August 8, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services (HHS)
200 Independence Ave, S.W.
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

Mr. Jeff Zients
White House Chief of Staff
The White House
1600 Pennsylvania Avenue, N.W.
Washington, DC 20502

Ms. Erin Richardson
Chief of Staff
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

Re: INFLATION REDUCTION ACT, SECTION 11202. MAXIMUM MONTHLY CAP ON COST-SHARING PAYMENTS UNDER PRESCRIPTION DRUG PLANS AND MA–PD PLANS

Dear Secretary Becerra and Administrator Brooks-LaSure:

The National Association of Chain Drugs Stores (NACDS), the National Community Pharmacists Association (NCPA), and the American Pharmacists Association (APhA) thank you and your teams at the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) for meeting with pharmacy industry leaders last month to discuss educating consumers about the Inflation Reduction Act's (IRA) new Part D redesign and prescription drug benefits. We appreciate your robust work to carefully implement these provisions of the recently passed IRA to provide relief for millions of Medicare beneficiaries by improving their access to affordable prescription medications.

Despite our support for these provisions of the IRA, we are very concerned about a recent recommendation from ten advocacy groups asserting CMS allow Medicare Part D beneficiaries to enroll at the pharmacy counter to "smooth" or spread out their spending on prescription drugs through monthly payments to their respective plans until the annual out-of-pocket cap of $2,000 is met under IRA §11202—Maximum Monthly Cap On Cost Cost-Sharing Payment under Prescription Drug Plans and MA-PD Plans. The advocacy groups' correspondence implies this new maximum monthly cap on cost-sharing program (hereafter "Smoothing Program") is comparable to Medicare's existing policy in the Part D Low-Income Subsidy (LIS) program. Presumably, under this proposal, enrollment would occur in a process similar to the LI-NET. We wish to correct this assumption, as the two models are vastly different—notably with the LI-NET, enrollment does not occur at the pharmacy counter but instead is accomplished by the LI-NET administrator, which is one health plan sponsor, while under the Smoothing Program, every Part D and MA-PD plan sponsor would need to participate.

Furthermore, the recommendation would exceed the IRA statutory intent and requirements for pharmacies, as well as shift plan enrollment obligations from the various Part D and MA-PD plan sponsors to community pharmacists. The suggested model would delay timely patient care delivery to patients at the pharmacy counter and further exacerbate administrative and financial challenges as discussed at our recent White House and HHS meeting.

Individually and collectively, we have raised concerns about the implementation of the Smoothing Program in our outreach to HHS and CMS since early January. We have also been forthcoming, and transparent about the negative impacts of enrolling patients in the Smoothing Program at the pharmacy counter on several IRA multi-stakeholder calls.

We support the intent of the IRA to make improvements to lower prescription drug costs for Medicare beneficiaries. However, the model put forth by the ten advocacy groups is not feasible, nor does it comport with the statute. The IRA requires pharmacies to "notify" an enrollee of notification from the plan that the enrollee has incurred out-of-pocket costs that make it likely the enrollee may benefit from making such an election. This would involve in some manner a pharmacy informing the beneficiary of this new benefit. **However, the text of the statute does not require pharmacies to enroll or register a beneficiary into the Smoothing Program or to document the encounter. Since pharmacies will be notified only that an enrollee "may" be eligible to make an election, Part D and MA-PD plan sponsors, not pharmacies, are best suited to enroll patients into the program.** Indeed, 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.

Although we appreciate the advocacy groups' acknowledgment of pharmacies as convenient access points, there is presently no technology or process for pharmacies to enroll beneficiaries into the Smoothing Program, nor do we expect such technology to be available in the near-to-mid-term. In addition, there is no 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 that would not reimburse pharmacists and pharmacies for providing that service. As HHS and CMS are aware, pharmacies are already struggling to stay afloat under the heavy burden of ever-increasing direct and indirect remuneration (DIR) fees imposed by plan sponsors and their pharmacy benefit managers (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 and support for that service.

Turning to other provisions of the Smoothing Program, the IRA 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 beneficiaries of their eligibility for the Smoothing Program. To do this, as we discussed in our meeting last month, pharmacists and pharmacies will need clear, standardized educational materials provided by CMS or by Part D plans ahead of 2025. **To help**

ensure a seamless approach for beneficiaries, we urge HHS and CMS to develop or require plans to develop clear, consumer-friendly, standardized educational materials for beneficiaries to help provide the intended affordable relief and improved access to life-saving medications and to mitigate health disparities.

We appreciate your consideration of our concerns and urge HHS to incorporate our feedback into the development of any guidance on this matter. For further discussion, please do not hesitate to contact Christie Boutte, Senior Vice President, Reimbursement, Innovation, and Advocacy, NACDS, at cboutte@nacds.org; Ronna Hauser, Senior Vice President, Policy and Pharmacy Affairs, NCPA, at ronna.hauser@ncpanet.org; or Ilisa Bernstein, Senior Vice President of Practice and Government Affairs, APhA, at ibernstein@aphanet.org.

Sincerely,

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President and Chief Executive Officer
National Association of Chain Drug Stores

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NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' chain 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.

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Founded in 1898, the National Community Pharmacists Association is the voice for the community pharmacist, representing over 19,400 pharmacies that employ nearly 240,000 individuals nationwide. Community pharmacies are rooted in the communities where they are located and are among America's most accessible healthcare providers. To learn more, visit www.ncpa.org.

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APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, 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. Visit www.pharmacist.com.