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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Center (Medicare Rights) appreciates this opportunity to comment on the Medicare Prescription Payment Plan (MPPP) draft guidance.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) https://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 polices 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.

 $\frac{https://www.aarp.org/content/dam/aarp/research/surveys_statistics/health/2021/drug-prices-older-americans-concerns.doi.10.26419-2Fres.00476.001.pdf.$

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)

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."

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 the 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,

Fred Riccardi

President

Medicare Rights Center

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