March 15, 2024

Submitted via email to PartDPaymentPolicy@cms.hhs.gov with the subject line "Medicare Prescription Payment Plan Guidance

Dr. Meena Seshamani, M.D., Ph.D.
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U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

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

Dear Dr. Seshamani:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the U.S. Centers for Medicare & Medicaid Services' (CMS) part two guidance regarding the Maximum Monthly Cap on Cost-Sharing Payments Program established by section 11202 of the Inflation Reduction Act (IRA).[1] We thank CMS for the timely issuance of this important guidance.

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 275 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and through the exchanges established by the Affordable Care Act. Our members are committed to increasing affordability of drugs and work closely with plans and issuers to secure lower costs for prescription drugs and achieve better health outcomes.

PCMA appreciates the timely issuance of additional guidance for the Medicare Prescription Payment Plan (referred to as M3P) for year one of the program. We also appreciate the opportunity to provide comments as both CMS and the industry work to bridge the application divide between congressional intent and successful program implementation. We would like to also thank the agency for the recently released final part one guidance and the issuance of draft model materials for beneficiary identification, notification and termination addressed in this

[1] CMS. "Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025." February 15, 2024. Available at Medicare Prescription Payment Plan Draft Part Two Guidance (cms.gov)

guidance. We are commenting on the actual model materials separately under the Paperwork Reduction Act process CMS has initiated.

PCMA would like to highlight some general concerns focusing on time constraints given the volume of novel model documents and processes needed. In recognition of the burden of these new administrative processes, we request that CMS allow for flexibility as the industry prepares for the launch of the M3P program by the end of the year. Given the need for time and resource allocation, we recommend that the model materials be expedited to the greatest extent possible and be finalized by late June. With regards to program implementation, we request maximum flexibility and ask for a grace period and enforcement discretion, especially since there will be beneficiary confusion, administrative hurdles, and an overall increase in complaints.

PCMA is also concerned that the final part one M3P guidance, released by CMS on February 29, 2024, includes references to many proposed part two M3P requirements not yet finalized. These references from a final guidance to a proposed guidance appear to indicate that CMS has seemingly assumed that some of its proposed requirements will be finalized even before considering stakeholder's feedback. We recommend that CMS consider all stakeholder's feedback in earnest before finalizing this part two guidance.

Our specific comments on CMS's part two guidance on M3P can be summarized as follows:

- **Required materials:**
  - Given the need for time and resource allocation, we recommend that the model materials be expedited to the greatest extent possible and be finalized by late June, or as soon as possible under the Paperwork Reduction Act's timeline for approval.
- **Likely to benefit**:
  - *Likely to Benefit Definition*: CMS should use True Out-of-Pocket costs (TrOOP) rather than out-of-pocket costs (OOPC) for likely to benefit threshold calculations.
  - *Likely to Benefit Communication*: CMS should provide clarifications with regards to the questions posed regarding beneficiary focused communication related to likely to benefit.
  - *Likely to Benefit Information Dissemination*: CMS should exclude the M3P election request form with the Member ID card to prevent beneficiary's submission of the election form when they may not be likely to benefit. CMS should consider not including M3P information in Explanation of Benefits (EOBs) and simply referring beneficiaries to a robust source. Finally, CMS should clarify which state and federal consumer financial

protection laws, if any, are applicable for the M3P program.

- **Language Access and Accessibility**

  - *Elections*: CMS should allow plan-sponsors to decide whether to allow beneficiaries in good standing to remain enrolled in their plan's M3P program yearly. CMS should provide guidance on how to disenroll members with delinquent balances due to the 60-day grace period if an auto-renew option is added.

  - *Multi-Language Insert (MLI):* CMS should provide all pharmacies with materials either for top-5 languages or 5% languages as proposed during the M3P guidance-related briefing and discussion on March 7, 2024.

  - *CMS Enrollee Education and Outreach*: All beneficiary-facing communication needs to be easy to understand and be provided through easy-to-access modes such as websites, YouTube, Facebook, and community settings.

  - *Pharmacy Process*: CMS should provide guidance on how to address difficulty in identifying populations likely to benefit. CMS should allow for flexibility in providing point-of-sale (POS) notification for those who may not benefit from the M3P program.

  - *Part D Sponsor Operational Requirements*: CMS should allow for a grace period when addressing M3P program-related complaints and grievances.

I. Required materials and content for beneficiary

The IRA requires Part D sponsors to notify prospective enrollees prior to the plan year through promotional materials of the option to participate in the M3P. In addition, Part D sponsors must provide educational materials to current enrollees. To facilitate this communication, CMS is requiring Part D sponsors to use existing Part D required materials to inform and educate enrollees about the program. Draft materials have been posted by CMS and are not the subject of these specific comments. Part D sponsors may also include information about the M3P in their own marketing materials.

In general, we do not have any concerns with most of the proposed required communications, and request that the model materials be finalized as soon as feasible. From a beneficiary, plan and PBM perspective, it would be helpful if CMS provided a website that housed all this information along with beneficiary focused educational materials and videos.

PCMA Recommendation: Given the need for time and resource allocation, we recommend that the model materials be expedited to the greatest extent possible and be

finalized by late June, or as soon as possible under the Paperwork Reduction Act's timeline for approval.

II. Likely to Benefit

a. "Likely to Benefit" Definition

PCMA recognizes that one of the most important aspects of the M3P program is to identify beneficiaries who are most "likely to benefit." The success of the M3P program depends on reaching these individuals as early as possible and in as many ways as possible. The $600 single claim threshold for identifying these individuals was finalized in part one of the guidance. We thank CMS for incorporating public comments in finalizing this number. In addition to the threshold value, CMS specifies that sponsors must assess current enrollees' costs from the current year based on their out-of-pocket costs (OOPC). We recommend that threshold calculations use True Out-of-Pocket (TrOOP) costs rather than OOPC. M3P should initially only be targeted to those likely to hit their maximum out-of-pocket costs.

PCMA Recommendation: CMS should use TrOOP rather than OOPC for likely to benefit threshold calculations.

b. Likely to Benefit Identification and Communication

From an administrative standpoint, CMS should note that PBMs cannot produce ad hoc notices along with coverage decision letters, so the "likely to benefit" notice would have to be coded into all client decision templates.

For communications related to "likely to benefit" status, we ask CMS for clarity on the following:

- Does CMS expect that the identification of "likely to benefit" beneficiaries be limited to those with favorable coverage determinations? Would that also include partially favorable decisions?
- How do we address a member requesting a Tier Exception? It is our concern that there would be compounded risk if, in an untimely coverage determination, the notice was also not delivered timely to the beneficiary.
- CMS should note that during a coverage review, it may not be known what quantity will be prescribed and what the day supply will be, whether 30 or 90 days. This will make it difficult to determine whether a member's cost share will be above the threshold of $600. Members who are not likely to benefit may receive a notification. How do we address this issue and mitigate it?
- Most importantly, if beneficiary expresses concern about the price of a drug, what should take priority: offering a coverage determination or tiering exception to get a lower price, versus offering the M3P "likely to benefit" information?

- Does the information need to be sent separately from the coverage determination notification or can it be included as an attachment with the decision? We recommend this requirement be applicable only for approved coverage determinations or appeals since sending the M3P information and election form when the request results in a denial would not benefit the beneficiary and may, in fact, lead to the submission of an election form when the request is denied. We also request CMS to provide instructions if the appeal is approved at the Independent Review Entity (IRE) stage.
- Does CMS envision a hierarchy of administrative steps from formulary tiering to exceptions processes and M3P program enrollment?
- CMS should clarify that members precluded from M3P, such as involuntary terminated members who have not paid, should not be sent a likely to benefit notice by pharmacies or by the plan.

***PCMA Recommendation*: CMS should provide clarifications with regards to the questions above when finalizing part two of the guidance.**

c. "Likely to Benefit" Information Dissemination

For CY 2025, CMS will require Part D sponsors to include the following M3P materials with the membership ID card hard copy mailing: information regarding the M3P and a M3P election request form. We would like to note that not all beneficiaries receive a new ID card each year. Is CMS comfortable with this mailing only going to members who are receiving an ID card? If not, CMS should clarify the requirement for plans to provide M3P information with the ID card mailing, given that not all beneficiaries are likely to benefit. If CMS prefers that all members receive M3P related information, it might be better to have it sent with a confirmation of enrollment communication or something similar.

PCMA also has concerns about including information about the M3P in the EOB document. EOBs are sent to enrollees multiple times throughout the coverage year, including late in the year, when M3P enrollment would be less beneficial. This requirement would also mean that members who are not likely to benefit from M3P enrollment would receive this information on multiple occasions. We recommend that CMS modify this proposal to require the inclusion of high-level information about the M3P in the EOB, and direct members to where they can learn more about M3P if they are interested.

In addition, PCMA urges CMS to work with federal consumer financial protection agencies to clarify that federal and state consumer financial protection laws and regulations do not apply to the M3P. In the M3P Final Part One Guidance, CMS alludes to the applicability of federal and state laws in the context of collection of unpaid balances, however, the final part one guidance is vague as to which specific laws and regulations apply. We are concerned that full applicability of consumer financial protection laws and regulations associated with consumer credit and

lending will undermine the goals of the M3P by confusing consumers and creating a barrier to access.

***PCMA Recommendation*: CMS should exclude the M3P election request form with the Member ID card to prevent beneficiary submission of the election form when they may not be likely to benefit. CMS should consider not including M3P information in EOBs and simply referring beneficiaries to a robust source. Finally, CMS should clarify which state and federal consumer financial protection laws, if any, are applicable for the M3P program.**

III. Language Access and Accessibility

a. Elections

CMS is developing a model "M3P Participation Request Form" for Part D sponsors that enrollees can use to initiate the request to opt into the program. Part D sponsors must accept an election request regardless of the format of the request and must contact the enrollee to collect all necessary information and to document their agreement to the M3P terms and conditions. Once the program election request is accepted by the Part D sponsors, the sponsor must communicate that the election request to participate in the M3P has been accepted and effectuated via written notice, according to the time frames in the final part one guidance.

PCMA realizes that the initial setup and enrollment will be time and resource intensive given the newness of the program. However, once elections are made, CMS should consider administrative simplifications and automation of some processes such as auto-renewal. Auto-renewal should be a choice for plan sponsors to offer to beneficiaries. There also needs to be a disenrollment process for those who may have opted into auto-renewal but are in the 60-day delinquency grace period or have been terminated from the program due to delinquency.

***PCMA Recommendation*: CMS should allow plan sponsors to decide whether to allow beneficiaries in good standing to remain enrolled in their plan's M3P program yearly. CMS should provide guidance on how to disenroll members with delinquent balances due to the 60-day grace period if an auto-renew option is added**.

b. Multi-Language Insert (MLI)

CMS should note that pharmacies do not have visibility into beneficiary language preference and needs. This information resides with the plan sponsor. Hence, the proposed requirement will be operationally difficult and require plans to create processes for providing pharmacies with the 5% language threshold specific notices based on beneficiary demographics and language needs at each pharmacy. However, beneficiaries can go to different pharmacies at various

points in time or at the same time with multiple prescriptions, which will add administrative complexity and lead to pharmacy level communication issues.

***PCMA Recommendation*: CMS should provide all pharmacies with materials either for top-5 languages or 5% languages as proposed during the M3P guidance-related briefing and discussion on March 7, 2024.**

IV. CMS Enrollee Education and Outreach

To facilitate broad education about the M3P, CMS will develop new Part D educational resources and will update existing Part D resources that provide individuals with information on Medicare Part D ("CMS-developed educational product"). Part D sponsors will be permitted to use this product to satisfy their requirements to provide information on: (1) their website; (2) alongside the election request form in the ID card mailing; and (3) alongside the Likely to Benefit Notice when sent prior to or during the plan year. Other interested parties (namely pharmacies and providers) are also encouraged to use this product to educate enrollees.

CMS should consider alternative ways for Part D enrollees to receive information in an easy-to-understand manner such as YouTube and Facebook videos. All educational materials, written/videos/websites) should be targeted to all literacy levels and should be focus group tested for ease of comprehension. Additionally, CMS should provide more information on how they plan to include M3P updates in the Medicare Plan Finder. Will they include static messaging, or will they be detailed based on beneficiary inputs? Another consideration is that Employer Waiver Group Plans (EGWPs) are waived from providing information on websites due to the nature of these plan types. Therefore, EGWPs, due to the waiver for websites, should not be required to post information on websites.

***PCMA Recommendation*: All beneficiary facing communication needs to be easy to understand and be provided through easy to access modes such as website, YouTube, Facebook, and community settings.**

V. Pharmacy Process

In the proposed guidance, CMS asks Part D sponsors to ensure that network pharmacies disseminate education and resources related to the M3P. We are concerned that network pharmacies may object to further requirements without contractual changes to add enforcement mechanisms for pharmacies to provide any information to a Part D enrollee at the (POS). It is important for CMS clarify to that a contractual provision compelling pharmacies to conduct this action is sufficient to satisfy the proposed "ensure" requirement. It is unrealistic and burdensome to require pharmacies to track and report this information to plan sponsors. Therefore, the contractual provision compelling the pharmacies to provide the information when appropriate should be enough.

PCMA asks that CMS elaborate on how the communication requirements will be applied to mail-order pharmacies and specialty pharmacies. CMS specifically calls out considerations for long-term care pharmacies and Indian Health Service (IHS) pharmacies but offers little on how POS notifications would work when the enrollee isn't in a physical pharmacy setting. Specifically, for IHS, Tribe and Tribal Organization, and Urban Indian Organization (ITU) pharmacies, the process for identifying ITU members is not visible to the pharmacy industry. The claim adjudication process can identify the ITU pharmacies, but there is not a systematic way to identify members. Moreover, ITU members do not pay a copay; however, this is accomplished through a pharmacy process that is a backend process, and ITU claim still returns a copay on the claim transaction for a Part D claim.

PCMA asks that CMS clarify M3P billing processes if members with supplemental coverage opt to enroll in M3P. Supplemental coverage changes patient's liability (less than or greater than the Part D copay). This necessitates CMS's guidance on how to counsel these beneficiaries for both the sponsor and pharmacy. We also encourage CMS and sponsors to consider suppression of POS notification to the pharmacy, when the program is not truly beneficial to avoid member dissatisfaction with their sponsor and/or pharmacy. In addition, if there are other scenarios where offering the program is not ideal due to possible member abrasion, CMS should clarify how sponsors should maintain rules and suppress pharmacy notification, such as member obtaining multiple qualifying prescriptions from multiple pharmacies in a short period of time.

PCMA Recommendation: CMS should provide guidance on how to address difficulty in identifying populations likely to benefit. CMS should allow for flexibility in providing POS notification for those who may not benefit from the M3P program.

VI. Part D Sponsor Operational Requirements

CMS proposes to monitor and collect data about beneficiary complaints and grievances reported via the Medicare Claims Tracking Module (CTM) to assess compliance with the M3P requirements. CMS is assessing whether an additional CTM category or subcategory for the program is appropriate for future years. CMS also states that the agency may conduct specific audits of Part D sponsors' implementation of the program as well.

PCMA requests clarity about the type of audits CMS proposes to use in monitoring plan compliance on M3P. We request that plans have some flexibility during the first couple years of the program, and this allows for CMS to consider how best to address initial M3P program related complaints and grievances.

PCMA Recommendation: CMS should allow for a grace period when addressing M3P program related complaints and grievances.

VII. Conclusion

We appreciate the opportunity to provide this feedback to CMS on ways to address M3P implementation for the first year. Our concerns and discussion focus on timing constraints, administrative complexities and the risk of beneficiary confusion mostly. If you need any additional information, please reach out to me at tdube@pcmanet.org.

Sincerely,

Tim Dube

Tim Dube
Senior Vice President, Policy and Regulatory Insights

cc: Debjani Mukherjee, Senior Director, Regulatory Affairs