April 2, 2024

VIA ELECTRONIC SUBMISSION — Regulations.gov

William N. Parham, III
Director, Division of Information Collections and Regulatory Impacts
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-10185. Medicare Part D Reporting Requirements (OMB Control Number: 0938 0992)

Dear Mr. Parham:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the Medicare Prescription Payment Plan (MPPP) elements the Centers for Medicare & Medicaid Services (CMS) proposes to add to the Medicare Part D Reporting Requirements. CMS proposed these elements via an information collection request (ICR) announced February 2, 2024.[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).

As reflected in several recent comment letters to CMS on Part D redesign and the Medicare Prescription Payment Plan,[2] PhRMA supports successful implementation of the MPPP program. This program, combined with an annual maximum OOP cap ($2,000 in 2025) in Part D,[3] presents a unique opportunity to improve affordability to some of the sickest and most vulnerable beneficiaries, particularly those dealing with multiple costly diseases and chronic conditions. As noted in our prior comments, plan sponsors, pharmacies, patient navigators, and advocacy organizations will play an important role in successful implementation of MPPP in conjunction with robust beneficiary education and outreach by the agency itself. Our comments

[1] 89 Fed. Reg. 7398-99 (Feb. 2, 2024).
[2] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/P-R/PhRMA-Comments-on-MPPP-Guidance_Final-92023.pdf; https://phrma.org/resource-center/Topics/Medicare/PhRMA-Comments-on-Medicare-Prescription-Payment-Plan-Draft-Part-Two-Guidance
[3] SSA § 1860D-2(b)(2)(E).

on this ICR address just a few of the many important elements of this outreach related to plan sponsor reporting. We agree with CMS that Part D end-of-year reporting is an "integral resource for oversight, monitoring, compliance, and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries," and that "reporting sections' data are analyzed for program oversight to ensure the availability, accessibility, and acceptability of sponsors' services."[4]

PhRMA is concerned that the limited number of data elements that plans would need to report under the proposed ICR appear more oriented towards plans' management of costs rather than beneficiary health needs. Of the four proposed elements, three of them relate to participants' failure to pay balances and plans' preclusion of individuals from electing into MPPP in a subsequent year; only one relates to plan outreach to individuals likely to benefit from MPPP. In order to evaluate and ensure effective oversight of plan outreach and communication to beneficiaries on the MPPP, CMS should: revise and expand on some of the data elements plans must report and ensure that plan reporting is coupled with meaningful agency analysis and public reporting to ensure that individuals likely to benefit from MPPP are being made aware of the program by their plan sponsors and opting into the program as appropriate.

Specifically, in addition to reporting the total number of individuals a plan identifies as likely to benefit from MPPP, **CMS should require plans to report whether these individuals were identified a) by the Part D sponsor, prior to the plan year, b) by the Part D sponsor, during the plan year, or c) by the pharmacy at the point of sale (POS).** Requiring this additional information will enable CMS to better evaluate the effectiveness of different mechanisms for enrolling beneficiaries in MPPP, including plans' effectiveness in identifying and contacting individuals prior to the plan year, which represents an important early opportunity for participants to opt in to MPPP. To determine whether plans are engaging in proactive notification, CMS must collect data in a manner that allows it to disaggregate and differentiate by mechanism of notification. By disaggregating information in this way, CMS should be better able to identify whether the "likely to benefit" (LTB) notices are being sent to all individuals eligible for such notices under CMS guidance. This would also provide CMS the ability to match the PDE data to the mechanism of notification, which is important because CMS intends to use different thresholds for the likely to benefit notification prior to the plan year (i.e., beneficiaries who hit the $2,000 cap in the first 9 months of 2024) as compared to likely to benefit notification requirements during the plan year in 2025 (i.e., beneficiaries with OOP costs at least $600 for a single prescription).

To further support effective oversight and evaluation of plans' role in successful MPPP implementation, CMS should require that, for each of the three notification mechanisms (by plans and pharmacies) described above, Part D sponsors identify both the total number of individuals who opted into the program, as well as the total number of individuals who were notified but chose <u>not</u> to opt in.

[4] 89 Fed. Reg. at 7399.

Under CMS' proposed reporting requirement, the agency will collect data only on the total number of individuals notified, but not a breakdown of those who opted into the program versus those who did not elect to participate. While CMS should be receiving each plan benefit package's total number of MPPP participants through the MARx data collection,[5] such data will not be itemized by mechanism of notification. Collecting data in a more granular way (based on each notification method) will allow CMS to monitor and evaluate each notification methodology and determine whether the agency needs to refine the program for future years, particularly with respect to education, outreach, or notification thresholds.

PhRMA also recommends CMS add additional elements to collect data that will assist in evaluating MPPP implementation overall, particularly whether MPPP is reaching individuals who would benefit from the program based on the high OOP costs they incur.

None of CMS' proposed data elements speaks to whether CMS' MPPP implementation is capturing beneficiaries with sufficiently high monthly or annual out-of-pocket costs that suggest that electing MPPP would be of significant benefit to them. CMS has finalized a $600 single prescription threshold for notifying individuals at the point of sale that they are likely to benefit from MPPP. However, CMS' analysis of 2021 PDE data illustrates that a lower $400 single day out-of-pocket cost threshold would result in the identification of an additional 1.6 million individuals who would likely benefit from MPPP.[6] In addition, the single prescription threshold fails to capture individuals with multiple recurring OOP costs for prescriptions at slightly lower dollar amounts. Thus, CMS' own data indicate that the likely to benefit notices at the current $600 single prescription will miss a large contingent of Medicare beneficiaries who would benefit from MPPP. **PhRMA strongly recommends that CMS consider how it can collect and evaluate data that will allow greater scrutiny of the MPPP's successes and opportunities for improvement, including if the current per prescription threshold is at the appropriate amount.** If Part D end-of-year reporting is not the appropriate information collection vehicle for such scrutiny, then CMS should consider other collections (such as via researchers, satisfaction surveys, or through work by the HHS Assistant Secretary for Planning and Evaluation) that would allow more detailed analysis as soon as MPPP launches. Such analysis, for example, could consider:

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[5] *See* 89 Fed. Reg. 5239 (Jan. 26, 2024).

[6] *See* https://www.cms.gov/files/document/medicare-prescription-payment-plan-part-1-guidance.pdf at pp. 24-25. CMS tables show that, based on 2021 PDE data, a $600 single prescription threshold would identify 597,000 beneficiaries, 98% of whom (585,000) actually would have benefited from MPPP. A $400 single day threshold would identify 2.4 million beneficiaries, 2.2 million of whom (or 90%) actually would have benefitted from MPPP. CMS data thus shows that more than 1.6 million individuals (2.2 million – 585,000) would benefit from MPPP but may not be specifically notified of the program.

- Mean and median annual and average monthly out-of-pocket costs of enrollees who elect to participate in MPPP.
- Mean and median annual and average monthly out-of-pocket costs of enrollees notified that they were likely to benefit but who did not elect to participate, including each mechanism of notification (at the point-of-sale, by the plan sponsor prior to the plan year, and by the plan sponsor during to the plan year).
- Number of enrollees who meet the annual out-of-pocket cap that were notified or not notified that they were likely to benefit from MPPP and the distribution of such enrollees for each month of the calendar year (in other words, number of enrollees in January who meet the catastrophic, number in February, etc.).

PhRMA supports CMS' efforts to conduct oversight and monitor the implementation of the MPPP at both the plan and beneficiary levels. Through this oversight CMS must ensure that the program is implemented in a manner that is fair and equitable to all Medicare beneficiaries. In addition, CMS should collect and evaluate MPPP-related data in ways that capture any discrimination in MPPP outreach efforts against certain beneficiary groups, including those with lower incomes. At a minimum, CMS should closely monitor MPPP participation trends by different demographic groups within Part D. While PhRMA defers to CMS as to the appropriate vehicle for collecting data on the MPPP's operations, ensuring that such data are gathered, assessed, and reported on represent important steps to promote the program's success and make adjustments to ensure it is achieving the goal of improving affordability for individuals likely to benefit from it.

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PhRMA appreciates the opportunity to provide feedback on the Part D Reporting Requirements ICR and the proposed new data elements for the MPPP. We look forward to opportunities for continued collaboration with CMS in implementing the MPPP which is an important beneficiary affordability improvement in Part D. We are happy to discuss these comments and provide any further details or supplemental materials that you may request.

Sincerely,

Rebecca Jones Hunt

Deputy Vice President, Policy & Research

/s/

Judy Haron

Deputy Vice President, Law

Kristin Williams

Senior Manager, Policy & Research