July 2, 2024

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program Draft Guidance; Comment Request.

ASHP is pleased to submit our comments on the Centers for Medicare & Medicaid Services' (CMS) draft guidance regarding the implementation of the drug pricing provisions of the Inflation Reduction Act (IRA) in Medicare Part D. ASHP is the collective voice of pharmacists who serve as patient care providers in hospitals, health systems, ambulatory clinics, and other healthcare settings spanning the full spectrum of medication use. 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.

ASHP appreciates the opportunity to comment on the draft guidance and we look forward to providing additional feedback as the agency further refines the drug price negotiation framework. As a general matter, **we urge the agency to implement the IRA drug pricing provisions in a manner that does not create new administrative costs for pharmacies or disrupt established workflows**. Our specific feedback on the proposed structure for the negotiated drug price framework is as follows:

- **Retrospective Access to Maximum Fair Price (MFP) Will Increase Costs for Pharmacies:** In the draft guidance, CMS proposes two options for payment facilitation, both of which are retrospective. As ASHP has stated in previous comments, a retrospective payment model is unworkable because it places undue administrative and financial burdens on providers, particularly for 340B covered entities. Under a retrospective rebate model, pharmacies will be forced to purchase Selected Drugs at prices significantly higher than Maximum Fair Price (MFP) and finance these inflated purchase prices until a retrospective rebate is provided. This will substantially increase the actual cost for pharmacies to purchase these medications and undermines the cost-saving intent of the IRA. These inflated carrying costs will be most severe for pharmacies affiliated with 340B covered entities that already have access to discounted medications under the 340B program. **Instead of finalizing either of its proposed options for access to MFP, we urge CMS to move to a prospective model crafted from elements of the MFP models CMS outlines in the draft guidance.**

  The simplest way of facilitating this system would be to provide prospective access to the MFP price at the time of purchase. With both MFP and 340B prices available, 340B covered entities could then select the 340B price for all eligible patients. Many covered entities already maintain separate 340B and non-340B inventories, either through physical separation of products or via third-party administrator (TPA) facilitated virtual replenishment. Allowing prospective access to both MFP and 340B prices would likely significantly reduce the burden of identifying and remedying duplicate discounts versus a retrospective model built on a refund system.

We support CMS's proposal that the Medicare Transaction Facilitator (MTF) receive and dispense aggregated payments. However, under our proposed prospective payment system, the occurrence of duplicate discounts with the 340B program would likely be limited. Given the smaller volume of claims, we propose that the MTF facilitates refund payments from covered entities to manufacturers when duplicate discounts are identified. The retrospective model proposed by CMS would require providers to wait for refunds from manufacturers, resulting in providers effectively subsidizing the costs of these medications, which runs counter to the IRA's key purpose – reducing the cost of medications. Requiring manufacturers, rather than providers, to carry costs until MFP can be trued up may also incentivize manufacturers to provide timely access to MFP and 340B prices. Further, this better aligns with existing systems for identifying and refunding duplicate discounts under the 340B program. This will require integration of TPAs with MTF, which we will address in more detail below.

- **An MTF That Is Independent of Manufacturers Should Facilitate Data Verification and Payments:** To build a prospective model outlined above, the MTF would also need to facilitate data verification. At the time of purchase, the covered entity would submit the claim as CMS as proposed. For drugs purchased at MFP, the MTF will need to take no additional action. However, for drugs purchase at the 340B price, the MTF will likely need to integrate or communicate with a covered entity's TPA. The TPA would submit the required data elements for each 340B claim to the MTF. Because current regulations limit access to proprietary 340B pricing data to covered entities, manufacturers, and the Health Resources and Services Administration (HRSA), the MTF could not make an independent determination of whether the MFP was higher or lower than the 340B price. However, the covered entity or TPA could provide the information with downstream manufacturer verification. The MTF could then verify 340B claims and flag claims where the MFP is lower than the 340B price. For claims where the 340B price is lower than the MFP, the MTF could notify the covered entity that the claim has been completed, allowing covered entities to properly manage inventory.

  As noted above, we prefer a framework with an independent MTF facilitating payments and other transactions. Specifically, we have serious concerns with providing claims and payment information directly to manufacturers. Claims data is proprietary, and once turned over to manufacturers, providers would have little control over how the data is used or stored. Claims data turned over to manufacturers, rather than an independent MTF, could also be used for manufacturer sales and marketing activities that would further contribute to escalating drug spending. An MTF-centric model would provide greater transparency for providers as well as increased CMS oversight, providing a higher degree of accountability and comfort than would likely be the case for manufacturer-specific communication. Further, a system where providers interact directly with manufacturers for the purposes of purchasing a single, or at best, a few drugs, fractures the system, creating new administrative burdens and introducing new security weaknesses. An independent MTF with significant CMS oversight, as well as buy-in from and engagement with manufacturers and providers, will be critical to successful implementation of the IRA's drug pricing provisions.

- **Integrate the MTF with TPAs to Avoid Disrupting 340B Claims:** In order to facilitate transactions efficiently, the MTF should be able to integrate with TPAs. The guidance does not directly address this issue, beyond stating that CMS "strongly encourages manufacturers to work with dispensing entities, covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders (e.g.,

wholesalers) to facilitate access to the lower of the MFP and the 340B ceiling price." However, TPAs are an intrinsic element of the 340B process – accounting for 340B claims within the IRA process will require engagement of TPAs. Many covered entities rely on TPAs for compliance assistance with HRSA and manufacturer 340B audits, as well as 340B program integrity requirements. Rather than duplicating these efforts, we urge CMS to integrate TPAs with the MTF to identify 340B claims without requiring new modifiers and to utilize existing processes for IRA compliance to the greatest extent possible.

- **Establish a Firm Time Limit for Adjudicating and Paying Claims:** In addition to ensuring appropriate oversight of, and transparency around, the interaction of MFP and 340B, CMS must establish a time limit of claims payment. Currently, there is no prompt payment requirement under CMS's proposed model. As such, providers are at significant risk of financial loss. This risk is further exacerbated by the fact that it is unclear whether HRSA or another entity will be responsible for disputes related to 340B that arise within the MFP context. To address these issues, **we urge CMS to convene another listening session focused on the interaction of 340B and MFP.**

As noted above, TPA integration with the MTF would also facilitate a prospective payment model. TPAs could assist the MTF in verification of the 340B claims and determination of whether 340B or MFP is the lower price for a given claim. Further, TPAs' understanding and engagement in 340B audits for duplicate discounts could also be utilized by the MTF in the IRA context, avoiding the need for creating a retrospective system of payment which could undermine the 340B program. We are concerned that a retrospective system opens the door to manufacturers using the determination of whether MFP or 340B prices apply as a pretext for limiting or delaying payment to covered entities. CMS should clarify that the statutory requirement that manufacturers provide access to MFP to 340B covered entities without any duplicate discounts does not mean that manufacturers can delay providing access to 340B pricing.

Again, we urge that for the purposes of addressing any duplicate discounts between MFP and 340B pricing, covered entities will provide any required refund to manufacturers rather than vice versa. This process could look similar to 340B audits, with a preference for the MTF to facilitate these processes. Allowing manufacturers to individually audit providers creates serious concerns around transparency and oversight and will almost certainly result in additional administrative and financial burdens, straining safety-net providers.

Thank you for your consideration of our comments. We continue to support CMS's efforts to create a workable IRA framework, and we stand ready to assist the agency in any way possible. Please do not hesitate to contact me at 301-664-8698 or jschulte@ashp.org if ASHP can provide any further information or assist the agency in any way.

Sincerely,

Jillanne Schulte Wall, J.D.
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