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Mr. William N. Parham, III
Director, Paperwork Reduction Staff
Office of Strategic Operations & Regulatory Affairs
U.S. Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Agency Information Collection Activities: Proposed Collection; Comment Request, Document Identifier CMS–10846

Dear Mr. Parham:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to comment on the information collection request (ICR) issued by the U.S. Centers for Medicare & Medicaid Services (CMS) titled: "Agency Information Collection Activities: Proposed Collection; Comment Request," as published in the *Federal Register* on July 7, 2023.[1]

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 plans offered for sale on the Exchanges established by the Affordable Care Act. In our comments below, we support CMS's proposed framework for the Manufacturer Discount Program (MDP) agreement and reiterate our support for several key aspects of it. We also repeat our recommendation that CMS work now to align the MDP with the future agreement for drugs subject to the Medicare Drug Negotiation Program (MDNP). Our detailed comments follow.

This ICR is related to the Inflation Reduction Act's (IRA) Part D benefit redesign provisions for plan year 2025. Under this ICR, and previous guidance,[2] CMS proposed a draft agreement for manufacturers to provide discounts during the initial coverage period and catastrophic period, in place of the existing Coverage Gap Discount Program (CGDP). PCMA provided comments to both documents, along with comments on CMS's draft program guidance for the MDNP issued

[1] 88 Fed. Reg. 43,355, July 7, 2023.
[2] CMS, "Medicare Part D Manufacturer Discount Program Draft Guidance and Request for Comment," May 12, 2023.

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on March 15, 2023.[3] **In these comments, we reiterate our recommendation to align the MDP and MDNP manufacturer agreements in order to most efficiently administer the Part D program on behalf of beneficiaries.** We also raise one additional concern, which has recently surfaced in the CGDP and which CMS should address in the MDP agreement and overall program guidance.

1. **PCMA supports CMS's efforts to make the MDP agreement similar to the CGDP agreement.**

The IRA simplifies Part D's standard benefit design, reducing cost sharing for beneficiaries. The law eliminates the current coverage gap and associated CGDP, replacing it with a new MDP as of January 1, 2025. The CGDP today provides a 70% discount for "applicable drugs" paid by manufacturers on behalf of beneficiaries at the point of sale for prescriptions that are dispensed during the Part D benefit's coverage gap. The new MDP instead provides a graduated discount of 10% or 20% for the same "applicable drugs" made by "applicable manufacturers" for all purchases beyond the beneficiaries' deductible including after they have reached the new out-of-pocket maximum, with some phase-ins related to manufacturer size.

In transitioning from the CGDP to the MDP, CMS states, "Because the MDP requirements largely mirror the requirements for the existing CGDP, CMS intends to implement the MDP in a manner similar to the CGDP."[4] Part D plans and their contracted PBMs play a crucial role in the administration of the current CGDP and also have a vested interest in maintaining a highly similar system for the MDP, since so many aspects of the Part D program are otherwise changing in ways that might confuse beneficiaries. We appreciate CMS's intentions on keeping the current framework in place with new terms, including the use of a third party administrator (TPA) to aggregate Part D data, distribute invoices to manufacturers, reconcile disputes, and reimburse Part D plans. **We support CMS's stated intention to largely mirror the CGDP, as reflected in the new draft agreement.**

2. **PCMA recommends that CMS align the new MDP with the agreement and process for Part D covered drugs assigned maximum fair prices.**

Finally, in implementing the agreement described in the final MDNP's direct negotiation guidance for initial price applicability year (IPAY) 2026, dated June 30, 2023,[5] CMS states that it will engage with a Medicare Transaction Facilitator (MTF) "to facilitate the

[3] CMS, "Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments." Available at https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf. March 15, 2023.
[4] CMS-10846, Supporting Statement-Part A.
[5] See Section 40.4 under which manufacturers must offer access to the MFP to all eligible dispensers.

exchange of data between supply chain entities to verify eligibility of MFP-eligible individuals." The role of the MTF would be to ensure that purchasers who dispense drugs at the maximum fair price (MFP) are reimbursed for the difference between their acquisition cost and the MFP within 14 days, as required by law. **PCMA believes that the best path forward is to delegate the role of MTF to the same TPA that will be administering the MDP.** The MDP TPA will have full available information to determine whether a particular claim is MFP-eligible. (MFP-eligible claims are exempt from being assessed the MDP.) We understand the TPA will need additional information for other carve-outs and exclusions, namely 340B claim and contract pharmacy status. We describe a potential approach below.

Given the statutory duplicate discount provision at SSA §§ 1193(d), CMS has the authority to require covered entities to report to the TPA this additional information within a certain period after dispensing the drug. We understand that covered entities have the capability to determine a 340B-eligible prescription under the replenishment model within days after the date of the drug being dispensed, in order to properly accumulate such prescriptions in their accumulator software. By providing this information to the TPA, the TPA can serve as a centralized clearing house for purposes of identifying MFP-eligible versus 340B-eligible prescriptions. Delegating these functions to any other vendor would require the development of a *de novo* system in place. By relying on the MDP TPA for MFP access, including in cases where a prescription is also 340B-eligible, CMS can best ensure that beneficiaries will receive the lower of the MFP or 340B price (where applicable) at the point of sale. Finally, using the existing claims adjudication system and TPA for both new discount programs makes seamless the experience for beneficiaries. It will also simplify explanation of benefits calculations and production, whether both discounts are either entered into separate Prescription Drug Event fields or the same one.

3. PCMA recommends that manufacturer discounts provided under the MDP and MDNP be provided to plans prospectively on a risk-adjusted basis.

We also continue to recommend that CMS provide risk adjusted interim payments to Part D plan sponsors to cover the "float" they are providing to pharmacies, both for MDP payments and MFP-based payments. Twenty percent of a high-cost specialty drug discount can be a significant burden for smaller plans to float to pharmacies, in the event of manufacturer disputes. In fact, nearly 100 individual drugs have per-claim costs whose MDPs in the catastrophic phase (20%) would exceed those drugs' entire Coverage Gap Discount Program liability today. More than 400 drugs have expected *annual* per-beneficiary MDP payments that exceed today's CGDP payments.[6] MFPs will be at least 25% lower than prices at the pharmacy counter today. Plan sponsors will be taking on significant financial

[6] PCMA analysis of the 2021 Medicare Part D spending dashboard.

risk if a manufacturer disputes having to offer the MFP for a given claim. CMS should provide upfront funding to plans for this estimated exposure.

4. **PCMA recommends that CMS create a limited exception to the 38-day repayment period for manufacturers.**

In working with our members on the transition to the MDP, we have become aware of a situation where through no fault of the manufacturer, there is a payment processing delay. Section 80.2.3 requires that manufacturers repay Part D sponsors no later than 38 calendar days from receipt of each invoice. However, we request that CMS consider waiving or extending this 38-day timeline when a late payment has occurred due to a reasonable cause, such as an issue with the manufacturer's payment portal account. Member companies have reported that failed payment initiation requires the intervention of the TPA, which can take several days or weeks. If the payment cannot be sent in 38 days, it triggers a penalty and manufacturers may instead appeal the claim, slowing down repayment. CMS should address this in the final guidance and allow an exception for payment processing errors. Any such exception should also be available for processing of MFPs and the resulting price differential, for similar reasons. A delayed payment is far preferable to a disputed one.

Conclusion

We appreciate the opportunity to comment on this ICR, as CMS finalizes the many changes that the IRA brings to the Part D program. **In summary, we strongly recommend that CMS merge the agreements and procedures for the discounts provided under the MDP and lower MFP prices offered through direct negotiation.** This recommendation simplifies the administration of both the MDP's and MFP's price structures at a time when CMS has many tasks on its list. We acknowledge there is significant work to be done, namely on 340B contract pharmacies and look forward to partnering with CMS and the rest of the industry on finding workable, efficient solutions on behalf of Medicare's beneficiaries. We hope our suggestions help CMS streamline its work in providing new and larger manufacturer discounts to beneficiaries in 2025, while providing an option for simplifying program operations as CMS rolls out additional requirements for 2026 and beyond. If you have any questions on these suggestions and recommendations, please do not hesitate to contact me directly at tdube@pcmanet.org.

Sincerely,

Tim Dube

Tim Dube
Vice President, Regulatory Affairs