American Pharmacists Association

September 20, 2023

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
7500 Security Boulevard Baltimore, MD 21244

Submitted via email: PartDPaymentPolicy@cms.hhs.gov

Re: 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

Dear Dr. Seshamani:

The American Pharmacists Association is pleased to submit comments on draft part one guidance for the Maximum Monthly Cap on Cost-Sharing Payments Program (MPPP), established by section 11202 of the Inflation Reduction Act (IRA).

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA thanks HHS for meeting with APhA in July to discuss educating consumers about the Inflation Reduction Act (IRA) and your ongoing work to implement the IRA provisions to provide relief for millions of Medicare beneficiaries by improving their access to affordable prescription medications.

APhA also appreciates the draft guidance and Fact Sheet clarifying that "[p]harmacies will be paid in full by the Part D sponsor, in accordance with Part D prompt payment requirements." To help ensure a seamless approach for beneficiaries, APhA urges CMS

to develop and/or require Part D plans to develop clear, consumer-friendly, standardized educational materials for beneficiaries to help provide the intended affordable relief to enrollees. APhA also urges CMS to update the Medicare.gov Plan Finder website to include information about the MPPP and the out-of-pocket cap to help beneficiaries when selecting a plan.

The draft guidance notes that it will be finalized by spring 2024 and that a draft part two guidance will be issued in early 2024 and finalized by spring or summer 2024. The implementation deadline of January 1, 2025, may not be adequate. APhA recommends CMS accelerate its timeline for issuing guidance to Part D plans to ensure that all final operations guidance is given with sufficient time to implement all facets of the MPPP by the effective date, or APhA recommends extending the implementation date.

§50. Pharmacy Payment Obligations and Claims Processing

50.1 Pharmacy Claims Processing Requirements

APhA appreciates the draft guidance stating that "consistent with section 1860D-12(b)(4) of the Act and 42 CFR § 423.520, Part D sponsors must reimburse a network pharmacy the total of a participant's OOP amount and the Part D sponsor portion of the payment for a covered Part D drug no later than 14 days after the date on which the claim is received for an electronic claim or no later than 30 days after the date on which the claim is received for any other claim."

The draft guidance states "[a]t this time, CMS is encouraging the adoption of an electronic claims processing methodology such as the one currently used for real-time COB billing transactions using NCPDP standards."

Most pharmacy transaction systems do not have an exception process to support actions for messages on paid claim responses and would incur technology costs, maintenance, and training of pharmacy personnel. Accordingly, APhA urges CMS to require Part D plans to pay pharmacies adequate dispensing fees to pay for any incurred pharmacy expenses if CMS elects to use the COB standard.

In addition, the draft guidance states, "Part D sponsors would utilize an additional Bank Identification Number (BIN) and/or Processor Control Number (PCN) unique to the Medicare Prescription Payment Plan to facilitate electronic processing of supplemental COB transactions for program participants."

APhA supports NCPDP's comments recommending each Part D Sponsor establish a unique BIN/PCN for this program and requests CMS require the PCN begin with "MPPP" to assist with claim billing orders so that pharmacy practice management systems can identify and process these claim responses.

APhA also supports the following NCPDP requests for guidance from CMS on how to manage the following scenarios:

- Patient has Supplemental Medicaid coverage and it is unknown to the pharmacy or plan:
  - Not returned with COB-OHI information.
  - When the pharmacy has not performed an E1 transaction to know if the beneficiary has Medicaid coverage.
- Beneficiary has more than two other payers:
  - In Version D.0, the standard is limited to providing three payers in the response.
  - In Version F6, the standard is limited to providing four payers in the response.
- Processing out-of-cycle reversals and adjustments.
- A claim is adjusted after the last invoice is received by the beneficiary at the end of the calendar year.

APhA also supports NCPDP's request for CMS to include a statement in the final guidance indicating there will be no impact to Automated TrOOP Balance Transfer (ATBT) processes and Financial Information Reporting (FIR) transactions will continue to reflect the TrOOP and Drug Spend by month using the original claim accumulators, as they currently do.

CMS may want to consider permitting participants the option to pay up to the maximum out-of-pocket (MOOP). The Part D plan would then use the financial

reconciliation outlined in Section 1860D–2(b)(2)(E)(v)(III)(gg) of the Inflation Reduction Act (IRA) to adjust for any overpayment.

50.2 Pharmacy Transaction Costs

The proposed guidance states that "[a]ny additional transaction fees or other costs pharmacies incur from processing claims under the Medicare Prescription Payment Plan or otherwise related to such program are considered allowable pharmacy costs associated with the dispensing of a covered Part D drug that may be paid through applicable dispensing fees."

APhA recommends CMS add a requirement for Part D plans, in addition to the term "allowable," as pharmacists' ongoing experiences with Part D plans and their pharmacy benefit manager (PBMs) is that they are often unlikely to reimburse pharmacies for costs that are "allowed." Accordingly, CMS must make it clear to Part D plans and PBMs that MPPP-related pharmacy costs for the COB methodology approach are required to be reimbursed to pharmacies through sufficient dispensing fees.

50.3 Requirements for Different Pharmacy Types

CMS is seeking feedback on "unique scenarios that may arise related to different pharmacy types participating in the program that may require alternative payment or claims processing standards."

APhA supports NCPDP's request for additional information on the following long-term care (LTC) scenarios:

- How should the process work when the patient pay amount is billed to the facility rather than directly to the beneficiary?
    - The pharmacy expects payment from the facility rather than the patient. Should the pharmacy submit the COB Medicare Prescription Payment Plan claim?
    - How would this be identified to the pharmacy?
    - Will the beneficiary or the legal representative of the beneficiary also receive the claim billing invoice?

    - If the beneficiary is not in a facility in January but enters a facility later in the year (while enrolled in the program), would the beneficiary continue to be billed for their monthly program payment amount?
- Will Low-Income Cost-Sharing Subsidy (LICS) retrospective eligibility be handled differently for LTC beneficiaries?
- When it would be beneficial for LTC patients to enroll in the program.

§60. General Part D Enrollee Outreach Requirements

CMS notes that "if a Part D enrollee has not already opted into the program, the Part D sponsor will notify the pharmacy to inform the individual about the program if their cost-sharing for covered Part D drugs exceeds a dollar threshold based on either an individual prescription or all prescriptions filled on a single day." CMS also states it will provide additional guidance on the contents of notifications and model language for education materials.

APhA reiterates the message from our August 8th joint letter that the text of the statute does not require pharmacies to enroll or register a beneficiary into the Smoothing Program or to document the encounter and that Part D and MA-PD plan sponsors, not pharmacies, are best suited to enroll patients into the program. Congress went as far as to title subclause clause (III) under Section 11202 as "PDP Sponsor and MA Organization Responsibilities." There is a clear line of demarcation from Congress on the responsibilities of Part D and MA-PD plans under the IRA. Where election into the MPPP occurs at the point of sale (POS) (i.e., opt-in) without delay, potential participants will likely require the assistance of pharmacy personnel to educate and inform them about the details of the MPPP and assist with the communication to the Part D sponsor. CMS should ensure that any actions at the pharmacy counter by pharmacy team members (i.e., how to correctly process MPPP claims, etc.) are reimbursed in full through an administrative fee to pharmacies that cover all of the costs for performing any services and any transaction fees that result (e.g., claim reversals and resubmissions).

60.2.4 POS Notification Requirements

APhA supports the language under §60.2.4 which states that if a prescription is picked up by another person who is not the Part D enrollee, then the pharmacy would be required to provide the person who is picking up the prescription with the relevant information, as the pharmacy will not be able to easily track down and notify the Part D enrollee directly.

§70. Requirements Related to Part D Enrollee Election

70.3.7 Retroactive Election in the Event the Part D Sponsor Fails to Process an Election within 24 Hours

The proposed guidance states "if a Part D enrollee has fulfilled all program election requirements, but the Part D sponsor is unable to process the election into the program in the required amount of time due to no fault of the individual, the Part D sponsor must process a retroactive election back to the original date" "when the individual should have been admitted into the Medicare Prescription Payment Plan (i.e., within 24 hours of the individual providing the requisite information for election into the program). In addition, the Part D sponsor must reimburse the participant for any OOP cost sharing paid on or after that date and include those amounts, as appropriate, in a monthly bill under the program within 45 days."

APhA requests CMS clarify that Part D plans are the only party responsible for the retroactive election and reimbursement to the participant and that the Part D plan, or its PBM, will not pass this administrative burden onto the pharmacy. For example, a patient who picks up their medication and pays the full copay, and later is retroactively enrolled in the program should not be permitted to return to the pharmacy for a refund as pharmacies lack the ability, reimbursement, and resources to provide any remedy.

APhA also supports NCPDP's comments requesting clarification from CMS on the reprocessing and reimbursement/billing of retroactive claims when a beneficiary participates in the program. Guidance is needed on how the reimbursement/billing process will work.

70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs

CMS is also seeking comments on different options (telephone only, mobile or web-based application, clarification code) to process elections into the MPPP in "real-time and near-real-time," at the POS beginning in 2026 or later.

Under all three options, if pharmacy personnel are required to educate and inform patients about the details of the MPPP and assist with the communication of the Part D plans, then pharmacies should be reimbursed for these costs and any transaction fees that result, such as for the claim reversal and resubmissions mentioned in the draft guidance.

Thank you for the opportunity to provide comments on the draft guidance. If you have any questions or require additional information, please contact APhA at mbaxter@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Vice President, Federal Government Affairs