Submitted electronically to: stephanie.carlton@cms.hhs.gov

February 14, 2025

Stephanie Carlton
Chief of Staff and Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Pharmacy Concerns with the IRA Medicare Drug Price Negotiation Program

Dear Acting Administrator Carlton,

We appreciate the opportunity to share an update on our efforts to ensure pharmacists can provide medicines that are part of the Medicare Drug Price Negotiation (MDPN) Program implemented as part of the Inflation Reduction Act (IRA).

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Together, our members employ 205,000 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.

American Pharmacists Association (APhA) is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists, scientists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to 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.

American Society of Consultant Pharmacists (ASCP) is the only international professional society devoted to optimal medication management and improved health outcomes for older adults, the medically complex and individuals with severe disabilities. Our thousands of member pharmacists manage drug therapies in various settings—including sub-acute and long-term care facilities (LTCFs), skilled nursing facilities (SNFs), assisted living communities, psychiatric hospitals, hospice programs, correctional facilities, and home and community-based care.

The National Alliance of State Pharmacy Associations (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 60 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

American Society of Health-System Pharmacists (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.

On January 29, 2025, CMS released a statement underscoring that the Agency is moving forward with the IRA per the statutory requirements and committed to incorporating lessons learned and efforts to bring greater transparency to the Program to achieve greater value for Medicare beneficiaries while fostering innovation.[1] However, we believe that without significant changes by the Trump administration the current program will negatively impact Medicare beneficiaries' access to selected drugs and cause significant patient and pharmacy disruption.

The MDPN Program is a complicated program that requires new methods for effectuating government set prices across the marketplace. A fundamental flaw in the program, as currently proposed, is that manufacturers are not required to provide discounts to pharmacies at the time of purchase. This puts pharmacies in the position of paying inflated prices for drugs and subsidizing the program at a loss until refunds are received. NCPA's survey, conducted in January 2025, indicated that approximately 61 percent of independent pharmacists are strongly considering not stocking one or more drugs with prices negotiated under Medicare Part D, while an additional approximately 33 percent have already decided not to stock one or more of the drugs, because of cash flow problems and payment delays related to IRA implementation, which would all but guarantee that CMS' attempt to reduce prescription drug prices will fail.[2] In addition, a study that NCPA recently commissioned stated that with MDPN drugs, the average pharmacy will float the program to the tune of $11,000 per week, with an estimated annual revenue loss of approximately $43,000 per pharmacy per year, which approximately equates to the salary of one full-time pharmacy technician.[3]

In addition to dispensing medications to the most vulnerable Americans, long-term care pharmacies provide nearly a dozen other services that ensure appropriate patient care. As currently crafted and prepared for implementation, the IRA will have a devastating impact on these pharmacies and their ability to continue to provide these needed pharmacists' services. As CMS looks to protect vulnerable long-term care residents from the unintended consequences of the IRA, the agency needs to understand and incorporate into its analysis the many non-dispensing related services provided by long-term care pharmacies that support better patient outcomes which were largely ignored by the previous Administration.

[1] See CMS Statement on Lowering the Cost of Prescription Drugs | CMS.
[2] See 1.27.2025-FinalExecSummary.NCPA .MemberSurvey.pdf.
[3] Unpacking the Financial Impacts of Medicare Drug Price Negotiation on Pharmacy Cash Flows. 3Axis Advisors January 2025.

Hospitals and health systems face similarly bleak economic impacts, with one hospital estimating a $2 million dollar working capital outlay just to purchase the drugs upfront at wholesale acquisition cost under the proposed MDPN rebate model. That number is optimistic, given that it assumes that all claims are validated, with no denials, and paid in a timely manner. These numbers are financially infeasible for many hospitals, particularly safety-net and rural providers.

This will have a cascading impact on patients' access and for that reason, we wanted to make you aware of the challenges patients may face during your administration, if action is not taken to freeze the program and fix the issues that need to be addressed.

The first round of maximum fair prices (MFPs) go into effect next year, and CMS has announced the next 15 drugs selected for this program.

CMS guidance to date fails to address pharmacy payment flow issues, as it does not ensure fair or timely reimbursement for pharmacies. We have contacted CMS staff, met multiple times, and engaged in all comment periods to highlight these concerns with IRA implementation and how it will impede patient access to much-needed medications. However, the previous administration failed to develop the necessary infrastructure that would protect our nation's patients, pharmacists, and pharmacies.

Our previous recommendations include requiring Part D plans and PBMs to pay pharmacies no less than the MFP plus a commensurate dispensing fee, running the MDPN program like the Part D coverage gap discount program, and ensuring the program is pre-funded, therefore ensuring manufacturer refund payments are received by pharmacies within 14 days of actually filling the prescription.

Additionally, we oppose mandatory participation in the MDPN Program via PBM/plan contracts as stated in CMS' recent Medicare Part D proposed rule,[4] and we oppose CMS requiring pharmacies to sign unconscionable legal agreements requiring pharmacist participation in the MDPN.[5] Without protections to pharmacies, this program will be destined to fail, and pharmacies will be left as collateral damage.

We would be happy to brief you on each of these solutions. Without action, patients, especially seniors and those with disabilities could go without their medication. This would leave the new Trump administration holding the bag for policy decisions made under the last administration. Given the rapid rate at which the IRA implementation is occurring, we wanted to reach out and share our concerns. **We urge CMS to freeze the MDPN program until we can meet and share**

[4] See Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly. Fed Reg Vol 89, No 237. December 10, 2024.

[5] See Draft Medicare Transaction Facilitator Program Agreement Between CMS and the Dispensing Entity and Draft Medicare Transaction Facilitator Data Module Contractor Agreement Between MTF Data Module Contractor and the Dispensing Entity.

our concerns in depth and work collaboratively to identify a method that will ensure the program is workable for patients and pharmacists.

Thank you for your time and the opportunity to share our perspective. We hope to be a resource to you and would love to expand upon our issues with IRA implementation and share our solutions.

Should you have any questions or concerns, please feel free to contact NCPA's Senior Director, Policy and Regulatory Affairs, Steve Postal, at steve.postal@ncpa.org; APhA's VP Government Affairs, Mike Baxter, at mbaxter@aphanet.org; ASCP's Senior Director of Policy & Advocacy, Jim Lewis, at jlewis@ascp.com; NASPA's Executive Vice President and CEO, Krystalyn Weaver, at kweaver@naspa.us; and ASHP's VP of Government Relations, Tom Kraus at tkraus@ashp.org or Jillanne Schulte Wall, ASHP's Senior Director of Health and Regulatory Policy, at jschulte@ashp.org.

Sincerely,

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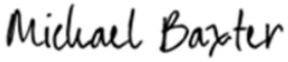
Senior Vice President, Policy & Pharmacy Affairs
NCPA



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