September 18, 2023

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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 National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the 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).

Summary of Recommendations:

- **To help ensure that CMS' goals are met of participants' having timely, uniform, seamless and consistent experiences, CMS should *require* that MPPP-related pharmacy costs for the coordination of benefits (COB) methodology approach are reimbursed through adequate and appropriate dispensing fees.**

- **We agree that there must be a unique nomenclature so that pharmacies may easily identify the relevant claim responses for the COB transactions. Specifically, the Processor Control Number (PCN) should begin with the letters "MPPP" so that pharmacy practice management systems can easily and properly identify and process these claim responses**.

- **With respect to enrollee notification, there is no requirement that the pharmacy provide counseling or consultation on the matter, nor for the pharmacy to document that the pharmacy has made such notification. We believe that CMS' adopting any of these actions as requirements would be unduly and unnecessarily burdensome on pharmacies, and that enrollee notification, counseling and consultation are the responsibilities of plan sponsors and their pharmacy benefit managers (PBMs). Moreover, if such actions were requirements of pharmacies, they could provide plan sponsors and their PBMs with new opportunities to audit pharmacies and subsequently claw back reimbursement.**

- **As CMS is aware, pharmacies are already struggling to stay afloat under the heavy burden of low reimbursement and direct and indirect remuneration (DIR) fees imposed by plan sponsors and their PBMs. It is very difficult to conceive of how pharmacists and pharmacies could take on the additional**

burden of beneficiary enrollment without fair and adequate reimbursement to help facilitate that service.

- **As stated in our previous meetings with HHS, we request CMS ensure pharmacies' reimbursements are protected as PDP and MA-PD plan sponsors may decide to recoup the costs of implementing the MPPP through retroactive fees, similar to DIR claw backs. Again, CMS' failure to take such steps likely would be devastating to pharmacists, pharmacies, and the patients we serve.**

- **While administratively burdensome, and a requirement for plans and PBMs, pharmacists and pharmacies may be notifying enrollees of their eligibility for the MPPP. To do this, pharmacists and pharmacies will need clear, standardized educational materials provided by CMS or by Part D plans well ahead of 2025. To help ensure a seamless approach for beneficiaries, we urge CMS to develop or require plans to develop clear, consumer-friendly, standardized educational materials for beneficiaries to help provide the intended affordable relief to enrollees. Pharmacies should not be expected to have to issue plan-specific education materials as it would be unduly burdensome for pharmacies to manage unique documents for ten, twenty, thirty plans or more.**

- **The burdens of any retroactive actions and reimbursements should be carried by the responsible party, i.e., the Part D sponsor, and that responsible party should not be able to shirk its responsibilities by passing the burdens on to pharmacies.**

- **In any scenario where election into the MPPP occurs at the point of sale (POS) without delay, potential participants will 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. In other words, pharmacy personnel essentially would be recruited to function as agents of the Part D sponsors; thus, pharmacies should be adequately reimbursed an administrative fee for performing these services. In addition, pharmacies should be reimbursed for the technology development costs to facilitate the election at POS and should be compensated for any transaction fees that result, such as for the claim reversal and resubmissions.**

<u>§50. Pharmacy Payment Obligations and Claims Processing</u>

We appreciate CMS' recognition that Part D sponsors must pay the pharmacy the participant's cost-sharing amount in addition to the Part D sponsor's portion of the payment no later than 14 days after the date on which the claim is received for an electronic claim or no later than 30 days for any other claim. In other words, to ensure that the MPPP has no effect on the amount paid to pharmacies, the Part D sponsor must pay the pharmacy for the amount the participant would have otherwise paid at the POS in addition to the sponsor's contracted portion of the payment.

We support CMS' policy of not having an impact on the amount paid to pharmacies. Moreover, we support CMS' policies that the MPPP's claims processing methodology ensures a timely, uniform, and seamless experience for all, provides a consistent participant experience, and minimizes disruptions to existing processes.

Under §50.1, CMS is encouraging the use of an electronic claims processing methodology similar to the one currently used for real-time COB billing transactions using the National Council for Prescription Drug Programs (NCPDP) standards. We support CMS' goals for a timely, uniform, seamless and consistent experience for participants, as well as for an approach that minimizes disruptions to existing processes. However, we believe

that if not implemented with specific elements and assurances, then CMS' proposed approach would not minimize disruptions to existing processes, and consequently could obfuscate CMS' goals for a timely, uniform, seamless and consistent experience for participants.

Generally, pharmacy transaction systems do not have an exception process to support actions for messages on paid claim responses. Pharmacies would have to engage in technology systems development to allow for this type of methodology. In addition to technology systems development time and costs, pharmacies would also have to engage in pharmacy personnel education and training—plus maintenance and similar ongoing resources and costs.

Should CMS opt to choose the COB methodology approach to meet CMS oversight and enforcement goals and purposes, as CMS mentions in its dismissal of the proposal for a method using a Part-D sponsored pre-funded payment card (similar to a Health Savings Account (HSA) card), then CMS should provide or require the necessary funding to ensure pharmacies are paid a dispensing fee to support the COB approach. We appreciate CMS' recognition of this under §50.2. However, the language of this section does not go far enough, as it merely recognizes that MPPP-related pharmacy costs are "allowable pharmacy costs." From our experience, we are confident that plan sponsors are highly unlikely to reimburse pharmacies for costs that are merely "allowed." As CMS is aware, pharmacies have been burdened with exorbitant retroactive fees, i.e., DIR fees, imposed by plan sponsors and their PBMs. In an environment where plans sponsors and their PBMs were free to impose DIR fees that grow exponentially every year, it is practically inconceivable that they would provide pharmacies with dispensing fees that cover costs that are "allowed." **Rather, to help ensure that CMS' goals are met of participants' having timely, uniform, seamless and consistent experiences, CMS should *require* that MPPP-related pharmacy costs for the COB methodology approach are reimbursed through adequate and appropriate dispensing fees.**

In addition, under CMS' proposal, Part D sponsors would utilize an additional Bank Identification Number (BIN) and/or Processor Control Number (PCN) unique to the MPPP to facilitate electronic processing of the COB transactions. **We agree that there must be a unique nomenclature so that pharmacies may easily identify these transactions. However, we believe that CMS' proposal does not go far enough in this requirement. There is likely a great deal of noise in paid claim responses, and it would be very burdensome and ineffective to rely on manual processes to identify these specific transactions. Specifically, the PCN should begin with the letters "MPPP" so that pharmacy practice management systems can easily and properly identify and process these claim responses.**

§60. General Part D Enrollee Outreach Requirements

Enrollee Notification

As CMS recognizes in the draft guidance, if a Part D enrollee who has not already opted into the MPPP incurs out of pocket (OOP) costs and they are likely to benefit from the new program, Part D sponsors are required to establish a mechanism to notify a pharmacy so that the pharmacy can notify the enrollee that they may benefit from the program and how to opt in if the enrollee would like to participate. CMS is proposing to base the notification determination on whether the enrollees equal or exceed a POS threshold regardless of whether the enrollee receives their medications through a retail pharmacy, mail order, long-term care pharmacy, specialty or home infusion.

CMS indicates that it will provide additional guidance on the contents of notifications and model language for education materials in a second guidance and welcomes further input on this matter.

We appreciate that CMS is developing additional guidance for notifications and education materials. As CMS develops this second guidance, we would like to remind CMS that the statutory language requires pharmacies to notify the potential participant. **There is no requirement that the pharmacy provide counseling or consultation on the matter, nor for the pharmacy to document that the pharmacy has made such notification. We believe that CMS' adopting any of these actions as requirements would be unduly and unnecessarily burdensome on pharmacies, and that enrollee notification, counseling and consultation are the responsibilities of plan sponsors and their PBMs. Moreover, if such actions were requirements of pharmacies, they could provide plan sponsors and their PBMs with new opportunities to audit pharmacies and subsequently claw back reimbursement.**

Under §60.2.4, CMS 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 in the appropriate circumstances. We appreciate CMS' recognition that in these situations it would likely be impossible for the pharmacy to track down and notify the Part D enrollee directly.

Enrollee Registration

We support the intent of the IRA and CMS' draft guidance to provide enrollees with new options to manage their OOP costs. The IRA requires pharmacies to notify an enrollee of notification from a plan sponsor that the enrollee has incurred OOP costs that the enrollee may benefit from making an election into the MPPP. However, the IRA does not require pharmacies to enroll or register an enrollee into the MPPP—this is evidenced by the title for subclause (III) under Section 11202 that Congress chose: "PDP Sponsor and MA Organization Responsibilities." There is a clear line of demarcation from Congress as to Congressional intent with respect to the responsibilities of plan sponsors under IRA.

Although we appreciate CMS' acknowledgment of pharmacies as convenient access points, there is presently no technology or process for pharmacies to enroll beneficiaries into the MPPP, nor do we expect such technology to be available any time soon. In addition, there is no known ability to set aside time and resources in pharmacy workflow for pharmacy personnel to enroll beneficiaries and perform related documentation tasks. We are especially concerned that a pharmacy enrollment requirement would not reimburse pharmacists and pharmacies for providing that service. **As CMS is aware, pharmacies are already struggling to stay afloat under the heavy burden of low reimbursement and DIR fees imposed by plan sponsors and their PBMs. It is very difficult to conceive of how pharmacists and pharmacies could take on the additional burden of beneficiary enrollment without fair and adequate reimbursement to help facilitate that service.**

The IRA also requires that the PDP or the MA-PD plan ensure that the election by an enrollee has no effect on the "amount paid to pharmacies" (or the timing of such payments) with respect to covered Part D drugs dispensed to the enrollee. **As stated in our previous meetings with HHS, we request CMS ensure pharmacies' reimbursements are protected under this provision as PDP and MA-PD plan sponsors may decide to recoup the costs of implementing this provision through retroactive fees, similar to DIR claw backs. Again, this would be devastating to pharmacists, pharmacies, and, ultimately, the patients we serve.**

As mentioned above, pharmacists and pharmacies may be notifying enrollees of their eligibility for the MPPP. To do this, pharmacists and pharmacies will need clear, standardized educational materials provided by CMS or by Part D plans well ahead of 2025. To help ensure a seamless approach for beneficiaries, we urge CMS to develop or require plans to develop clear, consumer-friendly, standardized educational materials for beneficiaries to help provide the intended affordable relief to enrollees. Pharmacies should not be expected to have to issue plan-specific education materials as it would be unduly burdensome for pharmacies to manage unique documents for ten, twenty, thirty plans or more.

§70. Requirements Related to Part D Enrollee Election

Under §70.3.7, if a Part D sponsor is unable to process an enrollee's election in the required amount of time due to no fault of the enrollee, the Part D sponsor must process a retroactive election and reimburse the participant for any OOP cost sharing paid. We ask CMS to clarify that the Part D sponsor is solely responsible for the retroactive election and reimbursement to the participant, and that the Part D sponsor shall not require the pharmacy to reverse and resubmit claims and/or require the pharmacy to process and provide the reimbursement to the participant. Pharmacies should not be held responsible and take on unnecessary risk because of the actions or inactions of the Part D sponsor. **The burdens of any retroactive actions and reimbursements should be carried by the responsible party, i.e., the Part D sponsor, and that responsible party should not be able to shirk its responsibilities by passing the burdens on to pharmacies.**

Under §70.3.9, CMS is seeking comment on options to process elections into the MPPP at the POS with no delay or a minimal delay beginning in 2026 or later. In general, and with respect to all three options that CMS poses in the draft guidance, it is our understanding that election into the MPPP without delay is not presently workable because PBMs, which would process the election and subsequent prescription drug claims, do not have the necessary information on file to process an election immediately. The PBMs would have to consult with the plan sponsor in order to determine whether the enrollee is eligible to elect into the MPPP. Our understanding is that this hurdle would first have to be overcome.

Also, with respect to all three presented options, telephone-only, mobile or web-based application, and clarification code, should the above-mentioned hurdle be addressed and overcome, there are pharmacy specific concerns that must be addressed. **In all three situations, and likely in any scenario where election into the MPPP occurs at the POS without delay, potential participants will 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. In other words, pharmacy personnel essentially would be recruited to function as agents of the Part D sponsors; thus, pharmacies should be adequately reimbursed an administrative fee for performing these services. In addition, pharmacies should be reimbursed for the technology development costs to facilitate the election at POS and should be compensated for any transaction fees that result, such as for the claim reversal and resubmissions that CMS mentions for all three options in the draft guidance on pages 35 and 36.**

Conclusion

In conclusion, NACDS and NCPA thank CMS for this opportunity to submit comments and for considering our recommendations. If we can provide any additional information, please do not hesitate to contact Christie Boutte, Senior Vice President, Reimbursement, Innovation and Advocacy, at cboutte@nacds.org or Ronna B. Hauser, PharmD, Senior Vice President, Policy & Pharmacy Affairs at ronna.hauser@ncpa.org.

Sincerely,

Steven C. Anderson, FASAE, IOM, CAE
President and Chief Executive Officer
National Association of Chain Drug Stores

B. Douglas Hoey, RPh, MBA
Chief Executive Officer
National Community Pharmacists Association

###

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.

###

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $78.5 billion healthcare marketplace, employ 240,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.