respect to the responsibilities of plan sponsors under IRA.

Although we appreciate CMS' acknowledgment of pharmacies as convenient access points, there is presently no technology or process for pharmacies to enroll beneficiaries into the MPPP, nor do we expect such technology to be available any time soon. In addition, there is no known ability to set aside time and resources in pharmacy workflow for pharmacy personnel to enroll beneficiaries and perform related documentation tasks. We are especially concerned that a pharmacy enrollment requirement would not reimburse pharmacists and pharmacies for providing that service. **As CMS is aware, pharmacies are already struggling to stay afloat under the heavy burden of low reimbursement and DIR fees imposed by plan sponsors and their PBMs. It is very difficult to conceive of how pharmacists and pharmacies could take on the additional burden of beneficiary enrollment without fair and adequate reimbursement to help facilitate that service.**

The IRA also requires that the PDP or the MA-PD plan ensure that the election by an enrollee has no effect on the “amount paid to pharmacies” (or the timing of such payments) with respect to covered Part D drugs dispensed to the enrollee. **As stated in our previous meetings with HHS, we request CMS ensure pharmacies' reimbursements are protected under this provision as PDP and MA-PD plan sponsors may decide to recoup the costs of implementing this provision through retroactive fees, similar to DIR claw backs. Again, this would be devastating to pharmacists, pharmacies, and, ultimately, the patients we serve.**

As mentioned above, pharmacists and pharmacies may be notifying enrollees of their eligibility for the MPPP. To do this, pharmacists and pharmacies will need clear, standardized educational materials provided by CMS or by Part D plans well ahead of 2025. To help ensure a seamless approach for beneficiaries, we urge CMS to develop or require plans to develop clear, consumer-friendly, standardized educational materials for beneficiaries to help provide the intended affordable relief to enrollees. 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.

§70. Requirements Related to Part D Enrollee Election

Under §70.3.7, if a Part D sponsor is unable to process an enrollee's election in the required amount of time due to no fault of the enrollee, the Part D sponsor must process a retroactive election and reimburse the participant for any OOP cost sharing paid. We ask CMS to clarify that the Part D sponsor is solely responsible for the retroactive election and reimbursement to the participant, and that the Part D sponsor shall not require the pharmacy to reverse and resubmit claims and/or require the pharmacy to process and provide the reimbursement to the participant. Pharmacies should not be held responsible and take on unnecessary risk because of the actions or inactions of the Part D sponsor. **The burdens of any retroactive actions and reimbursements should be carried by the responsible party, i.e., the Part D sponsor, and that responsible party should not be able to shirk its responsibilities by passing the burdens on to pharmacies.**

Under §70.3.9, CMS is seeking comment on options to process elections into the MPPP at the POS with no delay or a minimal delay beginning in 2026 or later. In general, and with respect to all three options that CMS poses in the draft guidance, it is our understanding that election into the MPPP without delay is not presently workable because PBMs, which would process the election and subsequent prescription drug claims, do not have the necessary information on file to process an election immediately. The PBMs would have to consult with the plan sponsor in order to determine whether the enrollee is eligible to elect into the MPPP. Our understanding is that this hurdle would first have to be overcome.

Also, with respect to all three presented options, telephone-only, mobile or web-based application, and clarification code, should the above-mentioned hurdle be addressed and overcome, there are pharmacy specific concerns that must be addressed. **In all three situations, and likely in any scenario where election into the MPPP occurs at the POS without delay, potential participants will require the assistance of pharmacy personnel to educate and inform them about the details of the MPPP and assist with the communication to the Part D sponsor. In other words, pharmacy personnel essentially would be recruited to function as agents of the Part D sponsors; thus, pharmacies should be adequately reimbursed an administrative fee for performing these services. In addition, pharmacies should be reimbursed for the technology development costs to facilitate the election at POS and should be compensated for any transaction fees that result, such as for the claim reversal and resubmissions that CMS mentions for all three options in the draft guidance on pages 35 and 36.**

Conclusion

In conclusion, NACDS and NCPA thank CMS for this opportunity to submit comments and for considering our recommendations. If we can provide any additional information, please do not hesitate to contact Christie Boutte, Senior Vice President, Reimbursement, Innovation and Advocacy, at cboutte@nacds.org or Ronna B. Hauser, PharmD, Senior Vice President, Policy & Pharmacy Affairs at ronna.hauser@ncpa.org.

Sincerely,



Steven C. Anderson, FASAE, IOM, CAE
President and Chief Executive Officer
National Association of Chain Drug Stores



B. Douglas Hoey, RPh, MBA
Chief Executive Officer
National Community Pharmacists Association

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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. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.

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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 \$78.5 billion healthcare marketplace, employ 240,000 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. NCPA submits these comments on behalf of both community and LTC independent pharmacies.



September 20, 2023

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

RE: Medicare Prescription Payment Plan Guidance

Sent via electronic mail to PartDPaymentPolicy@cms.hhs.gov

Dear Dr. Seshamani:

I am writing on behalf of the National Association of Benefits and Insurance Professionals (NABIP), formerly known as NAHU, which is an association representing over 100,000 licensed health insurance agents, brokers, general agents, consultants and employee benefits specialists. We appreciate the opportunity to provide comments on the Center's recently published sub-regulatory guidance on the Medicare prescription drug payment plan created by the Inflation Reduction Act.

NABIP members work daily to help millions of people and businesses purchase, administer and utilize health insurance coverage. Thousands of our members specialize in assisting Medicare beneficiaries with their coverage needs. As such, we are grateful for the opportunity to share feedback on this draft guidance. We've broken down our comments by topic, with the content developed by the members of our Medicare Working Group.

Program Intention, Integrity and Optimal Timeline

NABIP members who work directly with Medicare patients appreciate the intention of this program and this related guidance. Many beneficiaries have fixed incomes, and the program will provide financial assistance to many enrolled in Medicare. However, prescription-drug purchasing is confusing generally, particularly for many older Americans. While this program will be right for many, it will not be best for all, or in all circumstances. In order to ensure the integrity of the program, and to serve the best interest of affected beneficiaries, it will be imperative that all entities involved with rolling out this program are fully educated about all of its components. To do that effectively, we believe that your Center will need to accelerate its proposed implementation timeline and mandate prescription payment program education.

Currently, the proposed guidance and accompanying timeline state that CMS will finalize its guidance on outreach and enrollment in the payment plan program in the summer of 2024. However, brokers, issuers, pharmacists, SHIP counselors, providers, social workers and other entities who assist Medicare beneficiaries with their coverage and prescription-drug needs will need concrete details about the program and its implementation well before then. Helping seniors choose the appropriate coverage and educating them about how best to utilize their coverage is a complicated process. Each senior's particular prescription drug needs are especially complicated by factors such as geography, pharmacy network, medication dosage and delivery method and the fact that prescribed medications change so often. Adding a new layer of prescription drug payment assistance will be very helpful for many seniors, but it is critical that those who advise Medicare beneficiaries understand that program fully before they introduce it to their beneficiary clients. People who assist beneficiaries will need time to learn the program specifics themselves, then more time to build tools and resources to use when educating the Medicare population. These documents and other teaching and enrollment materials will need to be written in plain language and at an appropriate (sixth grade) reading level and translated as needed. This process will take time.

Additionally, from a broker's perspective, NABIP members believe appropriate education about this new program will be vital. Accordingly, we believe that specific details about the payment program and how it will work both for beneficiaries and on the back end needs to be part of the annual certification coursework all brokers who sell private Medicare products to seniors must complete. Not only should the overall details about the program be included in the NABIP and AHIP comprehensive training programs, but also each carrier offering Medicare Advantage and Part D products should be required to address how the payment program will impact their specific coverage options in the year ahead. Access to these certification programs typically opens in June. To ensure that the appropriate content is included in each of these certification courses, details will need to be finalized by CMS and made readily available to education providers by at least April 2024.

NABIP members recognize that finalized details about the new prescription drug payment program could be provided to agents later through a certification course amendment. However, after careful consideration, the members of our Medicare Working Group concluded that details about the new program are too important to be left to the amendment process. Medicare agents are not required to review the information in certification-course amendments, so we are concerned that too many agents will not absorb it before the program is fully launched in January of 2025.

Accordingly, NABIP members believe that the key to a successful launch and delivery of the prescription drug payment program will be an earlier release of all finalized guidance and requirements for program management and enrollment. For agents and brokers to be ready for the 2025 Medicare annual election period, which begins in the Fall of 2024, CMS will need to

have all details confirmed no later than April 2024. Our members can really only speak directly about Medicare agent training requirements, but we assume that access to finalized program details at an earlier pace than currently proposed will be beneficial and necessary for all other entities and individual who may advise seniors on their benefits and prescription-drug needs. It also will ensure understanding of the financial components for program integrity. If CMS believes that an accelerated timeframe is unrealistic, then we suggest that you give all due consideration to delaying its overall implementation until calendar year 2026. The new program and its potential to help seniors with confusing bills and dramatic expenses is great. It would be regrettable if expectations for the program were not met due to a lack of effective education and communication strategy.

Preserving the Program's Long-Term Financial Stability

In addition to ensuring a successful implementation of the prescription drug payment plan program, NABIP members are very invested in the program's long-term financial stability. To that end, our members have several suggestions to ensure that issuers are always fully compensated for the cost of prescription drugs that are subject to the payment plan program. First, we suggest that, much like beneficiaries may elect to have their Medicare premiums deducted from their Social Security payments, Social Security deductions be a payment option for beneficiaries to choose when opting into the monthly prescription drug payment program. Beneficiaries will appreciate this easy payment option, and issuers will appreciate the predictability of related payments.

Further, should beneficiaries fail to make their monthly payments and exceed their grace period, issuers should be permitted to institute Social Security deductions to recoup their costs. Otherwise, NABIP members are concerned some beneficiaries may unfairly take advantage of the new program resulting in issuers being forced to absorb their prescription drug costs. We also suggest that all enrollment material include explicit language about how beneficiaries may be disenrolled from the prescription drug payment program by their issuer should they fail to make their monthly payments on a timely basis. Similarly, we suggest that if an individual is disenrolled from the payment program for non-payment of monthly prescription drug cost installments, then that individual should not be permitted to enroll in the program with another issuer. Our concern is that individuals may enroll in the program with one issuer, particularly late in the year, fail to make their payments and then repeat the behavior during the next year with a different issuer.

Since beneficiaries with Part D coverage are apt to switch plans and issuers fairly regularly due to formulary and medication changes, we are concerned about issuers being stuck with unpaid bills from the prior plan year, particularly in the case for late plan year requests. Ultimately, the increased costs to issuers will be passed along to all consumers in the form of increased premiums. Private Medicare premiums are already on the rise, and beneficiaries cannot bear



additional cost increases. Further, if issuers encounter too much difficulty and costs in administrating the prescription drug payment program, they may opt to leave the service area, causing issues for all affected beneficiaries. This is especially true for Part D insurance issuers whose margins are not as strong as Medicare Advantage. Allowing issuers to easily recoup the costs they will be expending on the behalf of program participants and ensuring appropriate consequences for payment delinquency will go a long way toward keeping this program solvent and functioning for years to come.

We truly appreciate the opportunity to comment on this draft guidance, as well as your willingness to consider the viewpoints of all stakeholders. If you have any questions or need additional information, please do not hesitate to contact me at jgreene@nabip.org or (202) 595-3677.

Sincerely,

John Greene
Senior Vice President of Government Affairs
National Association of Benefits and Insurance Professionals



Submitted Electronically to: PartDPaymentPolicy@cms.hhs.gov

September 20, 2023

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

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 August 2023. NASP appreciates the agency's efforts to solicit stakeholder feedback, holding early discussions with NASP to consider implementation of the Inflation Reduction Act's provisions to establish the *Maximum Monthly Cap on Cost-Sharing Payments Program*. Our comments here are meant to offer assistance for ensuring that 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 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 unifying the voices of specialty pharmacy.

Section 50 – Pharmacy Payment Obligations and Claims Processing

CMS clarifies in the guidance that under the IRA¹, Part D sponsors must pay the pharmacy the enrollee’s cost-sharing amount in addition to the Part D sponsor’s portion of the payment. Since individuals will pay \$0 at the point-of-sale instead of the out-of-pocket cost sharing they would normally pay at the point-of-sale when filling a prescription, Part D sponsors must pay the pharmacy the enrollee’s cost-sharing amount in addition to the Part D sponsor’s portion of the payment. Part D sponsors are required to reimburse a network pharmacy the total of a participant’s out-of-pocket amount and the Part D sponsor portion of the payment for a covered Part D drug no later than 14 days after the date on which the claim is received for an electronic claim or no later than 30 days after the date on which the claim is received for any other claim. CMS also states that the timing of payment of the total of a participant’s out-of-pocket amount and the Part D sponsor portion of the payment for home infusion pharmacies “should follow current practices for payment of the Part D sponsor portion to be consistent with this requirement.” NASP would appreciate further clarification of what is meant by “current practices for payment” as it relates to home infusion pharmacies.

Ensuring accuracy and timeliness of payment to the pharmacy for MPPP enrollees is paramount, given the significant number of enrollees that will likely opt into the MPPP to support their specialty drug costs. NASP urges CMS to establish an oversight process that permits pharmacies to notify CMS and seek support to address pharmacy payment concerns if plans are not in compliance with the payment and timeliness of payment requirements under the law.

50.1 Pharmacy Claims Processing Requirements

It is imperative that implementation of the MPPP has no effect on the amount paid to pharmacies in accordance with the IRA law.² A Part D sponsor must pay the pharmacy for the amount the enrollee would have otherwise paid at the point-of-sale. NASP supports CMS’ suggestion that Part D sponsors report claims using two different Bank Identification Numbers (BINs) and Processor Control Numbers (PCNs) to facilitate electronic processing of COB transactions. This workflow outlined seems to be in line with standard billing practices for specialty pharmacy operators. NASP also supports having an initial claim return a response message indicating that an enrollee has opted-into the MPPP.

Pre-funded Payment Cards

CMS also raises the concept of permitting Part D sponsor-issued pre-funded payment cards (similar to a Health Savings Account (HSA) card) that a MPPP enrollee could present to a pharmacy to pay for their liability amount owed at the point-of-sale. In raising this option, CMS stated it is concerned this approach does not provide the same level of Part D sponsor oversight

¹ Section 1860D–2(b)(2)(E)(v)(III)(ff)

² Ibid.

to ensure that payments are only made for covered Part D drugs for the participant cardholder. CMS also stated that the agency sees concerns surrounding timeliness of issuing payment cards and participants needing to present a physical card at the point-of-sale, which could be forgotten, lost, or stolen, potentially causing delays in obtaining prescription drugs, elevated risk of fraud, and potentially adding additional costs to the Part D program. CMS also acknowledged that not all pharmacies may have the financial capabilities to enable a prefunded payment card system. NASP agrees with each of the concerns raised by the agency. We are particularly concerned about the negative impact a card may have on: timely access to specialty treatments; card compatibility concerns with pharmacy processing systems that are not uniform; and the resulting card-related fees, including processing fees that pharmacies could face.

50.2 Pharmacy Transaction Costs

CMS states “that any additional transaction fees or other costs pharmacies incur from processing claims under the MPPP or otherwise related to such program are considered allowable pharmacy costs associated with the dispensing of a covered Part D drug that may be paid through applicable dispensing fees.” NASP appreciates CMS’ recognition and acknowledgement that a pharmacy will incur costs as a result of new and additional MPPP requirements; however, the agency needs to understand that 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. Specialty pharmacies typically incur significantly higher costs due to accreditation requirements that validate capabilities, shipping/handling requirements, clinical staff training, extensive patient counseling and clinical support, and 24/7 call center support.

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 enrollee notification or direct MPPP-related management requirements the agency is considering or that a Part D sponsor could seek to place on pharmacies. While NASP seeks to streamline the services specialty pharmacies would be required to manage for the MPPP to ensure they are not disruptive to specialty drug access or overly burdensome on specialty pharmacies, 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.

50.3 Requirements for Different Pharmacy Types

It is important that CMS understand and appreciate the operational differences of closed-door specialty pharmacies that operate from a centralized location and support enrollees regionally and nationally through direct and ongoing engagement via call center calls and videos and courier delivery of medications. For these specialty pharmacies, NASP believes that enrollee education on the MPPP must not be required in advance of dispensing specialty medications, as such a

process in the absence of directly meeting with an enrollee could result in medication delivery delays, threatening patient care and clinical requirements for beginning a new therapy.

NASP recommends that CMS develop and permit specialty pharmacies to include a one-page standardized document about the MPPP and how to reach out to plan sponsors when delivering specialty medications to beneficiaries.

How to communicate about overlapping programs

CMS requests feedback for its next iteration of guidance on the best ways to educate and communicate with Part D enrollees about overlapping programs that can be utilized to support the patient's payment obligation. Specialty pharmacies often develop robust financial assistance tools and support systems to help patients manage their out-of-pocket obligations to ensure patients can begin and remain adherent to complex and costly drug treatment regimens for their medical conditions. Many specialty pharmacy patients receive direct financial assistance through foundations, grants and other forms of patient assistance. We understand that many patient assistance programs plan to continue providing direct support to patients to help support MPPP enrollee cost obligations. We encourage CMS to consider comments received from these programs to ensure that there is no disruption to how these programs will operate and work with enrollees and specialty pharmacies to identify support as needed to ensure an enrollee can remain in the MPPP without risk of being disenrolled for non-payment.

Section 60 – Requirements Related to Part D Enrollee Outreach

60.1 General Part D Enrollee Outreach Requirements

We understand that CMS plans to provide additional guidance concerning pharmacy communications to enrollees to notify them of the option to opt into the MPPP. We want to ensure that the requirement to notify enrollees of the MPPP is not exclusively or more significantly placed on the pharmacy through CMS guidance or directly by the plans. The IRA statute requires pharmacies to notify an enrollee once a plan sponsor has determined an enrollee may benefit from the MPPP. NASP looks forward to seeing the additional guidance and providing additional feedback.

NASP does not have specific comments on the threshold for when an enrollee should be notified of the MPPP option. We agree that all enrollees should be notified of the program and want to ensure that plans consider what option may be the best option for an enrollee (e.g., MPPP or LIS) based on an enrollees drug costs, particularly if a patient is prescribed high cost specialty drugs to manage their condition.

We encourage CMS to work to develop clear educational programs that can be shared with pharmacies well in advance of 2025, and we also encourage webinars with pharmacies and other stakeholder groups to ensure that there is clarity regarding implementation of the MPPP.

Section 70 – Requirements Related to Part D Enrollee Election

70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs

CMS proposes, as of 2026, to allow individuals to opt into the MPPP at the pharmacy and collect their prescription at the same pharmacy transaction. The IRA statute does not require pharmacies to enroll an individual into the MPPP. CMS also needs to be mindful of the differences between brick and mortar pharmacies and closed-door specialty pharmacies, where individuals do not go to the pharmacy to obtain their prescriptions but rather receive their prescriptions by delivery.

NASP is concerned that the technology and systems needed for pharmacies to enroll individuals into the MPPP do not yet exist and likely would not exist under the timeline envisioned by CMS for POS election at the pharmacy. We are also concerned of the liabilities and risk that could be placed on the pharmacy if a plan did not receive proof that an individual first consented to enrolling in the MPPP.

Pharmacies are already under immense pressure under limited and reduced Part D plans with significantly reduced reimbursement. Specialty pharmacies are heavily service-focused, supporting patients through call centers and direct phone and video engagement, and NASP does not believe it is feasible for these pharmacies to set aside the time and resources to support individual MPPP enrollment, especially with any enrollment process not reimbursing pharmacies for this service. We encourage CMS to first evaluate the MPPP enrollment process through its first two years to determine what additional systems may need to be in place to best support individuals. To identify any future viable options for real-time enrollment, CMS should rely on broad stakeholder engagement that includes representation from the specialty pharmacy community and third-party standard setting organizations such as NCPDP.

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 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



September 20, 2023

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

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

Dear Administrator Brooks-LaSure:

The National Health Council (NHC) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed guidance for the newly created Medicare Prescription Payment Plan (MPPP). The guidance begins to put in place provisions of the Inflation Reduction Act (IRA) that are of critical importance to Medicare beneficiaries — the ability to spread payment for prescription drug costs up to the new \$2,000 annual cap throughout a calendar year. The NHC and its members worked for years to advocate for this mechanism and are invested in its successful implementation. Earlier this summer, the NHC and the Alliance for Aging Research convened a stakeholder roundtable to develop recommendations to implement this and other considerations related to the out-of-pocket maximum provisions of the IRA. [The report](#) from that roundtable has informed these comments.

Created by and for patient organizations over 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, sustainable health care. Made up of more than 150 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 representing biopharmaceutical, device, diagnostic, generic, and payer organizations.

The NHC commends CMS for its continued efforts to reduce out-of-pocket costs and financial burdens on patients. While implementing this new program, it will be critical that CMS work with patients and their representatives to support choice and access to clear, understandable, and actionable information. This is particularly true for people with chronic diseases and disabilities who are most likely to avail themselves of this option.

The NHC appreciates that this guidance provides significant patient protections, is focused on assuring that patients are educated about their options under this new program and have the information they need to make sound financial decisions. We

have specific technical comments on how to administer this program in a way that will be patient-friendly and increase the chance of successful implementation of this new program. Specifically, the NHC calls on CMS to prioritize the creation of a point-of-sale election option as soon as the program is launched. Finally, we have included recommendations for ongoing monitoring and oversight from CMS.

Overarching Comment: Participant Outreach and Education

CMS is requesting input on the most effective tools and messengers for educating beneficiaries about the program, as well as how the new program will interact with existing programs to assist beneficiaries with payments.

In the experience of our members, there is no single answer to the question of which mode will be most effective for education and outreach. It is important that beneficiaries are reached through multiple channels and hear about options repeatedly and from different messengers. The NHC encourages CMS to partner with patients and patient groups from the outset to develop the specifics of what is included in educational materials and how to best disseminate them. In addition, because there is such a high-level of need for outreach and education, it will be important that CMS devote critical time and resources to this effort. Regardless of the messenger or tool, there are three key venues when beneficiaries will need to be informed of their options. These are the points of prescription, pharmacy fill, and plan election or change.

Technical Guidance

Participant billing requirements (section 40)

Beneficiaries should have the option to autopay costs they opt to smooth. This will reduce the burden on beneficiaries and reduce the likelihood of missed payments. We appreciate that the guidance includes the option to do an electronic fund transfer as well as credit card and check options. Part D beneficiaries are also able to deduct their premiums from Social Security benefits, and we recommend that MPPP payments should be eligible for this option as well. In general, CMS should encourage sponsors to offer as many payment options as possible and align billing with premium billing, timing, and payment methods.

The NHC also appreciates the clarity in the guidance on protections from debt collection and feels strongly these protections must remain in place to assure beneficiaries are not subject to inappropriate debt collection activities.

Finally, the NHC recommends that plans be required to notify beneficiaries when they have reached their \$2,000 cap. Plans should then be required to notify beneficiaries of what their remaining payments will be for the year. At this point, the payments remain stable and predictable, so beneficiaries should be able to use this actionable information. This will also remove any insecurity about people who choose smoothing but are unaware of the annual out-of-pocket (OOP) cap.

Requirements related to Part D enrollee outreach (section 60)

While much of the information on education and outreach will be included in part two of this guidance, the NHC encourages CMS to create standardized communications

materials for insurance plans, pharmacies, pharmacists, and providers. Materials should be developed with opportunities for input from multiple stakeholder types. Consistent, clear information about the option to smooth costs should be available at multiple points so that beneficiaries are aware of and understand their ability to opt into the smoothing option. Specifically, we encourage CMS to update the Medicare.gov Plan Finder to include information about the MPPP and the OOP cap to help beneficiaries when selecting a plan. All the information outlined below should be incorporated into this important tool.

One of the most important outreach tools will be a reliable, accessible monthly cost calculator that tells beneficiaries what their monthly obligation will be if they opt into the program. By making this tool available at each decision point, it will offer beneficiaries the most basic information they need when they need it. **CMS referred to this calculator in the technical memo, and the NHC encourages CMS to prioritize operationalizing the calculator before open enrollment begins in the fall of 2024.**

While the examples provided are helpful, the NHC believes the information can be simplified. Most beneficiaries need a simple month-by-month total of what their obligations are with a short explanation that monthly payments may vary depending on several variables, but the total OOP costs will not exceed \$2,000. The columns about monthly costs incurred and monthly cap, like the examples in the guidance, are not actionable information for most beneficiaries, and inclusion may overly complicate it.

CMS also requests information on targeted education and outreach. While outreach to those likely to benefit is important, situations will vary, and the priority should be getting all beneficiaries the information they need to make their own decisions about whether they will benefit and whether it fits their own financial situation.

People with chronic diseases and disabilities should be included in any targeted efforts, as they are the most likely to incur high costs, often exceeding the \$2000 annual cap. Their costs to manage their conditions may also be regular and predictable, making a monthly payment option very important and understandable. Patient groups are a key partner for reaching this population and are ready to help. The NHC recommends that CMS assemble patient groups' help line/navigators to provide input into outreach processes and tools. They have unique expertise in this area. Plans should also be required to provide information on MPPP to people with new diagnoses of chronic diseases and disabilities that are likely to include prescriptions for medicines covered by Medicare Part D. When a patient receives a diagnosis and a prescription, the provider should have access to information to share as well.

CMS also requests information about targeted notification at the POS. A notification requirement is not useful to beneficiaries if not accompanied by an easy way to opt-in at POS. If they need to step away, contact their plan to enroll, and then return to the pharmacy, it will impact uptake and medication adherence. We feel strongly that the option to opt into the program at POS needs to be available as soon as possible and offer additional comments in the following section. CMS also presents several options for a dollar amount threshold to trigger this targeted notification. The NHC encourages CMS to set the threshold as low as possible, potentially below the \$400 threshold proposed, to assure the greatest amount of information and outreach.

Requirements related to Part D enrollee election (section 70)

CMS states that “once an individual has opted into the program, OOP cost sharing for all covered Part D drugs must be included until the participant reaches the OOP threshold or opts out of the Medicare Prescription Payment Plan.” We commend this approach. Having to opt in for each prescription could present a barrier to participation and this approach will ease the beneficiary experience. In addition to opting in for the current year, we encourage CMS to require plans to automatically re-enroll beneficiaries who remain with an existing plan and opted into the MPPP in the prior year to streamline the process.

It is also laudable that CMS is requiring Part D sponsors to provide individuals with information about both the MPPP and Low-Income Subsidy (LIS) program prior to the plan year and upon opting into the Medicare Prescription Payment Plan. The more information the beneficiary has about all programs to assist them, the better. Once again though, it is important that beneficiaries have all the financial information readily available, and the decision is theirs to make. We also appreciate that a missed payment notice must come with information about LIS eligibility to assist beneficiaries in managing their payments.

CMS solicits comments on whether there is an interim solution that Part D sponsors could implement to prevent Part D enrollees from waiting 24-hours to receive their prescription at \$0 out of pocket while waiting for their election into the program to process. The NHC appreciates the “urgent election” process and urges CMS to require broad eligibility for that process to assist those that need swift approval.

We appreciate that CMS calls for the election following the individual when they change plans mid-year. When this occurs, the NHC recommends that the previous plan should be required to notify individuals that they will continue to receive bills from them for the balance of the year. This will help avoid confusion and wrongly ignored correspondence.

Request for information on real-time POS election (section 70)

We urge CMS to achieve POS election as swiftly as possible to negate the impact of wait times on beneficiaries. CMS should not wait until 2026 as proposed, and certainly not until after 2026, to achieve POS real-time or near-real-time election. If CMS continues to delay this option in final guidance, CMS should specify what technical barriers are hindering implementation, why the final timeframe was chosen, and steps they and/or stakeholders will take to address the specified barriers. POS election is a critical component of meeting the underlying goals of this program and minimizing the burden on beneficiaries. We urge CMS to make every effort to implement POS election when the program begins in 2025. The NHC and the patient community stand ready to work with CMS and other stakeholders to overcome barriers to achieving this goal and to create solutions to getting POS election in place for as many people as possible as soon as possible.

CMS also presents options for the methods of POS election. The NHC believes that the clarification code option will be the most effective and least burdensome for patients but that both phone and electronic options for election are feasible.

Procedures for termination of election, reinstatement, and preclusion (section 80)

The NHC commends the involuntary termination notice requirements in the proposed guidance. They provide important patient protection. The two-month grace period in the guidance for payment will help beneficiaries avoid being disenrolled. While two months is a reasonable grace period, we encourage CMS to pursue a longer period to further protect beneficiaries. In final guidance, CMS should also clarify that the grace period carries over into the next calendar year if non-payment happens at the end of a calendar year.

The NHC also recommends that final guidance should clarify the “good cause” option for beneficiaries to demonstrate why they did not pay. There should be clarity on how lenient and what types of causes the plans should consider and the timeframe and process for seeking this option. Also, it should be clear how the option is communicated to those who are behind on payment. We must hold plans to maximum leniency in these cases. This is especially true since repayment in full is still required.

Finally, the NHC recommends that CMS develop language and guidance on beneficiaries’ rights and responsibilities. This tool will help patient advocacy groups and others with education efforts as we implement this new program. In general, more tools from the patient perspective would be welcome.

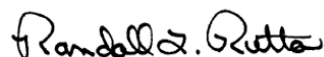
Additional Issues to Address

As with any new initiative, particularly one directly impacting beneficiaries, ongoing monitoring and oversight to refine the program is necessary. The NHC encourages CMS to put in place efforts to monitor the uptake and use of the program. This should include specific collecting and sharing data on the demographics and other characteristics of those using the program, data on numbers of people behind on payments or disenrolled, and other key information. In addition, CMS should monitor the unintended consequences on access, such as increased utilization management, of this and other parts of the Part D redesign during implementation.

Conclusion

The NHC appreciates the opportunity to provide input into the MPPP. 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 issues in greater detail. He is reachable via e-mail at egascho@nhcouncil.org.

Sincerely,



Randall L. Rutta
Chief Executive Officer



Submitted September 20, 2023
Sent via Electronic Mail

Dr. Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare Center for Medicare and Medicaid Services

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

Dear 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.

For over 40 years, NCPDP has been committed to furthering the electronic exchange of information between healthcare stakeholders. The NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting and other functions in the pharmacy services industry as named in Health Insurance Portability and Accountability Act (HIPAA). The NCPDP SCRIPT Standard and the Formulary and Benefit Standard are the standards in use in electronic prescribing as named in Medicare Modernization Act (MMA).

NCPDP submits the following comments in response to *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*, released August 21, 2023.

Section 50.1 Pharmacy Claims Processing Requirements

*To ensure that an individual's participation in the Medicare Prescription Payment Plan has no effect on the amount paid to pharmacies in accordance with section 1860D–2(b)(2)(E)(v)(III)(ff) of the Act, the Part D sponsor must pay the pharmacy for the amount the individual would have otherwise paid at the POS. An individual's OOP costs are net of any contributions made by supplemental payers to Part D that the individual may be entitled to and that reduce the OOP amount due. CMS is aware that the current coordination of benefits (COB) electronic billing process may be disrupted if a Part D sponsor initially returns an amount of \$0 in the National Council for Prescription Drug Programs (NCPDP) **telecommunications standard** response pricing segment field "Patient Pay Amount" (505-F5) on a Part D claim because this amount may be used by supplemental payers to determine if additional benefits are provided. Additionally, this amount may be used by Part D sponsors for other downstream reporting requirements, such as prescription drug event (PDE) records and explanation of benefits*

(EOB) reporting, which reflect the actual participant liability amounts as incurred.

NCPDP Comment: NCPDP requests CMS correct the standard name within the guidance. The correct NCPDP standard name is Telecommunication Standard. It is listed in the guidance as the telecommunications standard.

NCPDP recommends the establishment of a unique BIN/PCN for this program and requests that CMS require the PCN begin with “MPPP” to assist with claim billing order.

NCPDP is requesting guidance from CMS on the following:

- Supplemental Medicaid coverage:
 - Not returned with COB-OHI information.
 - When the pharmacy has not performed an E1 to know beneficiary has Medicaid coverage.
- Version D.0 Other Payer Response Segment.
 - The standard is limited to providing three payers in the response. CMS needs to provide guidance when there are more than two other payers for a beneficiary.
- Version F6 Other Payer ID Count (355-NT).
 - The standard is limited to providing four payers in the response. CMS needs to provide guidance when there are more than three other payers for a beneficiary.
- Processing out of cycle reversals and adjustments.
- What should occur if a claim is adjusted subsequent to the last invoice received by the beneficiary at the end of the calendar year.

NCPDP requests CMS includes a statement in final guidance there will be no impact to Automated TrOOP Balance Transfer (ATBT) processes and Financial Information Reporting (FIR) transactions will continue to reflect the TrOOP and Drug Spend by month using the original claim accumulators, as they currently do.

Section 50.3: Requirements for Different Pharmacy Types

NCPDP Comment: NCPDP is requesting additional information on the following LTC scenarios:

- How should the process work when the patient pay amount is billed to the facility rather than directly to the beneficiary?
 - The pharmacy expects payment from the facility rather than the patient. Should the pharmacy submit the COB Medicare Prescription Payment Plan claim?
 - How would this be identified to the pharmacy?
 - Who receives the claim billing – the beneficiary or the facility?
 - Is the program considered to be beneficial to LTC beneficiaries if they are in and out of LTC facilities throughout the year?
 - If the beneficiary is not in a facility in January but enters a facility later in the year (while enrolled in the program), would the beneficiary continue to be billed for their monthly program payment amount?
 - How should it be determined if the LTC patient will benefit from program enrollment?
- Will LICS retrospective eligibility be handled differently for LTC beneficiaries?

Section 50.4: Paper Claims

NCPDP Comment: NCPDP agrees paper claims should not be included in this process.

Section 70.3.5: Processing Election Requests During a Plan Year

Section 70.3.7: Retroactive Election in the Event the Part D Sponsor Fails to Process an Election within 24 Hours

NCPDP Comment: NCPDP requests clarification from CMS on the reprocessing and reimbursement/billing of retroactive claims when a beneficiary participates in the program. Guidance is needed on how the reimbursement/billing process will work.

Some NCPDP stakeholders believe there needs to be a timeframe limitation on retrospective reprocessing of prescriptions at the pharmacy.

Section 70.3.9: Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs

NCPDP Comment: NCPDP would like CMS to take the following into consideration when determining the best method for a real-time or near-real time point of service (POS) election options:

- Not all patient(s) and/or legal representative(s) are at the pharmacy to have the POS election conversation.
- Real-time enrollment is not possible with mail and LTC pharmacies because the patient is not present.

NCPDP stakeholders do not believe the Submission Clarification Code (SCC) option listed in the guidance is viable for enrolling beneficiaries into the program. In addition, pharmacies do not have the appropriate information to understand whether the individual making the request is the legal representative of the beneficiary or that the beneficiary has been sufficiently educated on the program. There is no way for this information to be passed through the standard.

Section 70.4: Mid-Year Plan Election Changes

NCPDP Comment: NCPDP requests additional clarification from CMS on possible stop-gap measures to prevent unexpected beneficiary behavior. For example, the beneficiary does not pay their balances and plan transferring occurs to avoid making program payments.

Section 80.1: Voluntary Terminations

NCPDP Comment: NCPDP asks CMS to create the following:

- Model language to provide to beneficiaries explaining member responsibility when enrollment from the program is terminated.
- Guidance for providers, pharmacies and/or processors explaining the turnaround time to process enrollments into and disenrollments from the program.
 - NCPDP recommends the timeframe for both elections and terminations be 24 hours.

NCPDP stakeholders believe the pharmacies should be held harmless in regard to the termination of a beneficiary from the program when claim activity has occurred prior to terminating the beneficiary from the program.

Appendix A: Definitions for Medicare Prescription Payment Plan

NCPDP Comment: NCPDP suggests utilizing the term “Patient Out of Pocket (OOP) Cost” in Appendix A

to replace the term “Patient Pay Amount” throughout the guidance. “Patient Pay Amount” has a specific definition, especially related to Prescription Drug Event (PDE) data. NCPDP stakeholders believe differentiation is necessary.

Appendix B: Additional Medicare Prescription Payment Plan Calculation Examples

NCPDP Comment: NCPDP is requesting additional examples of how the program should work when a beneficiary has multiple supplemental coverages throughout the benefit plan year.

NCPDP submits for CMS consideration a specific example of a situation where the secondary coverage for the beneficiary returns a higher Patient Out of Pocket Cost than what was on the original Medicare Part D claim. NCPDP requests feedback from CMS on how this type of scenario should be handled.

NCPDP thanks CMS for the opportunity to provide 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

NCPDP Standards Specialist

standards@ncdp.org

Respectfully,

A handwritten signature in black ink, appearing to read "Lee Ann C. Stember". The signature is fluid and cursive, with the first name "Lee" being the most prominent.

Lee Ann C. Stember

President & CEO

National Council for Prescription Drug Programs (NCPDP)

September 20, 2023

The Centers for Medicare and Medicaid Services
Part D Payment Policy

Submitted electronically: PartDPaymentPolicy@cms.hhs.gov

Re: Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Selected Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments (“Medicare Prescription Payment Plan Guidance”)

To Whom it May Concern:

Network Health (“NH”) appreciates the opportunity to provide feedback to the Centers for Medicare and Medicaid Services (“CMS”) on its proposals to implement the Medicare Prescription Payment Plan (“MPPP”) released on August 21, 2023. CMS requested feedback by September 20, 2023. The following is NH’s response.

CMS Proposal:

Section 70.3.5 Processing Election Request During a Plan Year

CMS proposes that when a Part D enrollee is already enrolled in a Part D plan and requests to opt into the MPPP during the plan year, Part D sponsors (“plan sponsors”) must process the election request within 24 hours to prevent delays in dispensing drugs to individuals when they opt into the program. CMS proposes to establish a 24-hour requirement for processing election requests during the plan year. CMS states the requirements are consistent with those established for processing expedited coverage determinations and that an identical time frame will be operationally feasible for plan sponsors to process election requests.

- **NH Response and Recommendation:**

We do not agree that an identical time frame will be operationally feasible for plan sponsors to process election requests. Requiring plan sponsors’ processing election requests within a 24-hour time frame places additional administrative burden on plan sponsors and possibly their prescription benefit managers (“PBM”). A 24-hour turnaround will require additional staffing for weekend coverage. NH believes that a 72-hour time frame would be an acceptable time frame to process these requests and does not believe there will be member harm.

For example, an enrollee presents at the point of sale (“POS”) and receives a prescription for Humira, a high-cost drug, with a \$2,000 cost share and now wants to opt into the program. The pharmacy would need to inform the enrollee to contact the plan sponsor and/or its PBM to

request enrollment depending upon how the plan sponsor and PBM operationalize the new enrollment processes. The involvement of people and possibly more than one entity in the process adds complexity and time for a process that currently does not exist. Plan sponsors and PBMs will need to add staff to process requests received on Fridays, Saturdays and Sundays, including holidays.

Further, this places new administrative burdens on pharmacies, which are already challenged with resources, to educate and inform beneficiaries at the POS, which has the potential to delay and disrupt others waiting (in line) to fill their prescriptions.

Note: We fully acknowledge that CMS is considering requirements for a POS enrollment in 2026 and later years.

Section 70.4 Mid-Year Plan Election Changes

CMS proposes to allow individuals to be able to opt into the MPPP regardless of whether they had participated in it under a prior plan. The prior plan sponsor is to continue to bill the participant monthly based on the accrued out of pocket costs while in the MPPP under that plan for the rest of the plan year, or the prior plan sponsor can offer the participant the option to repay the full outstanding amount in a lump sum, but not immediately.

The new plan sponsor is to calculate the individual's monthly cap for the first month of participation under its plan and cannot prevent an individual from opting into the MPPP because of termination from it for non-payment by a different (prior) plan sponsor or voluntarily opting out while in the prior plan.

CMS states plan sponsors should follow the established plan to plan reconciliation ("P2P") process to implement the MPPP for individuals switching plans mid-year.

- NH Response and Recommendation:

NH has concerns about using the P2P process for individuals who switch plans mid-year and opt into the MPPP with the new plan sponsor. Currently, it can take more than a month to reconcile information between payers using P2P. This, coupled with the proposal to process mid-year enrollment requests within 24 hours, places additional burden and financial risk on plan sponsors. If CMS finalizes the use of P2P for mid-year changes, NH recommends there be \$0 billing in the first month with the new plan sponsor to permit time for the P2P process to update information. The new plan sponsor could start billing in the second month after participants enroll in its Part D plan and opt into the MPPP.

NH is also concerned there will be gaming by beneficiaries switching Part D plans and opting into and out of the MPPP. For example, for a 5 Star plan sponsor, beneficiaries have a special

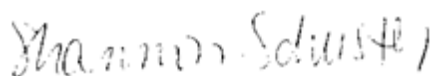
enrollment period throughout the year to enroll into the plan. The plan sponsors remain at risk for uncollected monthly MPPP amounts from participants and they cannot prevent individuals from enrolling into MDPP if termed for non-payment by a prior plan or voluntarily opted out under the prior plan. Even though there are proposed termination for non-payment procedures, plan sponsors, potentially along with their PBMs, will have to create new processes and assess their costs to implement the MPPP by June 2024 when the 2025 bids are due.

Conclusion:

Overall, the MPPP creates additional financial risk and administrative burdens on plan sponsors and PBMs (e.g., enrollment/disenrollment, billing, reconciliation, member materials, grievances, training, information system programming, bidding) and pharmacies in creating new processes to stand up by 2025 along with other significant Inflation Reduction Act changes occurring in 2025. NH requests that CMS consider developing and communicating model materials, tools and clear reporting expectations for industry use to ensure consistency by all involved in implementing this new program. Consistency should mitigate confusion by those implementing and importantly, help Medicare beneficiaries' understanding. CMS states it expects to provide a second set of draft MPPP guidance in early 2024 yet, that is a short time frame for review, feedback and finalization by June 2024 when the 2025 bids are due to CMS. NH believes it would be more reasonable and prudent to take a step-wise approach and proceed to implement the \$2,000 Part D out of pocket cap in 2025, and then assess beneficiaries' use of the MPPP and/or affordability challenges with their prescription costs before fully implementing the MPPP by program instruction.

NH appreciates CMS's consideration of our and other stakeholders' feedback.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Shannon Schuster". The signature is written in a cursive, slightly slanted style.

Shannon Schuster
Director, Regulatory Affairs



September 20, 2023

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

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

Dear Dr. Seshamani:

Thank you for the opportunity to submit public comments related to the part one draft guidance on the *Maximum Monthly Cap on Cost-Sharing Payments Program*. The National Multiple Sclerosis Society (Society) is pleased to offer our feedback relating to part one of the draft guidance, as the proposals outlined to implement the Maximum Monthly Cap on Cost-Sharing Program are a critical piece of section 11202 of the Inflation Reduction Act (IRA). We applaud the Centers for Medicare & Medicaid Services (CMS) for soliciting public feedback on developing the Medicare Prescription Payment Plan (MPPP) and creating a pathway for public input. 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.

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. We provide global leadership and fund research for a cure, drive change through advocacy, and provide programs and services to help people affected by MS live their best lives. To fulfill this mission, we fund cutting-edge research, drive change through advocacy, facilitate professional education, collaborate with MS organizations around the world, and provide services designed to help

people affected by MS move their lives forward. 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 it as an organization whose research investment exceeds \$1 billion to date.

Approximately 25-30% of people living with MS in the United States are on Medicare and 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 Inflation Reduction Act 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, make adjustments to ensure maximum beneficiary impact. The Society urges CMS to utilize all channels to engage stakeholders, especially Medicare beneficiaries who stand to benefit the most from these changes, and create opportunities for individuals to share their thoughts and priorities during the implementation of the MPPP.

During the MPPP implementation, it is vital that CMS partner with patient advocacy groups and other critical stakeholders to ensure Medicare beneficiaries are educated about the MPPP and other provisions of the IRA that will make it easier to access necessary medications. Part of the education process should include language, developed in partnership with stakeholders, that provides clear, consistent information about the MPPP with actionable instructions on how to enroll, how to find more information about the program, and provides resources so that beneficiaries can see how the program will apply to their individual situations. This is particularly true for individuals living with chronic diseases and disabilities who are most likely to benefit from this option. The Society is committed to working with CMS to ensure that the implementation of the MPPP is a success.

The Society supported the inclusion of a smoothing mechanism in the IRA that would allow Medicare beneficiaries to pay costs evenly over the course of a year and avoid a large, single lump-sum expense for necessary medicines. Although beginning in 2025, Medicare Part D beneficiaries will not pay more than \$2,000 out-of-pocket (OOP) for prescription drugs, individuals living with chronic diseases will still face initial OOP costs in the hundreds or thousands of dollars. We look forward to working with CMS to disseminate information about the MPPP and educate individuals living with MS, their care partners, and medical providers about their options to spread these OOP costs out over the course of the Part D plan year. We will follow our comments on this specific draft guidance with further details on how the Society believes it can partner with CMS to educate the MS community about the MPPP and other provisions of the IRA.

Section 40. Participant Billing Requirements

For the MPPP to achieve its intended goal of helping Part D enrollees better afford their medications, Part D sponsors must provide enrollees with flexible payment options. The Society agrees that Part D sponsors must offer multiple means of payment (e.g., electronic fund transfer, credit/debit card payment, and payment by cash or check). We also recommend that CMS provide clarity in its final guidance on how the MPPP will work with third-party payment programs (i.e., nonprofits that assist with prescription drug costs and what mechanisms will be provided that allow for those payments in the system). We also agree that sponsors should offer enrollees flexibility around choosing a specific day of the month for charges and bank withdrawals. We applaud CMS for clearly stating that late fees, interest payments, and other fees are not permitted under the program; however, we strongly urge CMS to

require Part D sponsors to offer the option of autopayments to MPPP enrollees. We believe this option will reduce the burden on enrollees and decrease the likelihood of missed/late payments.

While CMS encourages sponsors to prioritize payments towards Part D plan premiums to avoid loss of coverage, we also encourage sponsors to align premium billing cycles with MPPP billing cycles, so that enrollees are not receiving multiple bills per month which could cause confusion and lead to missed payments.

Finally, the Society recommends that plans be required to notify beneficiaries when they have reached the \$2,000 OOP cap (in 2025 and beyond) and what their remaining payments will be for the remainder of the year. Once this OOP cap is reached, payments remain stable and predictable, and beneficiaries should be able to use this information for monthly budgeting purposes.

Section 60. Requirements Related to Part D Enrollee Outreach

As mentioned above, the Society urges CMS to utilize all channels to engage and educate Part D enrollees about the option to opt into the MPPP. This education should begin as soon as possible and should be heavily promoted during the open enrollment period for the 2025 plan year. This way, beneficiaries will be aware of their options well ahead of time and will not be overwhelmed by these new options as they fill their prescriptions in January 2025. The Society encourages CMS to create standardized educational materials for insurance plans, pharmacies, and providers. Materials should be developed with opportunities for input from multiple stakeholder types, especially the patient community. Consistent, clear information regarding the option to spread costs should be available at multiple points so that beneficiaries are aware of and understand their ability to opt into the smoothing option. Specifically, we encourage CMS to integrate the Medicare.gov Plan Finder with the MPPP (and eventually the OOP cap), so that beneficiaries can understand how the options would work for them when they are selecting their plan. Additionally, we would like to see the final guidance require that MPPP figures be prominently shown on Medicare.gov accounts, so that beneficiaries, their care partners, and their support teams can easily keep track of payment amounts and scheduling. While the examples provided in the draft guidance are helpful, the Society recommends that the information be simplified. Most beneficiaries need a simple month-by-month total of their obligations along with a short explanation that monthly payments may vary depending on several variables but, beginning in 2025, the total OOP costs will not exceed \$2,000. The columns about monthly costs incurred and monthly cap, like the examples in the guidance, are not actionable information and may confuse many enrollees.

Given that many Part D beneficiaries are on fixed incomes, the Society believes that one of the most important beneficiary educational tools that CMS must provide is an accessible, easy-to-use monthly cost calculator so that individuals can determine what their monthly costs would be if they opt into the MPPP and if this program will work best for their individual needs and budgets. The Society urges CMS to prioritize the development of this tool before open enrollment begins in 2024 and work in partnership with the patient community to develop this tool.

While outreach and education are important for all Part D beneficiaries, we suggest that CMS and Part D sponsors specifically target Part D enrollees living with chronic conditions, including those who are newly diagnosed, who have a history of or who will likely incur high OOP costs earlier in the plan year and who will most likely benefit from the MPPP. Plans should also be required to provide information on MPPP to these individuals and to Medicare provider(s). We urge CMS to engage with patient and patient

advocacy groups as they will be a key and trusted partner for reaching this population and are ready to step in and help facilitate this dialogue. Additionally, we recommend that CMS regularly convene navigators/helpline/call-center staff members from patient groups to solicit input from those on the frontlines of patient outreach and support.

CMS also requests information about targeted notifications at the point-of-sale (POS) and what dollar amount threshold should trigger this notification. The Society encourages CMS to set this threshold as low as possible, potentially below the proposed \$400 threshold, to assure the greatest amount of information and outreach. However, we caution that a notification requirement is not as powerful of a tool for beneficiaries if it is not accompanied by an easy way to opt-in to the MPPP at POS. If individuals need to leave the pharmacy without their medication to contact their insurance plan to learn about their enrollment options, it will negatively impact uptake and medication adherence. Additionally, we recommend that the same process to opt-in to the MPPP be available to those utilizing mail-order pharmacies. We strongly recommend that CMS make the choice to opt into the program at POS available to roll out when the program begins in January 2025 and identify any technical barriers that could delay implementation at POS so that stakeholders can work together to mitigate barriers to optimize participation. Additionally, we recommend that specialty pharmacies (in-person and mail-order) be required to discuss the MPPP as an option for payment for all Medicare beneficiaries as a component of disease management processes.

Many individuals with MS and other chronic conditions rely on care partners or family members to routinely obtain medication for them. The Society asks CMS to clarify what documents would be required to prove that another person, who is not the enrollee, serves as a legal representative for the enrollee to opt into the MPPP. We also recommend that this information be included in general education about the MPPP so that there are no unnecessary or unintended delays or barriers to accessing essential medications.

Section 7.0 Election Procedures

The Society agrees that there should be multiple ways to opt into the MPPP (e.g., during Part D open enrollment, at the POS, a paper option that is mailed or faxed, via telephone, via website application, etc.). We also agree that if an individual's request to participate in the MPPP is denied, the Part D sponsor must send a notice of denial to the individual and include the reason(s) for the denial. If the request to participate is approved, the sponsor must send the enrollee the following: an overview of the program and participants' rights, examples of calculations of the maximum monthly cap and a link to a calculator, general information about applying for the Low-Income Subsidy, and the effective date of the individual's participation in the MPPP.

Additionally, we recommend that CMS have multiple ways for beneficiaries to opt out of the MPPP. For many reasons, individuals' financial circumstances and health needs may change over the course of a plan year, so we believe that it should be easy to both opt in and opt out of the MPPP.

The Society recommends that CMS implement a POS enrollment solution in 2025. Although the draft guidance allowed for a delay until 2026, we believe that it is important that beneficiaries both are educated about the new MPPP and be able to enroll in a place where access and cost of their

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

Additionally, we recommend that CMS consider, at minimum, a first-year implementation strategy that focuses on ensuring POS election in specialty and mail-order pharmacies. This subset of pharmacies is already accustomed to extended patient-pharmacy staff interaction at the POS, including discussions about OOP cost, and routinely dispenses the types of medications most often associated with high OOP burden. In contrast, retail community pharmacies see a much greater share of patients who have less-expensive medications and thus face lower upfront OOP costs under the traditional Part D benefit design. A POS election policy that facilitates POS election solely at specialty pharmacies is less than ideal, but it would promote access to this critical benefit to the patients likely to face the highest OOP costs while the components for bringing a POS election for the majority of U.S. retail pharmacies are put into place.

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

The Society applauds the patient protections included in the draft guidance, such as outlining the requirements of what a sponsor must include in an involuntary termination notice. While we feel that many of these requirements are reasonable, if a participant has failed to pay a monthly billed amount, we recommend that the grace period be up to 3 months. This allows time for an individual who may be experiencing a medical emergency or may need extra support or care due to living with chronic/complicated medical conditions.

Additionally, we urge CMS to clarify the definition of demonstrated good cause for failure to pay (i.e., does this include hospitalization, unexpected employment termination, weather emergencies, or natural disasters as these are some hardships that people may experience that impact their financial situation) and what the timeframes/process is for seeking this option. These are all reasonable barriers that people may experience, and we urge CMS to set up a way that beneficiaries can notify and work through circumstances that may arise that impact their ability to meet the financial obligation that comes with opting into the MPPP. We believe that CMS should urge sponsors to offer maximum leniency in these cases and find ways to work with beneficiaries to help them remain in good standing with the program.

Thank you again for the opportunity to provide feedback on part one of the draft guidance. We look forward to further communications regarding how the Society could partner with CMS to educate the MS community on the MPPP and other major provisions of the IRA. If you have any questions about our

comments and recommendations, please contact Nicole Boschi, Director of Regulatory Affairs at 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

September 20, 2023

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

RE: CMS Guidance on Medicare Prescription Payment Plan

Submitted electronically via PartDPaymentPolicy@cms.hhs.gov

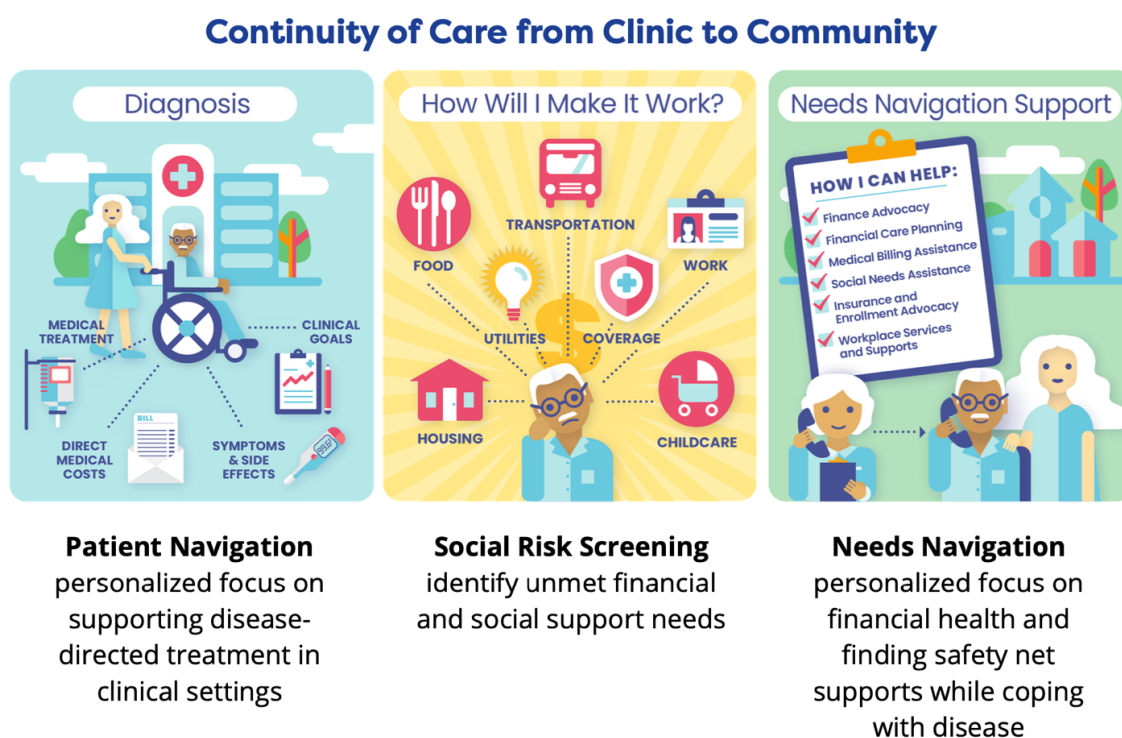
Dear Administrator Brooks-LaSure,

National Patient Advocate Foundation (NPAF) is pleased to submit comments on this guidance as it relates directly to the work we do and the people we serve.

Our direct patient services counterpart, Patient Advocate Foundation (PAF), has delivered skilled needs navigation services specifically supporting social and financial well-being for thousands of limited-resourced patients and families over its 26 years. Needs navigation, detailed in [this NPAF 2022 issue brief](#), is an effective intervention that responds to what patients and families report as their most pressing concerns that interfere with healthcare access and affordability.

The new Medicare Prescription Payment Plan is needed as a majority of over 2,800 patients surveyed by PAF in internal research done in 2019 (63 percent) reported financial distress as a top concern surpassing even the possibility of dying. Household material hardships such as food, energy and housing insecurity are frequent sources of concern contributing to dire circumstances and disparate health outcomes among people coping with complex chronic conditions. NPAF therefore advocates for expanding the availability of needs navigation services, which help overcome health system shortfalls by identifying and striving to address the constellation of patients' unmet social and financial needs. These are particularly prevalent in underserved populations and limited resourced communities. PAF's 2021 program evaluation data show that after navigation was provided, 77 percent of patients reported reduced distress and 100 percent reported a better understanding about health care costs and awareness of community resources that can help them.

Needs Navigation is an innovative intervention to address patients' top of mind financial and social concerns in the context of coping with their illness. [These services](#) are 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 and/or social burdens because of their medical conditions. Needs navigation services 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 illness. These services now should be expanded and integrated with the healthcare ecosystem 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 needs navigation could be integrated into existing health care:



We offer ourselves as a partner in CMS' effort to expand access to navigation services as PAF has developed specialized needs navigation expertise over its 27 years providing telephonic financial and social services to patients nationwide with limited resources and health care access challenges. In [2021 alone](#), PAF delivered comprehensive needs navigation to 20,374 people from all 50 states and Washington, D.C. Forty-six percent (46%) of these patients reported an annual household income under \$24,000.

With this perspective, we appreciate the opportunity to make the following comments regarding this guidance:

Capped monthly installment payments

We agree that monthly installment payments, as opposed to the current system, will be helpful for people with Medicare Part D who have high cost-sharing earlier in the plan year by spreading out those expenses over the course of the year. This will also allow beneficiaries to plan their expenses, which will take some of the variability out of their current medication payments. We also appreciate that CMS will be developing tools to help Part D enrollees decide whether the program is right for them. This is the kind of assistance that needs navigation services would provide as well.

Participant protections

We support the following participant protections within this guidance:

- Opt-out: That Part D sponsors must have a process to allow a participant who has opted into the Medicare Prescription Payment Plan to opt out during the plan year. Even with good upfront advice, circumstances can change and so the ability to opt out is needed.
- Termination procedures: That the termination procedures will include multiple mailed notices and a grace period since some participants may have unpredictable lives given their illnesses, other medical or other expenses, and so missing a bill may happen. For that reason, we also support that a Part D sponsor may only preclude an individual from opting back into the Medicare Prescription Payment Plan in a subsequent year if the individual owes an overdue balance to that Part D sponsor and that, if an individual pays off the outstanding balance during the subsequent year, the Part D sponsor must permit them to opt in after that point.
- Appeals procedures: That Part D sponsors must apply their established Part D appeals procedures to any dispute made by a Medicare Prescription Payment Plan participant about the amount of Part D cost sharing owed by that participant for a covered Part D drug. We hope that this dispute process will be easy for participants in this situation to access.
- Grievance process: That each Part D sponsor must provide meaningful procedures for the timely hearing and resolution of grievances between Part D enrollees and Part D sponsors. Timeliness is key since some people with serious illness may not have months or years to wait to resolve any grievances.
- Grievance procedures: That Part D sponsors must apply their established Part D grievance procedures to any dispute made by a Medicare Prescription Payment Plan participant related to

any aspect of the Medicare Prescription Payment Plan, including election requests, billing requirements, and termination-related issues other than disputes related to the amount of Part D cost sharing owed by that participant for a drug.

Again, we would note that many of these are situations where also providing needs navigation services would be helpful. We look forward to the next round of guidance for this new program in regard to the patient education that it will cover.

Conclusion

NPAF believes that expanding access to needs navigation services that include financial assessment and referral to appropriate services would improve beneficiaries' care. Providing needs navigation services directly to patients and caregivers is a hallmark of NPAF'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 Administration staff to discuss these comments and opportunities to scale needs navigation as part of efforts to achieve equitable and affordable healthcare reform.

Please contact me at Rebecca.kirch@npaf.org if NPAF can provide further details.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Rebecca A. Kirch".

Rebecca A. Kirch
Executive Vice President, Policy and Programs

September 20, 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

On behalf of the undersigned 24 patient and provider organizations, we appreciate the opportunity to provide feedback on CMS's Medicare Prescription Payment Plan (MPPP) Guidance issued August 21, 2023.

We greatly appreciate that CMS has been open to meeting with patient groups and that the guidance incorporates much of the feedback provided. 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 the importance of implementation of MPPP along with the \$2,000 out-of-pocket (OOP) cap in limiting the prescription drug cost liability of Medicare Part D beneficiaries that were prior to the passage of Inflation Reduction Act unlimited.

Please find our comments on the MPPP Guidance below:

Section 30: Program Calculations and Examples

We appreciate the inclusion of a variety of example calculations in the guidance as well as in appendix B. However, the scenarios are complex for those deciding whether to become an MPPP participant. Medicare beneficiaries are likely to expect that their monthly payments will be calculated as their total OOP costs divided by the remaining number of months of the year not to exceed \$166.67 per month. In terms of timing of opting into the MPPP, we concur with CMS's assessment that participants starting later in the program are likely to have higher monthly bills, compared to those starting earlier in the year. This however should not preclude them from participating in the MPPP.

We urge CMS to find ways to simplify the explanation of calculations for patients and providers. When providing detailed charts outlining the remaining costs for the rest of the plan year, we recommend only including the column for patient OOP costs incurred and monthly OOP costs. Removing the column with the maximum monthly cap amount will minimize confusion. "Decision trees" may also be needed to direct patients to the appropriate calculators. We urge such calculators be available on CMS' website as well as plan websites for ease of access.

Further, we urge CMS to add flexibility into the calculations, specifically the calculation of the maximum monthly cap in the first month rather adapting the calculation to be equal payments across all months (or a flat amount).

We strongly support educating beneficiaries at a high level regarding the program calculations. We request that CMS include language in their and the plans' materials stating that the OOP costs may vary from month to month, but their costs will never exceed \$2,000 for the year.

Section 40: Participant Billing Requirements

We appreciate CMS encouraging plans to offer multiple means of payment, such as electronic fund transfer (including automated payments), check or cash. We also support allowing participants to have the ability to request a specific day of the month for program charges and bank withdrawals.

Billing statement

We applaud CMS for requiring robust information to be included in the billing statement. Specifically, we applaud the intentional focus on sharing information about possible eligibility for the low-income subsidy (LIS) and noting that if eligible, enrollment in LIS will serve one better than opting into the MPPP. This message needs to be front and center in all messaging to potential MPPP participants.

We urge CMS to reserve information on the first page of the billing statement for critically important information to ensure that participants easily understand their OOP obligation and monthly responsibilities for the remainder of the plan year. The language and information should be clear and actionable including total, non-itemized OOP costs; OOP expectations on a monthly basis for the remainder of the plan year; and a reminder that there will be changes to the monthly OOP costs if the participant has a new prescription.

We request the following additions to the billing statement: 1.) Information about the Senior Health Insurance Information Program (SHIIP) and the availability of counselors who can serve as impartial stakeholders to answer questions and help Medicare Part D enrollees make a decision whether to opt-in to MPP; 2.) Explicitly outline the impact of noncompliance and highlight the importance of paying billing notices on time; 3.) Language that the participant will not pay more than \$2,000 in OOP for the year; and 4.) Notification when the MPPP participant has met the OOP cap or is expected to meet the cap based on the patient's current medication profile.

Lastly, we appreciate CMS' assurance that Part D sponsors and plans cannot seek debt collections against program participants.

40.1 Prioritization of Premium Payments

We strongly support CMS encouraging plans to prioritize paying Medicare Part D premiums over monthly MPPP payments to ensure Part D enrollees don't lose coverage.

Section 50: Pharmacy Payment and Claims Processing

We appreciate the detail with which the agency has outlined the processing of claims and coordination of benefits. We believe it is important to ensure that assistance provided by patient assistance programs, such as those offered by independent charitable foundations, be properly identified and continue to be included in the patient OOP calculation. Additionally, we seek clarification from CMS on this dynamic. Specifically, we ask the agency to clarify that the two-transaction pharmacy claims process allows for independent charitable assistance to be billed for the patient responsibility as a component of "Other Health Insurance" prior to application of any Medicare Prescription Payment Plan.

Section 60: Requirements Related to Part D Enrollee Outreach

60.1 General Part D Enrollee Outreach Requirements

We strongly support a robust effort to educate and conduct outreach on this new program. Given the complexities and possible confusion among prospective participants, effective outreach and education are going to be critical to the success of this program. As engagement with patient groups is critical for informing CMS's outreach strategy and tactics, we look forward to having the opportunity in Part 2 of the guidance to comment on model language for beneficiary communications and plan marketing materials. Additionally, education provided at pharmacies and by prescribing health providers will be critical to Part D enrollees understanding how they may benefit from participation in the MPPP.

We urge CMS to require plans to provide educational information in regular plan documents such as the Annual Notice of Coverage (ANOC) and Evidence of Coverage (EOC) documents. Additionally, the Medicare Plan Finder tool is a critical tool for educating beneficiaries on critical plan information, including MPPP. Many beneficiaries and their caregivers utilize this tool when making enrollment decisions, and as such, it will be critically important to highlight this new option on the website. While CMS plans to offer more details on how they will provide information on Plan Finder in Part Two of the guidance, we strongly support the development of a customizable analytical tool that could help enrollees determine if the new program would be beneficial.

We also encourage CMS to educate other stakeholders who play a part in educating beneficiaries. As pharmacies will have a significant role at the point of sale (POS) in notifying beneficiaries who may benefit from the program, we hope that CMS will offer specific educational materials to be deployed by pharmacies for review in Part 2. We also believe strongly that educating health care providers and prescribers will be another important step to help beneficiaries understand the benefits of the program and how to enroll. We encourage CMS to educate providers and prescribers so they, in turn, can help educate beneficiaries.

60.2.1 Identification of Part D Enrollees Who Are Likely to Benefit

We support the requirement for plans to conduct targeted outreach, both prior to and during the plan year, to Part D enrollees likely to benefit from participation in the MPPP. We encourage CMS to move away from monetary thresholds for conducting targeted beneficiary outreach. It is important to not make assumptions about what is beneficial for beneficiaries. Specifically, beneficiaries may face deductibles in other Medicare programs and participating in the MPPP could be beneficial even if the Part D enrollee has not filled a high-cost medication previously. Congressional intent for this specific benefit was to be widely applicable and establishing thresholds for proactive outreach runs counter to that intent.

60.2.3 Targeted Part D Enrollee Notification at POS

Part D sponsors must have a mechanism to notify a pharmacy when a Part D enrollee incurs OOP costs that make it likely that they will benefit from participating in MPPP. CMS is proposing to establish a POS monetary threshold. We support, based on CMS's data, setting the monetary notification threshold at the lowest level - \$400. To ensure as consistent an experience as possible across plans and pharmacies, we ask that CMS draft a standardized notice that can be delivered to the enrollee via email, push notification, SMS, voice call (if enrollee gives consent at time of enrollment), or paper hard copy at the pharmacy.

Section 70: Requirements Related to Part D Enrollee Election

70.1 Part D Enrollee Eligibility

We appreciate CMS stating clearly in the guidance that Part D sponsors cannot set a minimum OOP cost sharing amount that Part D enrollees must incur to participate.

70.3.8 Standards for Urgent Medicare Prescription Payment Plan Election

The guidance addresses retroactive election into the MPPP when a Part D enrollee has an urgent prescription fill for which they paid the OOP cost before the program was received and processed. Plans must provide retroactive election if the enrollee reasonably believes that any delay in filling the prescription may jeopardize their health. CMS should clarify how Medicare Part D enrollees would demonstrate or document such urgent need.

70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs

We recognize the complexity for pharmacies in operationalizing a POS election into the MPPP and that this would require establishing a new value in an existing National Council for Prescription Drug Programs (NCPDP) data field for the program which would potentially delay implementation. However, this should be a priority for 2025 implementation to the extent feasible. In lieu of full implementation in 2025, we urge CMS to explore utilizing the 1-800-Medicare telephone number combined with a POS “transition fill” policy. And to that point, there must be a telephone-only option for enrollment in the MPPP along with a mobile and web-based application. This is essential for those without access to technology, or those not comfortable with technology.

70.4 Mid-Year Plan Election Changes

We strongly support CMS requiring plans to process midyear elections within 24 hours. We encourage CMS to articulate what communication should occur between the old and new Part D plan sponsors. Additionally, there will need to be clear communications from the old plan to participants when their participation in the MPPP is ending and the responsibility for remaining MPPP payments.

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

Section 80.1 Voluntary Terminations

We support the guidance requirement that Part D plan sponsors must have a process in place to allow MPPP participants to opt-out during the plan year. This should be an option at any point during the plan. Further the Part D plan sponsor must provide the individual with a notice of termination. We urge that the guidance establish a timeframe by which the notice of termination is provided.

80.2.1 Notice Requirement

We urge CMS to clarify in the notice of a delinquent payment that any potential termination would only be for the MPPP and would not affect the individual’s current Part D plan enrollment or enrollment in a future plan.

80.2.2 Required Grace Period and Reinstatement

We support providing MPPP participants with a grace period of at least two months. We also strongly support CMS requiring Part D plans to communicate with beneficiaries within this window on the consequences of late payments and possible involuntary termination. Specifically, we recommend standardizing plan communications regarding grace periods and providing a timeline example (e.g., payment owed Feb.1, notified Feb. 15, April 1 grace period ends). Further, we recommend providing specific examples of “circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.”

80.3 Preclusion of Election in a Subsequent Plan Year

We appreciate CMS clearly stating that Part D sponsors may preclude an individual from opting into the plan in a subsequent year if the individual fails to pay the amount billed. However, the guidance is unclear if a plan may preclude enrollment for more than one year. Based on the statutory language, we recommend that CMS only allow Part D plans to preclude affected individuals for one year and not multiple years. We also recommended halting the preclusion once the beneficiary has made the outstanding payment.

80.4 Prohibition on Part D Plan Enrollment Penalties for Failure to Pay Medicare Prescription Payment Plan Amount Billed

As stated in the guidance, “Part D sponsors may only involuntarily disenroll a Part D enrollee from a Part D plan if the Part D enrollee fails to pay any monthly premium in a timely manner or if CMS grants a disenrollment request when a Part D enrollee engages in disruptive behavior that substantially impairs the Part D sponsor’s ability to arrange or provide for services to the individual or to other plan enrollees.” The guidance should define “disruptive behavior.”

80.5 Disenrollment

We support the guidance in making clear that sponsors may not prevent an individual who has switched plans from opting into the MPPP because the enrollee was terminated for non-payment from the first plan.

We urge CMS to clarify the policy regarding the remaining financial obligation in the event of the death of the beneficiary. We believe in this instance that the Part D plan should absorb the cost rather than seek remuneration from a beneficiary’s estate. Otherwise, this may discourage beneficiaries from participating in the program.

Section 90: Participant Disputes

We appreciate CMS requiring Part D sponsors apply their established Part D appeals procedures to any dispute made by a MPPP participant about the amount of Part D cost-sharing owed by the participant for a covered Part D drug. We recommend that CMS provide a set of minimum standards for all plans regarding disputes. We are also concerned that there are no clear requirements regarding the timeframes associated with disputes. We strongly recommend that CMS require sponsors to resolve disputes within a 24-hour period, leveraging the expedited review process.

Section 100: Data Submission Requirements

We recommend adding to the data submission requirements collection of demographic data of MPPP participants. Understanding the success or barriers in implementation of MPPP based on race/ethnicity and geographic region (rural/urban) for example, would be beneficial to future iterations of guidance and outreach and education efforts.

Part Two Guidance

Lastly, we look forward to commenting on items to address in Part Two of the guidance including:

- Description of and examples of standardized language that will be used for Medicare Part D enrollees, providers, plans, pharmacy staff
- Where information will be placed (website, Medicare & You, EOBs, etc.)
- Description of the role of pharmacy staff in educating Medicare Part D enrollees
- How election in the MPPP will work at the pharmacy counter
- Need for materials to be in multiple languages

- How CMS would like patient and provider groups to assist in educating Part D enrollees on the MPPP option
- How CMS is planning to get information out to underserved communities in particular

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. If you have questions about the issues raised, please contact Amy Niles, Chief Advocacy and Engagement Officer, Patient Access Network Foundation at aniles@panfoundation.org.

Sincerely,

ADAP Advocacy
 Alliance for Aging Research
 Bladder Cancer Advocacy Network
 Colorectal Cancer Alliance
 Community Access National Network
 Depression and Bipolar Support Alliance
 Gaucher Community Alliance
 HIV+Hepatitis Policy Institute
 International Myeloma Foundation
 International Waldenstrom's Macroglobulinemia Foundation
 Melanoma Research Foundation
 Multiple Sclerosis Association of America
 Myasthenia Gravis Foundation of America
 National Association of Medication Access & Patient Advocacy
 National Eczema Association
 National Gaucher Foundation
 National Kidney Foundation
 NCODA, Inc.
 Patient Access Network Foundation
 Schizophrenia & Psychosis Action Alliance
 The AIDS Institute
 The Pink Fund
 The Sumaira Foundation
 University of Pennsylvania



September 20, 2023

Sent Electronically

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

Deputy Administrator and Director, Center for Medicare & Medicaid Services

7500 Security Boulevard

Baltimore, MD 21244

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

Dear Deputy Administrator Seshamani,

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

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

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

Protecting Patients from “Lockout”

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

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

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

Point-of-Sale Election

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

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

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

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

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

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

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

Outreach and Education

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

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

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

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

Conclusion

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

Sincerely,

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

PATIENTS FOR AFFORDABLE DRUGS NOW™

Patients For Affordable Drugs Now Comments In Response to the Centers for Medicare and Medicaid Services' Solicitation for Public Comments on "Medicare Prescription Payment Plan Guidance"

September 20, 2023

Patients For Affordable Drugs Now (P4ADNow) is pleased to offer these comments in response to the Centers for Medicare and Medicaid Services' (CMS) Solicitation for Public Comments on "Medicare Prescription Payment Plan Guidance."

P4ADNow has signed onto detailed comments in a letter submitted to the agency by the Alliance for Aging Research (AAR) and several other patient organizations, and submits these supplemental comments to emphasize issues of particular importance to our patient community.

Patients For Affordable Drugs Now 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.

The requirement that Part D sponsors provide all Part D enrollees the option to pay their out-of-pocket (OOP) prescription drug costs in monthly, interest-free installments over the course of the plan year, instead of paying OOP costs at the point of sale is a significant change that will bring upfront financial relief and long-term predictability for Part D enrollees and our patient community. In particular, patients who take some of the costliest prescription medications will experience the most benefit .

We applaud CMS for the detailed and patient-focused thinking which you are bringing to the implementation of the program, and we recognize the intricacies of implementing a program of such complexity, especially given the *opt-in* nature of the program for Part D enrollees.

Specifically, P4ADNow applauds:

- *Universality of eligibility:* It is essential that all people on Medicare Part D are eligible for the Medicare Prescription Payment Plan, regardless of the level of their out-of-pocket spending.
- *Targeted outreach:* The requirement that Part D sponsors "conduct outreach directly to individuals who are likely to benefit from the program, both prior to and during the plan year," is a critical feature of the plan. While CMS has developed a standardized framework for assessing who is "likely to benefit" from the program, **P4ADNow**

encourages targeted outreach to be conducted to any enrollee who has reached at least \$2,000 in out-of-pocket costs in either or both of the last two plan years.

The success of the Medicare Prescription Payment Plan depends on patient-centered implementation. P4ADNow is concerned that it is unrealistic to assume that long, complex conversations will be successfully held at the pharmacy counter. The reality necessitates an increased focus and specificity on targeted outreach in the agency's second round of guidance.

P4ADNow urges:

- *Focus on outreach to patients who purchase their prescription drugs through specialty pharmacies:* Specialty pharmacies already conduct comprehensive, individualized work with patients who take expensive prescription drugs. Given this existing informational infrastructure and the fact that patients using specialty pharmacies are likely to take expensive prescription drugs, specialty pharmacies are a ready-made target for education and outreach regarding the program that will help those most likely to benefit in the greatest amount.
- *Patient focus groups:* If CMS has not done so already, we suggest a convening of patient focus groups to better understand how information about the program and the process for opting into it are best communicated to those enrollees who are "most likely to benefit."
- *Attention to and tracking of the impact of the plan on premiums:* Even though the Inflation Reduction Act holds premium increases to no more than six percent from 2024 to 2029, the Prescription Payment Plan could potentially put increased pressure on premiums. We assume that not all patients upon opting in at the pharmacy counter will make all payments later, or on time. Given that some percentage of non-payment is likely, it is important that CMS monitor and consider what adaptations may be necessary to make as experience is gained.

P4ADNow thanks CMS for ensuring patients inform 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.

Paytient Technologies Inc. Public Comment for CMS re: Medicare Part D Prescription Payment Plan Part 1 Guidance

Overview

We believe the Medicare Part D Prescription Payment Plan provided for in Section 11202 in the Inflation Reduction Act of 2022 (IRA) solves a critical need for American seniors— ensuring certainty of affordability for prescription medication by allowing members to pay out-of-pocket costs over time.

Paytient Technologies Inc. submits these comments based on our experience administering interest-free, fee-free payment plans for out-of-pocket healthcare expenses for nearly 1M Americans in partnership with the nation's largest payers and Fortune 500 employers.

We include key learnings and best practices for program administration and member engagement to help ensure CMS and PDP and MA-PD sponsors are prepared to implement the IRA's requirements for the plan year beginning January 1, 2025.

Our comments address:

- I. The widespread utility and impact of payment plans for prescription drugs
- II. Recommendations pertaining to certain sections of CMS Part 1 Guidance
- III. Member engagement recommendations relevant to CMS's forthcoming Part II Guidance

About Paytient Technologies Inc.

Paytient is the creator and leading provider of Health Payment Accounts, a solution that helps Americans more easily and equitably access and afford healthcare. Founded in 2018 in Columbia, Missouri, the company has partnered with health plans to provide nearly 1M Americans with an ability to pay for out-of-pocket healthcare expenses over time - always without interest or fees. Our partners include Fortune 500 employers and national payers which collectively represent 60% of the commercially insured lives in the U.S. The improved ability to access and afford care is a welcomed improvement in healthcare as evidenced by a world class consumer experience with a 94 Net Promoter score (NPS) and 4.9 stars on Trustpilot.

Contact: David Smith
Senior Director of Strategic Partnerships
david@paytient.com

I. The widespread utility and impact of payment plans for prescription drugs

Today, Paytient provides interest- and fee-free payment plans to nearly 1M Americans with Health Insurance Marketplace or employer-sponsored coverage. Our plans offer the ability to pay out-of-pocket costs for medical and pharmacy care as well as dental, vision, and veterinary care with certain groups. Pharmacy usage is the #1 reason why people use Paytient— over 50% of our transactions are at the pharmacy.

Member feedback tells us that prescription payment plans ensure more equitable access to care that might otherwise be deferred. Our data shows:

- **Payment plans are broadly utilized by high and low income individuals** . Those who use the Paytient card are evenly split between those who earn more than \$50K/year and those who earn less. Perhaps unexpectedly, 24% of usage is from members earning \$75K+ per year.
- **Seniors benefit from the ability to pay over time**. In a survey of Paytient users over 60 years old, 1/5th reported the ability to pay over time helped them access care they couldn't otherwise afford, and 60% said the payment plans made paying for care less stressful.
- **The ability to pay for care over time improves access to care even among insured populations**
 - In a 2023 survey of Paytient users with Health Insurance Marketplace coverage, 67% reported that without the ability to pay for care over time, they would have foregone or delayed care.
 - This number is up from 43% in the same study conducted in early 2022.
- **The Pharmacy Payment Plan comes at a critical time for American seniors**. In early 2023, [Gallup reported](#) 38% of Americans said they or a loved one had deferred care due to cost, a record figure, up 12 percentage points from the previous year. When seniors don't seek the care they need, particularly through medication non-adherence, they have a higher risk of hospitalization, which increases costs for both plan sponsors and members. The CDC has [reported](#) that medication non-adherence costs the U.S. \$100B-\$300B annually. The Prescription Payment Plan will reduce medication non-adherence and create tangible societal benefit.

The improved ability to pay for care results in a meaningful improved ability for people to get care. We've included an [appendix of feedback](#) we've received from our users regarding their experience paying for prescriptions over time.

Accordingly, our cumulative experience informs our perspective that the Medicare Part D Prescription Payment plan will materially improve seniors' ability to access prescription medications, while simultaneously reducing the financial stress they feel and improving health outcomes.

II. Recommendations pertaining to certain sections of CMS Part 1 Guidance

Re: Section 50.1 Pharmacy Claims Processing Requirements

Paytient has experience with both card-based and health plan integrated (i.e. real time supplemental COB billing transactions using NCPDP standards) payment plans that we administer in partnership with major insurance carriers, representing the vast majority of PDP or MA-PD plan sponsors. There are

several program design tradeoffs to consider that influence operational and technical complexity, plan sponsor risk, and member experience, which we outline below.

1. Card-based or plan-integrated model considerations and tradeoffs.

- a. The advantages of a card-based model are that i) the participant has a card in hand that would instantly pay the pharmacy the total out-of-pocket amount due via a line of credit, ii) swiping a credit card reinforces to the participant that money has been spent that they will owe, and iii) a spending card has a familiar form factor that many participants would easily understand.
- b. The disadvantages of a card-based model are as CMS has outlined. Physical cards can be forgotten, lost, or stolen. They're more open to fraud and bring higher costs for plan sponsors, merchants & pharmacies. Thus, we agree with CMS that an integrated model is favorable to ensure equitable access, reduced risks, and lower plan administrative costs.
- c. The plan-integrated model is the most inclusive program design. Eliminating the need for an additional card to be present at the pharmacy point of sale is helpful to ensure more seniors can take advantage of the program. Some technical integration is required between plan sponsors and new program partners.
- d. Based on our experience with these models, we believe the timeline to be operational with either model for the 2025 plan year is achievable.

Recommendation 1: For the reasons stated above, we recommend the plan sponsor-integrated model as a uniform standard for adjudicating and managing the patient's liability.

Re: Section 60.2.1 Identification of Part D Enrollees Who Are Likely to Benefit

The examples in this section illustrate the implications of the statutory requirements for various real life situations. We offer a few observations based on our experience with pharmacy payment plans.

1. 75% of our users choose to use a payment plan for pharmacy transactions with an average value of \$70. Our members consist primarily of full-time, benefit-eligible employed Americans with employer-sponsored insurance or Health Insurance Marketplace coverage.
2. The CMS Part 1 Guidance published 8/21/23 discussed \$400 and \$700 as thresholds for seniors most likely to benefit. Given our experience serving nearly 1M Americans, we believe the threshold is less than \$100. If our experience is an indicator of demand, a lot of people are going to opt into this program.

Recommendation 2: Lower the first payment by spreading the cost of the transaction evenly over the months left in the plan year so that inability to afford the first payment doesn't cause seniors to forego medication.

3. High OOP pharmacy costs could happen any time of year, and CMS has recognized that seniors with high OOP costs late in the plan year would not be likely to benefit from the Prescription Payment Plan. Thus, the statutory requirement that payment plans be paid in full by the end of

the plan year disadvantages seniors who happen to have high OOP costs toward the end of the plan year.,

Recommendation 3: Ideally, we recommend a rolling 12 month repayment period from time of use. If not possible, we recommend, for charges incurred after October 1, extending the repayment schedule to at least March 31 of the following year, giving seniors a meaningful time over which to spread high OOP pharmacy costs no matter when those more expensive medications are required. This will keep seniors from deferring or delaying care until January, when they would be likely to benefit again, which could damage their health.

Re: Section 60.2.3 Targeted part D Enrollee Notification at POS

1. Regarding CMS's request for comment about whether notification of a patient's likelihood to benefit at the Pharmacy POS should be triggered by a single prescription or the balance due for all prescriptions being filled in a single day:

Recommendation 4: We recommend triggering the notice based on the total out of pocket due because this better captures the financial impact on the patient and their likelihood to benefit from the program.

2. Regarding CMS's request for comment on outreach in 2025 if a Pharmacy POS notification is not operational:

Recommendation 5: We suggest reducing the trigger for notification to match the monthly OOP max with no prior TrOOP accumulation for the following reasons:

- a. Technically, seniors begin to benefit from the program as soon as they reach the monthly OOP max and are able to spread the remaining cost over time.
- b. When given the option, the average transaction value at the pharmacy that our members choose to pay over time is \$61.
- c. 75% of pharmacy transactions paid over time are for a value of less than \$70.
- d. This leads us to believe that seniors would welcome the opportunity to pay over time for smaller balances than CMS is currently contemplating.

Re: Section 80.3 Preclusion of Election in a Subsequent Plan Year

The provision in the Act that allows Part D sponsors to preclude an individual from opting into the Prescription Payment Plan in a subsequent year if the individual fails to pay is critical to minimizing program risk. Our concern is that if members fail to pay their payment plan bills and change their Part D coverage to a different plan sponsor in the following plan year, the new plan sponsor may not be aware of the member's failure to pay with the previous plan sponsor. This provision of the Act is only

enforceable if payers are aware of unpaid balances with other payers so that they can preclude the member from program participation in a subsequent year.

Recommendation 6: Set up a centralized administrative layer for the Program so that this provision can be enforced even if a participant fails to pay and changes their Part D coverage to a new plan sponsor each year. This will reduce overall Programmatic costs due to a reduction in fraud, waste and abuse.

III. Member engagement strategies relevant to CMS's forthcoming Part II Guidance

Member engagement and education is critical for program adoption, which is why we appreciate CMS's specificity around notices from plan sponsors and at the Pharmacy POS.

Re: CMS's request for input regarding education and outreach best practices, which it will address in Part 2 Guidelines next year, here are a few recommendations.

Recommendation 7: Introduce the program through multiple touchpoints to build awareness. Multi-channel and multi-lingual campaigns can help inform seniors in the various places where they consume information about their Medicare Part D coverage. At program launch, plan sponsors should send dedicated communications about the program and incorporate messaging into existing materials.

Recommendation 8: Utilize trusted sources of information to help explain the program to seniors. Call centers will require training and resources. Medicare brokers and agents who support seniors during enrollment and while they are using their Medicare plans will need to be able to explain the program and answer questions. Pharmacists should also be made aware via fliers, FAQs, and training.

Recommendation 9: Use examples and stories to explain the payment plans. CMS could consider a standard communication similar to the Health Insurance Marketplace health plans' Summary of Benefits & Coverage where the out-of-pocket costs related to common health scenarios are explained (e.g. managing type 2 diabetes).

Recommendation 10: Ensure the participant is notified of the entire payment plan in a timely manner. Paytient users are able to see all the payments they will owe with the amounts due and due dates at any time. Given that each prescription payment plan has a different number of payments with varying amounts due, we suggest creating a standard statement format across all plan sponsors. Plan sponsors should be required to provide this information in a timely manner, ideally at the Pharmacy POS, so seniors can make informed decisions regarding their personal budgets.

Appendix: Member feedback regarding paying for prescriptions over time

The following feedback was collected from Paytient users via surveys from 2019 to 2023.

- *"This is a great option for retirees living on a budget to pay medical expenses overtime without interest and free of stress.*
- *[The ability to pay for care over time] makes taking care of myself, way less stressful! Thank you for making this possible for seniors to have healthcare and a meal on the table!*
- *Easy to use for old folks*
- *So nice to have with prescription costs*
- *I love [The ability to pay for care over time], I use it for all my prescriptions!*
- *So sweet to be able to use this card at the pharmacy for prescriptions and other items! Will use it time and time again!*
- *The Service is Amazing, it's Extremely Easy To Use from my phone app and the card works Great at Docs and Pharmacy, not to mention the FABULOUS no interest pay back options!! I am loving this service and they continually keep in contact with me through my email!!*
- *[The ability to pay for care over time] absolutely hands-down is the way to take care of medical, dental and prescriptions and make them affordable. Plus, no interest and flexible repayment arrangement*
- *This is a great idea for consumers like me. My income has been reduced due to a change in job position. The flexible payment arrangement works for me due to the low monthly repayment schedule and allows freedom from burdensome past due Dr bills. Thank you so much and I commend your company for thinking about people like myself. This is a perfect fit for my budget, and another benefit from using [The ability to pay for care over time] is the fact that there's no interest! Again, I feel sincere appreciation for you all!*
- *So easy and convenient to have my card on file at my pharmacy.*
- *Easy to use and no hassles. I never have to worry about whether or not I can pay for medical or pharmacy bills.*
- *It's a really good card to have for copays at the doctor or pharmacy if you're low on cash.*
- *I just love using [The ability to pay for care over time]. Especially today it really came in handy. I was at the pharmacy and kind of strapped for cash and remembered my Paytient card. What a life saver.*
- *I love having this option to pay for my pharmacy needs. Thank you so much*
- *I love it, it gives me a way I can pay for my medicine and doctor visits when I don't have the funds to pay for it myself.*
- *It is quick and easy. No worries about medicine or doctor's copays.*
- *I love being able to get medicine or an office visit and to be able to pay you in monthly payments.*
- *Great for medicine copay, can choose deduction/payment options*
- *It's helped me with my medicine and co-payment when you're living from month to month.*
- *My experience with Paytient is great. This company has made it possible to get your medical needs paid for now, but pay much later on your terms, and with no interest. A great way to help people. Everytime I go to pay for my medicine or medical needs, Paytient is always approved, a*

big weight off of my mind. I then go online and choose my monthly terms to pay back, wow, what company does that! A great company!

- *It's a real lifesaver for me.*
- *I would not be able to go to doctor and get my medicine if it was not for Paytient. I was new to it and had no idea how it worked. I called them and the rep. was very polite took time to set everything up for me and explain it all. I made appointment charged it so I could get medication.*
- *Paytient is a lifesaver when you need medicine or to see a doctor, but are running low on cash.*
- *I like the fact that if I do not have cash but need my medicine filled, I do not have to worry knowing I can use my Paytient card and then set up the payments I want to make each time I get paid.*
- *I was unsure I would have enough cash for the appointment. Then I remembered I could pay with Paytient. I set up the payment, and I do not feel stressed because I know it will be taken out of my check, and the bill will be paid. I also had to get my children cold medicine the same week and was able to use paytient again. Makes me feel like I have my life together.*
- *I loved being able to know I was able to pay for my medicine and Copays. I want to pay this back fast as possible because it's so handy*
- *I really love it and I get a chance to get medicine that I need. It is a blessing to have it*
- *It feels good to know that I can depend on using my Paytient card when I don't have the funds to purchase my medicines and also my OTC meds. I was able to pull out my card and next my transaction was approved in just seconds. Thanks Paytient*
- *Me encanta porque me saca de casos de emergencia financiera y la uso cuando necesito comprar mis medicinas (I love it because it takes me out of financial emergencies and I use it when I need to buy my medicine.)*
- *So helpful and so easy to get you medicine especially when money is very tight*
- *I love it! I didn't have the money to pay for the prescription. I swiped the card, and got my medicine!*
- *I love it, it gives me a way I can pay for my medicine and doctor visits when I don't have the funds to pay for it myself.*
- *Prescriptions have been successful and we appreciate being able to schedule payments that suit our finances, especially with no interest tacked on!*
- *Many thanks for this excellent service. We do hope it continues onward throughout the upcoming years!*
- *I thought using Paytient to help pay for costs related to prescriptions was easy and a great solution to help curb costs.*
- *Having an option to use this card, in the same way I would a credit card to pay for medical visits, prescriptions, and supplies takes the stress of not always having the out of pocket money right then. The flexible and affordable monthly payments are awesome. It is a blessing to have this card.*
- *This card has helped me pay for tons of medical co-pays and prescriptions that can be costly at times, but allow me to budget within my means to pay them off. It's been a lifesaver, especially for larger medical needs.*

- *I couldn't go to the doctor without Paytient in my wallet. All of the customer service employees are FANTASTIC. Every encounter with them has been friendly, very helpful, and done within minutes of needing help. The ability to set my own payment amounts and length to so very helpful. If you want to pay it off early just contact customer support. The only minor inconvenience with the card is you can't use it for prescriptions. That would set this to 6 star status.*
- *I used it for my prescriptions, it's wonderful to be able to pay for and not worry about it.*
- *Yes. It's a big relief to have funds available for prescriptions and medical care and not be stressed out!!*
- *We are having somewhat financial difficulties but are getting close to the end of that, but during this time it was so nice to be able to split up those payments when we needed it most.*
- *I love that I can pay for unexpected co-pays and prescriptions with no interest!*
- *First time user was able pay for a clinic visit and the prescription, with no issue at all*
- *Very good program!!! Needed to get my prescriptions filled at the last minute and Amber the representative was very patient and helpful and got me set up!!! Was able to use the card instantly!!!*
- *So far so good, it is very helpful not worrying about how you are going to pay for your prescription when you need it, not when you can afford it. Thank you.*
- *The Paytient app is incredibly simple and quick to set up your payment plans, including paying it off immediately, and breaks down your plans by the amount each payment would be. As someone who has worried about paying for expensive prescriptions and medical equipment, Paytient offers me peace of mind that my wallet isn't going to take a huge hit at once, and I won't be left paying interest for having to use a credit card to cover my costs. There was virtually no set up time - my card came in the mail and I was able to use it at my next visit seamlessly. I also still can't get over that I'm able to use this for vet costs*
- *I love it! I didn't have the money to pay for my prescription. Swiped the card, and got my medicine!*
- *Very satisfied it helps me with the cost of my prescriptions.*
- *Conveniently I was able to pay for a high price prescription with the Paytient card. Almost left it, and thought about how my payment plan would make it easier to afford it.*
- *I feel privileged to have access to extra financial help for medical visits & prescriptions. I don't have to pay up front in a lump sum.*



September 20, 2023

Submitted via email to 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: 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**

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 one guidance regarding the Maximum Monthly Cap on Cost-Sharing Payments Program established by section 11202 of the Inflation Reduction Act (IRA) (P.L. 117-169).¹ We thank CMS for the timely issuance of this important guidance. As stated in the guidance, this program will also be known as the Medicare Prescription Payment Plan (MPPP) and establishes the statutory requirement that all Medicare prescription drug plans 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.

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.

¹ 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." August 21, 2023. Available at [Medicare Prescription Payment Plan Part 1 Guidance \(cms.gov\)](https://www.cms.gov/medicare/prescription-drug-payment-plan/part-1-guidance).



This guidance focuses on operationalizing the statute via administrative and process requirements related to billing, claims, and coverage. The statute requires that Part D plan sponsors provide the pharmacy the OOP costs at the POS that the enrollee would have paid had they not opted into the MPPP, in addition to the Part D plan's portion of payment. Moreover, the amount that the Part D sponsor may in turn bill the MPPP participant, also referred to as enrollee, for a month cannot exceed a maximum monthly cap calculated based on a statutory formula.

PCMA appreciates the timely issuance of this draft guidance for year one of the program, given that our CMS colleagues are simultaneously working on other IRA focused programmatic changes such as drug negotiation. As an industry, we 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 eagerly await additional draft guidance on which we can provide additional feedback. Specifically, we identify later in this letter an area needing immediate clarity, because the MPPP interacts with other statutory changes to the Part D standard benefit design.

We appreciate the examples provided for calculations of the maximum monthly cap for the first and then subsequent months. However, we are concerned about certain administrative and operational aspects of the program. Given the time constraints, the success of the program will be dependent on timely issuance of the final guidance that includes clarifications, details, and templates requested in this document. Our comments below are mainly feasibility and administrative functionality focused, with a request for administrative flexibility when possible. Additionally, we have woven in comments related to potential enrollee outreach and helpful model documents as appropriate throughout the document.

Our comments on CMS's part one guidance on MPPP can be summarized as follows:

- **General Comments:** Timing of initial and final MPPP-related guidance issuance for both parts one and two will determine the level of preparedness and implementation success. During the first few years of the program, success may be dependent on enforcement flexibility and discretion allowing for phasing-in certain components and requirements of the program to afford Part D plans sufficient time for implementation following issuance of all final MPPP guidance.
- **Section 40:** Plan flexibility in determining the best way to bill beneficiaries will allow for a variety of options that streamline the beneficiary billing process.
- **Section 50:** Administrative tools, such as a second Rx BIN/PCN, may be needed for facilitating MPPP claims processing but does not need to be reflected on beneficiary identification cards. Beneficiary confusion should be minimized as much as possible with minimal changes to current processes and documents where possible.

- **Section 60:** Standardization of notices focused on beneficiary education will be helpful in providing consistent messaging with regards to who may benefit from enrolling in MPPP. This standardization effort should extend to operational aspects of the program such as the dollar amount threshold for the trigger for MPPP eligibility and be set to one number for simplicity's sake.
- **Section 70:** Real-time or near-real-time eligibility exchanges will require the development of thoughtful technological solutions and cannot be applied to program election processes which are not processed electronically or telephonically. Moreover, operational tools beyond real-time or near-real-time eligibility exchanges should include guidance and model language on the communication that will occur between a beneficiary's old Part D plan and the former enrollee about their amounts owed.
- **Section 80:** Given the possibility of beneficiary non-payment, future changes to the program should be based on the analysis of actual beneficiary behavior data with regards to the payment plan. Moreover, the nascency of the program along with a lack of data on beneficiary behavior calls for stronger incentives that ensure payment of beneficiary cost sharing bill amounts.
- **Section 90:** Successful program implementation requires dispute management including coverage decision appeals management and complaints tracking. Given that implementation of any new program will lead to an increase in disputes at the plan level, there needs to be a hold harmless policy where MPPP-related complaints do not negatively impact the performance of plans, specifically Star Ratings.
- **Maximum Out-of-Pocket (MOOP) Statutory Language:** Clarity on how to interpret the new statutory language regarding MOOP will allow for plans and PBMs to accurately calculate MPPP billing requirements.

The complexity of the program requires processes for constant and real-time communication and triangulation of enrollee data between plans, PBMs and pharmacies. Based on this, some recommendations provided in our comments apply to PBMs while others are plan focused. The intention for these cross-industry recommendations is to highlight areas of concern that, though not directly PBM related, will affect the successful management of beneficiaries and their prescription benefits by PBMs.

I. General Comments

The successful implementation of MPPP on January 1, 2025, will require many operational and administrative changes including IT related coding changes which take time. Our input related to the overall process of implementing MPPP focuses on timing, administrative examples, and guidance needed.

- **Timing of Guidance:** Successful implementation will require timely issuance of the final part one guidance by the end of 2023, especially since there will be a need to change current administrative work processes including IT codes for billing and claims. For part two of the guidance, we are concerned that an early 2024 draft guidance with commenting opportunity will not provide sufficient time for developing member communications. CMS should aim to provide part two of the draft guidance before the year's end and seek to finalize each document within three months of the close of comments.

PCMA recommendation: We recommend that CMS issue a draft of the part two guidance in 2023 and finalize the guidance no later than the end of the first quarter in 2024. Alternatively, CMS should consider phasing-in certain components and requirements of the program to afford Part D plans sufficient time for implementation following issuance of all final MPPP guidance.

- **Program Calculations and Examples:** We request that the final guidance include examples and program calculations from CMS to clarify the actual workflow based on the type of pharmacy, type of plan, and different ways in which enrollees may move through the program. Additionally, PBMs request that CMS provide us with examples of billing updates due to claims reprocessing or adjustments, including ones where there are multiple reasons for reprocessing, such as retroactive low-income subsidy (LIS) status change, Medicare as the secondary payer claims, or reversals.

PCMA recommendation: We strongly recommend that these examples are created in sets or modules by plan types including enhanced plans, Employer Group Waiver Plans (EGWPs), or other secondary insurance where Medicare is the secondary payer.

- **Type of Guidance:** In addition to the parts one and two guidance for MPPP, the industry requests that CMS consider other adjunct guidance such as 2025 Medicare re-design related technical guidance and the 2025 Prescription Drug Event (PDE) guidance for early publication to facilitate a successful open enrollment for next year. Similarly, we recommend that CMS provide the Advanced Notice and Part D Call Letter by the end of the year (Q4 2023) as well.

Due to large volume of changes required for calendar year 2024, 2025, 2026, the extent of development required for pharmacies, plan sponsors, and PBMs to implement the MPPP and the additional contracting required to support the MPPP, the final guidance is needed as soon as possible. With the final part one guidance not available until early next year and part two guidance not available until the spring, the industry will have six months or less for contracting, IT coding, testing, implementation of the changes, as well as ensuring that operational processes and training are conducted in time for open enrollment.

PCMA recommendation: CMS should issue part one final guidance by Q3 of 2023 to ensure successful implementation and part 2 guidance by the end of 2023. Additionally, we are requesting that CMS entertain an enforcement discretion beyond 1/1/2025 and or allow for phasing-in of components of the program.

II. Section 40 – Participant Billing Requirements

Section 40 addresses billing requirements and the discussion includes cash flow, payments, and billing flexibility as aspects of administrative processes that need to be considered to help beneficiaries understand their bills.

PCMA is concerned that plans will experience cash flow issues given that they will be paying pharmacies the beneficiary cost-sharing amount that would have been due at POS. While plan bids may include expected losses, without clear instruction and advance guidance that the Office of the Chief Actuary will accept these solvency issues as claims costs, plans will lack sufficient information to properly address this risk. Medical debt is widely studied, and while seniors experience the lowest debt among all age groups, more than one-in-five already owe a provider more than they can afford.² We are concerned that initial bidding guidance may not allow for enrollee delinquency, instead pushing the risk out for at least one year which takes us into 2026.

Another concern is that smaller plans may have decreased ability from a solvency perspective to “float” this much money to pharmacies, without repayment from participants. Given the potential risk to the industry, we request that CMS provide guidance on how to project and account for cash flow issues in bids, specifically related to enrollee death and conscious delinquency not related to financial hardship. CMS should consider prospective payments as an acceptable outcome until the risk is more accurately predicted and incorporated. In cases of non-hardship-related enrollee delinquency, plans should be given flexibility as it relates to debt collection activities in accordance with state and federal laws.

In an effort to assist and foster prompt payment, CMS encourages the use of multiple payment methods and suggests allowing the enrollee to pick the day of the month for payment withdrawal. PCMA would like to note that this might get complex and result in bill generation issues in the first year of the program, and we are concerned about the need to determine ways to collect cash from individuals who would prefer to pay cash. Additionally, CMS should seek out ways to simplify members’ billing experience, such as allowing for a single statement including MPPP amounts due and premiums paid to the plan. This idea can be further expanded with a request that CMS considers the creation of an MPPP accumulator in the PDE,

² See KFF. “Health Care Debt In The U.S.: The Broad Consequences Of Medical And Dental Bills.” June 16, 2022. Available at <https://www.kff.org/report-section/kff-health-care-debt-survey-main-findings/>, finding that 22% of seniors 65 and older currently hold medical debt.

like today's true out-of-pocket (TrOOP) accumulator, that tracks how much each enrollee owes across all their current and former MPPP programs. This may help the industry identify enrollees who need further education regarding the intent and structure of the program.

Simple billing along with adequate beneficiary education prior to enrolling in MPPP should prevent easily avoidable scenarios such as nonpayment. CMS should also give beneficiaries the flexibility to pay more than the maximum monthly cap, but do not exceed the actual incurred claims, to avoid larger amounts due near the end of the year. For simplicity's sake, sharing information on the LIS program on the bill may not be necessary and could potentially be confusing. Additionally, we are concerned that re-worked retroactive claims will lead to enrollee confusion. There will also be issues with post-disenrollment monthly billing. In this scenario, it is possible that the member could be receiving a cost-share bill from multiple Part D plan sponsors which causes confusion. One solution to alleviate and or prevent this confusion is for plans to bill the members in full or provide them with payment plan options that are over a shorter period with a few installments.

For the first year, plans should have flexibility regarding when members receive the cost-share bill, given that it may take several weeks to generate bills and mail them early in the process. Plans should be able to determine cost-share payment due dates that should be no less than 15 days after bill generation and be able to send bills by mail or electronically. CMS should allow plan flexibility to explore opportunities to reduce the number of communications and reduce beneficiary confusion.

PCMA recommendation: CMS should allow plans flexibility with billing and allow them to offer options that streamline the beneficiary billing process.

III. Section 50 – Pharmacy Payment Obligations and Claims Processing

Section 50 addresses pharmacy payment along with claims processing processes. Here CMS acknowledges the difficulty of ensuring coordination of benefits (COB) via an electronic billing process and suggests the use of two separate Part D plan sponsor BIN/PCN combinations. While this solves one set of problems, even with two BIN/PCN combinations, there will be administrative challenges that will require system enhancements. For example, the most fundamental issue will be that currently plans do not have a way to inform PBMs in real time when members have enrolled in MPPP. To be able to do this, plans will require two separate lines of eligibility for each member enrolled in MPPP.

PCMA notes that CMS is not requiring that the MPPP BIN/PCN be printed on member ID cards and agrees with this approach. Given the limited space on beneficiary ID cards and the chance of members opting-in or -out at any time during the year, issuing and re-issuing ID cards could be confusing to members. The MPPP BIN/PCN information should only be transmitted to the pharmacy electronically and or be included in member communication related to their election.



This will allow pharmacies to track beneficiary enrollment in real time without needing to wait for the enrollee to come into the pharmacy with their physical card.

PCMA recommendation: We agree that the second Rx BIN/PCN for the MPPP election should not be required to be included on the ID card.

Another concern is that pharmacies will be responsible for processing and submitting all COB data appropriately and in the proper order, with MPPP being last. For these submissions, the current National Council for Prescription Drug Programs (NCPDP) standard allows for only three payers to be listed on the COB contractor data, and there may be limited situations where there needs to be additional payers. CMS should provide guidance to outline their expectations of how this situation should be handled. Separately, there will be challenges with claims that process post-POS, specifically with claims adjustments such as COB through other payers, long-term care post-consumption billing, and retrospective LIS changes. Currently, pharmacies have at least 90 days to reverse and reprocess claims. However, this will be a challenge for MPPP billing and require that pharmacies track and reverse both primary and MPPP claims, which could lead to scenarios where the beneficiary may have terminated from the MPPP by the time of adjustment.

CMS should take into account specific nuances related to the education of beneficiaries regarding the payment plan. Pharmacies should not be required to educate the beneficiary on the payment plan in advance of dispensing the product, since it could delay the delivery of medication. As pharmacies must process a claim prior to knowing whether a member is “likely to benefit” from MPPP or has been terminated from the MPPP, pharmacies should be allowed to include materials about the payment plan along with the dispensed product when the beneficiary is “likely to benefit,” and they or their representative either pick up the prescription or receive it via a delivery or mail service.

Typically mail-service pharmacy is used when someone is already stable on therapy. Additional outreach about changes in costs related to maintenance medication could confuse beneficiaries. In the event that a beneficiary receives a mail-order prescription for the first time under their plan, they will receive an initial bill by mail with options available to automate payments going forward. These pharmacies should be allowed to include materials about the payment plan in the packaging for these fills, and all others.

In addition to our specific comments in this section, we agree with CMS’s concerns related to the debit card concept. PCMA is concerned that tracking and oversight of pre-funded Part D sponsor-issued debit cards for enrollees to present at the pharmacy to pay for their amount owed at the POS will be difficult. These cards can unknowingly be used for non-Part D drugs. Moreover, there may be access issues related to the timeliness of issuing payment cards. Participants will need to present a physical card at the POS, which could be forgotten, lost, or stolen, hindering access to prescription drugs. Lost and stolen cards would also increase the risk of fraud, waste, and abuse for the Part D program.



We also support the exclusion of paper claims from the payment plan. Additionally, CMS should clarify that this exclusion includes all instances of direct member reimbursement, on real “paper” or otherwise through online or telephonic submissions, for in- and out-of-network claims.

PCMA recommendation: CMS should consider additional guidance to address the corner case where a beneficiary has more supplemental coverages than the current NCPDP standard will allow to be passed to the pharmacy on a claim response.

IV. Section 60 – Requirements Related to Part D Enrollee Outreach

Section 60 addresses identifying individuals who may benefit from the program, as well as ways to communicate and educate beneficiaries about this program. In addition to the examples provided regarding those who may benefit, we request that CMS provide examples of those beneficiaries who may not benefit and incorporate this into its communication efforts with beneficiaries preceding and during and following open enrollment for plan year 2025. Once identified, the Evidence of Coverage (EOC) notice would be an appropriate vehicle to inform them of this lack of benefit.

The MPPP process relies on the plan to identify enrollees that will benefit, i.e., eligible Part D beneficiaries, and then inform the PBM of the beneficiary’s election. The pharmacy or pharmacist is not privy to the plan PBM communication and probably will not know of election eligibility or status until after the fact. However, when a member is “likely to benefit,” the PBM will send a NCPDP-approved message code to the pharmacy that will indicate the need to educate the beneficiary on the program. Neither the pharmacy nor the PBM can enroll, and currently, there is no real-time enrollment processes triangulating this pharmacy, plan, PBM MPPP programmatic workflow. Therefore, the burden of education, capturing election-related data, and or determination of whether an individual is the legal representative of the beneficiary should not be imposed on the pharmacists.

PCMA supports CMS’s plan to issue a model template similar to the “Medicare Prescription Drug Coverage and Your Rights” (CMS-10147)³, where a code is sent to the pharmacy and then the pharmacy provides the model notice to the potential participant. We support model language issued by CMS to help ensure that messaging to participants is consistent. Including this message across multiple known and trusted documents, such as explanation of benefits (EOB), EOC, and annual notice of change (ANOC), provided to Part D enrollees would be helpful.

PCMA recommendation: CMS should provide a templated single notice that all pharmacists can use to educate beneficiaries who may benefit from enrolling in MPPP.

³ [Form Instructions \(cms.gov\)](https://www.cms.gov/medicare/coverage/prescription-drug-coverage/medicare-prescription-drug-coverage-and-your-rights)



We acknowledge that identification of beneficiaries who will likely benefit before the start of the coverage year is key, but we would prefer flexibility from CMS on how to identify and communicate with these beneficiaries.

As for ways to identify MPPP-eligible beneficiaries, we ask that the threshold be set based on a single claim not a batch of claims and that it be based on patient's pay amount with the flexibility of assessing other factors such as whether the member has additional supplemental coverage or is LIS eligible. We recommend and support the approach of using a claim-level threshold trigger of \$700. We believe that using one number instead of a range for 2025 will be easier for the initial system's implementation, messaging for the member, and communication for the pharmacy. Communication burden could be lowered for the Medicare eco-system at-large if CMS's Medicare Communication office took on the responsibility of identifying and notifying eligible beneficiaries who may benefit from MPPP.

For the LIS population, we are concerned that notification about MPPP will be confusing for these beneficiaries. As CMS noted, we do not expect LIS beneficiaries to benefit from MPPP participation. They should not be identified or communicated to as "likely to benefit." The LIS program is designed to provide access to prescription drugs for nominal cost sharing. The IRA expands eligibility for LIS, greatly improving access for another group of beneficiaries. As such, CMS should not over-complicate the transition to full LIS for these individuals, or those already fully eligible. Given this lack of benefit, CMS should provide specific model language on how plan sponsors should inform potential participants on the two programs, i.e., LIS and MPPP.

PCMA recommendation: CMS should consider using \$700 on a single claim as the threshold for the trigger for MPPP eligibility as well as allowing flexibility for the consideration of other factors. CMS should also provide model language on how plan sponsors inform potential participants about the benefits and appropriateness of LIS versus MPPP.

Unique Pharmacy Scenarios: We appreciate that CMS recognizes the need for different processes for different types of pharmacies.

PCMA recommendation: We recommend that for long-term care settings, CMS should clarify whether plan sponsors would bill the participant or the facility under the MPPP.

V. Section 70 – Requirements Related to Part D Enrollee Election

Section 70 addresses Part D enrollee election methods that minimize potential confusion and operational challenges. Most importantly, real-time or near-real-time eligibility exchanges between plan sponsors and pharmacies may not exist outside of claims processing. One proposed solution for this lack of real-time processes is using an NCPDP Submission Clarification Code (SCC) during claims processing to enroll members into the program.

However, this may not be a viable solution since PBMs do not have the authority or necessary information to effectuate an election request in real time using a SCC. Facilitation of real time would require a new process to task network pharmacies to obtain and transmit information real time.

For election requests, we recommend that the 24-hour time frame for processing election requests during the plan year be expanded to 72 hours for non-urgent requests. This extension is requested based on the complexities and steps required to fulfill telephonic and electronic enrollments such as recorded statements for telephonic enrollment along with enrollee's attestation and electronic signatures for online enrollment with required selection of activation buttons such as "opt in now" and "activate."

However, flexibility is required since it will not be feasible to process a paper enrollment that is received via fax within 24 hours. In addition, plan sponsors should also be given flexibility to manage the application of retroactive activity in claims processing for members in this program, while adhering to required time frames for refunds. Plan sponsors should be allowed to provide the beneficiary with the option to apply retroactive refunds to offset future MPPP payments. Beyond regular Part D plans, CMS should consider the impact of this program on EGWPs. There are unique situations where the existing guidance may not align perfectly with existing mechanisms used by EGWP plans. One example is that some EGWPs use group-level enrollment and may need to rely upon direct post-EGWP enrollment elections into the MPPP. Additionally, flexibility may be needed in terms of the collection of premiums and or balances as the retiree group plans are the ones that deal directly with potential participants.

PCMA recommendation: *We recommend that CMS provide the industry with more time to discuss and consider approaches to technological solutions to support real-time or near-real-time eligibility exchanges. We recommend that CMS allow for exceptions on timelines for enrollments that are not processed electronically or telephonically.*

Midyear Enrollments: For enrollments that are off-cycle or midyear, plan sponsors should have the flexibility to give members an option as to when their election into the payment plan becomes effective. This way beneficiaries who are having difficulty affording a prescription will be able to elect immediately; while others who are learning about the payment plan for the first time could start on the first day of the following month which would ensure that their enrollment aligns with the start of the month. In addition, the election date can take into consideration the time that it takes to process the election and provide the election information to the PBM. These midyear enrollment changes will require clear communications from the old plan to participants when their participation in the MPPP is ending and the responsibility for remaining MPPP payments. Otherwise, beneficiaries could get confused with their multiple MPPP outstanding balance bills. CMS should consider this situation when developing educational materials and model language.

MPPP serves a similar purpose as the LIS or “Extra Help” program, while eligibility differs. We recommend CMS include language about MPPP in LIS informational materials, and *vice versa*, with clear instructions as to who to call or where to go to apply for that program is one way of addressing plan hopping and can help identify enrollees facing financial hardship.

PCMA recommendation: *CMS should provide guidance and model language on the communication that will occur between the old Part D plan and the former enrollee about their amounts owed. CMS should consider adding model language on MPPS within the LIS program, and vice versa.*

Retroactive Enrollments: Retroactive election should not be a mandatory requirement for the first year of program operations. However, plans should be able to offer it if they are operationally able to do so. For PBMs, retroactivity will be complex, and it may involve the creation of MPPP COB transactions while the plan is concurrently performing other functions related to billing and payment of balances. Given the level of difficulty and the level of effort required to address this, we suggest that CMS defer the requirement for this functionality beyond plan year 2025.

PCMA recommendation: *CMS should defer the implementation of retroactive election beyond plan year 2025.*

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

Section 80 addresses Part D sponsors procedures for both voluntary and involuntary terminations from the program along with processes for reinstatement and preclusion. For this section, our concerns focus on enrollee cost sharing, past-due bills, and delinquency.

We agree with the proposal that Part D plan sponsors must provide the individual with a notice of termination. Plans should be provided with the flexibility to include this notice with the next monthly bill. We are also concerned about beneficiary confusion post-termination, especially with regards to outstanding MPPP balances. For example, if they switch plans and elect into another payment plan with the new plan sponsor, they could receive three bills each month: premium from current plan sponsor; cost sharing from the current plan sponsor; and cost sharing from the former plan sponsor. One way to address and alleviate this issue of multiple bills is to require payment in full for their remaining cost-sharing balances upon termination.

For enrollees who are not paying their MPPP cost-sharing bills, a two-month grace period operationally becomes four months since incurring the cost by the time they are terminated from the program. Additionally, there needs to be stronger incentives for members to pay their cost-sharing bill. Given that some enrollees may be delinquent with payments, CMS needs to determine when a beneficiary not paying their cost-sharing bills is determined to be fraud,

waste, and abuse. Any magnitude of delinquency will eventually put pressure on bids, resulting in an increase in beneficiary premiums and Medicare direct subsidy payments to plans to address bad debt related losses.

PCMA recommendation: CMS should prepare for future changes by analyzing data on beneficiary behavior with the payment plan and unpaid cost-sharing bills. Additionally, CMS needs to establish much stronger incentives for members to pay their cost-sharing bill.

VII. Section 90 – Participant Disputes

Section 90 addresses participant disputes. We agree that successful dispute resolution will require the parsing of each type of dispute and then creating guidance based on the type. Generally, plans delegate coverage decisions (CDs) and coverage decision appeals (CDA) to PBMs. However, for the MPPP program, plans may be doing their own billing, and PBMs may not have visibility into this process. As such, PBM CDA teams will not have access to any of the information needed to determine if the enrollee is being billed correctly, such as when the beneficiary enrolled in the program, how much they have already paid, and the impact of any retroactive adjustments for retroactive LIS, etc. To process these cases under the existing CDA system, the industry will need a lot of guidance on the topics and related questions posed below:

Case Classification & Adjudication Times:

- Will these be initial CDs, or will they be Level 1 appeals?
- Will they be pre-service or post-service requests?
- Will members be allowed to have an expedited review?
- How long will PBMs have to decide and notify the beneficiary?
- Will PBMs autoforward to the Independent Review Entity (IRE) if a timely decision is not made?

Effectuation: Today effectuation involves entering an override in a claims processing system and or issuing a reimbursement check. Current CDA disputes are never resolved by adjusting a billing statement.

- How will PBMs effectuate a favorable decision?
- What would the date/time of effectuation be for these cases?

Letters: PBMs need guidance on how to communicate final decisions, i.e., letter template and model language. If final decisions are processed as CDs, CMS will need to update the OMB-approved CD denial notice or provide guidance permitting plans to use a different letter. Accordingly, PBMs and plans will likely need to modify their entire suite of Part D CDA letters to accommodate this new scenario. This will be extremely burdensome for both plans and PBMs. Additionally, for denials, CMS requires a case-specific explanation for why the request was denied and should provide sample

language for a few different denial scenarios. The creation of these case-specific denial letters will help enrollees receive the right type and amount of information regarding the denial reason.

CDA Reporting: This will be a time and resource intensive process requiring significant IT-related work process changes to the existing CDA software systems to process these new types of cases. The system updates need to be done in a way that allows the targeted data to be captured and reportable, so it is critical to have the reporting requirements finalized before the IT project kicks off.

Grievance versus Appeals Process Distinction: Please note that it is unusual for disputes regarding member eligibility and participation to be handled as grievances. Generally, when a member receives some kind of unfavorable determination from the plan, a resulting dispute is handled as an appeal, not a grievance. Hence, clarification regarding the use of grievances instead of appeals is much appreciated.

We suggest that from this list above, CMS should start with the topics that require IT changes and focus on them first, such as CDA reporting. However, all the topics and questions above require guidance so that timely coverage determination appeals and disputes are adjudicated regarding the prescription drug benefits, including MPPP, an individual is entitled to under the Part D plan.

PCMA recommendation: CMS should establish a set of minimum standards for adjudicating all disputes that include the type of dispute and time frames associated with resolving these disputes.

In addition to CDs and CDAs, CMS should also consider a grace period for complaints tracking related to MPPP. This grace period will allow plans to track the types of complaints, resolve them, and evaluate their frequency rate and impacts on overall performance. During the first few years of the program, MPPP-related complaints should be excluded from overall Star Ratings.

PCMA recommendation: CMS should create an MPPP-related complaints tracking module and apply a hold harmless policy where MPPP-related complaints do not negatively impact the performance of plans, specifically Star Ratings.

VIII. CMS should state more explicitly that the first maximum monthly payment is based on the statutory MOOP

We have reviewed the guidance in detail and have observed that every example throughout the many sections always begins with a \$2,000 annual maximum out-of-pocket (MOOP) threshold, for the first month, followed by actual incurred costs or subsequent months. Under the current draft guidance, plans and PBMs are confused about whether the \$2,000 used in each example is based on simplifying assumptions for purposes of illustration, or if MPPP should instead be based upon the actual MOOP for the marketed plan. The statute directs plans to calculate the



first monthly payment based on the threshold as defined at SSA section 1860D-2(b)(4)(B)(i)(VII) (\$2,000 for 2025 and then adjusted annually for inflation), rather than the enrolled individual's actual MOOP based on the plan they have selected. We humbly request that CMS more specifically state this assumption in the final guidance. We believe that Medicare Advantage prescription drug plan and Part D plans will have continued flexibility with all of the benefit design parameters, based on actuarial equivalence standards and for enhanced plans. Further, notwithstanding our request to exclude them from MPPP, EGWPs should continue to be able to provide robust wrap-around coverage, without having to wholesale change how they would calculate MPPP if it applied to them.

PCMA recommendation: CMS should explicitly say in the final guidance that all MPPP first month calculations are based upon the \$2,000 MOOP for 2025, not actual enrolled plan MOOPs.

IX. Conclusion

We appreciate the opportunity to provide this feedback to CMS on ways to address MPPP implementation for the first year. Our concerns and discussion focus on administrative complexities and the risk of beneficiaries' non-payment of copayments, with limited repercussions against the beneficiary. If you need any additional information, please reach out to me at tdube@pcmanet.org.

Sincerely,

Tim Dube

Tim Dube
Vice President, Regulatory Affairs

September 20, 2023

VIA ELECTRONIC SUBMISSION — PartDPaymentPolicy@cms.hhs.gov

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RE: Medicare Prescription Payment Plan Guidance – Part One

Dear Dr. Seshamani,

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

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

¹ CMS, Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments, Aug. 2023.

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

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

³ De Avila, J. L. M., D.O.; Zhang, J.X. (2021). Prevalence and Persistence of Cost-Related Medication Nonadherence Among Medicare Beneficiaries at High Risk of Hospitalization. In JAMA Network Open (Vol. 4, pp. e210498).

Major benefit design changes were included as part of the Part D redesign provisions of the Inflation Reduction Act (IRA), including a maximum annual cap on out-of-pocket (OOP) costs, paired with a maximum monthly cap on cost sharing program in which Part D enrollees may elect to participate. The Maximum Monthly Cap on Cost-Sharing Payments Program, now known as the Medicare Prescription Payment Plan (MPPP), requires careful policy development and thoughtful implementation of key operational details.

PhRMA first submitted comments on this program in June as part of our response to CMS' *Calendar Year (CY) 2025 Part D Redesign* guidance.⁴ In those comments, we encouraged CMS to develop key education and outreach tools for beneficiaries on the program, to keep beneficiary protections at the forefront of operational calculations and effectuation decision-making, and not to delay decisions related to the infrastructure and effectuation details. Our comments were intended to ensure that the program is able to meet its goal of improving affordability for Medicare beneficiaries.

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

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

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

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

⁵ CMS. Technical Memorandum on the Calculation of the Maximum Monthly Cap on Cost Sharing Payments Under Prescription Drug Plans. July 2023. <https://www.cms.gov/files/document/monthly-cap-cost-sharing-technical-memo-july-2023.pdf>.

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Section 20 – Overview

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

As noted by CMS, the program is likely to offer significant benefit to many enrollees in improving drug affordability but will not offer the same benefit to all enrollees. Successful implementation of MPPP will not only require broad education to raise awareness of the program and clearly explain the potential benefit and how to elect the program, but also necessitate changes in Part D plans and pharmacies' financial and operational workflows.

Further, as noted in the draft guidance, because beneficiary election into MPPP is voluntary, beneficiary education and outreach will be a critical factor in both the uptake and the success of the program, especially in the early years of implementation.

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

The MPPP will have varying effects, depending upon the variability and level of a beneficiary's monthly out-of-pocket costs as well as their individual financial situations. While there will be a clear benefit for those who may hit their MOOP early in the year, for others, there may not be a benefit. As such education and outreach are critical, and ***we applaud CMS for seeking input on the tools and decision supports that will be most beneficial to Part D beneficiaries as they determine whether to opt in to MPPP***.

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

Section 30 – Program Calculations and Examples

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

⁶ CMS. Technical Memorandum on the Calculation of the Maximum Monthly Cap on Cost Sharing Payments Under Prescription Drug Plans. July 2023. <https://www.cms.gov/files/document/monthly-cap-cost-sharing-technical-memo-july-2023.pdf>.

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

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

Section 40 – Participant Billing Requirements

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

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

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

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

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

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

Section 50 – Pharmacy Payment Obligations and Claims Processing

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

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

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

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

Section 60 – Requirements Related to Part D Enrollee Outreach

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

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

60.1 General Part D Outreach Requirements

Part D beneficiaries have different financial situations and many choices for prescription drug coverage today, resulting in highly varied OOP costs for medicines. For this reason, general outreach and education on the MPPP program to all Part D beneficiaries will be critical to ensuring that beneficiaries have a clear understanding of how opting into the MPPP may impact their monthly OOP costs.

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

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

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

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

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

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

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

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

60.2 Targeted Part D Enrollee Outreach Requirements

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

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

⁹ CMS. Technical Memorandum on the Calculation of the Maximum Monthly Cap on Cost Sharing Payments Under Prescription Drug Plans. July 2023. <https://www.cms.gov/files/document/monthly-cap-cost-sharing-technical-memo-july-2023.pdf>.

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

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

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

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

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

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

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

Proposed standard for beneficiaries “likely to benefit” from MPPP

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

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

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

CMS projects that at a \$400 threshold, just over 2 million Part D beneficiaries would be identified as likely to benefit from the MPPP. This translates to 4 percent of Part D beneficiaries, based on a total number of 50 million beneficiaries in 2022.¹⁰ ***PhRMA recommends CMS use a relatively low threshold for notification at the POS, either the \$400 level or even lower***, in order to ensure that a larger pool of potential MPPP participants are identified. For example, the threshold could be \$400 for prescriptions for an extended supply (i.e., 90 days), but lower for those filling 30-day prescriptions.

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

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

adherence and abandonment of medicines at the pharmacy counter.¹¹ In fact, research shows rates of abandonment for Part D beneficiaries average 55 percent for all prescription drugs with cost-sharing higher than \$250, no matter how critical the medicine.¹² This abandonment or lack of adherence to prescribed medicines can worsen health outcomes and further widen existing health disparities.¹³

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

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

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

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

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

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

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

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

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

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

Section 70 – Requirements Related to Part D Enrollee Election

70.2 Interactions Between LIS and Medicare Prescription Payment Plan

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

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

70.3.5 Processing Election Request During a Plan Year

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

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

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

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

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

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

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

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

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

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

¹⁵ <https://www.igvia.com/locations/united-states/blogs/2021/11/understanding-the-impact-of-cost-sharing-in-pharma>

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

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

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

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

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

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

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

Overall Considerations for POS Election

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

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

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

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

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

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

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

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

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

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

Section 90 – Participant Disputes

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

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

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

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

Sincerely,



Rebecca Jones Hunt

Deputy Vice President, Policy & Research

/s/

Judy Haron

Deputy Vice President, Law



Kristin Williams

Manager, Policy & Research



Daniel Fellenbaum

Senior Director, Policy & Research

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

POS Election Option 1. Telephone-Only

Operational Opportunities: Telephone Option

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

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

Implementation Challenges: Telephone Option

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

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

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

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

POS Election Option 2. Mobile or Web-Based Application

Operational Opportunities: Mobile/Web-based Application Option

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

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

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

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

Implementation Challenges: Mobile/Web-based Application Option

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

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

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

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

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

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

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

POS Election Option 3. Clarification Code

Operational Opportunities: Clarification Code Option

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

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

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

Implementation Challenges: Clarification Code Option

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

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

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

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

¹⁷ <https://standards.ncdp.org/Our-Process.aspx>

Per the attached memo, PrimeWest Health is respectfully submitting the following comments:

Thank you for the opportunity to review and comment on the Cost-Sharing Payments under prescription drug plans. The option to participate in the program must be offered to all members, including LIS members. This is unfortunate given the out-of-pocket cost expense for the LIS population is quite small. This new program will require significant administrative complexities if any of our members opt into the program. Given the level of complexity associated with this new requirement, we have identified practical problems of administration and the exposure to financial risk as indicated below.

Section 40. Billing requirements

Plans are billing member instead of member paying pharmacy – We are a DSNP plan. Per the LIS example and information in the draft guidance, this program does not benefit LIS members. 100% of our members are LIS. This would be burdensome to DSNP plans to create a billing system for a couple of members that may choose this program if they didn't understand how it worked.

60.1 Outreach requirements

Our plan is a DSNP. By publishing this program as an option in open enrollment materials and on the enrollment form, would only serve to confuse our members who are already dealing with Medicaid, Medicare, Part D and LIS programs. It is difficult to explain and offer a program that is not going to be in the best interest of the member. Per the example on page 54-55 (Example B7), the member's payment would increase each month throughout the year which would not be advantageous for a low income member on a fixed budget.

Because our DSNP members always have a LICs level of 1-3, this program does not benefit them, but only serves to confuse members and increase their payment throughout the year..

70.2 Interactions between LIS and Medicare Prescription Payment Plan

DE-SNP plans – all of our members are LIS. The guidance states in section 70.2:
participation in the Medicare Prescription Payment Plan is unlikely to benefit LIS enrollees.

Since 100% of our members are LIS, we would ask that DE-SNP plans be exempt from the payment plan requirements so we do not confuse members.

70.3 Election procedures

Because our DSNP members will not benefit from this program, if this is mandated for LIS/DSNP members, we would need to create all of the same billing and opt in mechanisms that a commercial Medicare plan would need, just in case someone opts in. This is administratively burdensome for the plan and not in the best interest of low income members enrolled in a DSNP only plan.

70.3.3 Processing election request of time of enrollment

Our DE SNP plan is integrated with MN Medicaid and we contract with the state of MN to do enrollment processing. Medicaid eligibility is not determined until 6 business days prior to the end of the month. This would not be consistent with the 10 day expectation to process requests received on the enrollment form. For example an enrollment form is received on Sept 2. Medicaid eligibility is not determined until 9-22-23 which is after the 10 day notice to the member which is the time that the enrollment form would be considered complete. Notice wouldn't be able to be sent out until Medicaid eligibility for the month of enrollment is confirmed.

Section 80, enrollees would most benefit by opting into the Payment Plan just before the gap and then not paying their monthly payment. There would be no repercussions and maximum costs would be avoided. It would also be beneficial to incur costs and change plans. Are there any policies in place to negate these actions?

Thank you!

Phi-free

Bethany Krafthefer, MBA

[Pronouns](#): she, her, hers

Chief Operating Officer

Direct Phone 320-335-5392

Direct Fax 320-762-8750

September 20, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW Washington, DC 20201

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Directors**

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Dear Administrator Brooks-LaSure:

On behalf of the members of the Public Sector HealthCare Roundtable (the Roundtable) and the public sector employees, retirees, and their dependents they serve, we thank you for the opportunity to provide our feedback on the Medicare Prescription Payment Plan under Part One of the Maximum Monthly Cap on Cost-Sharing Payments Program guidance.¹

The Roundtable is a non-profit, non-partisan coalition of public sector purchasers from across the United States, including states, counties, and municipalities. We are working together to bring a voice to the tens of millions of public sector employees, retirees, and their dependents. Over 15 percent of the American workforce is employed by public sector entities, and collectively they spend \$43 billion annually on health care benefits, including prescription drug benefits. These current and former public servants are the bedrock of their communities, performing vital roles such as teachers, firefighters, and law enforcement. They often receive modest incomes for their service, and the health benefits our public sector employers provide are an important component of their compensation structure. Roundtable members have a fiduciary duty to the public sector consumers that we serve to offer high-quality benefits at an affordable cost.

The Medicare Advantage program has enabled our members to better serve their beneficiaries via Employer Group Waiver Plans (EGWPs). EGWPs ensure care coordination, Part D drug coverage, and stable benefits and premiums for millions of public sector retirees. Studies show that EGWP beneficiaries spend \$2,200 less on member cost sharing, while receiving additional benefits, compared to those covered by a standard plan. In addition, our members consistently see high satisfaction rates among the EGWP beneficiaries they serve.

While the benefits of allowing Part D monthly payments for medications is an important option for many Part D enrollees, we strongly believe that most, if not all, EGWP beneficiaries are already shielded from the high out-of-pocket costs that the Prescription Payment Plan intends to attenuate. As a consequence of the unique protections already offered by EGWP plans, coupled with the negative impact the requirement could have on EGWP enrollment and participation, we ask that CMS consider an EGWP exemption of these requirements under the authority granted by 42 CFR § 423.458(c).

42 CFR § 423.458(c) provides CMS the authority to waive or modify any Part D requirement that “hinders the design of, the offering of, or the enrollment in” an EGWP Part D plan. Generally, EGWPs offer enrollees a more predictable out-of-pocket expense structure and better alleviate overall financial burdens compared to the standard Part D benefit. For instance, one of our Roundtable member EGWPs exempts enrollees from any Part D deductible and requires enrollees pay only a \$7.50 co-payment for a 34-day supply of generic prescriptions and a maximum coinsurance cost of \$100 for a 34-day supply of brand name and specialty drugs.

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

In fact, coinsurance maximums likely provide better protection for enrollees who start an expensive drug in the second half of the year when the Maximum Monthly Cap would greatly exceed our current coinsurance maximums. Furthermore, when opting for home delivery, members pay even less per day-supply. Notably, no enrollee under this EGWP has reached the proposed per-prescription or daily copay threshold for point of sale (POS) notification, underscoring the protective nature of this benefit design for enrollees.

As showcased above, EGWP enrollees already have robust cost protections in place, and being offered an alternative payment option with limited benefits can inadvertently confuse enrollees and expose them to opportunities to accrue potentially burdensome debt or late payment fees from failing to pay the monthly amount. For example, the guidance does not specify the cumulative amount owed if each monthly bill is not paid before the next one is issued. Enrollees must comprehend both the monthly amounts owed and the complete balances, including any outstanding arrearages, to avoid accumulating unnecessary debt. In these scenarios, the total amount owed may need to be communicated to enrollees. Nevertheless, the risk of misunderstanding of the program likely exceeds the Program's benefits in scenarios where cost-sharing is already very limited, as is the case in EGWPs offered by our members.

Adding to this confusion is how the election to participate in the program will be incorporated in the plan enrollment process. Some of our members offer a combined Medicare Advantage and EGWP benefit plan, electronically sending approved enrollment requests to both MA and PDP contractors. This enrollment approach offers a simplified, streamlined experience for enrollees to enroll in coverage. However, unlike individual plans, there is no specific PDP enrollment form that would be able to incorporate the election option. Consequently, adding this option will cause additional administrative burden to our members and add further complexity to the enrollment process, again imposing additional risks to enrollees.

Finally, there are significant cost concerns unique to our members and the EGWPs they contract with. Our members would operate the Prescription Payment Plan through their Part D insurance carriers, who would design and build the processes necessary to administer the payment plans. We expect these processes to significantly increase our administrative costs, translating into higher bids and thus costs for the enrollees our EGWPs serve.

As a consequence of these dynamics, CMS should consider excluding EGWP plans from the Prescription Payment Plan on the grounds that it would directly hinder the design, offering, and enrollment of EGWP Part D plans. It is crucial to acknowledge the exceptional circumstances of public sector employees and retirees as this rule is finalized, particularly when contrasting our member's historically and presently protective design with the standard Part D benefit. Ultimately, the risks imposed by the program on enrollees served by our members significantly outweigh its proposed benefits.



We appreciate and share CMS' commitment to ensuring Medicare beneficiaries are adequately protected from high-out-of-pocket prescription drug costs and welcome the opportunity to work with CMS in further developing and implementing the Prescription Payment Plan. If you have any questions please reach out to Andrew MacPherson, Public Sector HealthCare Roundtable Senior Advisor, at andrew@healthcareroundtable.org.

Sincerely,

A handwritten signature in black ink, reading "Thomas R. Lussier". The signature is fluid and cursive, with a long horizontal stroke at the end.

THOMAS R. LUSSIER
Administrator

Good afternoon,

SCAN Health Plan (SCAN) is pleased to submit comments in response to the ***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***. We applaud the Administration for its leadership in developing policies that improve the health care of Medicare beneficiaries.

SCAN strongly supports the Administration's effort to make health care more accessible, equitable, and affordable.

Section 90 – Participant Disputes

CMS Proposal: CMS requests public comments on whether sections 30 and 40 should be further amended to accommodate this new program.

SCAN Comment: SCAN supports that amendments are needed. In addition, we recommend providing examples of disputes that would qualify as an appeal or grievance related to this program. We recommend amending Section 40.5.2 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, which currently limits plans to choose a single cost-sharing level for formulary exceptions. CMS should consider allowing plans to apply a Specialty cost-sharing to non-formulary Specialty drugs obtained through the formulary exception process as opposed to applying a single cost-sharing to all non-formulary medications obtained through formulary exceptions in light of Part D plans' liability increases in the Catastrophic Coverage stage due to Inflation Reduction Act of 2025.

CMS should consider applying a hold harmless policy to ensure that individual and overall Plans' Star Ratings are not negatively impacted due to MPPP program.

Thank you for the opportunity to provide comments on the draft guidance.

Sanaya Lim-Heng

Director, Medicare Compliance

3800 Kilroy Airport Way Suite 100 Long Beach California 90806

Email: s.lim-heng@scanhealthplan.com



15000 Alton Road, Suite 100, P.O. Box 22616
Long Beach, CA 90801-5616

VIA ELECTRONIC SUBMISSION: PartDPaymentPolicy@cms.hhs.gov

September 20, 2023

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 (CMS)
7500 Security Boulevard, Mail Stop C4-26-05
Baltimore, MD 21244-1850

RE: SCAN Health Plan Comments on Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments

Dear Dr. Seshamani:

SCAN Health Plan (SCAN) is pleased to submit comments in response to the *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*. We applaud the Administration for its leadership in developing policies that improve the health care of Medicare beneficiaries.

SCAN strongly supports the Administration's effort to make health care more accessible, equitable, and affordable.

The following includes background on SCAN and comments on selected provisions in the proposed rule.

I. SCAN Background

SCAN Health Plan, one of the nation's foremost not-for-profit MA plans, serves over 270,000 members in California. SCAN Desert Health Plan and SCAN Health Plan also provide MA coverage to people in Arizona, Nevada, and Texas. Independence at Home, a SCAN community service, provides vitally needed services and support to seniors and their caregivers regardless of plan membership. SCAN is proud to have earned a 4.5-star rating from CMS in each of the last six years and been named one of the best insurance companies for MA in California by *U.S. News and World Report* for the fifth straight year.

II. SCAN Comments on Selected Provisions

Introduction

SCAN Response: SCAN recommends that CMS ensure the release of the 2025 RxHCC (risk adjustment) model to reflect changes in the Part D benefit design, 2025 draft BID instructions and Advance Model Notice no later than December 31, 2023, as it is an imperative.



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Program Calculations and Examples

CMS Proposal: CMS will require Part D sponsors to correctly calculate the monthly caps based on the statutory formulas, determining the amount to be billed (not to exceed the cap), and sending monthly bills to program participants.

SCAN Response: SCAN recommends that CMS continue to share additional maximum monthly cap calculations with the plans, e.g., COB claims, EGWPs, retro claims, retro eligibility, reversals. SCAN also recommends releasing specific calculation examples that Member Services / Help Desk could communicate to the member about their monthly cap if they opt into the program.

Participant Billing Requirements

CMS Proposal: CMS requires that Part D sponsors bill participants who are in the Medicare Prescription Payment Plan and incur OOP costs an amount for each month that cannot exceed the applicable maximum monthly cap. CMS specifies that Part D sponsors must have a financial reconciliation process in place to correct inaccuracies in billing and/or payments.

SCAN Response: SCAN recommends that CMS provide additional information regarding collecting amounts owed under the program, especially when a beneficiary disenrolls from the plan, and allowing the plan to charge the full amount owed. SCAN also recommends that CMS simplify the billing requirements.

Pharmacy Payment Obligations and Claims Processing

CMS Proposal: CMS states that the Part D claim would be submitted using one BIN/PCN combination, and then a second transaction would be submitted using a separate BIN/PCN combination for the final MPPP participant liability amount.

SCAN Response: SCAN supports the above approach.

Pharmacy Payment Obligations and Claims Processing

CMS Proposal: CMS indicated that they would provide additional guidance on marketing and communications procedures and content in the next phase of the guidance release.

SCAN Response: SCAN recommends that CMS release all 2024 final Marketing and Member Communication materials (e.g., ANOC, EOC, etc.) to the plans no later than April 1, 2024. In addition, any additional beneficiaries' marketing and communication materials should contain standardized/model language issued by CMS describing this program and who is likely to benefit from this program.



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Requirements Related to Part D Enrollee Election

CMS Proposal: CMS requires that Part D sponsors provide the option to opt into the Medicare Prescription Payment Plan to all Part D enrollees, including enrollees who are LIS-eligible individuals.

SCAN Response: SCAN is concerned about the operational feasibility of implementing the following timeframes and recommend extending these timeframes for CY2025:

1. Part D sponsors must process an enrollee's election request within 24 hours when an enrollee is already enrolled in a Part D plan and requests to opt into the MPPP during the plan year.
2. Part D sponsor is required to process the program election request within 10 calendar days of receipt, or the number of calendar days before the plan enrollment starts, whichever is shorter.

SCAN will require a new premium billing/tracking model that currently does not exist. A high-level of effort will be required to implement.

Procedures for Termination of Election, Reinstatement, and Preclusion

CMS Proposal: CMS is seeking comments for voluntary terminations, involuntary terminations, notice requirements, required grace period and reinstatement, preclusion of election in a subsequent plan year, Prohibition on Part D Plan Enrollment Penalties for Failure to Pay Medicare Prescription Payment Plan Amount Billed and disenrollment.

SCAN Response: SCAN agrees with the procedures outlined for termination of election, reinstatements, and preclusion.

Participant Disputes

CMS Proposal: CMS requested public comments on whether sections 30 and 40 should be further amended to accommodate this new program.

SCAN Response: SCAN does not anticipate any issues with sections 30 and 40 as written. SCAN recommends that CMS provide examples of disputes that would qualify as an appeal or grievance related to this program. In addition, CMS should consider applying a hold harmless policy to ensure that individual and overall Plans' Star Ratings are not negatively impacted due to the MPPP program.



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Data Submission Requirements

CMS Proposal: CMS will require Part D sponsors to report information related to the Medicare Prescription Payment Plan on Prescription Drug Event (PDE) records and through new annual reporting requirements. CMS will provide more information about data collection requirements through the PRA process and invite feedback on the proposed elements through the requisite public comment periods.

SCAN Response: SCAN supports the reporting efforts described in Section 100 of this draft guidance.

Thank you for the opportunity to submit comments on the 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. SCAN truly appreciates your commitment to improving the health of older adults and vulnerable populations and hopes you will take our concerns into consideration. Please do not hesitate to contact me at 562-989-5168 if you would like additional information.

Sincerely,

Sharon K. Jhawar PharmD, MBA, BCGP
Chief Pharmacy Officer
sjhawar@scanhealthplan.com



SCHOOL EMPLOYEES RETIREMENT SYSTEM OF OHIO

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RICHARD STENSURD
Executive Director

KAREN D. ROGGENKAMP
Deputy Executive Director

September 20, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW Washington, DC 20201

Dear Administrator Brooks-LaSure,

The School Employees Retirement System of Ohio (SERS) purchases health care services for over 36,500 nonteaching retirees of Ohio's school systems and community colleges, their spouses and dependents, who are eligible for Medicare. SERS retirees represent school secretaries, cafeteria staff, janitors, bus drivers and other low-wage school employees. Residing in all 50 states, SERS benefit recipients received an average annual pension of \$15,963 and therefore, have modest incomes in retirement. They do not contribute to Social Security during their work in the public sector, so many depend entirely on their SERS pension in retirement. Therefore, it is vitally important that the health and prescription drug benefits that SERS provides reflect retirees' modest ability to pay out-of-pocket costs. We appreciate the opportunity to provide comments on the draft guidance for the new Medicare Prescription Payment Plan.

Compared to the standard Part D benefit, SERS' EGWP prescription drug plan provides enrollees with more predictable out of pocket expenses and creates less financial hardship overall. For example, SERS' members are not responsible for any Part D deductible, pay a \$7.50 co-pay for a 34-day supply of generic prescriptions, a max coinsurance of \$100 for a 34-day supply of brand name and specialty drugs. Members pay even less than this per days' supply when they pick home delivery options. In 2022, fewer than 1% of SERS enrollees met the proposed daily copay threshold for the Prescription Payment Plan POS notification, demonstrating that the SERS benefit design protects enrollees. In a majority of these few cases, 90-day fills for brand-name drugs were part of the daily total.

We believe that SERS' EGWP plan design achieves enrollee protection from high out-of-pocket costs that the Prescription Payment Plan intends. In fact, SERS' coinsurance maximums likely provide better protection for enrollees who start an expensive drug in the second half of the year when the Maximum Monthly Cap would greatly exceed our current coinsurance maximums. For SERS, the Prescription Payment Plan raises several concerns and questions for SERS as an EGWP sponsor and public pension system:

1. The SERS Health Care Fund and Trust, established pursuant to Chapter 3309 of the Ohio Revised Code, is a separate trust fund, established in compliance with Internal Revenue Code Section 105(e). We do not believe that SERS has the authority to participate in the Prescription Payment Plan under the terms of the Fund and Trust.
2. The program would transition SERS enrollees from low monthly expenses at the pharmacy to a position wherein they accumulate potentially burdensome debt or late payment fees.
3. The monthly billing requirement is limited to amounts below the monthly cap; there is no reference to a cumulative amount owed if each monthly bill is not paid before the next is billed. Is the inclusion of the total

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CATHERINE P. MOSS <i>Retiree-Member</i>	BARBRA M. PHILLIPS <i>Employee-Member</i>	JAMES A. ROSSLER, JR <i>Appointed Member</i>	AIMEE RUSSELL <i>Employee-Member</i>
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amount owed allowed? Our experience with premium billing suggests enrollees need to understand both monthly amounts owed and complete balances, including arrearages.

4. How is CMS expecting plan sponsors to collect unpaid debt if a member dies or is disenrolled before making final payment?
5. Since by design, our prescription drug plan currently has out-of-pocket cost protections in place our greatest concern is that the burden of administering the Prescription Payment Plan and the risk of enrollees' misunderstanding the program exceeds the program's benefits when cost sharing is intentionally low.

On behalf of SERS and its enrollees, we request that CMS offer an exclusion for EGWPs, or an exclusion for plans with no deductible and/or specifically low per-prescription cost sharing based on the historic and current protective plan design compared to the standard Part D benefit. This will avoid any question of authority for the system to extend credit to its enrollees. Exclusion will also help enrollees avoid confusion about the intent of the program, and the potential for accumulating unnecessary debt.

Sincerely,

Richard Stensrud
Executive Director

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September 15, 2023

The Honorable Chiquita Brooks-LaSure, Administrator
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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

Dear Administrator Brooks-LaSure:

Security Health Plan of Wisconsin, Inc., appreciates the opportunity to submit recommendations in response to the proposed Rates and Payment policy changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program for 2024 to improve beneficiary protections, increase access to care, including behavioral health services, and promote equity in coverage and care.

Headquartered in central Wisconsin and serving 225,000 members in all 72 Wisconsin counties, Security Health Plan is the 5th largest health plan by membership and 6th largest by premium volume in Wisconsin. The health plan is part of the Marshfield Clinic Health System.

Security Health Plan is a not-for-profit health plan with coverage for large and small employers, individuals and families through the Federally-facilitated Exchange, Medicare and Medicaid beneficiaries, plus benefit administration for self-funded employers.

Security Health Plan supports efforts to improve prescription drug coverage for seniors in the Medicare program, while at the same time ensuring that implementation and maintenance of appropriate safeguards are not burdensome or detrimental to coverage providers. SHP fully supports the concept of creating predictability and support to consumers that face high-drug prices, but we also take this opportunity to raise concerns about the implementation of this policy that is likely to unfairly burden payers and could have the unintended consequence of making coverage less affordable and more complex.

Our comments are centered around the current topics. First, this regulation would require health plans to serve as a financier of the purchase of high-cost drugs in a manner that we have never fulfilled before. Additionally, the implementation of the rule is complex in the timeframe proposed in the draft regulation. Finally, we feel strongly that eligibility criteria must be clearly established uniformly to prevent a patchwork of coverage differences between plans.

Operational Burdens and Challenges

Operationalizing a program such as the Medicare Prescription Payment Plan (MPPP) will require building infrastructure that has not previously existed. The timing as outlined in the draft guidance presents significant challenges for updating systems to meet expectations. We request you consider delaying the implementation of these rules until plan year 2026. This is specifically because of the complexity of the rule, as well as the fact that more details are necessary as we plan our approach in terms of actuarial review and soundness, as well as communication and education of consumers and partners such as retail pharmacies and brokers/sales professionals. Further, it is imperative that CMS develop standardized communication to assist in conveying program details to members and that they be able to communicate to enrollees the details of how payments are applied, the prioritization of premium payments, and the consequences of failure to pay.

Enrollment Parameters Must Be Clearly Defined

The proposed regulations leave significant questions about developing and implementing parameters for enrollment in coverage that allows for smoothing of out-of-pocket costs. To provide maximum clarity, we propose that enrollment in this program be limited to those enrollees that met their out-of-pocket maximum in the previous plan year for the first three years of this regulation. In subsequent years, we then propose that enrollment be limited to the first 4 months of a plan year because of the complexity of enrolling a member, and the diminishing returns when it comes to coverage through the plan year. We also recommend CMS take into consideration actuarial questions associated with the cost of establishing a complex program such as this, and possible changes in utilization patterns. This is further justification for a delay in implementation.

Billing requirements

Security Health Plan has concerns that allowing multiple bills during the month are likely to cause confusion for members. Members may not be clear on where these payments are being applied to. The confusion associated with this could be unintentionally burdensome on members. Security Health Plan proposes CMS develop standardized communication of the program to assist with this. Additionally, we have significant concerns regarding the risks to plans and the collection process. Examples include, member joins a plan then leaves for another plan and/or death. Security Health Plan seeks better definition and guidance to the collection expectations, requirements and existing rules that payments have to be prioritized to outstanding premium owed.

In conclusion, Security Health Plan appreciates the opportunity to comment and provide recommendations on these important policies for beneficiaries and issuers related to prescription drug plans. We welcome additional opportunities to engage with the Administration. Please contact me with any questions or to discuss these recommendations further.

Regards,



Krista Hoglund, ASA, MAAA
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Security Health Plan of Wisconsin, Inc.
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715-221-9485

September 20, 2023

Via Electronic Communication Only

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: Part D Payment Policy – Medicare Prescription Payment Plan Guidance
7500 Security Boulevard
Baltimore, MD 21244-1850
PartDPaymentPolicy@cms.hhs.gov

RE: Medicare Prescription Payment Plan Guidance – Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments

Dear Centers for Medicare & Medicaid Services (CMS), HHS Team,

On behalf of Sempre Health, we write to support the Maximum Monthly Cap on Cost-Sharing Payments Program or “Medicare Prescription Payment Plan” (sometimes previously referred to as “the OOP Smoothing Program”).

The Inflation Reduction Act (IRA) aims to make health care more accessible, equitable, and affordable and to make Medicare stronger for current and future enrollees. While the draft guidance by CMS will do much good, we write to ask that CMS ensure the draft guidance appropriately covers accessible, equitable, and affordable issues in the prescription filling process — as well as certain other routine challenges to medication access and adherence in the Medicare population.

Currently, Part D enrollees must pay their full OOP prescription costs at the pharmacy point of sale (POS). Beginning on January 1, 2025, enrollees have the option to pay their OOP prescription drug costs in monthly installments over the course of the plan year, instead of paying OOP costs at the POS.

As highlighted by CMS in its [August 2023 Fact Sheet: Medicare Prescription Payment Plan](#), this new drug law makes improvements to Medicare by expanding benefits, lowering drug costs, and improving the sustainability of the Medicare program for generations to come. The new drug law provides meaningful financial relief for millions of people by improving access to affordable treatments and strengthening Medicare, both now and in the long run.

A. CMS Should Provide Guidance On Additional Election Options, Including Text Messages, Phone App, Smart Speakers, and Emails (Section 70)

It is clear, based on requirements in the Eligibility, Enrollment, and Disenrollment chapter of the Medicare Prescription Drug Benefit Manual, Part D sponsors must have the following mechanisms available to Part D enrollees who wish to opt into the Medicare Prescription Payment Plan:

- An election option through the Part D (or MA-PD) plan enrollment process;
- A paper option that can be faxed or mailed;

- A toll-free telephone number, that must provide the individual with evidence the election request was received (e.g., a confirmation number); and
- A website application that must provide the individual with evidence the election request was received (e.g., a confirmation number).

However, in a concerted effort to improve access and reduce barriers in the opt-in process, CMS should also make it clear that Part D sponsors may also have the following mechanisms available to Part D enrollees who wish to opt into the Medicare Prescription Payment Plan:

- A text messaging option that must provide the individual with evidence the election request was received (e.g., a confirmation number);
- A phone application option that must provide the individual with evidence the election request was received (e.g., a confirmation number);
- A smart speaker (e.g., Google, Amazon, Apple, etc.) option that must provide the individual with evidence the election request was received (e.g., a confirmation number);
- An email option that must provide the individual with evidence the election request was received (e.g., a confirmation number);
- Any additional electronic signature collection mechanism option that can obtain an electronic sound, symbol, or process, attached to or logically associated with the opt-in information and executed by a person with the intent to elect the Medicare Prescription Payment Plan, that must provide the individual with evidence the election request was received (e.g., a confirmation number);

As with the mandated election mechanisms, these additional election mechanisms must capture an accurate time and date stamp at the time the applicant electronic request is satisfied with an electronic signature or a clear and distinct step that requires the applicant to activate an “Opt In Now,” or “I Agree,” type of button or tool (e.g., “Reply YES to opt in”).

B. To Prevent Disruption to the Participant Experience at the Point of Fill, the Claims Processing Workflow should include a Digital Proof Requirement (Section 50)

Option #1 — Secondary-Payor System. Given the technology infrastructure already exists to apply the Bank Identification Number (BIN) and/or Processor Control Number (PCN) unique to the Medicare Prescription Payment Plan to facilitate electronic processing of supplemental COB transactions for program participants, Sempre Health recommends this is as the primary method for pharmacy claims processing. In other words, because the Part D sponsor’s Medicare Prescription Payment Plan BIN and PCN can be applied as a secondary payor on the original claim of the Part D Sponsor, Sempre Health agrees with CMS that this is the most convenient method for processing.

Option #2 – Pre-Funded Payment Card. For the reasons outlined by CMS, a Part D sponsor-issued pre-funded physical payment card would likely be more disruptive to the participant experience due to the logistical challenges issuing a physical payment card, mailing a card, requiring a participant to have the card on their person, and the continuous risk of loss, theft, or damage.

In either case, there may be potential errors in the system not yet accounted for. For either case, upon opting into the program, Sempre Health urges CMS to require Part D sponsors to also provide the participant the requisite information via text message, email, digital card, Apple/Android Card, or another digital medium/proof of the Medicare Prescription Payment Plan information so the participant can provide the pharmacy this BIN/PCN or pre-funded payment card information at the POS.

Whether there is a problem applying the Medicare Prescription Payment Plan BIN/PCN as a secondary payor, or problems with a pre-funded physical card, a digital proof of election into the Medicare Prescription Payment Plan will solve a lot of headaches down the road. In other words, an ounce of prevention is worth a pound of cure.

C. The Medicare Prescription Payment Plan Should Thoroughly Cover Accessibility, Equitable, and Affordable Issues — And Not Be Confined to the Traditional Monthly Payment Plan Structure

Because this program will not reduce the amount of money that an individual pays in out-of-pocket costs, rather it will help individuals with high costs spread those costs out throughout the year, both Part D sponsors and the program participants should have additional options on how to spread the costs out throughout the year. Especially, if it is already using the “Option #1 Secondary-Payor System” mentioned above.

While a monthly payment plan is one smoothing option, there are other ways to spread costs out throughout the year that will be less administratively less burdensome for both Part D sponsors and participants. In other words, whether an individual doesn’t elect, opts out, is involuntarily terminated from, or enters into a dispute resolution process with such program – the Part D sponsor should still be able retain the ability and the individual the right to continue to spread the costs out throughout the year – the main purpose of this Congressional approved program.

One such alternative is for the Part D sponsor and its partners to be able to apply a real-time discount at the POS based on the normalized annual out-of-pocket costs. A 30-day prescription real-time POS discount would be the same monthly payment amount, but it would be different for a 90-day prescription.

For example, the annual OOP threshold for 2025 is \$2,000. If a participant has a 90-day prescription that costs \$1500 OOP (equivalent to a 30-day prescription that has a \$500 OOP incurred costs), this real-time discount cap could be \$500 ($\$2000/4$) vs. the max monthly cap of \$166.67 ($\$2,000/4$). Here is an illustrative chart comparing the max monthly cap OOP payment with a 90-day real-time discount payment:

Month	OOP Costs Incurred	Max Monthly Cap Payment	Balance	Real-Time Cap Payment	Balance	Max Monthly Cap vs Real-Time Cap
January	\$1500.00	\$166.67	\$1833.33	\$500.00	\$1,500.00	+\$333.33
February	\$0.00	\$166.67	\$1666.66	\$0.00	\$1,500.00	-166.67
March	\$0.00	\$166.67	\$1499.99	\$0.00	\$1,500.00	-166.67
April	\$500	\$166.67	\$1333.32	\$500.00	\$1,000.00	+\$333.33
May	\$0.00	\$166.67	\$1,166.65	\$0.00	\$1,000.00	-166.67
June	\$0.00	\$166.67	\$999.98	\$0.00	\$1,000.00	-166.67
July	\$0.00	\$166.67	\$833.31	\$500.00	\$500.00	+\$333.33
August	\$0.00	\$166.67	\$666.64	\$0.00	\$500.00	-166.67
September	\$0.00	\$166.67	\$499.97	\$0.00	\$500.00	-166.67
October	\$0.00	\$166.67	\$333.30	\$500.00	\$0.00	+\$333.33
November	\$0.00	\$166.67	\$166.63	\$0.00	\$0.00	-166.67
December	\$0.00	\$166.63	\$0.00	\$0.00	\$0.00	-\$166.63
Total	\$2,000	\$2,000		\$2,000		\$0.00

Depending on the participant’s preference and earnings schedule, they may rather reach the \$2,000 OOP threshold through four (4) real-time POS discount payments rather than twelve (12) monthly cap discount payments.

The main point here is that CMS should allow the flexibility for a Part D sponsor to cap payments based on a participant’s schedule preference (e.g., monthly vs. quarterly) and medium preference (monthly payment plan vs. real-time POS discount) if the total cap and discount remain

the same at the end of a calendar year. CMS should focus less on the means of the timing of the maximum monthly cap and more on its intended purpose. In reality, most Part D sponsors offer a 90-day discount for prescriptions (2.5x OOP payments vs. 3x OOP payments) that make a 90-day prescription quite attractive, and would become even more affordable if Part D sponsors had the flexibility to apply the 2025 OOP threshold of \$2,000 in a variety of manners.

Without considering the growing popularity of 90-day prescriptions to improve participants adherence rates, the max monthly payment plan fails to address key real-world considerations for how to acutely address accessible, equitable, and affordable issues in the prescription filling process throughout the 12-month benefit cycles.

Even when comparing apples-to-apples — 30-day OOP costs for maximum monthly caps and 30-day OOP costs for real-time POS discounts, both of which could be offered through “Option #1—Secondary Payor System” mentioned above — participants may prefer to this same cap immediately at the POS vs. having to opt into a monthly payment plan, despite the OOP costs and discount amounts being equal. We know in everyday practice, a significant number of individuals would rather pay their balances upfront than on a monthly basis, given the option between the two.

Since the Part D sponsor could just as easily leverage the “Option #1 — Secondary-Payor System” mentioned above to calculate and apply the maximum monthly payment cap or the real-time POS payment cap, it should have the flexibility to offer both payment methods to its participants. An additional participant pain point in monthly payment plans are the financial and credit terms and conditions one may face if their payments become outstanding for any reason.

D. The Payment Default Terms Should Be Restorative and Favorable to the Participants Where Possible, Not Punitive or Retributive (Section 40)

Given the purpose of the program, Part D sponsors should be regulated with appropriate default terms and caps that are favorable to participants. The following are recommended restorative default and cap terms for the respective financial terms:

Financial Term	Default Term / Cap Terms
Payment Due Date	Last date of the following month
Grace Period	90 calendar days
Same-Day Payment Fees	None
Online Payment Fees	None
Phone Payment Fees	None
Mail-In Payment Fees	None
Credit Card Fees	None
Late Fees	Up to \$.50 per day after the Grace Period
Other Fees	Up to .05% of total balance
Interest Rate	USD LIBOR – 1 month

In other words, Part D sponsors should not use the Medicare Prescription Payment Plan as a stick to penalize participants who already are or may be at risk of struggling with access and affordability issues that prevent them from filling or paying for their prescriptions on time.

E. The Medicare Prescription Payment Plan Should Reward Program Participants Who Improve their Medication Adherence Measures

Currently, besides the Part D Low-Income Subsidy (“LIS” or “Extra Help”) program, the Medicare Prescription Payment Plan is the only supplementary support program for traditional POS payments. Both programs will likely encounter continued outreach, education, and election challenges — like other programs with the same designated purposes, which will be covered in the Medicare Prescription Payment Plan Draft Part Two Guidance.

In the meantime, CMS should reconsider POS safe harbors for Part D sponsors and participants who improve their medication adherence measures.

Conclusion

To improve accessible, equitable, and affordable issues in the prescription filling process — as well as certain other routine challenges to medication access and adherence in the Medicare population — CMS should provide guidance on additional election options.

To prevent disruption to the participant experience at the point of fill, the claims processing workflow should include a digital proof requirement. In addition, CMS should think outside the traditional monthly payment plan structure. Part D sponsor payment default terms should be restorative and favorable to participants —not punitive or retributive.

Lastly, the Medicare Prescription Payment Plan should reward program participants who improve their medication adherence measures.

Respectfully Submitted,

Tai Chung

September 20, 2023

TAI CHUNG, MBA, ESQ.

Deputy General Counsel

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September 20, 2023

Submitted via Electronic Filing: PartDPaymentPolicy@cms.hhs.gov

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Re: Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments

Dear Dr. Seshamani:

The Senior Care Pharmacy Coalition (“SCPC”) appreciates the opportunity to provide comments on the August 21, 2023 memorandum issued by the Centers for Medicare & Medicaid Services (“CMS”), entitled *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* (the “Draft Guidance”), and particularly Sections 50 (“Pharmacy Payment Obligations and Claims Processing”), Section 60 (“Requirements Related to Part D Enrollee Outreach”), and Section 70 (“Requirements Related to Part D Enrollee Election”). Respectfully, we believe that the Draft Guidance does not properly account either for how pharmacies, and especially long-term care (LTC) pharmacies, bill Part D Plans (PDPs) for drugs, or for the nature of the LTC pharmacy patient population.

For these reasons, more fully explained below, **we urge CMS to significantly revise Sections 50 and 60 to simply require that manufacturers and Part D Plans engage in a single transaction which will determine co-pay amounts (if any) to be collected by the pharmacy, and to eliminate beneficiary “notice” requirements for the LTC patient community.** The Draft Guidance’s proposals for pharmacies are unnecessarily complex and costly, and will not benefit beneficiaries, pharmacies, or the Medicare program. There is no need to create a duplicate and wasteful claims process – much less a process that likely will prove unworkable and unduly disruptive in the marketplace. Existing systems can meet the agency’s operational goals while avoiding undue burden for pharmacies and other affected stakeholders.

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.¹ 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: Importantly, the Draft Guidance fails to recognize that residents of long-term care facilities typically are dually-eligible for both Medicare and Medicaid, and as such *do not pay co-pays* on their medications.² 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 – Pharmacy Payment Obligations and Claims Processing: Section 50 of the draft Guidance correctly notes that the Inflation Reduction Act ("IRA") requires a Part D Plan (PDP) to fully reimburse a pharmacy for the costs of a drug (without deduction for beneficiary co-pays) if a beneficiary elects to participate in the proposed "Payment Program." However, the Draft Guidance proposes to address concerns regarding "supplemental payers" through an unnecessarily convoluted process that would require pharmacies to submit each claim to a PDP twice, once with a \$0 co-pay and once with a co-pay amount based on the beneficiary's coverage details. It is inappropriate to impose such an overly complicated and duplicative double billing system on pharmacies to address a small percentage of claims which may afford Part D beneficiaries access to supplemental payers. Such a system would double the administrative burden and related cost pharmacies incur, would increase the complexity of pharmacy audits, and would increase both the potential for and investigation of possible fraud, particularly given that current regulations offer a

¹ This figure is based on pre-pandemic facility occupancy rates. Our members also serve an increasing number of individuals with LTC needs, including Medicare beneficiaries, living in community settings and at home.

² See SSA 1860D-14(a)(1)(D)(i). This is not only true of nursing home residents, but also true for Home and Community Based beneficiaries. Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (March 31, 2023) ("Per section 1860D-14(a)(1)(D)(i) of the Act, full-benefit dually eligible beneficiaries who are receiving home and community-based services qualify for zero cost sharing if the individuals (or couple) would have been institutionalized otherwise"), available at <https://www.cms.gov/files/document/2024-announcement-pdf.pdf>; see also Briesacher, et al., *Nursing Home Residents and Enrollment in Medicare Part D*, J Am Geriatr Soc. 2009 Oct; 57(10): 1902–1907; doi: 10.1111/j.1532-5415.2009.02454.x (noting nursing home residents have zero copays).

viable and less burdensome alternative approach, as described below. **We strongly urge CMS to abandon its proposal that pharmacies bill two different BIN/PCN combinations for the same claim.**

First, it is unclear whether the Draft Guidance intends to address “supplemental payers” that are Medicare secondary payers. If so, the existing Medicare Secondary Payer rules are adequate to address any concerns raised by the proposed Payment Program. PDPs, like Medicare Part C Plans and Medicare fee-for-service coverage, are prohibited from paying any claim when a primary payer is available, 42 U.S.C. § 1395y(b)(ii)(B)(i). Accordingly, pharmacies, like other providers, currently bill primary payers before billing Medicare. Further, pharmacies are aware when other available coverage exists in a secondary pay situation and routinely bill the primary payer (for example, a group health plan or workers’ compensation insurer) so that the pharmacy does not bill the PDP initially. Thus, the MSP rules do not create any coordination of benefits issues for beneficiaries who elect to participate the “Payment Plan.” Further, Medigap plans do not cover prescription drugs, and therefore are not “supplemental payers.” While the Part D statute does describe how PDPs themselves can provide “supplemental prescription drug coverage,” *see, e.g.* 42 U.S. Code § 1395w–115(b)(2)(a), such supplemental coverage is entirely the responsibility of the PDPs, does not require pharmacies to get involved in any coordination of benefits, and is not a basis upon which to impose significant costs, administrative burden, and heightened audit risk on pharmacies.

Second, current Part D regulation addresses coordination of benefits with other payers of prescription drugs, such as State Pharmacy Pharmaceutical Assistance Programs (SPAPs). 42 C.F.R. § 423.464. To the extent these are the “supplemental benefits” plans of concern, we note that current regulation and the Medicare Prescription Drug Benefit Manual obligate the PDP, not the pharmacy, to coordinate benefits with such supplemental payer programs. Current regulation is explicit that coordination of benefits is to be managed between the Part D Plan and the supplemental or other benefits plan, *not through the pharmacy*. 42 C.F.R. § 423.464(f)(6).³ Thus, while Part D Plans already should be coordinating coverage with supplemental payers, to the extend additional coordination is necessary CMS should not shift the burden onto pharmacies to submit multiple versions of each claim; the agency should rely on the existing payer-to-payer coordination of benefit processes regarding supplemental payers relevant to the Payment Program.

³ The regulation provides: “[i]n the process of coordinating benefits between the correct Part D plan of record and another entity providing prescription drug coverage when that entity has incorrectly paid as primary payer for a covered Part D drug on behalf of a Part D enrollee, the correct Part D plan of record must achieve timely reconciliation through working directly with the other entity that incorrectly paid as primary payer, unless CMS has established reconciliation processes for payment reconciliation, *rather than requesting pharmacy claims reversal and re-adjudication*” 42 C.F.R. § 423.464(f)(6) (emphasis added). *See also* Medicare Prescription Drug Benefit Manual (the Manual), Chapter 14. SCPC recognizes that the Manual also imposes a role for pharmacies on pharmacies with respect to SPAPs, Manual, Chapter 14, §504, but this Manual provision is inconsistent with the regulatory requirement. Since a regulation supersedes guidance, the Manual provision is not enforceable. In any event, the Manual provision is an inappropriate predicate for extending the double billing requirement on all Part D claims, because so few Part D claims involve SPAPs, particularly for the LTC patient population.

Third, the proposal is particularly unworkable for those LTC pharmacies that principally serve residents of LTC facilities. As noted above, it is commonly the case that LTC residents who are Part D beneficiaries will have \$0 co-pays because they are FDBEs. CMS acknowledges that “[i]f Part D copay is already \$0, the COB transactions to OHI is not necessary,” Draft Guidance at §50.1. Since Part D copays are zero for the most nursing facility residents, we strongly recommend that the final guidance exempt claims for all beneficiaries with a NCPDP location code of “2” (denoting resident of nursing facility), “3” (denoting resident of skilled nursing facility) or “4” (denoting resident of assisted living facility) from the duplicate claims submission requirements.

Section 60.2.3, 60.2.4 and 70.3.9 – Targeted Part D Enrollee Notification and Point of Sale Notifications: CMS has proposed that pharmacies, after receiving a notification from a Part D Plan, must inform the beneficiary of the option to enroll in the Medicare Prescription Payment Plan. **We urge CMS to clarify that the “Part D Enrollee notification at the point of sale” should not apply to residents in LTC facilities or to LTC pharmacies, because there is no meaningful “point of sale” whereby LTC facility residents and LTC pharmacies directly interact.** For residents in LTC facilities, LTC pharmacies receive prescriptions through facility staff and do not directly interact with residents in filling those prescriptions, nor do they collect any co-pays before dispensing prescriptions. Patients do not pick up prescriptions from LTC pharmacies as they do in retail pharmacies. Rather, LTC pharmacies deliver the medications to LTC facilities, after which facility staff administer or assist in self-administration of medications to patients.

Since the outset of Part D program, CMS has acknowledged that: “[l]ong-term care pharmacies generally provide drugs directly to the skilled nursing facilities and nursing facilities where the patient resides, not directly to the patient, under a medical benefit. They also engage in a significant coordination of benefits effort that would require that at least some claims be processed off-line, and not in real time. Given the manner in which long-term care pharmacies provide prescription drugs to residents of long-term care facilities, as well as the way in which they process claims, it would be impracticable for these pharmacies to provide beneficiaries with information regarding covered Part D drug price differentials at the point of sale.” 69 Fed. Reg. 46632, 46666 (Aug. 3, 2004). The statement remains valid. Just as LTC pharmacies are exempt from other Part D beneficiary notice requirements. *e.g.*, 42 C.F.R. § 423.132(d)(1)(c), so too CMS should exempt LTC pharmacies from the proposed Point of Sale notification requirements regarding the Medicare Prescription Payment Plan.

The same conclusion also should apply to the proposed “Real Time POS Election and Other POS Needs” proposed in Section 70.3.9 of the Draft Guidance. We urge CMS to clarify in that section as well that the requirements do not apply to LTC pharmacies.

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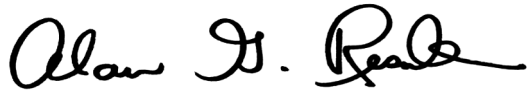
Meena Seshamani, M.D., Ph.D.

September 20, 2023

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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 or (717) 503-0516.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Alan G. Rosenbloom". The signature is fluid and cursive, with the first name "Alan" being the most prominent.

Alan G. Rosenbloom
President & CEO
Senior Care Pharmacy Coalition

Attachment



Via Electronic Submission: PartDPaymentPolicy@cms.hhs.gov

September 20, 2023

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 (Medicare Prescription Payment Plan)

Agency: Centers for Medicare and Medicaid Services (CMS), HHS

Introduction

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.

The Medicare Prescription Payment Plan (MPPP) program will cap out-of-pocket (OOP) spending and extend medication costs over time. In 2025, the annual OOP cost threshold will be \$2,000. The Medicare Prescription Payment Plan is an Opt-In program offered as Medicare beneficiaries enroll in their Part D application plan during Medicare Enrollment periods, but it is available throughout the plan year. This program will be hugely beneficial to many Medicare beneficiaries, and we applaud CMS for making this option available.

The SNP Alliance thanks CMS for this opportunity to comment on draft updates to the Medicare Prescription Payment Plan outlining additional guidance and education on the program for SNPs. We appreciate that CMS is including organizations like the SNP Alliance in the process of educating Part D enrollees about the program.

The current language allows for MPPP to be offered to Medicare enrollees that are already utilizing 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. The SNP Alliance believes it is vital that during Medicare Enrollment, Part D enrollees receive education on the MPPP program and the LIS program, and that all enrollees are encouraged to apply for the appropriate program.

Given the timing of the MPPP program in 2025, the SNP Alliance suggests that CMS examine a phased approach for participation. Our suggestion encourages CMS to focus on 1) targeted outreach and education ensuring only those who will benefit from the program opt in as the initial phase, and 2) general education and outreach to all other Medicare Advantage beneficiaries (dual eligibles, those on Medicare Saving Program, and those on LIS) in the second phase. Our recommendation to defer general



outreach/education allows for CMS and health plans to garner more experience with the program to ensure only those who will benefit from the program take part in the program.

Feedback from SNP Alliance membership echoes the magnitude of just how hard it will be for the D-SNP population to figure out if the MPPP program benefits them or not. Since most D-SNP enrollees will already be enrolled in LIS programs it is expected that there will be few enrollees able to receive help from the MPPP program. However, it will be challenging to assure that current LIS eligible members are not confused by the new option and understand which option is best for them. CMS states that the MPPP will not be the best choice for most of those eligible for LIS programs. The need for ongoing and extensive education around the best program fit is crucial.

We have outlined our comments and concerns below. We want to make sure we understand this policy correctly as well as to request additional clarity in a few areas.

SNP Alliance Comments of Support

1. Which model documents or other materials would be helpful to update and develop for interested parties;

We agree with CMS that there should be a consistent communication strategy and consistent language about the Medicare Prescription Payment Plan publicized in all CMS model documents such as Annual Notice of Change (ANOC), Evidence of Coverage (EOC), and Summary of Benefits (SB). Likewise, CMS created materials such as Member Handbook and Medicare & You should also require the same consistent language. We ask that CMS release the model document earlier in year, especially year one, to allow for plan feedback on the MPPP program.

As CMS proceeds, we recommend that CMS anticipate the need for specific language provisions, appropriate messages and communications tailored to SNPs serving large numbers of LIS members including dually eligible individuals for whom the new MPPP program may not be appropriate. CMS may need to allow separate but consistent materials targeted to these SNP members, especially for those enrolled in integrated Medicare-Medicaid plans.

The SNP Alliance appeals to CMS for specific education and outreach materials on Medicare Advantage Plans with \$0 Prescription Drug Costs. We hope that Part 2 guidance 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 MPPP program.

We recommend that CMS develop an out-of-pocket calculator for Medicare beneficiaries to use to compare participation in Medicare Prescription Payment Plan program with other programs (particularly LIS). The calculator should include features such as a medication list (including refill frequency) to allow Medicare beneficiaries the chance to see if their medication costs and the monthly amount billed meet the MPPP program threshold for participation. The SNP Alliance would also like the calculator to have an indicator to show cost-sharing amounts calculations. Individuals with low, stable drug costs (such as LIS enrollees) are not likely to benefit from the MPPP program.



2. Ways to most effectively conduct outreach and education to interested parties about the program;

The SNP Alliance encourages CMS content for the MPPP program to be audience specific and in digestible formats. Education on the MPPP program needs to be simple for the audience. This education needs to address the intent of MPPP, programmatic requirements, and other CMS program options available such as Low-Income Subsidy (LIS) as well as take into consideration that many SNP members may already be enrolled in LIS and may not even be aware of that they are already enrolled in an LIS program.

To ensure SNP enrollees are not enrolling in MPPP when it is unlikely to help them, we urge CMS devise outreach and educational materials for the SNP population that (1) assesses the impacts to LIS/dually eligible individuals and (2) provides robust communication tools to support this population. As stated above, we believe such a two-phase implementation will enable plans to opt-in individuals most likely to benefit.

Interested parties for the MPPP program include health plans, pharmacies, and insurance brokers. Each interested party sees the MPPP through a different lens. Health plans will need to know the operational and technical expertise to appropriately aid Medicare beneficiaries to enroll in a Medicare Prescription Payment Plan; pharmacies will want to know fiscal repercussions of the payment plan mechanism; finally, insurance brokers will want to know if they should sell on the MPPP or the LIS benefit. Additionally, we encourage CMS to produce standardized language for pharmacies to notify patients at the point of sale on MPPP enrollment.

All stakeholders must be educated on which programs are best for SNP members. Within the targeted outreach and education phase, there should be concerted efforts to connect with Chronic Condition Special Needs Plans (C-SNPs) plans and C-SNP members not on LIS. C-SNP members may have recurring medication costs that could benefit from the Medicare Prescription Payment Plan. Associations that support those chronic conditions such as such the American Diabetes Association or American Heart Association may be a good conduit to outreach and education opportunities.

3. How to leverage existing resources and information, including the State Health Insurance Assistance Program (SHIP);

The SNP Alliance supports utilizing existing resources and organizations such as State Health Insurance Assistance Program (SHIP) or Area Agencies on Aging (AAAs) as mechanisms for disseminating information about the MPPP program.

These organizations should not be relied upon to create the content, but as information distributors. Their networks and distribution platforms are widespread. As CMS develops additional information in Part 2 of the guidance, we recommend that the roles and responsibilities of existing resources and organizations such as State Health Insurance Assistance Program (SHIP) or Area Agencies on Aging (AAAs) be further outlined along with plans for any additional funding that may be needed for them to incorporate this new program into their current responsibilities.



Furthermore, we support CMS's need to create content that is usable for government organizations such as State Medicaid agencies, State Offices on Aging, and any other entities that can share or use materials as learning tools.

4. How to communicate about overlapping programs (e.g., LIS and Medicare Savings Programs)

We agree with CMS that both programs, the Medicare Prescription Payment Plan, and the Low-Income Subsidy, will need separate language in the CMS model materials and other CMS approved documents. However, we encourage CMS to provide a document outlining the similarities and differences between the programs and clearly delineating both programs' eligibility criteria and programmatic benefits.

These materials, presentations, and talking points will help direct interested parties and resource organizations as they inform Medicare beneficiaries which program is best based on their income and prescription drug costs. The SNP Alliance proposed calculator would be a great resource and tool, not just for Medicare beneficiaries to see month by month "Does the MPPP Program Benefit Participant This Month?", but also for other stakeholders who may be assisting an individual to assess if the MPPP program is appropriate.

SNP Alliance Concerns

The SNP Alliance would like to highlight several concerns in the following sections:

1. Readability and Language
2. Operationalization of MPPP for SNP plans
3. SNP Plans with \$0 or Nominal Prescription Drug Costs

The current language does not account for unique situations and policies for certain D-SNPs and State Medicaid programs.

Readability and Language

1. The SNP Alliance proposes that CMS's materials meet the reading levels that State Medicaid agencies require. Additionally, we hope CMS works with states with FIDE/HIDE SNP plans that have more defined prerequisites regarding accessibility, including reading level and language access requirements. We respectfully request special attention be paid to supplying more details in Part 2.

Also, we would support CMS in any efforts to make the MPPP educational materials readable on technological devices such as computers, tablets, and smartphones. This 508-compliance policy addresses how information and communication is made accessible to persons with disabilities. We look forward to guidance on CMS's roles and responsibilities around accessibility and conformance in Part 2.

Additionally, for persons with differing forms of cognitive impairment ranging from Alzheimer's Disease and related dementia to persons with intellectual and developmental disabilities, legal



guardians and family caregivers likely will handle making decisions. CMS should consider how information will be disseminated to such responsible parties beyond plan communication and materials tailored to decision-makers.

Operationalization of MPPP for SNP Plans

2. The SNP Alliance is genuinely concerned about operational difficulties that the SNP plans will undergo to implement the MPPP program. Acknowledging that the system changes and new processes for the MPPP program are built for Medicare Advantage plans and yet are applicable for the SNP plans, our members expect this to be extremely difficult to build. SNP plans do not necessarily have the existing infrastructure to leverage or the financial/staff resources to deploy to the MPPP effort. It will require systems changes (enrollment file formats to indicate a new cost-share type and NCPDP changes so pharmacists are aware of the election at point of sale) and new processes (plans will need to build education tools, billing and collecting processes, enrollment/election processes, etc.). The SNP Alliance has significant concerns that there is insufficient time for an implementation of this magnitude. For plans serving large numbers of dual eligibles, this substantial build will be for little benefit since most enrollees have minimal, if any, cost-share for Part D drugs and will not benefit from participating in the MPPP program.

Operationally, the SNP Alliance asks CMS to consider developing a standardized language and cost threshold for pharmacies to notify Medicare beneficiaries about the MPPP program at point of sale (POS). This chance for enrollment is uncharted because there is no current infrastructure for such an enrollment procedure. The education requirements, training, and enrollment processes will need to be carefully designed to avoid program confusion. Any additional information about required training for MPPP enrollment would be welcome in Part 2.

SNP Plans with \$0 and Nominal Prescription Drug Costs

3. The SNP Alliance appreciates the opportunity to address with CMS how the MPPP program will impact SNP enrollees with \$0 copays or those with minimal copays for prescription drugs. The plans that have zero cost for prescription medications, specifically D-SNP members, are already enrolled in the appropriate LIS programs. A program such as the MPPP will rarely be the right choice for them. In the current examples provided by CMS, enrollees would have to incur over \$166.67 in cost sharing in the first month of participation for the MPPP program to be the optimal choice. A D-SNP member with LIS would never hit that amount in the first month.

Further, individuals with low, stable drug costs (such as LIS enrollees) are not likely to benefit from the MPPP program even if they do have nominal copays for prescription drugs. There are SNP members such as C-SNP members who will accumulate costs throughout the year. Those out of pocket (OOP) costs, mainly incurred during the second half of the year, will add up over the remaining months. The MPPP program will spread those cost share over those few months resulting in higher MPPP bills than the beneficiary would have paid at POS. For those members, the added stress of receiving significant bills could outweigh the benefit of reducing the cost during prior months. Many SNP members lack the financial resources to pay for their prescriptions now. Due to the financial hardship and the MPPP structure, SNP members with minimal copays would not be able to fill their prescriptions at the end of the year.



The SNP Alliance entreats CMS set a *de minimus* amount for collection. A *de minimus* collection threshold, where collection below that amount would not be allowed, would allow SNP members with low drug costs to continue accessing their medications throughout the entire calendar year.

As SNP plans continue to grow throughout the country, we stand ready to work closely with CMS on strategies to clearly explain options to low-income vulnerable populations with complex care needs. And, we look forward to providing input as CMS moves forward with development of details in Part 2. Support and assistance with our comments, please contact Regan Hunt, SNP Alliance Associate Director of Health Policy, at rhunt@snpalliance.org.

Sincerely,

Michael Cheek

Michael W. Cheek

President & CEO



September 20, 2023

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: Solicitation of Comments on 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*

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 One Guidance on Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans (Guidance). 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 300,590 people in the United States who will be diagnosed with breast cancer and the almost 44,000 who will die from the disease in 2023 alone.

Komen and the breast cancer community that we represent are extremely supportive of the new policies that both cap out-of-pocket (OOP) spending under Medicare Part D and allow for a beneficiary to spread their OOP costs out across a plan year. This has long been a policy priority for Komen as the costs of cancer treatment in the U.S. are astronomically high and expected to rise, adding an increasing burden for patients. More and more stakeholders in the cancer community are recognizing the financial toxicity associated with treatment, 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 Medicare Prescription Payment Plan (MPPP) to help address some of the financial challenges associated with breast cancer treatment, and we know that CMS shares our goal to ensure that patients benefit as much as possible from the new law.

Komen's comments on the Guidance begin with recommendations for outreach and enrollment to Part D enrollees and proceeds to feedback on specific sections of the Guidance.

Outreach and Education to Part D Enrollees

Komen appreciates that CMS requests feedback on the best ways to educate Part D enrollees about the program to help inform the development of draft part two guidance on MPPP.

Komen urges CMS to develop easy to understand educational tools to explain the program, which must also be culturally and linguistically appropriate and ensure people from historically marginalized communities can benefit from MPPP. We also urge CMS to accommodate people who have differing audio and visual capabilities and/or reading levels. Literacy, particularly health literacy, should not be a barrier to entry into MPPP. A 2022 report on the state of health literacy in the U.S. states that at least 88% of adults living in the U.S. have health literacy inadequate to navigate the healthcare system and promote their well-being. The report also notes that improving health literacy requires more than just sharing information with patients and the public and that easy access to technology (i.e., having access to a computer or a phone and to a network and knowing how to use it) is essential to ensuring that technology contributes to the solution rather than aggravating inequities.¹ As such, Komen recommends including non-technology dependent modes of enrollment and outreach to ensure those in the digital divide have access to the program.

CMS should consider collaborating with trusted stakeholders, including patient advocacy groups such as Komen, to help craft effective messaging and tools for patients and to help get this information out to consumers. Komen asks CMS to work with these stakeholders to develop and harmonize efforts to raise awareness of MPPP across a variety of platforms and communication methods. Partnering with patient advocacy groups will ensure that patients see tools coming from trusted partners which are tailored to their needs. Komen directly engages with patients through its Patient Care Center (PCC)². Using the services provided through our PCC, during the Medicaid redetermination process (“Medicaid Unwinding”), Komen has been able to inform the breast cancer community about the process, helping to deliver messaging and resources that might have been missed or overlooked from government sources.

Finally, Komen requests that CMS provide resources and tools to potential enrollees well in advance of the open-enrollment period. Ample prep-time will enable participants to make an informed decision. Additionally, those counseling enrollees need sufficient time to understand the program.

Recommendations for Specific Portions of the Guidance

Section 30 – Program Calculations and Examples

Komen appreciates that the Guidance includes specific calculations and examples of how OOP cost sharing payments will be calculated. This transparency increases stakeholders' understanding of the program's mechanics and helps to identify potential challenges for their communities.

The Guidance notes that if OOP costs incurred in the first month of participation in the program are less than the maximum monthly cap, a Part D sponsor cannot bill the participant more than their actual incurred OOP costs. Instead, Part D sponsors must bill the participant the lesser of the actual OOP costs or the first month's max monthly cap. Komen supports this approach and asks CMS to take steps to ensure compliance by Part D sponsors. Beneficiaries are unlikely to be able to enforce this protection. As

¹ Claude Lopez, Bumyang Kim, Katherine Sacks. Health Literacy in the United States Enhancing Assessments and Reducing Disparities. Milken Institute. 2022. Available at https://milkeninstitute.org/sites/default/files/2022-05/Health_Literacy_United_States_Final_Report.pdf.

² The Komen Patient Care Center is a trusted, go-to source for timely, accurate breast health and breast cancer information, services and resources. Our navigators offer free, personalized navigation services to patients, caregivers, and family members. <https://www.komen.org/support-resources/patient-care-center/>

such, we encourage CMS to review sponsors' implementation of the policy, audit ongoing charges to patients in MPPP, and consider if penalties for failure to comply with this patient protection should be implemented.

Komen asks CMS to consider simplifying certain aspects of MPPP to ensure maximum participation and benefits for beneficiaries. As the Guidance notes, the timing of a patient's costs, whether they hit the annual OOP maximum and when in the year a patient enrolls in the program will impact the financial benefit a patient receives. Komen worries that unintended gaps in communications could lead to patients missing the opportunity to sign up for this beneficial program. Also, there may be a lack of understanding that, depending on their OOP costs, patients could have months with higher monthly payments than there would be otherwise.

In addition, Komen asks CMS to consider other ways to provide equitable benefit for people, including considering a fixed maximum monthly cap. CMS also should consider an "opt-out" approach rather than a proactive "opt-in" for patients entering the program. This approach would give patients the opportunity to benefit in month one versus when they enroll in the program. We suggest that the statutory language giving beneficiaries "the option to elect" participation could possibly be interpreted to permit beneficiaries to opt-out rather than opt-in.

40 – Participant Billing Requirements

Komen is pleased the Guidance includes details on the how MPPP participants may be billed by Part D sponsors and the mechanics of payment. Komen believes that it is crucial to incorporate patient protections in the MPPP billing and payment processes. We appreciate the Guidance's clear statement that Part D sponsors may not bill a participant more than the maximum monthly cap, nor late fees, interest payments, or other fees, such as for utilizing different payment mechanisms, under the program.

Komen also agrees with the elements identified in the Guidance for inclusion in billing statements to MPPP participants. We ask that CMS consider requiring the billing statement to include an explanation of the MPPP participant's OOP costs to date and how this might impact future payments. This could help beneficiaries prepare for future program payments, particularly towards the end of the year when participants may incur larger bills. Similarly, when considering how Part D sponsors implement their financial reconciliation process, we ask CMS to consider if additional notification is necessary when an MPPP participant elects to pay more than the monthly cap to ensure that the participant understands this is optional.

CMS requests comments on specific requirements related to debt collection for amounts due under the program. Komen asks CMS to ensure debt collection activities do not exacerbate the existing medical debt crisis in the US. According to a 2022 poll conducted by KFF, 100 million Americans are saddled with medical debt.³ The poll found that a quarter of adults in the US with health care debt owe more than \$5,000, and about 1 in 5 with any amount of debt said they do not expect to ever pay it off. Notably, 63% of those surveyed reported cutting spending on food and other essentials. As such, Komen encourages CMS to limit how and when enrollees can be turned over to private debt collection companies. We also suggest that any debt collection efforts include information on support for enrollees in paying outstanding debts.

³ Noam Levy, [Diagnosis Debt:100 Million People in America Are Saddled With Health Care Debt](#), published June 16, 2022, Kaiser Health News.

60 – Requirements Related to Part D Enrollee Outreach

Komen thanks CMS for ensuring that enrollment information in MPPP is available in multiple forms, prior to and during Part D open enrollment. Komen supports this approach because it is during this time that patients will be most engaged in understanding their options for Part D coverage. Additionally, Komen agrees with informing enrollees about MPPP as part of the annual notices that inform Part D enrollees about changes for the upcoming plan year.

The Guidance notes that Part D plans and pharmacies will be required to identify specific times when a patient might benefit from the smoothing program. We agree with this requirement and encourage CMS to work with stakeholders to identify relevant times for MPPP counseling. For example, targeted outreach may be especially important upon the diagnosis of breast cancer or a reoccurrence, when an initial breast cancer treatment is prescribed or when there are changes to a patient's treatment protocol. We suggest that targeted outreach be performed using multiple modes of communication (i.e., phone, mail, email) to ensure enrollees receive the information.

Komen looks forward to learning more about MPPP marketing and communications procedures and content in the next phase of implementation of MPPP. Komen supports the development by CMS of model language and standardized materials, including language about the availability of the Low-Income Subsidy (LIS) program under Part D. Komen asks that such model language be culturally competent and that pharmacists be provided with the resources necessary to connect patients with resources in their native language.

The Guidance notes that CMS is seeking to balance identification of people with potential issues affording their medications with precision, to ensure that someone does not have initial relief but then later face higher monthly payments than they would have if not enrolling in MPPP. Komen agrees that this scenario may be particularly confusing for patients, providers, Part D sponsors, and other individuals counseling on the MPPP. Again, we urge CMS to consider using an opt-out method of enrollment and setting a fixed monthly cap to guard against harm to patients. Without those policies, individuals counseling on MPPP, particularly pharmacists and Part D sponsors, must be specifically educated on this potential situation. We urge you to include clear language outlining the scenarios in which someone may not wish to enroll in MPPP that explicitly identifies the tradeoffs between lower monthly payments at the beginning of the year and higher ones at the end.

70 – Requirements Related to Part D Enrollee Election

Komen supports the Guidance's requirement that Part D sponsors have multiple mechanisms available to Part D enrollees for enrollment in MPPP. Again, Komen asks that all enrollment mechanisms be available in culturally and linguistically appropriate forms which account for individuals' differing audio, visual and literacy abilities.

The Guidance specifies what Part D sponsors must provide to participants upon approval for MPPP. Komen agrees with the inclusion of examples of calculations of the max monthly cap in the first month and subsequent months and including example calculations describing scenarios in which the program would not be beneficial to an individual. We ask that CMS consider whether the notice could be tailored to the enrollee's specific situation. Participants would benefit from knowing their own anticipated costs under MPPP, rather than just examples that may or may not apply to them. If such detail is impossible or infeasible in the first year, we ask CMS to consider if such information could be provided in subsequent years based on MPPP data from the previous year.

Komen supports the Guidance's requirement that, if a Part D sponsor receives an election request that does not have all necessary elements required to consider it complete, the sponsor must not immediately deny the request. Especially as MPPP begins, enrollees need the opportunity to supplement their requests. Komen suggests that the notification from Part D sponsors, requesting the additional necessary documentation, be conducted using multiple modes of communication. As seen during the current Medicaid Unwinding, regular mail alone is inadequate for protecting people from missing vital communications about their health insurance coverage.

Komen supports requiring plans to process MPPP election requests within 24 hours to prevent delays in dispensing drugs to individuals when they opt into the program. People, especially those undergoing treatment for breast cancer, need timely processing to mitigate stress and ensure the best possible outcomes from their care. We encourage you to tailor educational materials for use by oncologists or other individuals who interact with cancer patients so that someone is notified about the program and can enroll as quickly as possible. For example, CMS could work with common electronic health record companies to have a trigger when an expensive medication is prescribed to a Medicare beneficiary to remind the provider to ask if the patient needs more information about MPPP.

CMS requests feedback on options to effectuate election into the MPPP at the point-of-sale (POS) in real-time or near-real-time beginning in 2026 or later. Komen urges CMS to develop all the proposed options, including telephone-only, web based and online applications to ensure no one is left out of MPPP because of challenges accessing the system.

Komen notes that many Americans face a "digital divide" and lack access to reliable computers and/or smart phones with internet access. The COVID-19 pandemic exposed stark inequities in Americans' access to technology and skills to utilize it. As such, telephone-only options are vital for ensuring that all Medicare beneficiaries can learn about the program and improving health disparities. Komen also notes that technology can play a role in improving access to health care services. In a 2021 study, the Kaiser Family Foundation found that reported telehealth use among Medicare beneficiaries was higher for those under the age of 65 who qualify for Medicare due to a long-term disability (53%), beneficiaries enrolled in both Medicare and Medicaid (55%), Black (52%) and Hispanic (52%) beneficiaries, and those with 6 or more chronic conditions (56%).⁴ This data suggest that technology can improve access for historically marginalized groups.

Komen applauds CMS for planning to create a calculator tool for use during the MPPP election process, which accounts for individual circumstances. Komen strongly urges CMS to make a similar calculator publicly available for use anytime an enrollee may be considering enrollment in MPPP. As the Guidance notes, the timing of enrollment in MPPP and amount of OOP costs may alter the utility of the program for people. We ask that the public calculator also allow for data inputs to account for an individual's specific situation and that it provides a side-by-side comparison, like those provided in the Guidance, so the user can see the timing and amounts of costs should they choose to enroll that month or later in the year.

Komen also encourages CMS to construct tools which prompt enrollees to consider their future health care needs, including treatment plans, and other household costs during election counseling. Breast cancer treatment involves a variety of modalities occurring at strategic intervals depending on the

⁴ Wyatt Koma, Juliette Cubanski and Tricia Neuman, [Medicare and Telehealth: Coverage and Use During the COVID-19 Pandemic and Options for the Future](#), (published May 19, 2021).

patient's preferences, disease stage, and type of breast cancer. We encourage CMS to work with patients and providers to consider appropriate ways to account for future health care needs as part of the election process. Additionally, patients' preferences and risk tolerance may influence their choices and should be respected. For example, young parents and other caregivers may expect money to be tighter during certain periods of the year. Enrollees should be counseled to consider household and other expenses as they evaluate the benefit from enrollment in MPPP.

Komen asks CMS to consider providing extra support to pharmacists and providers located in medically underserved areas in implementing POS election requirements. Many Americans must overcome significant barriers when accessing health care services, often including transportation. While enrollees need timely determinations, they also need to be able to receive services in their preferred geographical location. Support to pharmacies in these areas could include funds for enrollee counseling during the POS process, over the phone and/or in-person, or software modernization. We also ask CMS to consider if guidance from the Office of the Inspector General on how Part D plan sponsors can support their network pharmacies without violating fraud and abuse laws would be helpful.

Komen supports establishing standardized coding, such as a new value in an existing National Council for Prescription Drug Programs (NCPDP) data field for the MPPP. We encourage CMS to consider whether codes are needed to indicate any time an enrollee receives counseling on MPPP and not just for successful elections. Such data could enable analysis of denials and circumstances which may cause enrollees to determine MPPP is not beneficial for them. We also note that CMS has recently proposed new codes to increase access to patient navigation services and we encourage the Agency to include counseling about MPPP in the training for that program.

Komen was pleased the Guidance reiterates Part D sponsors' obligation to not discriminate against any person based on race, color, national origin, disability, sex, or age in admission to or participation in the program. We agree that patients need protection from predatory practices, including evaluation of their ability to pay costs, during MPPP election. We encourage CMS to work with Part D sponsors and pharmacies to eliminate or reduce biases during the election process. This may mean training and oversight of the POS process which would be supported by collection of additional information at the POS as discussed above.

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

Komen supports the protections for patients included in the Guidance around late payments and termination from the smoothing program. Komen appreciates the inclusion of a grace period for late payment, details on its timing and clarification that individuals must be allowed to pay their overdue balance during the grace period to remain in the program. These provisions should reduce terminations resulting from missed communications and other logistical challenges. However, Komen asks CMS to consider setting a grace period longer than 2 months, especially in the first years of implementing the MPPP as beneficiaries get used to the new program.

Komen applauds CMS for including flexible standards in application of the grace period. The Guidance indicates that Part D sponsors must reinstate an individual who has been terminated from the MPPP if the individual demonstrates good cause for failure to pay the billed amount within the grace period and pays all overdue amounts. To demonstrate good cause, the individual must establish a credible statement that the failure to pay the monthly amount billed within the grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee. We ask CMS to provide examples of what could constitute good cause and

indicate who will make such determinations. Komen is concerned that the party expected to implement this flexibility may need additional detail for consistent and equitable application of the good cause standard. We also appreciate that the Guidance allows for Part D sponsors to reinstate an individual who has been terminated from MPPP if the individual pays all overdue amounts billed, even if the individual does not demonstrate good cause. Komen suggests that CMS explore options to encourage this practice by Part D sponsors.

Komen supports the details provided in the Guidance on notice requirements for involuntary termination from MPPP. The proposal provides patients with information on how, when, and why they could be terminated from MPPP, options for avoiding termination, and the consequences of termination. Komen reiterates its request that all notices in MPPP be in culturally and linguistically appropriate forms that account for individuals' differing audio, visual and literacy abilities.

Komen appreciates that a Part D plan sponsor is prohibited from disenrolling a Part D enrollee from a Part D plan for failure to pay any amount billed under the MPPP. In addition, a Part D sponsor cannot decline future enrollment into a Part D plan based on an individual's failure to pay a monthly amount billed under the MPPP. These protections ensure MPPP benefits enrollees and does not harm their overall Medicare coverage. We encourage CMS to require involuntary termination notices to clearly state that the enrollee remains enrolled in Part D coverage and that the termination only applies to their MPPP participation.

Komen applauds CMS for requiring Part D sponsors to make multiple attempts to contact enrollees and provide sufficient time for payment prior to involuntary termination from MPPP. We ask CMS to consider adding another mode of communication to these notice requirements. CMS may want to require Part D sponsors to attempt to call beneficiaries and/or notify their pharmacy to advise the enrollee to contact their Part D sponsor regarding participation in MPPP. Again, Medicaid Unwinding has shown the inadequacies of mail-only communications to people in preventing avoidable disenrollment from health insurance.

Komen appreciates that the Guidance includes additional guardrails and details on preclusion from election into MPPP in plan years following an involuntary termination from the program. Komen believes patients will benefit from these details on exclusion from MPPP in subsequent plan years. Komen does, however, express concern with the approach that a Part D sponsor that offers more than one Part D plan may have different preclusion policies for each plan. We worry this may create uneven implementation and application of MPPP and create significant confusion for enrollees. We encourage CMS to consider standardizing rules across all Part D plans to avoid any adverse selection, since it is patients with high drug costs who will be the likeliest to know about the policy taking effect.

100 – Data Submission Requirements

Komen supports the collection of data on MPPP to facilitate assessment of the program's benefits for patients. The Guidance indicates that Part D sponsors will be responsible for annually reporting data elements related on their MPPP, both at the beneficiary-level and contract-Plan Benefit Package (PBP) levels. We ask CMS to consider if data collection should include enrollees' demographic information and other elements related assessment of health equity, especially for those who are involuntarily disenrolled.

Komen looks forward to working with CMS to ensure smooth implementation of MPPP. Please contact Valerie Nauman, Komen's Manager of Federal Policy and Advocacy, at vnauman@komen.org with any questions or if we can otherwise be helpful.

Sincerely,

A handwritten signature in blue ink that reads "Molly L. Guthrie". The signature is fluid and cursive, with the first name "Molly" being more prominent than the last name "Guthrie".

Molly Guthrie
Vice President, Policy & Advocacy
Susan G. Komen



September 19, 2023

VIA Electronic Filing: PartDPaymentPolicy@cms.hhs.gov

Subject: "Medicare Prescription Payment Plan Guidance"

The Assistance Fund (TAF) appreciates this opportunity to provide input on the guidance the Centers for Medicare & Medicaid Services (CMS) released in August related to the Maximum Monthly Cap on Cost-Sharing Payments Program (hereafter "the program").

As CMS proceeds with implementation of the program, TAF encourages CMS to protect the ability of Medicare Part D beneficiaries to apply charitable assistance to their out-of-pocket exposure. Charitable assistance offers tens of thousands of Medicare beneficiaries badly needed financial protection. Creating impediments to the use of charitable assistance could lead to an unnecessary financial burden for many of them.

About The Assistance Fund

TAF is an independent charitable patient assistance organization that helps patients and families facing high medical out-of-pocket costs by providing financial assistance for their copays, coinsurance, deductibles, and other health-related expenses. We are ranked as a top charity in publications like *Forbes*, GuideStar, and Charity Navigator. TAF's mission is to provide underinsured people living with life-threatening, chronic, and rare diseases access to critical treatment through financial assistance, education, and advocacy.

Currently, TAF provides financial support to roughly 24,000 Medicare Part D beneficiaries.

Comments

TAF is seeking to clarify and simplify the process for beneficiaries who are eligible for charitable patient assistance through the coordination of benefits (COB) process. We believe this would streamline the process for beneficiaries, charities, and plan sponsors. Specifically, TAF seeks to ensure that the two-transaction pharmacy claims process (as outlined in the "Medicare Prescription Payment Plan Part 1 Guidance") allows for independent charitable assistance to be billed for the patient responsibility as a component of "Other Health Insurance" prior to application of any Medicare Prescription Payment Plan. TAF also seeks to ensure that charitable

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assistance provided will be properly identified and continue to be included in the patient's true out-of-pocket cost (TrOOP).

Current Process

Presently, beneficiaries provide the pharmacy with a TAF membership card, including the TAF BIN/PCN information for electronic billing. Pharmacies bill Part D plans as they typically would and then separately bill TAF for the beneficiary copay expenses.

Concerns with Proposed Process

TAF is concerned that the proposed process could remove a logical point for beneficiaries to employ charitable assistance.

Under the proposed process, beneficiaries who elect to participate in the program do not have any costs payable to the pharmacy. The pharmacy bills the Part D plan for the entirety of the costs, including beneficiary cost-sharing and the normal transaction amount. As such, the logical point at which Medicare Part D beneficiaries would present charitable assistance may be obfuscated, and Part D plans will pass on copay costs to monthly bills sent to beneficiaries that might otherwise have been directly billed to and covered by charitable assistance. Under this scenario, tens of thousands of Medicare beneficiaries would undertake significant new financial burdens, solely due to operational issues.

- To that end, we encourage CMS to ensure that the program includes a requirement that the pharmacy ask each Medicare beneficiary if he/she has any copay assistance at the point of transaction—even if he/she is participating in the program.
- In CMS' proposed two-step billing process, ensure that charitable assistance is billed directly by the pharmacy as a component of the coordination of benefits under "Other Health Insurance." In addition, CMS should ensure that the second BIN/PCN sent to the Part D plan includes reporting on charitable assistance to be applied to the patient's TrOOP.

Claims Processing and Coordination of Benefits

Consider the below example.



Applying the general flow shown in “Example 2 with OHI” with modified amounts for illustration.

- \$100 Negotiated Price in Initial Coverage Phase of Defined Standard Plan.
 1. Pharmacy submits \$100 claim to Part D plan’s primary BIN/PCN.
 2. Pharmacy receives paid claim response reflecting \$25 patient pay amount and \$75 total amount paid.
 - a. Pharmacy receives paid claim response message that the individual has opted into the Medicare Prescription Payment Plan and is provided with the plan’s Medicare Prescription Payment Plan BIN/PCN to bill the final participant responsibility amount as a COB transaction. (Important note to confirm: the two-transaction process would occur whether or not the Part D plan has record of any OHI.)
 3. Pharmacy submits COB transaction to independent charitable patient assistance program.
 4. Pharmacy receives paid claim response on COB transaction to independent charitable patient assistance program reflecting \$25 total amount paid.
 5. Pharmacy submits COB transaction for \$0 to the plan’s Medicare Prescription Payment Plan BIN/PCN. This transaction needs to indicate that \$25 was paid from the independent charitable patient assistance organization and should be applied to TrOOP.
 6. Pharmacy receives paid claim response on COB transaction reflecting \$0 patient pay amount.

Finally, we encourage CMS to request the addition of the amount of independent charitable patient assistance support utilized by the beneficiary to the billing statement.

Sincerely,

Danielle Vizcaino
President and CEO, The Assistance Fund



TEACHERS' RETIREMENT SYSTEM

of the State of Kentucky

GARY L. HARBIN, CPA
Executive Secretary

ROBERT B. BARNES, JD
*Deputy Executive Secretary
Operations and General Counsel*

ERIC WAMPLER, JD
*Deputy Executive Secretary
Finance and Administration*

September 19, 2023

SENT VIA EMAIL

PartDPaymentPolicy@cms.hhs.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW Washington, DC 20201

Dear Administrator Brooks-LaSure:

On August 21, 2023, the Centers for Medicare & Medicaid Services (hereinafter "CMS") of the U.S. Department of Health and Human Services released *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* (hereinafter "Draft Guidance"). This new program was established by Section 11201 of the Inflation Reduction Act (hereinafter "IRA"), Public Law 117-169.

Beginning in plan year 2025, this new program redesigns the Medicare Part D prescription drug benefit, in part, to establish a new out-of-pocket (hereinafter "OOP") annual cap of \$2,000 for Medicare beneficiaries. As CMS now refers to the new Medicare OOP smoothing program as the Medicare Prescription Payment Plan (hereinafter "MPPP") and to enrollees of MPPP as participants, this comment letter adheres to that language.

On behalf of the 38,000 retirees of Teachers' Retirement System of the State of Kentucky (hereinafter "TRS"), thank you for the opportunity to provide feedback on the MPPP under Part One of the Maximum Monthly Cap on Cost-Sharing Payments Program guidance.¹

TRS is a comprehensive retirement plan for Kentucky's public-school teachers that includes annuity, life insurance and retiree health insurance benefits. TRS serves 38,000 on a self-funded Medicare Part D Employer Group Waiver Plan (hereinafter "EGWP"). With 2.3 million prescriptions a year, 53% of the TRS days supply is done through mail order where TRS retirees have a zero deductible, can obtain a 90-day supply of a tier one preferred generic for a \$10 copayment, and can obtain a 90-day supply of a tier two preferred brand for a \$20 copayment.

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

Issue of Unpaid Debts

TRS respectfully requests that CMS carefully consider and provide guidance on the situation that will confront Part D sponsors, including TRS, upon the death of MPPP participants. TRS strongly recommends that in order to avoid confusion on this matter such guidance be provided in both narrative form and plan calculation examples.

Specifically, in implementing the MPPP, the issue will arise whether a Part D sponsor may use certain monies to pay for an unpaid balance of a deceased participant. In the example of TRS, both state and federal law preclude using the TRS Health Insurance Trust, which is a federal Internal Revenue Code Section 115 trust, to pay the unpaid balance of the decedent. Such an obligation would constitute a private interest, i.e., debt or obligation, of the decedent for which the use of Section 115 trust funds is prohibited.

On page five of the Draft Guidance, CMS specifically solicits comments on procedures for termination of election, reinstatement and preclusion. Section 80 of the Draft Guidance provides some detail on implementation of MPPP related to these situations. In addition, Section 80.5 of the Draft Guidance discusses disenrollment, and death triggers an involuntary disenrollment under 42 CFR 423.44(b)(3)(iii).

However, the information provided in the Draft Guidance does not specifically address the situation of a deceased MPPP participant. Likewise, the plan calculation examples in the Draft Guidance do not include an example tailored to the death of a MPPP participant.

Analysis of Use of Section 115 Trust Funds

TRS manages its hospital and medical health insurance retiree plan pursuant to Kentucky state law through a federal Internal Revenue Code (hereinafter “IRC”) Section 115 trust. Such trusts are often referred to as “integral part” trusts because to be tax exempt, they must constitute an essential function of the governmental employer.

Kentucky statutory law² creates the Kentucky Teachers’ Retirement System Insurance Trust Fund intended to be established as a trust exempt from taxation under IRC Section 115 (hereinafter “TRS insurance trust fund” or “TRS Section 115 trust”). The Kentucky statute reads, in part:

Trust fund assets are dedicated for use for health benefits as provided in KRS 161.675, and as permitted under 26 U.S.C. secs. 105 and 106,³ for present and future eligible recipients of a retirement allowance from the Kentucky Teachers’ Retirement System.

² KY Rev Stat §161.677(2).

³ IRC Sections 105 and 106 provide little guidance on what types of accident or sicknesses may be covered, but the Sections refer to IRC Section 213(d) for the definition of “medical care.” That section reads as follows:

Assets of the trust fund shall not be used for any other purpose and shall not be used to pay the claims of creditors or any individual, person, or employer participating in the Kentucky Teachers' Retirement System.⁴ (Emphasis added)

In examining KRS 161.675, this statute contemplates the provision of "... a broad program of group hospital and medical insurance for present and future eligible recipients ..." ⁵ and that "(t)he coverage provided shall be as set forth in the contracts and the administrative regulations of the board of trustees." ⁶

Similar language is contained in the Trust Agreement of the TRS Insurance Trust Fund. Article II, Trust and Trust Administration, Section 2.01(d) states, in part, "Trust assets shall not be used to satisfy the claims of any creditor of any employer, the Commonwealth, or the Trustees; Article II, Section 2.01(f), states, in part, "At no time shall any part of the Trust Fund be used for, or diverted to, purposes other than for the exclusive benefit of eligible recipients under KRS 161.675 and for defraying the reasonable expenses of administering the Trust."

Next, these comments turn to an analysis of federal tax law, specifically IRC Section 115, which is consistent with Kentucky law on the matter of the permissible use of trust funds for private interests, debts or obligations.

Section 115 states that gross income does not include income —

- derived from any public utility or the exercise of any essential governmental function and accruing to a State or any political subdivision thereof, or the District of Columbia; or
- accruing to the government of any possession of the United States, or any political subdivision thereof.

The term "medical care" means amounts paid:

(A) for the diagnosis, cure, mitigation, treatment, or prevention of disease, or for the purpose of affecting any structure or function of the body,

(B) for transportation primarily for and essential to medical care referred to in subparagraph (A),

(C) for qualified long-term care services (as defined in section 7702B(c)), or

(D) for insurance (including amounts paid as premiums under part B of title XVIII of the Social Security Act, relating to supplementary medical insurance for the aged) covering medical care referred to in subparagraphs (A) and (B) or for any qualified long-term care insurance contract (as defined in section 7702B(b).

⁴ KY Rev Stat (KRS) §161.677(1)(a).

⁵ KY Rev Stat §161.675(1).

⁶ KY Rev Stat §161.675(2)(a).

The Internal Revenue Service (hereinafter “IRS”) discusses private interests in relation to a Section 115 trust in Revenue Ruling 90-74:

The income of an organization formed, operated, and funded by political subdivisions to pool their casualty risks is excluded from gross income under section 115(1) of the code. Similarly, the income of an organization formed, operated, and funded by one or more political subdivisions (or by a state and one or more political subdivisions) to pool their risks in lieu of purchasing insurance to cover their public liability, workers’ compensation, or employees’ health obligations is also excluded under section 115(1) if private interests do not, except for incidental benefits to employees of the participating state and political subdivisions, participate in or benefit from the organization. (Emphasis added)

A trust established under Section 115 is exempt as an instrumentality of government. Pursuant to IRS guidance, the following requirements for exemption under Section 115 can be inferred:

- 1) The trust must be maintained by a state or local governmental entity;
- 2) Benefits paid by the trust must satisfy an obligation that would otherwise have had to have been paid by the sponsoring governmental entity (which will normally be the case if the trust is used to pay benefits under a plan maintained by the sponsoring entity); and
- 3) The trust must not benefit “private interests.”⁷

Analyzing the three prongs in relation to the TRS Section 115 trust and in the case of a deceased MPPP participant, prong one (trust maintained by a state or local governmental entity) is clearly met. The TRS insurance trust fund was created by Kentucky statutory law and is maintained by a board of trustees under the authority of the Commonwealth of Kentucky.

Regarding prong two, while Section 11202 of the IRA requires “... each PDP sponsor offering a prescription drug plan and each MA organization offering an MA-PD ...” to provide a smoothing option to all Part D enrollees, it will depend on the facts and circumstances of the payments and the regulatory structure of the smoothing program as to whether a particular payment made by a Section 115 trust would be for an obligation that would otherwise have had to have been paid by the sponsoring governmental entity. This can occur in several common scenarios. First, if TRS is asked to pay for any portion of the \$2,000 OOP plan year minimum on behalf of a deceased MPPP participant, then such a payment by the Section 115 trust would violate prong two. Such a payment would not otherwise have had to have been paid by the sponsoring governmental entity because it

⁷ U.S. Income Portfolios, BNA, Vol. 395-3rd, IV (B), VEBAs and Other Welfare Funding Arrangements.

was the private debt of the decedent. Also, someone could disenroll from Part D before any recoupment of the \$2,000.

Regarding prong three (the prohibition on benefiting private interests), the OOP costs, while now capped for Medicare Part D beneficiaries at \$2,000 per plan year, can be viewed in no other way than as a private obligation or debt of the beneficiary. Requiring payment of this private obligation by a Section 115 trust would violate both state and federal laws barring use of these trust funds to benefit a private interest.

Contrast the individual private obligation described in the paragraphs above to the IRS's ruling in the case of two defined benefit plans created by a state to provide retirement, death and workmen's compensation benefits funded through a Section 115 trust: "... there is ... no private proprietary interest involved, since the beneficiaries receive benefits from trust income but are not entitled to access to trust corpus. The beneficiaries, like the beneficiaries of a charitable trust, are large classes instead of specified and definitely ascertainable individuals."⁸

Participants of a MPPP plan would constitute a large class, but individual deceased plan participants would be specified and definitely ascertainable individuals and, therefore, payment by the Section 115 trust of their debts would constitute a private proprietary interest. The distinction is drawn quite clear by this IRS ruling.

Section 115 Summary

The analysis above shows that state and federal law is consistent on the issue of prohibiting the use of a Section 115 trust from paying private debts.⁹ Therefore, it is the position of TRS that using funds from the TRS Section 115 trust to pay the unpaid MPPP balance of a deceased MPPP participant would violate both state and federal law and jeopardize the tax-exempt status of the trust.

Request of EGWP Exemption for TRS and all Public Sector EGWPs

Because a Section 115 trust is prohibited from paying private debts, TRS requests an exemption for the TRS EGWP. Also, as a Public Sector Healthcare Roundtable (hereinafter "Roundtable") member, TRS supports the Roundtable's request of an exemption on behalf of all public sector EGWPs and endorses the Roundtable's comments.

⁸ IRS General Counsel Memorandum 34704, December 2, 1971.

⁹ KY Rev Stat §161.716 provides that in the event federal laws are in conflict with the Kentucky Revised Statutes pertaining to the Teachers' Retirement System, federal laws shall take precedence. In addition, when necessary to comply with federal laws, the board of trustees may defer or stop payments of allowances until the conflict is resolved, and the board of trustees shall adopt such regulations as are necessary to remove any conflicts with federal laws and to protect the interests of the members, survivors of members, and the system.

Specifically, TRS would incorporate and highlight the following points in the Roundtable's comments:

While the benefits of allowing Part D monthly payments for medications is an important option for many individual Part D enrollees, we strongly believe that most, if not all, EGWP beneficiaries are already shielded from the high out-of-pocket costs that the Prescription Payment Plan intends to attenuate. As a consequence of the unique protections already offered by EGWP plans, coupled with the negative impact the requirement could have on EGWP enrollment and participation, we ask that CMS consider an EGWP exemption of these requirements under the authority granted by 42 CFR § 423.458(c).

42 CFR § 423.458(c) provides CMS the authority to waive or modify any Part D requirement that "hinders the design of, the offering of, or the enrollment in" an EGWP Part D plan. Generally, EGWPs offer enrollees a more predictable out-of-pocket expense structure and better alleviate overall financial burdens compared to the standard Part D benefit. ...

As showcased above, EGWP enrollees already have robust cost protections in place, and being offered an alternative payment option with limited benefits can inadvertently confuse enrollees and expose them to opportunities to accrue potentially burdensome debt from failing to pay the monthly amount. ...

The new Prescription Payment Plan may inadvertently harm enrollees that are already protected from high prescription costs through enrollee confusion and potential for accumulating unnecessary debt. Adding to this confusion is how the election to participate in the program will be incorporated in the plan enrollment process.

Utilization Increases Because of Zero Cost Share at Point of Sale

Under the Draft Guidance, MPPP participants will pay zero at the point of sale. Charging zero at the point of sale means TRS could experience spiraling utilization by retirees, especially in the utilization of lifestyle drugs rather than lifesaving drugs. Meanwhile, TRS members who think they're getting something for nothing will struggle to understand smoothing and how this is charged to their credit card well after the transaction.

In closing, TRS appreciates and shares CMS' commitment to ensuring Medicare beneficiaries are adequately protected from high-out-of-pocket prescription drug costs. TRS welcomes the opportunity to work with CMS in further developing and implementing the MPPP in a way that helps those who need it without harming those who don't. While this helps *individuals* in Part D, Kentucky's retired teachers who are in Part D as an EGWP already are protected and aided through rebates and subsidies that lower premiums and improve cost share. To use a one-size-fits-all approach would subject these Kentucky retirees to a cumbersome, bureaucratic process that would

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September 19, 2023

cost them more at mail order.

Sincerely,

A handwritten signature in blue ink that reads "Jane C. Gilbert". The signature is written in a cursive style with a large initial "J" and a distinct "C" for the middle name.

Jane Cheshire Gilbert, CPA
Director of Retiree Health Care
Teachers' Retirement System of Kentucky

JG/mh



29219 Canwood Street
Suite 101
Agoura Hills, CA 91301

September 20, 2023

Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. Seshamani:

Thank you for the opportunity to provide comments on the Maximum Monthly Cap on Cost-Sharing Payments Draft Part One Guidance (the “Guidance”). Our review of the Guidance yielded the following concerns and suggestions:

- **General**

- The Guidance as currently written is heavily dependent on the existing health plan and pharmacy infrastructure. The changes required to comply with the Guidance will require a substantial monetary and resource investment on the part of the health plans and pharmacies. It is possible to operationalize the Medicare Prescription Payment Program by leveraging new entrants to the market; however, this would require CMS to be supportive of allowing the adoption and use of alternative processes and tools relative to those documented in the Guidance.

- **Section 40. Participant Billing Requirements**

- The billing requirements as articulated in the Guidance will necessitate Part D sponsors to develop new competencies in lending/payments. These competencies are a significant departure from the core competencies of a health plan and will result in substantial changes to their operating model.
- Allowing payment of monthly balances via a credit card account or cash will likely result in unanticipated costs to participants. Payment via credit card may result in finance charges to participants with outstanding balances on their credit card. Cash payments will need to be handled by a third-party vendor (e.g., Walmart). Typically, these vendors charge individuals a processing fee of \$3.00 - \$7.00 per transaction, and they often times limit the amount of money accepted per payment, which could cause a short payment. We would recommend excluding these payment methods from the acceptable payment list so participants do not incur unnecessary fees or unknowingly arrive in a non-payment situation.

- **Section 50. Pharmacy Payment Obligations and Claims Processing**

- Financial technology organizations offer multiple solutions which function similarly to a pre-funded payment card without the limitations described in the Guidance. Some of these solutions can consider eligibility and participation in the Medicare Prescription Payment Program, along with merchant-type and merchandise being purchased, when approving the transaction in real-time at a pharmacy. We would encourage CMS to explore some of these solutions as acceptable alternatives to the Claims Processing approach described in the Guidance. Additionally, we would suggest that CMS encourage financial processing networks (e.g., Visa, Mastercard) to provide financial technology organizations enabling the Medicare Prescription Payment Program access to the Inventory Information Approval Systems (IIAS) to ensure that participants' transactions are limited to the purchase of approved medications.

Thank you in advance for considering these comments. We look forward to discussing in more detail our concerns and suggestions. In the meantime, please do not hesitate to reach out should you have questions.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Michael Epstein', with a stylized flourish at the end.

Michael Epstein
Managing Director
The Tay Group, LLC

UNITEDHEALTH GROUP®

9900 Bren Road East, Minnetonka, MN 55343

September 20, 2023

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

RE: Medicare Prescription Payment Plan Guidance

Dear Dr. Seshamani:

UnitedHealth Group (UHG) is pleased to respond to the Centers for Medicare and Medicaid Services' (CMS) request for comments regarding the *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, dated August 21, 2023*.

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 business platforms—UnitedHealthcare (UHC), our health benefits business; and Optum, our health services business. Our workforce of 380,000 people serves the health care needs of 149 million people worldwide, funding and arranging health care on behalf of individuals, employers, and the government. We are one of the nation's most progressive health care delivery organizations, serving people within many of the country's most respected employers, in Medicare serving nearly one in five seniors nationwide, and in Medicaid supporting underserved communities in 32 states and the District of Columbia.

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 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

UHG is committed to helping our members cover the cost of their prescription drugs while providing the simplest experience and quality supported care. Part D enrollees who elect to participate in the Medicare Prescription Payment Plan (the “program”) will benefit from having their out-of-pocket (OOP) costs spread out during the calendar year. UHG agrees with CMS that providing targeted education and decision tools to Part D enrollees who are considering whether to opt-in to the program (“participants”) will be important, especially in the first year of the program.

Section 40 – Participant Billing Requirements

Electronic Payment Options

CMS encourages Part D sponsors to offer participants flexibility around requesting a specific day of the month for withdrawals from a bank account, and UHG supports this flexibility. UHG notes that CMS’s encouragement of allowing participants to select the day for “program charges” should not lead to selecting the date when a bill is generated and sent to the participant. Managing multiple billing due dates for different participants would add additional complexity and cost to the program. UHG believes that if participants need additional time outside of the standard billing timeframe, participants will have that flexibility and protection through the required two-month grace period.

CMS could also consider giving participants additional payment flexibilities by allowing participants to make their payments through deductions from their monthly Social Security payments.

Billing Statements

CMS proposes to require certain information be included on participant billing statements, including “the remaining total OOP cost sharing balance.” UHG encourages CMS to clarify that the total OOP cost sharing balance should include any OOP cost sharing that has been incurred, but not yet billed, and any OOP cost sharing balances that have previously been billed, but not yet paid by the participant. UHG believes that including both the incurred OOP cost sharing, as well as any prior OOP cost sharing balances, in the total OOP cost sharing balance on the billing statements will help ensure that participants have the most accurate information about program amounts owed.

Financial Reconciliation Process

In Section 40.2 of the draft guidance, CMS requests comment on additional financial reconciliation standards that may be appropriate for the program. UHG encourages CMS to consider issuing standards on the timing and frequency of the financial reconciliation process to ensure a consistent approach by Part D sponsors. Additionally, it will be important for CMS to consider the impact of the standards that apply to this program’s financial reconciliation process on any future Part D guidance related to incorrect collections of enrollee cost-sharing and premiums.¹

¹ Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4201-P), 87 FR 79452.

Section 50 – Pharmacy Payment Obligations and Claims Processing

UHG agrees with CMS that the adoption of an electronic claims methodology will help to ensure a timely, uniform, and seamless implementation of the program. Electronic processing will allow Part D sponsors to directly message the pharmacy for participants who have opted-in to the program and will help ensure that Part D sponsors have appropriate oversight of the payments that are made to the pharmacy on behalf of the participant. UHG requests that CMS provide Part D sponsors flexibility to implement electronic processing of claims.

Section 60 – Requirements Related to Part D Enrollee Outreach

UHG agrees with CMS that there will be participants who are more “likely to benefit” from the program, and that the outreach and education materials that are sent to Part D enrollees should be focused on Part D enrollees who would benefit the most from the program.

General Part D Enrollee Outreach Requirements

CMS has indicated it will provide additional guidance on marketing and communications procedures and content in its next phase of the guidance. UHG asks that CMS provide clear direction to Part D sponsors on how this program should be described and promoted to Part D enrollees in the context of other plan benefits and features.

UHG encourages CMS to provide Part D sponsors with model language and training materials to use for educational campaigns during open enrollment, as well as for annual participant materials. UHG believes standardized language and materials would best help support Part D enrollees in deciding whether the program is right for them. Specifically, UHG recommends CMS provide Part D sponsors with model language and training materials in guidance documents such as:

- Medicare Managed Care Manual Chapter 2 and 3 enrollment guidance
- Annual Notice of Change, Evidence of Coverage, and Explanation of Benefits models

UHG also urges CMS to consider whether it might be beneficial to develop a tool, for example, within Plan Finder, that will allow Part D enrollees to see how their OOP costs might be impacted if they choose to opt-in to the program. UHG believes that this type of tool will better help Part D enrollees understand if they are “likely to benefit” from the program.

Targeted Part D Enrollee Notification Prior to POS

UHG supports CMS’s concept of having Part D sponsors identify Part D enrollees who are “likely to benefit” from the program. As CMS continues to consider the specific parameters for identifying Part D enrollees prior to the plan year who are likely to benefit, UHG recommends CMS allow Part D sponsors the flexibility to design targeted campaigns for Part D enrollees who are taking specific high costs drugs and/or who may have a history of higher OOP costs above a specific threshold early in the plan year.

Targeted Part D Enrollee Notification at POS

UHG appreciates CMS’s desire to strike the right balance in identifying individuals with potential cash-flow concerns at the pharmacy and providing key, precise information about the program at the

POS. UHG recommends the point-of-sale (POS) notification threshold be based on a single claim instead of all claims in a single day because Part D enrollees may obtain their prescriptions from more than one pharmacy in a single day, and it could be operationally challenging to ensure the threshold accumulator is accurate in real time at the POS. UHG also recommends CMS set the POS notification threshold at \$700 for at least the first six months of the calendar year to allow Part D sponsors to identify the enrollees who are most likely to benefit from the program.

POS Notification Requirements

UHG understands that Part D sponsors must notify a pharmacy when a Part D enrollee incurs OOP costs for a single prescription that equal or exceed the POS threshold, and that CMS intends to provide additional specifics around the pharmacy notification process in the part two guidance. In order to reduce the administrative burden on pharmacies and Part D sponsors, UHG recommends that the pharmacy notifications be provided through the claims system rather than through calls, faxes, or other communications. CMS could consider requiring claims messaging similar to what plan sponsors provide currently for safety concurrent Drug Utilization Review. UHG also recommends CMS allow Part D sponsors to turn off messaging for participants who have already opted-in to the program, which would limit unnecessary, duplicative questions to the participant regarding the program.

UHG recommends that CMS issue a model template, similar to the “Medicare Prescription Drug Coverage and Your Rights” (CMS-10147), where a code is sent to the pharmacy and the pharmacy provides the model notice to the prospective program participant. Having a standardized notice template that is accessible by all pharmacies will help ensure that the information provided is consistent. UHG believes that as part of the program materials, it would be beneficial if CMS provides a model notice or other template that pharmacies could give to participants that outlines their financial obligations under the program. Having pharmacies directly provide participants a notice that includes the incurred cost sharing at the POS, as well as the participant’s payment obligations under the program, will help to ensure that participants are not surprised when they receive their first program bill. Such a notice may also have the added benefit of prompting conversations between participants and pharmacies about potential lower cost drug alternatives.

Section 70 – Requirements Related to Part D Enrollee Election

Election Requests for Employer Group Waiver Plans

UHG supports CMS’s proposal to allow participants multiple options to opt-in to the program. UHG seeks clarification on how the requirement in 70.3.1— that there must be “[an] election option through the Part D (or MA-PD) Plan enrollment process” —applies to Employer Group Waiver Plans (EGWPs) that use the Group Enrollment Mechanism defined in Section 40.1.6.1 of the Medicare Advantage Enrollment and Disenrollment guidance. UHG recommends that EGWPs have the ability to allow their Part D enrollees to opt-in to the program through a process that is completed during or immediately upon completion of plan enrollment. This approach will best serve the Part D enrollees by providing a mechanism for them to communicate their intent to opt-in to the program directly to the Part D sponsor. A separate mechanism also furthers CMS’s goal of maintaining a clear distinction between Part D plan enrollment and program participation.

Continuing Plan Enrollment

UHG supports having integrated annual notices that provide Part D enrollees with information about the opportunity to opt-in to the program but encourages CMS to consider allowing opt-in elections to carry over into the next plan year for those participants with no overdue program balance who intend to remain in the same Part D plan. UHG believes this approach will lead to a better participant experience and can be communicated effectively through the annual notices along with information about how a participant can notify the Part D sponsor that they wish to change their election.

Processing Election Requests During a Plan Year

In Section 70.3.5 of the draft guidance, CMS proposes a 24-hour requirement for processing program election requests during the plan year, noting that this timeframe is consistent with the existing requirements for processing requests for expedited coverage determinations. Given the operational differences in the processing requirements for election into the program, as compared to enrollment activities and expedited coverage reviews, UHG recommends that CMS consider allowing Part D sponsors up to 48-hours to process program election requests. Providing this additional time will also allow Part D sponsors to make any requests for additional information from a Part D enrollee due to an incomplete election request. UHG also recommends that upon approval of a program election request, the information participants receive about their rights, responsibilities, and protections include an express confirmation of the participant's acknowledgement of and agreement to the financial responsibilities and obligations that come with participating in the program.

Retroactive LIS Eligibility and Election

UHG recommends that Part D sponsors have flexibility to manage the application of retroactive activity in claims processing for program participants while maintaining adherence to the required timeframes for refunds under 42 CFR §§ 423.800(e) and 423.466(a). For example, Part D sponsors should have the flexibility to notify participants of retroactive activity by letter, providing an updated EOB, or including updates on the next program monthly bill.

Request for Information on 2026 Real-Time or Near-Real-Time POS Election and Other POS Needs

In Section 70.3.9 of the draft guidance, CMS indicates that it is considering options to effectuate real-time or near-real-time POS elections beginning in 2026 or later. UHG respectfully requests that CMS provide additional time for Part D sponsors to provide comment on potential technology solutions that might be feasible to implement under the proposed implementation timelines. Based on the proposed POS opt-in mechanisms, real-time eligibility exchanges between Part D sponsors and network pharmacies to support such a process may not currently exist, which means that development of new technology could be needed to enable network pharmacies to obtain and transmit information in real-time.

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

Preclusion of Election in a Subsequent Plan Year

The proposed CMS guidance for involuntary terminations from the program creates the potential for participants to move to a new plan with a different Part D sponsor each year without paying any outstanding program balances. To mitigate this risk, UHG ask CMS to implement a system that would allow plan sponsors to share information, possibly through CMS, about involuntary

terminations for non-payment and to allow sponsors to deny program election requests for members who were previously involuntarily terminated from a prior plan sponsor's program for non-payment and still have an outstanding program balance with that prior plan sponsor.

UHG requests that CMS consider the downstream impacts of allowing participants to change Part D plans and sign up for a new plan sponsor's program despite non-payment in the previous plan's program. For example, program participants may be incentivized to change Part D plans if they receive a bill with high OOP costs at the end of a plan year. Further, more frequent Part D plan changes may impact plans' Star Ratings, the ability to track participants' prescription drug use and adherence, and the overall management of costs and health outcomes.

September 20, 2023

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

Dear Administrator Brooks-LaSure,

We are writing to provide comments on the Medicare Prescription Payment Plan (MPPP) Guidance, as published by the Centers for Medicare & Medicaid Services (CMS) on August 21, 2023. 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](#).

[The MPPP, i.e., the “OOP smoothing program,” holds tremendous promise for Medicare beneficiaries struggling to afford their medications](#). In combination with the annual OOP cap of \$2000, the MPPP will be particularly impactful in alleviating the [“too much, too soon”](#) nature of Medicare Part D cost sharing wherein beneficiaries often face huge lump-sum payments at the beginning of each calendar year. This is particularly the case for patients needing a high-cost specialty drug or multiple non-specialty brand-name medications. If implemented successfully, the MPPP will lead to greater affordability for patients, reductions in prescription abandonment, increases in medication adherence, and improved outcomes.

We are delighted to see that the MPPP guidance incorporates several of the [recommendations made by us in a Health Affairs Forefront article published earlier this year](#). We offer below additional comments on key sections of the MPPP 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.

Introduction

Better Naming Conventions Can Improve Beneficiary Understanding

We applaud CMS for actively considering how the program will be perceived by beneficiaries and the potential pitfalls around language that could be avoided. We agree with CMS’ recommendation that all Part D sponsors be mindful of the language used when referring to Medicare Prescription Payment Plan participants so as not to cause confusion or alarm if, for instance, a Part D enrollee is informed that their participation in the Medicare Prescription Payment Plan has been terminated. However, we wish to caution CMS that referring to the smoothing program as a “plan” may still cause some beneficiaries to conflate it with their existing Part D plan (rather than as a separate program). Hence, Part D plans informing them about their termination from this MPPP “plan” may also cause confusion or alarm. Additionally, the program title should attempt to emphasize the monthly nature of the plan since monthly payments are integral to its operation. We recommend “Medicare *Monthly* Prescription Payment *Option*” as a possible alternative for consideration.

Section 30: Program Calculations and Examples

Calculator & Visual Tools: Help Beneficiaries/Caregivers Visualize Monthly Payments

We appreciate that the purpose of the presented calculations in the guidance document is to ensure Part D plan sponsors program their claims and billing systems correctly for 2025. Further, we agree with CMS’ plan to develop tools to help people with Medicare Part D and their caregivers learn what payments might

look like under this program. 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 estimate 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 caregivers. Importantly, calculators and visual tools need not be limited to patients proactively considering enrollment in the MPPP prior to the plan year or prior to point of service (POS) notification: they may also have a role to play at the point of service. It may be possible for some large retail pharmacies to install tablets at the pharmacy counter so that a patient could visualize in real-time what their OOP costs would look like under the program before making a decision to enroll or not. This would be ideal for patients who were missed in outreach efforts prior to the plan year and would be finding out about the MPPP for the first time at the pharmacy counter.

Tools Should Permit Personalized Calculations

The tools to be developed by CMS should allow beneficiaries or individuals assisting them to enter their current medications (and potentially any medications their provider may have previously prescribed, but the beneficiary had abandoned due to high out-of-pocket costs) and see their estimated monthly out-of-pocket costs regardless of what time of year they were entering the program.

Tools Should Project OOP Costs in the Current Calendar Year AND 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.

Section 40: Participant Billing Requirements

Flexibility for Beneficiaries is Critical for Successful MPPP Implementation

We applaud CMS for encouraging Part D sponsors to offer multiple means of payment. However, given the significant penalties associated with missing payments—i.e., termination from MPPP participation and preclusion in future years—surely the multiple modes of payment (particularly, the ability to set up recurring automatic payments) should be requirements rather than mere recommendations for Part D plan sponsors. We have similar concerns around CMS not explicitly requiring plans to allow participants flexibility around requesting a specific day of the month for program charges and withdrawals from the bank account. [The income and assets of Medicare beneficiaries can vary widely](#), and some beneficiaries

may not be able to participate in the MPPP if they do not have control over when their monthly payments occur (for instance, a patient who previously would time pharmacy visits to coincide with their social security check may no longer be able to use such a strategy). This is why it is vital that CMS require Part D plans to also offer greater flexibility around choosing the date for monthly payments.

Section 50: Pharmacy Payment Obligations and Claims Processing

Researchers Must Be Able to Effectively Evaluate the Impact of the MPPP

CMS indicates that “industry claims processing solutions must have no impact to PDE cost/payment field reporting, meaning PDE financials must reflect participant and plan liability amounts as if the MPPP did not apply.” From the beneficiary’s perspective, this is the right requirement for the claims processing. However, we also need to ensure that the claims are set up in a way that researchers can evaluate the impact/success of the MPPP program and how it may be improved upon. CMS must ensure that a rigorous quantitative evaluation of all aspects of the MPPP can be conducted by CMS or other researchers in the future using Medicare claims data (as opposed to just relying on qualitative surveys). 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.

Section 60: Requirements Related to Part D Enrollee Outreach

Careful Wording Will Be Needed When Conducting Outreach to Patients Who Will Benefit

We applaud CMS’ proposed effort to identify beneficiaries who are “likely to benefit” such as those incurring high OOP costs earlier in the year. While we fully support the rationale behind identifying such patients for the purpose of outreach, CMS must be careful to not use “likely to benefit” language during outreach in a way that may create the false impression that the remaining beneficiaries are likely to be harmed.

Consider A Lower POS Notification Threshold and Single-Day Prescription Accumulation

In Section 60.2.3, CMS asks for feedback “on the range of potential POS notification thresholds from \$400 to \$700, along with specific factors for CMS to take into consideration when determining the threshold for 2025, including using a single prescription versus single day accumulation to count toward the threshold.” We are concerned that the proposed POS notification thresholds of \$400 to \$700 are in fact too high. A recent weighted, nationally representative survey of elderly U.S. patients found that [approximately 20.2% beneficiaries reported cost-related medication nonadherence](#). Further, 8.5% of patients reported foregoing basic needs to afford medications. Extrapolating to the wider Medicare population, this means that nearly 5 million beneficiaries engage in this “extreme form of cost coping.” CMS’ proposed \$400 threshold will identify 2.2 million patients, which is less than half of patients in such circumstances. Additional recent polling has indicated that [75% of Medicare beneficiaries are unable to afford more than \\$200 in medication costs each month](#). Given these findings, a POS notification threshold lower than \$400 may be more appropriate.

We understand and agree with CMS that “there is limited visibility into possible future prescription costs, and therefore almost any threshold has the potential to identify Part D enrollees whose subsequent cost patterns will cause them to no longer meet the definition of likely to benefit.” Given the necessity of targeted outreach, the wisest course of action would be to err on the side of caution and identify the

largest possible number of patients who may benefit. The visual tools and calculators can then allow these patients to determine if it makes sense for them to participate in the MPPP given their individual circumstances.

CMS also asks for feedback on whether a single prescription or a single day accumulation of prescriptions should be used to count toward the threshold. Our recommendation would be to use all prescription filled on a single day given many patients may be taking multiple brand-name medications with OOP costs that do not trigger the threshold independently but when combined may identify them as an ideal MPPP participant. However, we are cognizant of the logistical difficulties in implementing the single day accumulation approach. If CMS chooses to opt for the simpler single prescription approach, then this makes the rationale for using a lower POS notification threshold even stronger. We also note that CMS' modeling of the single prescription vs. single day accumulation OOP cost threshold (\$400) revealed that the single-day accumulation method identified approximately 200,000 more potential beneficiaries. While this number may seem trivial in terms of the wider Medicare population, it represents a large patient population in absolute terms and would also constitute nearly 10% of the MPPP participants flagged by CMS' modeling exercise. This substantial number of beneficiaries should not be left behind.

POS Part D OOP Costs Should Not Be the Sole Basis for Enrollee Outreach/Notification

We understand the necessity and importance of this approach to identify patients who may benefit from the MPPP. However, this method may overlook a critical group of patients likely to benefit from the MPPP: those who have previously foregone needed (but expensive) medications because of high out-of-pocket costs and hence do not currently incur high POS OOP costs. 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 POS OOP costs since they are not filling (i.e. they had previously abandoned) the expensive Part D OOP specialty drug. Hence, we recommend that CMS consider using historical medical Part A and B claims to identify patients with diseases requiring high-cost specialty medications (e.g., rheumatoid arthritis, multiple sclerosis, and cancer) and conduct outreach to such patients prior to the plan year.

Partner with charitable foundations to identify beneficiaries in advance, especially for 2025

CMS states that "given a POS enrollment option is not likely for 2025, it will be of particular importance that Part D enrollees who are likely to benefit from this program are reached out to prior to receiving a POS notification, to minimize the need to leave the pharmacy without their prescriptions." In addition to our above suggestions, we also recommend that CMS partner with charitable foundations who have been historically providing financial assistance to Medicare Part D beneficiaries and are ideally situated to help identify patients likely to benefit from the MPPP.

Thank you for your consideration of our comments.

Sincerely,



Jalpa A. Doshi, PhD
Professor
University of Pennsylvania



Pengxiang Li, PhD
Senior Research Investigator
University of Pennsylvania

We appreciate the opportunity to provide comment on the Prescription Payment Plan Guidance. Given the short timeframe for implementation and the high degree of complexity the current proposal envisions, CMS may wish to consider directly implementing the maximum monthly cap on cost sharing with Part D beneficiaries. CMS would process participant enrollments, collect cost sharing from beneficiaries, and remit cost sharing payments to Part D contractors. The CMS administered program would have the ability to require or allow auto-deduction from the beneficiaries' social security payments in a manner similar to Part B premium deductions. Auto-deduction of Part D cost sharing will improve the beneficiary experience, protect beneficiaries from fraud and abuse, and be eco-friendly versus a decentralized monthly billing process.

The option of participating in a centralized CMS-led process would preclude the need for plan to plan (P2P) transitions and prevent beneficiaries from moving from one Part D plan to another to avoid repayment of accrued cost sharing. Centralizing the function would also ensure consistency of process and related beneficiary communications and technology (such as on-line enrollment and standardized payment options) and enhance accuracy of billing and reimbursements particularly when beneficiaries elect to participate retroactively, change Part D plans during the year, or have retroactive LIS changes. A centralized process would have economies of scale to be more efficient than individual Part D contractors implementing the process independently.

If a centralized option is not feasible, CMS may wish to consider centralizing as many functions as possible and allowing the social security deduction payment option. Given the significant financial protection provided by the new out of pocket maximum, targeted outreach (beyond standard member materials) should perhaps be limited to the beneficiaries likely to benefit from smoothing to avoid beneficiary confusion. Specifically, it seems members who are dual eligible, LIS or enrolled in plans with no Part D member cost sharing are unlikely to benefit from this program. Additionally, there is concern that the proposed variable monthly billing may be difficult for beneficiaries to anticipate and understand. CMS may wish to consider a simplified program such as an annual opt-in with level billing set at 1/12 of the MOOP with a year-end reconciliation of any beneficiary overpayment if the MOOP is not reached in the calendar year.

Libba Yates

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Date: September 6, 2023

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 the draft guidance for the Medicare Prescription Payment Plan shared in September 2023.

Support

The Wisconsin Bureau of Aging and Disability Resources supports the following policies described in the guidance:

Education

- Requirement for notices into include information about the Low Income Subsidy (LIS); suggestions for information and resources include:
 - o Fact sheets about the Medicare Prescription Payment Plan program and the LIS programs for State Health Insurance Assistance Program (SHIP) counselors to use
 - o Fact sheets with space to calculate cost/benefit of prescription payment program. Factsheets should include LIS income limits and SHIP referral information. Pharmacies could potentially share the factsheet in paper, by QR code scan, text, or email.
 - o Processes that improve the process for transferring LIS applications to states for Medicare Savings Program (MSP) eligibility consideration

(Reference: 70.2 Interactions Between LIS and Medicare Prescription Payment Plan, pages 27-28)

- Requirement for Part D sponsors and pharmacies to provide education through general and targeted outreach

(Reference: 60.1 General Part D Enrollee Outreach Requirements, page 19;
60.2 Targeted Part D Enrollee Outreach Requirements, page 19)

- Requirement for Part D sponsors to include program information in annual notices of change (ANOC)
 - o We suggest that the ANOC include a chart depicting how the program could have helped the person in the current year; for those with stable prescription needs, it could be a helpful tool to decide.
 - o The ANOC could also include a workspace for estimating next year's costs.

(Reference: 70.3.4 Processing Election Request Before a Plan Year Begins While Remaining in Same Plan, pages 29-30)

Enrollment

- Protections regarding involuntarily disenrollment due to nonpayment of bills requiring Part D plan sponsors to:
 - o issue timely notices for missed payments,
 - o offer a grace period of at least two months if a program participant fails to pay a monthly billed amount
 - o provide a reinstatement process to allow individuals to resume participation in the program in the same plan year if they demonstrate good cause
 - o develop procedures for the timely hearing and resolution of grievances.

- Inability of Part D plan sponsors to terminate Part D plan enrollment due to nonpayment of bills or decline future plan enrollments

(Reference: 80.4 Prohibition on Part D Plan Enrollment Penalties for Failure to Pay Medicare Prescription Payment Plan Amount Billed, page 41)

- Ability of beneficiaries to opt in to (or out of) the program prior to the start of the calendar year or any time during the calendar year

(Reference: 70.1 Part D Enrollee Eligibility, page 27; 80.1 Voluntary Terminations, page 38)

- Ability of beneficiaries to enroll into the program electronically or via paper or phone

(Reference: 70.3.1 Format of Election Requests, page 28)

- Requirements for Part D sponsors to acknowledge enrollment requests by mail or electronically

(Reference: 70.3.3 Processing Election Request at the Time of Enrollment in a New Plan, page 30)

- Requirement for Part D sponsors to request missing information from an enrollment request rather than automatically denying an incomplete request

(Reference: 70.3.3 Processing Election Request at the Time of Enrollment in a New Plan, page 30)

- Requirement for Part D sponsors to mail denial notices with the reason for denial and appeal rights

(Reference: 70.3.3 Processing Election Request at the Time of Enrollment in a New Plan, page 30)

- Requirement for Part D sponsors to process mid-year enrollment requests within 24 hours, unless the beneficiary is attempting a real-time, immediate enrollment at the pharmacy counter (see 70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs and related comment in support of the “clarification code” option)

(Reference: 70.3.5 Processing Election Request During a Plan Year, page 32)

Payment

- Requirements for billing statements listed in the guidance
 - o We recommend that billing statements be written in plain language with a step-by-step calculation explanation.

(Reference: 40. Participant Billing Requirements, page 13)

- Requirements will apply uniformly to all pharmacy types
(Reference: 50.3 Requirements for Different Pharmacy Types, page 18)
- Requirement that bills continue and not exceed the monthly cap after an involuntary termination; policy that Part D sponsors
(Reference: 50.3 Requirements for Different Pharmacy Types, page 18)
- Establishment of a two month grace period for unpaid bills
(Reference: 80.2.2 Required Grace Period and Reinstatement, page 40)
- Requirement for Part D sponsors to reinstate involuntarily terminated beneficiaries who demonstrate good cause; option for Part D sponsors to reinstate involuntarily terminated beneficiaries who pay all overdue bills even if they did not have good cause
(Reference: 80.2.2 Required Grace Period and Reinstatement, page 40)

Against

The Wisconsin Bureau of Aging and Disability Resources is against the following policies described in the guidance:

Involuntary disenrollment

- **Beneficiaries who are involuntarily disenrolled** from the program for nonpayment of bills **should not be prohibited from future participation.**

(Reference: 80.3 Preclusion of Election in a Subsequent Plan Year, page 40)

Comments and suggested changes

- CMS should consider renaming this payment option so it doesn't include the word "plan," which may be confused with Part D and Medicare Advantage *plans*. E.g., "Medicare Prescription Payment Agreement"

Appeals and grievances

- We recommend that CMS share examples of how the Part D grievance procedures may apply to Medicare Prescription Payment Plan issues

(Reference: 90. Participant Disputes, pages 41-42)

Data

- We recommend CMS also require that Part D sponsors collect and report the following data elements:
 - o Number of miscalculated payment agreements
 - o Number of grievances related to the Medicare Prescription Payment Plan program and grievances outcomes (e.g., in favor or against beneficiary)
 - o Number of appeals related to the Medicare Prescription Payment Plan program and appeal outcomes (e.g., in favor or against beneficiary)
 - o Number of enrollment requests submitted with SHIP assistance

(Reference: 100. Data Submission Requirements, pages 42-43)

Education

- It would be helpful for CMS to provide an Excel spreadsheet template to help beneficiaries and advocates calculate estimated costs, in addition to a Medicare.gov Plan Finder feature.
- Part D sponsors will be required to conduct targeted outreach "prior to and during the plan year". Since, as CMS notes, program enrollment will be increasingly less beneficial as the calendar year progresses, CMS should **"cut-off" targeted outreach during the last quarter of the year** so as not to confuse beneficiaries who would likely no longer benefit and to avoid confusion during the Open Enrollment Period.

(Reference: 60.2.2 Targeted Part D Enrollee Notification Prior to POS, page 23; 60.2.4 POS Notification Requirements, page 26)

- The combined cost of prescriptions should be used to determine whether a beneficiary would likely benefit from participation (regarding targeted outreach), rather than individual prescription cost share.

(Reference: 60.2.3 Targeted Part D Enrollee Notification at POS, page 24)

Enrollment

- **Clarification is needed on whether beneficiaries must re-enroll in the program each year** and how that would work procedurally.
- **Consider tracking whether the beneficiary received assistance to enroll** from someone who is not their legal representative, such as a case manager or State Health Insurance Assistance Program (SHIP) counselor. **We recommend that CMS track SHIP assistance**, i.e. through a checkbox (or verbal question) asking, "Did a State Health Insurance Assistance Program (SHIP) counselor help you with this application (or help you understand this program)?"

(Reference: 70.3.1 Format of Election Requests, page 29)

- Part D sponsors should be required to attempt at least two phone calls on separate days and send a letter to collect missing signatures on enrollment requests.

(Reference: 70.3.1 Format of Election Requests, page 29)

- **CMS should require Part D sponsors to give beneficiaries 30 days (instead of 21 days) to respond to requests for missing information.** Due to mail delays as well as the time it may take to gather the required information, 21 days is insufficient time.

(Reference: 70.3.3 Processing Election Request at the Time of Enrollment in a New Plan, page 30)

- **We support the option for pharmacists to use a new “clarification code” to process real-time enrollments at the pharmacy counter.** This would allow the beneficiary to immediately get their prescriptions, regardless of their access to technology, and therefore would ensure equitable access to the program.
 - o The phone option described in the guidance is also viable, with the potential drawback of long wait times; some beneficiaries have pay-per-minute phones, so this is less ideal as an option.
 - o A web-based enrollment would not be accessible to all beneficiaries and so would only be viable as an addition to the code or phone options.

(Reference: 70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs, pages 34-36)

Payments

- **CMS should require, rather than encourage, that Part D sponsors offer:**
 - o **Multiple means of payment** (including auto-pay with a bank, credit and debit cards, checks, cash, etc.).
 - o **Flexibility** around requesting a specific day of the month for program charges and withdrawals from bank accounts.

Reference: 40. Participant Billing Requirements (page 12)

Explanation: Flexibility in payment methods and dates is necessary for low-income Medicare beneficiaries, who often lack access to technology like online banking and are paying multiple bills on limited, fixed budgets. Uniformity in this process will improve equity in the program and also reduce confusion.

- **CMS should *not* allow plans to auto-deduct Medicare Prescription Payment Plan bill payments from Social Security checks.**
- **CMS should require, rather than encourage, that Part D sponsors apply payments first to premiums** to avoid disenrollment, when in doubt.

(Reference: 40.1 Prioritization of Premium Payments, page 14)

- **Beneficiaries should not be penalized for Part D sponsors' billing or payment processing mistakes.**

(Reference: 40.2 Financial Reconciliation Process, page 14)

Medicare.gov

- **The Medicare.gov Plan Finder should be updated** to reflect projected costs for people who are enrolled or are considering enrolling in the Medicare Prescription Payment Plan program.
 - o Program participation should be able to be toggled on and off to compare projected costs
 - o For both Medicare.gov accounts and anonymous searches
- **Program enrollment information and notices should be visible online to people with Medicare.gov accounts**, including enrollment confirmation notices, billing statements, and termination notices.
- It seems the guidance requires this already, but to confirm, the Medicare.gov Plan Finder should allow simultaneous enrollment into the Medicare Prescription Payment Plan while electronically enrolling into a Part D (PDP or MA-PD) plan.

(Reference: 70.3.1 Format of Election Requests, page 28; 70.3.3 Processing Election Request at the Time of Enrollment in a New Plan, page 29)

Notices

- **CMS should consider standardizing the envelope and notice design**, such as paper color, to make it easy for participants to identify bills and for advocates to describe the notices. (Many low-income beneficiaries do not open their mail timely and/or receive lots of Medicare plan advertisements; it would be easy for them to miss these important bills.)
- **CMS should require inclusion of information about free and unbiased SHIP services, with state contact information, on program notices.**

(Reference: 40. Participant Billing Requirements, page 13; 80.2.1 Notice Requirement, page 39)