

June 27, 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-10882. The Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare
Prescription Payment Plan Model Documents**

Dear Mr. Parham:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this second opportunity to comment on *The Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882)*.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 recent comment letters to the Centers for Medicare & Medicaid Services (CMS) on Part D redesign and the Medicare Prescription Payment Plan (M3P),² PhRMA supports successful implementation of the M3P program. This program, combined with an annual maximum OOP cap (\$2,000 in 2025) in Part D, the \$35 copay for covered insulins, and changes to the Extra Help Program,³ presents a unique opportunity to significantly improve affordability for some of the sickest and most vulnerable beneficiaries, especially those with multiple costly diseases and chronic conditions.

PhRMA commends CMS for addressing some of our concerns with the initial M3P model documents.⁴ In particular, we support CMS' decision to:

¹ 89 Fed. Reg. 46,122 (May 28, 2024).

² PhRMA, Comment Letter on Medicare Prescription Payment Plan Guidance – Part One (Sept. 20, 2023), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/P-R/PhRMA-Comments-on-MPPP-Guidance_Final-92023.pdf; PhRMA, Comment Letter on Medicare Prescription Payment Plan Guidance – Part Two (Mar. 15, 2023), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Comment-Letters/PhRMA-Comments-on-Draft-Part-2-MPPP-Guidance_Final-31524.pdf.

³ Social Security Act (SSA) § 1860D-2(b)(4)(B)(i)(VII).

⁴ PhRMA, Commenter Letter on Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (Apr. 29, 2024).

- Include in the “Participant Request Form” (Exhibit 2) a brief description about the program at the top of the form, a placeholder for the plan’s phone number, and a clear section header for the part of the form an authorized representative would need to fill out; and
- Add optional language that plans can use in the “Voluntary Removal” Notice (Exhibit 6) for three different scenarios in which a beneficiary may choose to voluntarily end their participation in the M3P program: (1) general language; (2) termination from the program only; and (3) disenrollment from the Part D plan and termination from the program;
- Include language in the “Likely to Benefit” Notice that informs beneficiaries that if they choose to leave the M3P program they would still owe their plan for any unpaid amounts that were incurred during their participation in the program.

General Comments

PhRMA appreciates that CMS updated the model notices to increase readability, uses plain language, includes explanatory instructions to Part D plans in each notice, and specifies elements within each notice that may be tailored by plans. We support CMS’ decision to require model notices to include all model language exactly as written, except where otherwise indicated in the model notices. Content standardization ensures that all beneficiary notices are consistent across Part D plan sponsors. As we noted previously, standardizing these materials in the entirety, or key content within them, is particularly important in the first year of the M3P program.

It is imperative that CMS implement the M3P program in a manner that benefits Medicare beneficiaries and we appreciate CMS’ efforts to improve the program’s model notices. We are pleased to offer the following additional comments to reiterate key issues expressed in our April 29, 2024 comments.

Exhibit 2: Medicare Prescription Payment Plan Participation Request Form

We appreciate that CMS included a description of the M3P at the top of Participation Request Form, however, we recommend the following two additional changes:

- Add a placeholder for the plan’s phone number in the section for the plan’s information in the event a beneficiary may need assistance while filling out the form (currently, the form only includes plan name, address, fax number, and email); and
- Add a clear header to the section of the form that is meant to be filled out by an authorized representative of the beneficiary.

We reiterate our recommendation that CMS provide guidelines for plans regarding the terms and conditions that plans can place at the end of the form to ensure clarity on content and to ensure that onerous terms related to the program are not added by plans.

Exhibit 3: Part D Sponsor Notice to Acknowledge Acceptance of Election to the Medicare Prescription Payment Plan

We believe it is important for beneficiaries to understand they can re-elect into the M3P program after termination for missing a payment. We recommend that CMS add language under the

“What happens if I don’t pay my bill?” section of this notice stating that a beneficiary can be reinstated in the program if they repay any owed amounts to their plan.

Under the “Can I leave the Medicare Prescription Payment Plan” section, we appreciate CMS including language regarding a beneficiary's obligation to repay any amounts owed to a plan if the beneficiary no longer participates in the payment option. Since this section also discusses a beneficiary leaving or changing Medicare drug plans, CMS should include additional language regarding paying amounts owed to a Part D plan when they change plans. This section, as currently written, could be confusing to beneficiaries as the “Keep in mind” bullet points switch back and forth between leaving the M3P plan, a Part D plan, and enrolling in a new M3P plan with a new Part D plan.

Finally, we continue to encourage CMS to add language notifying the beneficiary that they must annually elect to participate in the program. This language will help avoid a situation where a beneficiary assumes that one enrollment into the M3P will suffice so long as they do not change Part D plans.

Exhibit 4: Part D Sponsor Notice for Failure to Make Payments Under the Medicare Prescription Payment Plan & Exhibit 5: Part D Sponsor Notice for Failure to Make Payments Under Medicare Prescription Payment Plan – Notification of Termination of Participation in the Medicare Prescription Payment Plan

We welcome CMS including language in the model materials to help distinguish between failing to make payments under the M3P program and continuing enrollment in the Part D plan. It is vital that beneficiaries understand the distinction between M3P and the program’s goals and enrollment in Part D. We are also pleased that the model materials contain consistent language about other programs that could help lower costs, which may help additional beneficiaries to reduce their overall health costs.

We offer the same recommendation to CMS regarding clear and consistent language about reinstatement into the M3P program. The model materials should make clear that beneficiaries have an opportunity to re-elect into the M3P program provided they repay any outstanding balances. The exact steps required to effectuate re-enrollment should be clearly detailed in the notices.

Exhibit 6: Part D Sponsor Notice of Voluntary Removal from the Medicare Prescription Payment Plan

As noted above, we thank CMS for including in the “Voluntary Removal” notice additional optional language that plans can use for three different scenarios in which a beneficiary may choose to voluntarily end their participation in the M3P program: (1) general language; (2) termination from the program only; and (3) disenrollment from the Part D plan and termination from the program.

PhRMA appreciates this additional opportunity to provide feedback on the Medicare Prescription Payment Plan Model Documents ICR. We look forward to continued collaboration with CMS in implementing the M3P, which is an important beneficiary affordability improvement in Part D. These model documents represent one piece of the broader implementation efforts related to the M3P program. We encourage CMS to move forward with its larger education and outreach efforts related to the program. PhRMA is happy to discuss these comments and provide any further details or materials.

Sincerely,



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Deputy Vice President, Policy & Research

/s/

Judy Haron
Deputy Vice President, Law



Kristin Williams
Senior Manager, Policy & Research