April 10, 2023

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Mr. William N. Parham, III
Director, Paperwork Reduction Staff
Office of Strategic Operations and 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 February 7, 2023.[1] This ICR is related to the Inflation Reduction Act's (IRA) Part D benefit redesign provisions for plan year 2025. Under this ICR, CMS proposes 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). CMS's initial program guidance for the Medicare Drug Negotiation Program (MDNP), issued on March 15, 2023, describes the policy around an agreement for that distinct program and specifically solicits input on the MDNP agreement.[2] PCMA will be commenting on the MDNP guidance, and any subsequent related ICRs, separately. **However, we include in these comments our recommendation to align the** Manufacturer Discount Program (**MDP) and MDNP manufacturer agreements in order to most efficiently administer the Part D program on behalf of beneficiaries.**

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

[1] 88 Fed. Reg. 7976, February 7, 2023.
[2] 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.

for sale on the Exchanges established by the Affordable Care Act. In our comments below, we support CMS's proposed framework for the MDP agreement, raise several policy and payment questions about MDP administration that are not addressed in the ICR, and recommend that CMS work now to align the MDP with the future agreement for drugs subject to the Medicare Drug Negotiation Program. Our detailed comments follow.

1. **PCMA Supports CMS's Efforts to Make the MDP Agreement Similarly 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" for all purchases beyond the beneficiaries' deductible including after they have reached the new out-of-pocket maximum.

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."[3] 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.**

2. **Operational Questions for the new MDP**

In the Supporting Statement accompanying this ICR, CMS writes "Stakeholders should anticipate MDP guidance and related documents to be released in mid-2023, and will have an opportunity to comment on the guidance."[4] We appreciate that CMS is under a number of competing timelines for IRA implementation. In advance of this formal comment opportunity, we are providing the guiding questions and suggestions below based on our conversations with our member companies.

[3] CMS-10846, Supporting Statement-Part A.
[4] *ibid*.

- **We recommend that CMS clarify that the discount is available for all applicable drugs to which a deductible does not apply.** We expect that plans will continue to use actuarial equivalence testing, or offer enhanced alternative plans, that eliminate or reduce the statutory deductible. Beneficiaries frequently choose plans without deductibles. CMS should make clear to beneficiaries that they will benefit from the MDP even in plans without deductibles. Further, CMS should clarify that the MDP applies to applicable drugs that are otherwise excluded from the deductible, such as vaccines and insulins addressed under Sections 11401 and 11406 of the IRA, and other preventive services and zero cost-sharing drugs plans might cover under other avenues.

- **We recommend that CMS continue to provide monthly interim payments to Part D plans to cover the "float" they are providing pharmacies on behalf of manufacturers.** Figure 1 below is an updated graphic based on the current CGDP's process flow. In this figure, we note that Part D plans currently receive estimated monthly payments for CGDP purposes. The Congressional Budget Office estimates that aggregate statutory discounts provided by manufacturers under the IRA will be higher than under prior law.[5] The new discounts will cover prescriptions dispensed after the deductible is satisfied (if applicable), not just in the coverage gap. With a much lower spending threshold in play, this means that plans must pay pharmacies for discounts for a higher number of beneficiaries, for a longer period of time, and for more dollars overall, than under the current program. A monthly interim payment will allow plans to build the discounted amount into their pharmacy reimbursement rates up front.

- **We recommend that the new MDP interim advance payments be risk-adjusted using the same factors as the direct subsidy.** Because the new MDP is essentially a broad-based manufacturer discount available for nearly all brand drugs, the same factors that drive overall utilization will drive access to these manufacturer discounts. The discount is a part of the standard benefit and thus should be accounted for in the standardized bids plans submit, and in payments made by CMS to provide the standardized benefit.

- **We recommend these interim payments account for both the 10% initial coverage period discounts and the 20% catastrophic coverage period discounts.** CMS does not make interim payments for the CGDP during the catastrophic period today, because CGDP is not payable in that period. The IRA greatly reduces the reinsurance payments CMS makes to plans, replacing those funds with both increased plan liability and the MDP. Therefore, since the MDP now continues into the catastrophic period beginning in 2025, we believe it is appropriate for CMS to make risk adjusted interim payments of these discounts to plans for that benefit phase, just as it will for the plan liability portion.

[5] CBO, How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act, February 2023. Available at https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf.

- **We recommend CMS continue to require full reconciliation of MDP amounts on a quarterly basis, as it does with CGDP today.** For the reasons listed above, it is crucial that plans be made whole for manufacturer discounts – or reimbursed for disputed claims – on a timely basis, since these payments are made to pharmacies at the point of sale. We believe that reconciliation with manufacturers will be simpler by the nature of continuing discounts into the catastrophic phase and beginning them at the end of the deductible phase. There will be fewer "straddle claims" that require claim-level detail to fully validate. The disputes will be over lower stakes, since the manufacturer is arguing over whether 10% or 20% is applied, rather than 0% or 70%. While the number of disputes may be higher, we believe the validation process will not be as burdensome as the CGDPs is today.

- **We recommend that CMS use the same fields in the monthly Explanation of Benefits (EOB) document for the new MDP amounts as it does for the current CGDP.** CMS should try to reduce the number of changes that beneficiaries see in their EOBs in 2024, 2025, and 2026. The description of the field can include easy to understand language on what has changed, but CMS should not undertake a broad-based redesign of this or other beneficiary communications materials until all of the IRA's provisions have been implemented.

- **CMS should establish a process to hold Part D plans harmless, in the event that a manufacturer is unable to meet its financial obligations under the MDP.** On at least one occasion, a manufacturer with an up-to-date CGDP agreement declared bankruptcy.[6] These manufacturers' drugs would continue to be considered "applicable drugs." There is also the possibility that manufacturers may sign an agreement and yet refuse or be unable to pay the MDP discounts owed, outside of bankruptcy protection, and despite the likelihood of civil monetary penalties (CMP) being assessed by CMS for non-payment. We recommend CMS establish a funding mechanism through which Part D plan sponsors can be reimbursed for validly-provided, but uncollectable MDP discounts that were already paid through to pharmacies. Any CMPs collected from non-compliant manufacturers could form the basis of such a funding mechanism.

3. PCMA Recommends that CMS Align the New MDP Agreement with the Forthcoming Agreement for Part D Covered Drugs Assigned Maximum Fair Prices

Finally, in implementing the agreement described in the direct negotiation guidance dated March 15, 2023,[7] CMS acknowledges that while "manufacturers must provide access to

[6] In February 2023, Akorn Pharmaceuticals, Inc., Labeler Code P1194, filed for Chapter 7 bankruptcy protection.

[7] See Section 40.4 under which manufacturers must offer access to the MFP to all eligible dispensers. The new negotiated price for MFP drugs is the MFP plus any dispensing fees. Pharmacies, however, are

the Maximum Fair Prices (MFP) to MFP-eligible individuals, as a practical matter that will be accomplished by Part D plan sponsors without additional steps required of the manufacturer." **PCMA continues to urge CMS to either append the additional terms and conditions of the MFP agreement to the final MDP agreement, or incorporate by reference the policies and procedures in the MDP agreement.**[8] CMS does not need to undertake any additional steps to ensure that beneficiaries will receive MFP at the point of sale.

We would also recommend that CMS fold into the MDP policies and procedures a process by which it would provide risk adjusted interim payments to Part D plan sponsors to cover the "float" they are providing to pharmacies. MFPs will be significantly lower than today's pharmacy acquisition costs, meaning plan sponsors will be taking on significant financial risk in the event that a manufacturer disputes having to offer the MFP for a given claim. CMS should provide upfront funding to plans for this estimated exposure. Figure 2 attached to this letter adds to the process flow where CMS can streamline access to MFP.

In addition to simplifying pharmacy, Part D plan, manufacturer, and contractor operations, combining the two agreements has other positive attributes for CMS. First, from a program integrity standpoint, CMS needs to implement an exclusion to the MDP for drugs with MFPs. If PBMs are running point-of-sale programs to operationalize both discount programs, then they can build in the appropriate logic at the National Drug Code (NDC) level. Second, PBMs are the only actor in the prescription drug supply chain that can implement point-of-sale price reductions. The March 15, 2023 guidance puts forth a requirement that "other dispensers" be reimbursed in full in 14 days. We do not believe that in the pharmacy benefit that this timing is appropriate. CMS should rely on PBMs to make sure all pharmacy benefit dispensers are reimbursed appropriately at the point of sale. Third, using the existing claims adjudication system for both new discount programs makes seamless the experience for beneficiaries. It will also simplify EOB calculations, whether both discounts are either entered into separate Prescription Drug Event (PDE) fields or the same one.

In summary, we strongly recommend that CMS merge the agreements and procedures for the discounts provided under the MDP and lower prices offered through direct negotiation. This recommendation simplifies the administration of the MFP agreement at a time when CMS has many tasks on its list. We acknowledge that for price applicability year 2028 and beyond, CMS's agreement with manufacturers and providers and dispensers will need to account for drugs selected based on Part B expenditures, providing discounts to beneficiaries at physician offices, hospital outpatient departments, and other Part B payable locations. However, medical claims are not processed in real time

acquiring the product through standard wholesale or specialty channels, at something more similar to much higher list prices.

[8] We are attaching to these comments our public comments on the Part C & D proposed rule for plan year 2024, which explains our rationale in more detail.

and coinsurance is typically not collected at the point of care. A program administered through Part D plans and the new MDP agreement may not work without additional connection points to providers' medical benefit claims submissions systems.

Conclusion

We appreciate the opportunity to comment on this ICR and related guidance. 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,

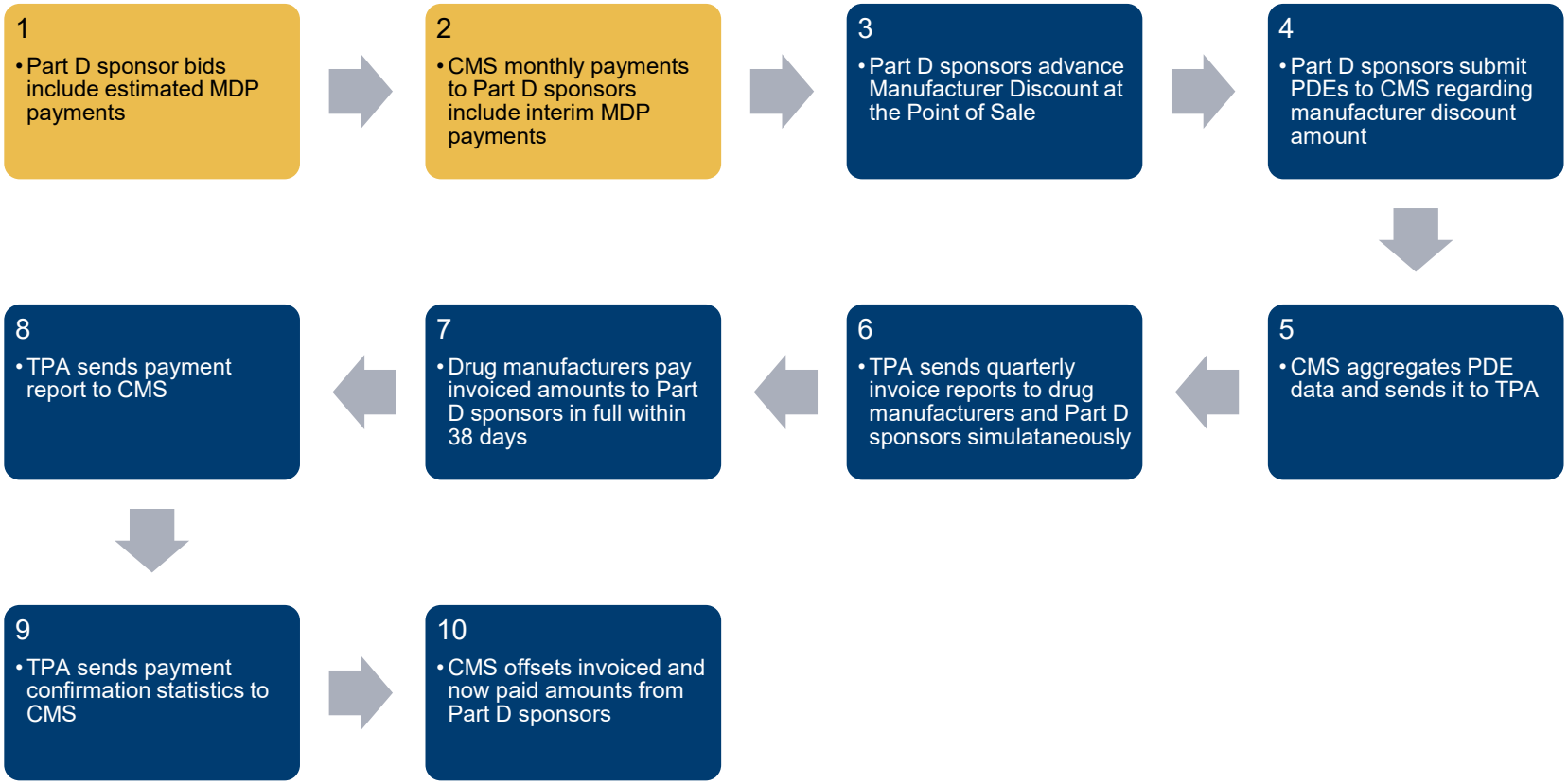
Tim Dube

Tim Dube
Vice President, Regulatory Affairs

Attachment: Figures 1 and 2

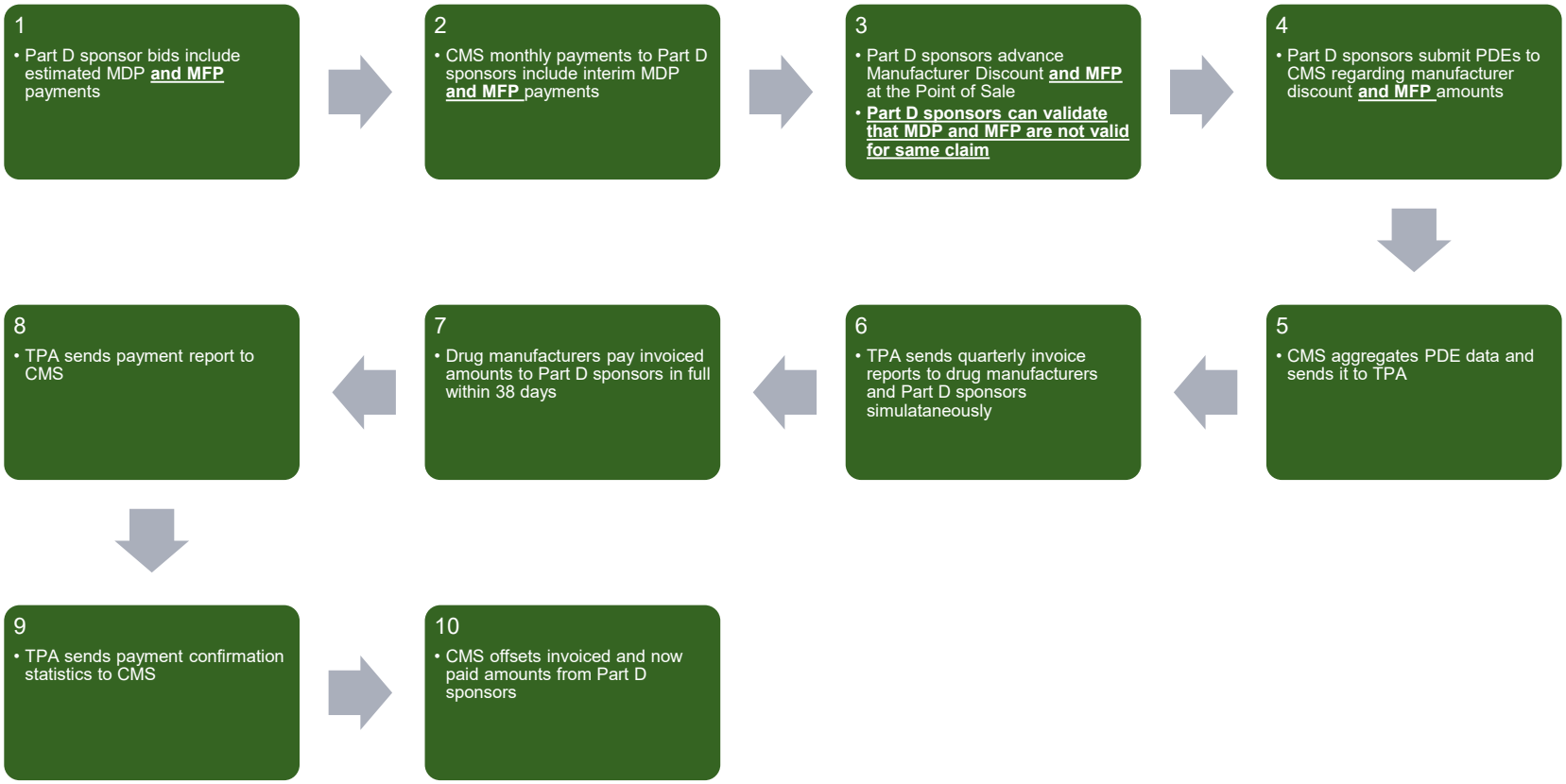
Enclosure: PCMA Comments on CMS-4201 Proposed Rule, February 13, 2023 (see pages 19-20)

Figure 1: In Transitioning from the Coverage Gap to Manufacturer Discount Program, Only Minor Modifications to the Process Flow are Needed[9]



[9] Adapted from Figure 1 (page 9) of the CMS Coverage Gap Discount Program Technical Guide Version 1.0 August 2021. Available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/Coverage_Gap_Discount_Program_Technical_Guide_08.2021.v1.pdf. Boxes 1 and 2 are not included in the technical guide for CGDP but are accurate to our best understanding. We've added them here for clarify, and to assist in reviewing Section 2 of our letter.

Figure 2: Incorporating Access to Maximum Fair Prices in the MDP Process Flow Also Requires Only Minor Modifications[10]



[10] Further adapted from Figure 1 (page 9) of the CMS Coverage Gap Discount Program Technical Guide Version 1.0 August 2021. Available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/Coverage_Gap_Discount_Program_Technical_Guide_08.2021.v1.pdf. **Emphasis** shows where access to MFP fits into the existing MDP program flow.