Submitted electronically via PartDPaymentPolicy@cms.hhs.gov

March 14, 2024

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Center for Medicare
Centers for Medicare & Medicaid Services
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P.O. Box 8016
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Re: Medicare Prescription Payment Plan: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments

Deputy Administrator Seshamani,

The National Community Pharmacists Association (NCPA), The American Pharmacists Association (APhA), the National Association of Chain Drug Stores (NACDS), the American Society of Consultant Pharmacists (ASCP), the National Alliance of State Pharmacy Associations (NASPA), and the American Society of Health-System Pharmacists (ASHP) appreciates the opportunity to provide feedback on CMS' *Medicare Prescription Payment Plan [M3P]: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments.* We also sincerely appreciate CMS for listening to the pharmacy communities' feedback on the Medicare Prescription Payment Plan ("M3P"). We encourage CMS to maintain its position of requiring interested beneficiaries to enroll through their Part D sponsor or Pharmacy Benefit Manager (PBM) in the final guidance and future guidance on this matter beyond 2026. It is very difficult to conceive how pharmacists and pharmacies could take on the additional burden of beneficiary enrollment in the future without fair and adequate reimbursement to help facilitate that service.

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 $94 billion healthcare marketplace, employ 230,000 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.

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.

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.

ASCP is the only international professional society devoted to optimal medication management and improved health outcomes for older adults. ASCP's thousands of pharmacist members manage drug therapies and improve the quality of life of geriatric patients and others living in various settings, including sub-acute and long-term care facilities (LTCF), skilled nursing facilities (SNFs), assisted living communities, psychiatric hospitals, hospice programs, correctional facilities, home and community-based care.

NASPA, founded in 1927 as the National Council of State Pharmacy Association Executives, is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA's membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

ASHP is the largest association of pharmacy professionals in the United States, representing 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health-system community pharmacies. For over 80 years, ASHP has championed innovation in pharmacy practice, advanced education and professional development, and served as a steadfast advocate for members and patients. In addition, ASHP is the accrediting body for pharmacy residency and technician training programs, and provides comprehensive resources to support pharmacy professionals through every stage of their careers.

We advocate that CMS should make significant changes to this proposed draft guidance, or it will cause mass upheaval and confusion at the pharmacy counter where pharmacies are already facing significant economic pressures in Medicare Part D stemming from the implementation of CMS' *Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; etc. Final Rule*, and other cash flow concerns noted by CMS.

In addition to the specific recommendations addressed in the provisions of the draft guidance below, we provide a summary of overarching recommendations applicable to this guidance:

Summary of Recommendations:

- **To help ensure that CMS' goals are met of participants' having timely, uniform, seamless and consistent experiences and access, as mentioned in the part one final guidance CMS should *require* that plan sponsors and PBMs provide timely, reasonable, and appropriate reimbursement to pharmacies to cover drug's acquisition cost and dispensing fees for M3P-related pharmacy costs under the coordination of benefits (COB) methodology approach.**
- **To minimize administrative burden, we ask for flexibility to permit electronic delivery of the Likely to Benefit Notice, which could be automated upon notification from the PBM. We support allowing for other forms of POS notifications from the plan to the pharmacy to the enrollee. Instead of merely allowing for hard copies, we advise that a hard copy be available to beneficiaries upon request, but pharmacies can also provide the notifications via SMS text messaging, QR codes, patient portal, or other electronic methods.**
- **With respect to the "Medicare Prescription Payment Plan Likely to Benefit Notice," the guidance is silent on whether this notice needs to be provided by the pharmacy for initial medication fills, refills, and transfers once the beneficiary has been enrolled into the M3P. Again, a pharmacy should have flexibility similar to the plans as to how this notice is distributed to patients (e.g., written, electronic, QRC, etc.). We recommend that the notice only be provided for initial fills and prescription transfers to satisfy this requirement to help ensure continuity of care at the pharmacy counter.**
- **CMS' guidance must call for unique nomenclature so that pharmacies may easily identify the relevant coverage information for the COB transactions. Specifically, we suggest the Processor Control Number (PCN) should begin with the letters "MPPP" so that pharmacy staff as well as pharmacy practice management systems, can easily and properly identify and process these claims to the M3P.**
- **We recommend that CMS specify a standardized means by which all Part D sponsors shall notify the pharmacy that the likely-to-benefit threshold has been met and the model notice should be offered to the enrollee. We also recommend use of the "Beneficiary Likely to Benefit from <TBD acronym>" value in NCPDP Approved Message Code (548-6F) field for this purpose.**
- **With respect to enrollee notification, we support CMS' proposal to not require pharmacies to provide counseling or consultation on the matter. We believe that CMS should adopt this proposal in the final guidance to prevent undue and unnecessary burden on pharmacies, and that enrollee counseling and consultation are the responsibilities of plan sponsors and their pharmacy benefit managers (PBMs).**
- **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. If a pharmacy must readjudicate multiple claims for new program participants, this could create additional financial and administrative strain on the**

pharmacy team and breed disruption in patient care. As such, it is also imperative for pharmacies to not change the date of service of the primary Part D claim to reflect the M3P enrollment date due to practice management systems (e.g., Drug Utilization Review (DUR), billing challenges, including secondary payor reimbursement, patient refills, and pharmacy workflow. The service date is not intended to change and could lead to serious system failure, including cycle fill logic, across the pharmacy enterprise. We recommend that the claim transaction date and the M3P enrollment date remain separate for clarity, billing processes, and seamless patient care. We note that while this is beneficial to patients, given that there are multiple transactions for each drug, there will be a significant burden and cost to pharmacy. Furthermore, systems that are capable of sending the M3P claim without reversing the primary claim should be allowed to do so.

- **In regard to pharmacy processes, we agree that pharmacies play a vital role in operationalizing the M3P. However, we are concerned that the draft part two guidance does not address how pharmacies will be notified if a "likely to benefit" beneficiary declines to enroll in the M3P. We recommend CMS require that plan sponsors and their PBMs create a process for beneficiaries to decline to participate in the M3P and then notify a pharmacy if the beneficiary declines participation in M3P to help pharmacies stay informed and comply with CMS' guidance.**
- **As stated in our previous meetings with HHS and CMS, we request that CMS ensure pharmacies' reimbursements are protected as PDP and MA-PD plan sponsors and their PBMs may decide to recoup the costs of implementing the M3P through clawbacks, similar to DIR fees, and implement new pharmacy auditing requirements for the "*Medicare Prescription Payment Plan Likely to Benefit Notice*" and subsequently claw back reimbursement. Specifically, we encourage CMS to explicitly state that a pharmacy is not required to document that the pharmacy has made such notification. Said differently, PBMs should not be allowed to audit and claw back payment from pharmacies without documentations related to the enrollee notification. Again, CMS' failure to take such steps likely would be devastating to pharmacists, pharmacies, and the patients we serve.**
- **We are encouraged by CMS' action in recent months to hold PBMs more accountable. To that end, we respectfully request that CMS explicitly state in the final guidance that pharmacies should not pay transaction fees for retroactively rebilling claims, and that the Part D sponsors and PBMs should timely reimburse pharmacies under the M3P.**
- **To help ensure a seamless approach for beneficiaries, we urge CMS to ensure that any communication from plan sponsors and PBMs to pharmacies regarding the M3P is clear and standardized to align with the CMS' standardized educational materials. 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.**
- **We strongly recommend CMS consider establishing a pathway for pharmacies to have some form of recourse if they are improperly reimbursed by a plan sponsor or a PBM by leveraging the Medicare Complaints Tracking Module (CTM) under the new M3P.**
- **Lastly, given the difficulty envisioning how LTC pharmacies can communicate the Likely to Benefit Notice with no point-of-service that is traditionally found in retail pharmacy,**

we request that CMS exempt LTC pharmacies from being required to communicate this Notice, and that CMS should require that the Part D sponsors work directly with LTC beneficiaries and facilities and not LTC pharmacies to effectuate this guidance.

20. Overview of the Medicare Prescription Payment Plan

CMS discusses how Part D sponsors must perform general and targeted education and outreach to Part D enrollees and provide communications to program participants, including instructions on using CMS-provided model materials that will be issued through the OMB ICR process. In Section 30.3 of the draft guidance, CMS states that "Though Part D sponsors are not required to use the model materials and content verbatim, they must base their developed materials on CMS's model materials and must include the elements and information included in CMS's model materials in their developed materials. CMS notes that the 'Medicare Prescription Payment Plan Likely to Benefit Notice,' […]is a standardized material that Part D sponsors are required to use in the form and manner provided by CMS." **We support CMS providing such model materials.**

30. Outreach, Education, and Communications Requirements for Part D Sponsors

The draft guidance mentions that under section 1860D-2(b)(2)(E)(v)(III)(dd) of the Act, Part D sponsors must have a mechanism in place to notify a pharmacy when an enrollee incurs OOP costs for covered Part D drugs that make it likely the Part D enrollee may benefit from participating in the Medicare Prescription Payment Plan. **We request CMS to provide clarification on the nature of that "mechanism" in its final guidance.** The draft guidance further states that Part D sponsors must also "ensure" that a pharmacy, after receiving such notification, informs the Part D enrollee about the program. **We stress that CMS should emphasize that a pharmacy must demonstrate willful negligence of this draft guidance, not merely that the pharmacy did not document providing the Likely to Benefit Notice to the Part D enrollee before the Part D sponsor or PBM addresses the pharmacy.** For example, the pharmacy should not be penalized for instances where the patient may not want to opt-in but also does not bother to opt-out, and asks the pharmacy to stop relaying the message from the plan. Continuing to provide paper notices is a waste of pharmacy and natural resources. **We ask CMS only require pharmacies to provide one copy of the Likely to Benefit Notice for initial fills and transfers. Requiring one Likely to Benefit Notice per prescription would require great administrative burden on the pharmacy and a redundancy of notices to the beneficiary.**

30.1.1 Required Mailings with Membership ID Card Issuance

The draft guidance states that under § 423.2267(e)(32), the membership ID card is a model communications material that Part D plans must provide to Part D plan enrollees. The Part D plans must provide the card to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment in the Part D plan or by the last day of the month prior to the plan effective date, whichever is later. The membership ID card must be provided in hard copy, and Part D plans may also provide a digital version, in accordance with § 423.2267(d). **We ask CMS if the membership ID card will have "4RX information" (i.e., BIN/IIN-PCN-Group-ID) needed to process the payment plan coordinated benefit.**

Additionally, the draft guidance states that "Part D sponsors are encouraged to provide the CMS-developed educational product, described in section 40.1 of this guidance, to satisfy the requirement to furnish information regarding the Medicare Prescription Payment Plan alongside the election request form in the membership ID card issuance packet. If Part D sponsors develop and use alternative informational materials in lieu of the CMS-developed educational product to satisfy this requirement, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR Part 423 subpart V." CMS mentions this again in similar language in 30.2.2.1 and 30.2.2.2 of the draft guidance. **We ask CMS to prohibit Part D sponsors and PBMs from using alternative information materials to steer patients to vertically integrated or preferred pharmacies.**

30.2.1 Notice for Part D Enrollees Likely to Benefit

To support Part D sponsors in meeting this requirement, CMS states that it is "developing a standardized notice for Part D enrollees identified as likely to benefit from the Medicare Prescription Payment Plan, the 'Medicare Prescription Payment Plan Likely to Benefit Notice.' Part D sponsors are required to use this standardized notice to satisfy their obligation to perform targeted outreach to Part D enrollees who are identified as likely to benefit prior to and during the plan year, including those identified through the pharmacy notification process. This outreach, when performed outside of the pharmacy POS notification process, may be done via mail or electronically (based on the Part D enrollee's preferred and authorized communication methods). If the enrollee is identified through the pharmacy notification process, this outreach must be completed at the pharmacy POS (see section 30.2.2.3 below)."

To minimize administrative burden, we ask for flexibility to permit electronic delivery of the Likely to Benefit Notice, which could be automated upon notification from the PBM. We support allowing for other forms of POS notifications from the plan to the pharmacy to the enrollee. Instead of merely allowing for hard copies, we advise that a hard copy be available to beneficiaries upon request, but pharmacies can also provide the notifications via SMS text messaging, QR codes, patient portal, or other electronic methods.

30.2.2.3 Requirements for Identifying Part D Enrollees Likely to Benefit at POS

According to the draft guidance, "CMS encourages Part D sponsors to provide pharmacies with additional educational material on the Medicare Prescription Payment Plan, such as the CMS-developed educational product described in section 40.1, which could also be distributed to Part D enrollees along with the notice." **We ask CMS to prohibit Part D sponsors and PBMs from forcing pharmacies through contract terms to hand out this additional educational material, or using additional educational material to steer patients to vertically integrated or preferred pharmacies.**

Additionally, according to the draft guidance, "When a Part D enrollee opts into the Medicare Prescription Payment Plan after receiving the 'Medicare Prescription Payment Plan Likely to Benefit Notice' from the pharmacy, in addition to providing the notice of acceptance of election, as described in section 30.3.2 of this guidance, the Part D sponsor is responsible for clearly communicating additional necessary next steps to the Part D enrollee. Next steps may include,

but are not limited to, how to proceed with filling any outstanding prescriptions." **We ask CMS to prohibit Part D sponsors and PBMs from using this language to steer patients to vertically integrated or preferred pharmacies.**

30.4 Language Access and Accessibility Requirements

According to the draft guidance, under section 1860D–2(b)(2)(E)(v) of the Act, both CMS and Part D sponsors are required to provide Medicare Prescription Payment Plan information and educational materials to Part D enrollees. CMS requires outreach materials and communications be provided in a culturally competent manner to all Part D enrollees, including those with limited English proficiency (LEP) or reading skills and diverse cultural and ethnic backgrounds. **We assert that the obligation to provide this material falls solely on Part D plans and that pharmacies should not be required to provide these materials.**

50. Pharmacy Processes

In the guidance, CMS states that pharmacies play an important role in operationalizing the Medicare Prescription Payment Plan. **We remind CMS that pharmacies are facing significant economic pressures in Medicare Part D stemming from the implementation of CMS' *Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; etc. Final Rule*, and other cash flow concerns. In this draft guidance, CMS does not contemplate reimbursement for pharmacies to operationalize the Medicare Prescription Payment Plan, creating yet another unfunded mandate and administrative burden for pharmacies. Therefore, we request that CMS provide guidance to Part D Sponsors to reimburse pharmacies for costs (paper, M3P COB claim transaction fees, beneficiary education, etc.) to operationalize the Medicare Prescription Payment Plan.**

CMS also states that under section 1860D–2(b)(2)(E)(v)(III)(dd) of the Act, Part D sponsors must have a mechanism to notify a pharmacy when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the Part D enrollee may benefit from participating in the program. Furthermore, section 1860D–2(b)(2)(E)(v)(III)(ee) of the Act requires Part D sponsors to ensure that a pharmacy, after receiving such a notification from the Part D sponsor, informs the Part D enrollee that they are likely to benefit from the M3P. Given this statutory requirement, Part D sponsors must ensure that their pharmacy network contracts include a provision requiring pharmacies to provide this notification to Part D enrollees.

We are wary that by requiring Part D sponsors to "ensure that a pharmacy, after receiving such a notification from the Part D sponsor, informs the Part D enrollee that they are likely to benefit from the Medicare Prescription Payment Plan" creates an audit liability for pharmacies. We request that CMS provide clarity in its final guidance for instances where the Part D enrollee receives notification from the pharmacy that the beneficiary may benefit from participating in the program, yet takes no action to enroll or decline the Medicare Prescription Payment Plan. Would a rejection pop up on the screen that needs to be acknowledged? As stated above, continuing to provide paper notices is a waste of pharmacy and natural resources.

50.1 Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount

In this draft guidance, CMS refers to the Part 1 guidance that "CMS stated that the likely to benefit notification required at the pharmacy POS will be based on the OOP costs incurred for a single prescription." In addition, the Part 1 final guidance sets the cost-sharing threshold for a single covered Part D drug at $600 or more and, if the beneficiary has not already opted into the program, the Part D sponsor will be required to notify the pharmacy to inform the individual about the program. Our organizations recommend CMS clarify that the M3P only applies through the initial coverage phase up to the $2,000 OOP spending threshold under the 2025 Part D Redesign Program. **We ask CMS to only require pharmacies to provide one copy of the Likely to Benefit Notice for initial refills or transfers. Requiring one Likely to Benefit Notice per prescription would require great administrative burden on the pharmacy and a redundancy of notices to the beneficiary.**

We are concerned that the notification process outlined in this section is very general. We recommend that CMS specify a standardized means by which all Part D sponsors shall notify the pharmacy that the likely-to-benefit threshold has been met and the model notice should be offered to the enrollee. We also recommend use of the "Beneficiary Likely to Benefit from <TBD acronym>" value in NCPDP Approved Message Code (548-6F) field for this purpose.

We also want to clarify that as this section does not indicate where the beneficiary should "seek advice" from, CMS should explicitly state that the beneficiary should seek advice from the plan, PBM, or an insurance agent.

We also concur with the NCPDP recommendation that CMS change the term "primary Part D claim response" to "Medicare Part D claim response."

50.2 Pharmacy POS Notifications Late in the Plan Year

Like the above section, we are concerned that the notification process outlined in this section is very general. We recommend that CMS specifically call out the use of the Approved Message Code values in the final guidance. Additionally, we also recommend standardization for providing information utilizing the NCPDP Approved Message Codes applicable to the M3P program.

50.3 Pharmacy POS Notifications in Retail and Non-Retail Pharmacies

CMS states that it is aware that some pharmacy types may not have direct contact with Part D enrollees and/or may lack a practical means for providing a hard copy of the "Medicare Prescription Payment Plan Likely to Benefit Notice" directly to the Part D enrollee, and that pharmacies may also choose to provide the Likely to Benefit notice in other modes of communication such as through a patient portal or secure e-mail. **As also stated above, to minimize administrative burden, we ask for flexibility for all pharmacies to permit electronic delivery and/or notification through the individuals' residential care facility of the Likely to Benefit Notice, which could be automated upon notification from the PBM. We support allowing for other forms of POS notifications from the plan to the pharmacy to the enrollee. Instead of merely allowing for hard copies, we advise that a hard copy be available to**

beneficiaries upon request, but pharmacies can also provide the notifications via SMS text messaging, QR codes, patient portal, or other electronic methods. Please see our additional comments in section 50.3.1 regarding LTC pharmacies.

We also request clarification from CMS that a PBM or a plan sponsor auditing for compliance shall not penalize a pharmacy for providing the Likely to Benefit Notice in advance, and documenting the date, of the first claim.

Additionally, we argue that the Part D sponsor cannot "ensure" that the pharmacy provides the Likely to Benefit Notice and pharmacies should not be held liable for failure to provide this notice, and Part D sponsors should "encourage" rather than "ensure" such an event. Additionally, CMS should note that if the beneficiary does not come pick up the medication, there is no way for the pharmacy to give the Likely to Benefit Notice to the beneficiary.

50.3.1 Long-Term Care Pharmacies

In the guidance, CMS states that long-term care pharmacies typically do not have a POS encounter between the pharmacy and the enrollee (long-term care resident). CMS should note that LTC pharmacies take care of LTC patients in a variety of settings. **We ask CMS to clarify if this section applies to all patients residing in a LTC facility including assisted living, group homes, other types of congregate living as well as patients residing at home and receiving LTC pharmacy at home services and not exclusively patients residing in a skilled nursing facility. We also seek clarification from CMS on the method to determine whether the likely-to-benefit notification processes for a long-term care pharmacy are dependent on a characteristic of the enrollee or the pharmacy (e.g., residence, level of service, pharmacy permit type, LTC provider network, etc.).**

For LTC pharmacies, CMS states in the guidance that the "pharmacy delivers medications that are kept in the custody of long-term care facilities until time of administration. In addition, long-term care pharmacies often use retrospective or post-consumption billing (i.e., billing after the drug is dispensed to the facility for an enrollee). As such, when the POS notification is received by a long-term care pharmacy, the plan sponsor is not required to ensure that the long-term care pharmacy provides the 'Medicare Prescription Payment Plan Likely to Benefit Notice' prior to dispensing the medication." In LTC pharmacy, we note that medication can be dispensed at the facility or directly to the enrollee (i.e., assisted living residents). However, often there is no direct pharmacy to enrollee visibility, and billing is done at the end of the month, with medication dispensed and consumed prior to billing. **Therefore, we have difficulty envisioning how LTC pharmacies can communicate the Likely to Benefit Notice with no point-of-service that is traditionally found in retail pharmacy. LTC pharmacies send bills for copays in most cases to the responsible party which is usually family members. Furthermore, dispensing pharmacists are often not the same as the consultant pharmacists often found in long-term care, which creates a situation where the dispensing pharmacist does not know the enrollee at all. This makes enrollee notification and education of the LTC beneficiary even more difficult.**

CMS maintains in the guidance that "the plan sponsor can require the long-term care pharmacy to provide the notice to the Part D enrollee at the time of its typical billing process**." However, we ask CMS if "at the time of…typical billing process…" refers to when online billing is done, or monthly invoice of private-pay portion to the enrollee's responsible party? The ability for the LTC pharmacy to provide any kind of notice directly to the Part D enrollee is limited, as there is often no way for the LTC pharmacy to make contact with the beneficiary. If the LTC pharmacy is able to make contact, the enrollee is unlikely to be able to understand and/or respond. In the final guidance, CMS should amend language stating that the plan sponsor "can require" the long-term care pharmacy to provide the notice to language stipulating that the LTC pharmacy "can attempt" to deliver the notice so that individual plan sponsors are not penalizing LTC pharmacies unable to get this notice to the correct individual or responsible party. The additional administrative burden on LTC pharmacies involves many steps and workflow changes to the pharmacy. CMS should compensate pharmacies for any additional administrative burden.**

Finally, we request clarification from CMS that the Likely to Benefit Notice does not apply to residents covered by Medicare Part A as their medications are subject to the Consolidated Billing requirement.

<u>50.4 Readjudication of Prescription Drug Claims for New Program Participants</u>

CMS states that for claims to be processed appropriately using the M3P BIN/PCN methodology, the date of service on the primary Part D claim and the additional program-specific transaction must be on or after the date of program effectuation. **We appreciate this clarification, so that Part D sponsors all have the same policy regarding effective date and ineligibility of old claims. However, it is also imperative for pharmacies to keep the date of service/transaction of the primary Part D claim due to practice management system (Drug Utilization Review (DUR), billing challenges, including secondary payer reimbursement, and pharmacy workflow). The service date is not intended to change and could lead to serious system failure across the pharmacy enterprise. We recommend that the claim transaction date and the M3P enrollment date remain separate for clarity, billing processes, and seamless patient care. Further, we request that the date of program effectuation be the first day of the month in which the Part D enrollee opts into the Medicare Prescription Payment Plan to minimize the number of claims needed to be reversed in order for the cost share to be applied to the payment plan.**

CMS also states that when the Part D enrollee returns to the pharmacy after their election into the Medicare Prescription Payment Plan has been effectuated, the plan sponsor must require the pharmacy to reverse and reprocess all three claims, so the program participant pays $0 at the pharmacy for all three drugs. **We note that while this is beneficial to patients, given that there are multiple transactions for each drug, there will be a significant burden and cost to pharmacy for which the pharmacy could be paid a fee in the M3P COB claim. Furthermore, systems that are capable of sending the M3P claim without reversing the primary claim should be allowed to do so.**

CMS notes that, "in general," plan sponsors are not required to provide that pharmacies reverse and reprocess claims under the Medicare Prescription Payment Plan that have already been paid for by the Part D enrollee. **We ask that CMS prohibit plans and PBMs from requiring pharmacies to reverse and reprocess claims under the M3P that have already been paid and picked up by the Part D enrollee, as this would cause a date of service conflict.**

50.5 Processing of Covered Part D Claims for Program Participants in Special Settings
50.5.1 Long-Term Care Pharmacies

Regarding the diversity of payment arrangements between residents, LTC pharmacies and LTC facilities, CMS states that "In some situations, long-term care pharmacies do not collect Part D cost-sharing from the enrollee but instead bill the long-term care facility for the final patient OOP responsibility. When such an arrangement is in place between a long-term care pharmacy and a long-term care facility, and an enrollee in a long-term care facility is participating in the M3P billing the participant's Part D plan's M3P BIN/PCN for the participant's OOP costs (when the pharmacy would not have otherwise directly billed the enrollee) may result in additional financial burden on that participant. In such cases, CMS encourages Part D sponsors to take the participant's particular circumstances into account when considering M3P billing practices and to work with the participant, their authorized representative, and the long-term care pharmacy to understand the best billing approach for the participant."

We are concerned this guidance is unclear and provides minimal direction to Part D sponsors about actively working with patients and LTC pharmacies to ensure patients who would benefit from M3P receive appropriate notice can benefits while also ensuring it does not raise costs on participants. We encourage CMS to be more direct in its .guidance and promote a system in which the long-term care facility and Part D plan coordinate directly and provide the participant and their authorized representatives with a detailed M3P billing plan that does not increase costs to the participant into which they might opt in. Lastly, given the difficulty envisioning how LTC pharmacies can communicate the Likely to Benefit Notice with no point-of-service that is traditionally found in retail pharmacy, we request that CMS require that the Part D sponsors work directly with LTC beneficiaries and facilities and not LTC pharmacies to effectuate this guidance.

Conclusion

We thank CMS for the opportunity to provide feedback, and we stand ready to work with CMS to offer possible solutions and ideas.

Should you have any questions or concerns, please feel free to contact NCPA at steve.postal@ncpa.org (Steve Postal, Director, Policy and Regulatory Affairs), APhA at mbaxter@aphanet.org (Mike Baxter, Vice President, Federal Government Affairs), NACDS at cboutte@nacds.org (Christie Boutte, Senior Vice President, Reimbursement, Innovation and Advocacy), ASCP at jlewis@ascp.com (Jim Lewis, Senior Director of Policy & Advocacy), NASPA at jcover@naspa.us (Joni Cover, Vice President of Strategic Initiatives), and ASHP at jschulte@ashp.org (Jillanne Schulte Wall, Senior Director, Health and Regulatory Policy).