June 24, 2024

VIA ELECTRONIC SUBMISSION — Reginfo.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 respond to the second opportunity for public comment on the Medicare Prescription Payment Plan (M3P) elements the Centers for Medicare & Medicaid Services (CMS) proposes to add to the Medicare Part D Reporting Requirements as detailed via an information collection request (ICR) announced May 24, 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).

PhRMA applauds CMS for incorporating recommended changes to the reporting requirements based on the comments it received after the initial release of the ICR. Specifically, PhRMA supports the inclusion of new measures to better delineate the efficiency of the "likely to benefit" identification process, measures to better track election request processing, and measures related to unsettled balances.

PhRMA believes the inclusion of these data elements in the reporting requirements will enable CMS to better evaluate the effectiveness of different mechanisms for enrolling beneficiaries in M3P, including plans' effectiveness in identifying and contacting individuals prior to the plan year, which represents an important early opportunity for participants to opt into M3P. By collecting data in a more granular way, CMS will be better positioned to determine whether the agency needs to refine the program for future years, particularly with respect to education, outreach, or notification thresholds. Such improvements will impact the affordability and medication adherence for some of the sickest and most vulnerable beneficiaries, particularly those dealing with multiple costly diseases and chronic conditions.

[1] 89 Fed. Reg. 45898-99 (May 24, 2024).

While we appreciate the inclusion of the above noted data elements, PhRMA remains concerned that CMS did not make additional changes as detailed in our initial comments on the ICR that will further support effective oversight and evaluation of plans' role in successful M3P implementation. **In particular, CMS should add data elements that will assist in evaluating M3P implementation overall, particularly whether M3P is reaching individuals who would benefit from the program based on the high out-of-pocket costs they incur.**

As noted in our previous comments, none of CMS' proposed data elements speak to whether CMS' M3P implementation is capturing beneficiaries with sufficiently high monthly or annual out-of-pocket costs that suggest that electing M3P 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 M3P. However, CMS' analysis of 2021 PDE data illustrates that lowering the single day out-of-pocket cost threshold to $400 would result in the identification of an additional 1.6 million individuals who would likely benefit from M3P.[2] In addition, the single prescription threshold fails to capture individuals with multiple recurring out-of-pocket 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 M3P. **PhRMA strongly recommends that CMS consider how it can collect and evaluate data that will allow greater scrutiny of the M3P'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 reconsider 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 M3P launches. As previously detailed in our first set of comments on the ICR, such analysis, for example, could consider:

- Mean and median annual and average monthly out-of-pocket costs of enrollees who elect to participate in M3P.
- 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).

[2] See Centers for Medicare & Medicaid Services (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), 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 M3P. A $400 single day threshold would identify 2.4 million beneficiaries, 2.2 million of whom (or 90%) actually would have benefited from M3P. CMS data thus shows that more than 1.6 million individuals (2.2 million – 585,000) would benefit from M3P but may not be specifically notified of the program.

- Number of enrollees who meet the annual out-of-pocket cap that were notified or not notified that they were likely to benefit from M3P and the distribution of such enrollees for each month of the calendar year (i.e., number of enrollees in January who meet the catastrophic, number in February, etc.).

PhRMA continues to support CMS' efforts to conduct oversight and monitor the implementation of the M3P 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 M3P-related data in ways that capture any discrimination in M3P outreach efforts against certain beneficiary groups, including those with lower incomes or certain health conditions or diagnoses. At a minimum, CMS should closely monitor M3P participation trends by different demographic groups within Part D. While PhRMA defers to CMS as to the appropriate vehicle for collecting data on the M3P'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 this additional feedback on the Part D Reporting Requirements ICR and the additional new data elements for the M3P. We look forward to opportunities for continued collaboration with CMS in implementing the M3P, 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
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/s/
Judy Haron
Deputy Vice President, Law

Kristin Williams
Senior Manager, Policy & Research