Submitted September 20, 2023

Dr. Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Center for Medicare and Medicaid Services
Sent via Electronic Mail

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 National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) Accredited Standards Developer (ASD) consisting of more than 1,500 members representing entities including, but not limited to, claims processors, data management and analysis vendors, federal and state government agencies, insurers, intermediaries, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, professional services organizations, software and system vendors and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

For over 40 years, NCPDP has been committed to advancing the electronic exchange of information between healthcare stakeholders. The NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting and other functions in the pharmacy services industry, as named in the Health Insurance Portability and Accountability Act (HIPAA). The NCPDP SCRIPT Standard and the Formulary and Benefit Standard are the standards in use in electronic prescribing, as named in the Medicare Modernization Act (MMA).

NCPDP submits the following comments in response to *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*, released August 21, 2023.

Section 50.1 Pharmacy Claims Processing Requirements

To ensure that an individual's participation in the Medicare Prescription Payment Plan has no effect on the amount paid to pharmacies in accordance with section 1860D–2(b)(2)(E)(v)(III)(ff) of the Act, the Part D sponsor must pay the pharmacy for the amount the individual would have otherwise paid at the POS. An individual's OOP costs are net of any contributions made by supplemental payers to Part D that the individual may be entitled to and that reduce the OOP amount due. CMS is aware that the current coordination of benefits (COB) electronic billing process may be disrupted if a Part D sponsor initially returns an amount of $0 in the National Council for Prescription Drug Programs (NCPDP) telecommunications standard response pricing segment field "Patient Pay Amount" (505-F5) on a Part D claim because this amount may be used by supplemental payers to determine if additional benefits are provided. Additionally, this amount may be used by Part D sponsors for other downstream

reporting requirements, such as prescription drug event (PDE) records and explanation of benefits (EOB) reporting, which reflect the actual participant liability amounts as incurred.

NCPDP Comment: NCPDP requests CMS correct the name of its standard within the guidance. The correct name is Telecommunication Standard. It is listed in the guidance without proper name capitalization as the telecommunications standard.

NCPDP recommends each Part D Sponsor establish a unique BIN/PCN for this program and requests that CMS require the PCN to begin with "MPPP" to assist with claim billing sequencing.

NCPDP is requesting 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
- Beneficiary has more payers than the standard supports:
  - In the Telecommunication Standard, Version D.0, the standard is limited to providing three payers in the response
  - In the Telecommunication Standard, Version F6, the standard is limited to providing four payers in the response
- Processing out-of-cycle reversals and adjustments occurring beyond the standard time limits the plan supports for acceptance of these updates
- A claim is adjusted after the last invoice is received by the beneficiary at the end of the calendar year

NCPDP requests CMS 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.

Section 50.3: Requirements for Different Pharmacy Types

NCPDP Comment: NCPDP is requesting additional information and guidance on the following long term care (LTC) concerns:

- 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 program (if beneficiary opted in) 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 Subsidy (LIS) retroactive eligibility be handled differently for LTC beneficiaries?
- When would it be beneficial for LTC patients to enroll in the program?

Section 50.4: Paper Claims

NCPDP Comment: NCPDP agrees paper claims should not be included in this process.

Section 70.3.5: Processing Election Requests During a Plan Year
Section 70.3.7: Retroactive Election in the Event the Part D Sponsor Fails to Process an Election within 24 Hours

NCPDP Comment: NCPDP requests 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.

NCPDP is requesting CMS provide guidance on what should happen when a patient picks up their medication and pays the full copay and later is retroactively enrolled in the program? Should the patient be allowed to return to the pharmacy for a refund?

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

NCPDP Comment: NCPDP requests CMS take the following into consideration when determining the best method for the real-time or near-real-time point of service (POS) elections options:

- Not all patient(s) and/or legal representative(s) are physically present at the pharmacy to have the POS election conversation.
- Real-time enrollment is not possible with mail order, specialty pharmacy and LTC pharmacies because the patient is not present.

NCPDP members do not believe the Submission Clarification Code (SCC) option listed in the guidance is viable for enrolling beneficiaries into the program. In addition, pharmacies do not have the appropriate information to understand whether the individual making the request is the legal representative of the beneficiary or the beneficiary has been sufficiently educated on the program. The standard does not support transmission of this information.

Section 70.4: Mid-Year Plan Election Changes

NCPDP Comment: NCPDP requests additional clarification from CMS on possible stop-gap measures to prevent unexpected beneficiary behavior. For example, the beneficiary does not pay their balances and plan transferring occurs to avoid making program payments.

Section 80.1: Voluntary Terminations

NCPDP Comment: NCPDP requests CMS create the following:

- Model language to provide beneficiaries an explanation of member responsibility when enrollment from the program is terminated
- Guidance for providers, pharmacies and/or processors explaining the turnaround time to process enrollments and disenrollments from the program
    - NCPDP recommends the turnaround time for both elections and terminations be 24 hours.

NCPDP members believe the pharmacies should be held harmless regarding the termination of a beneficiary from the program when claim activity has occurred prior to the plan terminating the beneficiary from the program.

Appendix A: Definitions for Medicare Prescription Payment Plan

NCPDP Comment: NCPDP suggests utilizing the term “Patient Out of Pocket (OOP) Cost” as defined in Appendix A to replace the term “Patient Pay Amount” throughout the guidance. “Patient Pay Amount” has a specific definition, especially related to Prescription Drug Event (PDE) data. Using this term could cause confusion when relating it to the program.

Appendix B: Additional Medicare Prescription Payment Plan Calculation Examples

NCPDP Comment: NCPDP is requesting additional examples of how the program should work when a beneficiary has multiple supplemental coverages throughout the benefit plan year.

NCPDP submits for CMS consideration the enclosed specific example of a situation where the secondary coverage for the beneficiary returns a higher Patient Out of Pocket Cost than what was on the original Medicare Part D claim. NCPDP requests feedback from CMS on how this type of scenario should be handled.

NCPDP thanks CMS for the opportunity to provide comments and for the consideration of our comments. NCPDP looks forward to continuing its work with CMS.

For direct inquiries or questions related to this letter, please contact:
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Respectfully,

Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)

Enclosure:

- MPPP Tertiary Example Last Payer PPA Greater than Med D PPA – Excel Spreadsheet