

October 30, 2025

Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016

RE: Request for CMS to Require Upfront Manufacturer Discounts for Maximum Fair Price Effectuation under the Inflation Reduction Act

Dear Administrator Oz:

For decades, the American people have been at the mercy of a healthcare system that rewards obscurity and inefficiency. Those defects especially plague the delivery of critical pharmaceutical therapies, which have become more expensive and less available to those who need them most. This administration understands the drug affordability crisis facing Americans. That is why it has made reform in this area a priority. The American Society of Health-System Pharmacists (ASHP), the Hematology/Oncology Pharmacy Association (HOPA), the National Pharmaceutical Association (NPhA), and the undersigned state pharmacy associations share those goals.

Congress and President Trump are on the same page here. The Inflation Reduction Act (IRA) empowers the Centers for Medicare & Medicaid Services (CMS) to negotiate drug prices directly with manufacturers for Medicare beneficiaries and then commissions CMS to ensure that those negotiated prices serve as the maximum fair price (MFP) offered to beneficiaries, pharmacies, and other providers delivering the therapies. President Trump has likewise issued an executive order directing CMS to improve transparency in the IRA's negotiation program and seek policy recommendations to "promote a more competitive, efficient, transparent, and resilient pharmaceutical value chain that delivers lower drug prices for Americans."¹

Unfortunately, pharmaceutical manufacturers have halted that progress. They have lobbied hard for a negotiation program that leaves manufacturers in control of honoring the MFP. Under the manufacturer-preferred system, drug companies can force pharmacies and other providers to pay far more than the MFP for the very drugs subject to CMS's price negotiations. Manufacturers may later provide pharmacies with a retrospective rebate, but that puts pharmacies at the mercy of manufacturer discretion and timing. This is in direct conflict with President Trump's order to make the IRA's drug pricing transparent.

We submit this letter to express deep concern regarding this manufacturer-preferred system. CMS should reject that system and instead require manufacturers to apply **upfront discounts**—not retrospective rebates—to dispensing entities for three reasons:

¹ Federal Register, Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First." Available at: <https://www.federalregister.gov/documents/2025/04/18/2025-06837/lowering-drug-prices-by-once-again-putting-americans-first>

1. The manufacturer-preferred system of rebates is inconsistent with the text and purpose of the IRA. CMS not only has clear statutory authority to require manufacturers to honor MFPs with upfront discounts, but doing so is also the only way to achieve Congress's objectives. Congress knows how to authorize CMS to use rebates. It chose not to here.
2. The manufacturer-preferred system of rebates is also inconsistent with the administration's commitments to regulatory simplification, administrative efficiency, and pharmaceutical price transparency. Individual manufacturer rebate plans are administratively cumbersome for both CMS and providers and introduce avoidable variability in the accurate reconciliation of drug prices.
3. Finally, the manufacturer-preferred system of rebates is inconsistent with a sustainable healthcare delivery system. It directly threatens the viability of the very providers on whom the success of the IRA's negotiation program depends. Allowing manufacturers to charge pharmacies prices far above those set by CMS misallocates the statutory responsibility and shifts the cost burden away from the entities on whom Congress placed it.

As explained in more detail below, the consequences of the manufacturer-preferred system of rebates are profound and inconsistent with both the administration's and Congress's goals. Congress has empowered CMS to implement a standardized, upfront discount model, and CMS should exercise that authority to realign the program with the IRA's text and purpose. Doing so will harmonize CMS policy with the administration's deregulatory and drug-pricing transparency priorities. Most importantly, it will safeguard beneficiary access to discounted therapies.

I. The IRA Neither Requires nor Allows Manufacturers to Saddle Pharmacies with the Cost Burden of the IRA's Drug Price Negotiation Program

A. Manufacturers are Solely Responsible for Effectuating MFP

Section 1191(a) of the Social Security Act directs the Secretary to establish a drug price negotiation program and to enter into agreements with manufacturers of selected drugs under the program. The agreements set the MFP that manufacturers may charge Medicare beneficiaries and dispensers for the negotiated drugs. The IRA leaves no doubt about who is responsible for honoring, and who will benefit from, the MFPs: it is **manufacturers** who must "provide access" to the prices both to "dispensing entities" and to Medicare beneficiaries "before . . . any other discount." The IRA nowhere suggests that CMS can shift that obligation to dispensing entities, nor does it provide any basis for allowing manufacturers to require that dispensing entities bear the initial cost burden of the pricing discounts. Quite the opposite. The IRA **entitles** dispensing entities to those pricing discounts—it doesn't make them cash lenders to manufacturers.

B. Rebates Are Inconsistent with Congressional Intent

The manufacturers want to flip the IRA's policy objectives on their head by forcing pharmacies to pay inflated prices first and hope for rebates later. However, two of Congress's principal goals were to inject price certainty and price transparency for the negotiated drugs. Rebates flunk both of those goals. And we know Congress did **not** want rebates because it **knows** very well how to authorize CMS to use

rebates. The 340B Drug Pricing Program expressly tells CMS that the amount required to be paid may “take into account any rebate or discount.” The IRA contains no such language suggesting manufacturers may use rebates to honor a drug’s MFP.

C. CMS Has a Clear Model for Upfront Discounts in the 340B Program

To be sure, Congress left the details of the IRA’s drug price negotiation program to CMS, which has discretion (within limits) to establish procedures to ensure compliance with the statute’s requirements. Here, CMS does not need to reinvent the wheel. Instead, it should look to the 340B Drug Pricing Program’s use of **upfront discounts** as the model. The 340B statute has been interpreted under long-standing guidance to require prospective discounts to covered entities. Methods of providing upfront discounts under 340B are well established and dispensing entities have a long history of successfully managing separate 340B inventories and utilizing replenishment models for 340B drugs.

Aligning the IRA’s drug price negotiation program with the established, prospective discount model of the 340B program ensures uniformity, predictability, and efficiency—all things the administration has worked hard to infuse in government. Manufacturers are already trying to exploit the current misalignment to inject rebates into the 340B program. That regressive step is most effectively rebuffed by establishing a **uniform, prospective discount requirement** for MFP. This approach is legally sound, programmatically efficient, and fully aligned with the legislative intent of the IRA.

On the other hand, permitting a manufacturer-preferred system of rebates has the effect of unlawfully shifting a statutory manufacturer obligation onto providers. That contravenes both the letter and the purpose of the law. Without an express statutory directive, CMS lacks the authority to impose such a shift, and the current implementation must be amended to reflect the program Congress legislated.

II. The Manufacturer-Preferred System of Rebates Is Misaligned with the Administration’s Deregulatory and Price Transparency Initiatives

A. The Administration’s Commitment to Deregulation and Transparency

The administration is intent on reforming the regulatory landscape in healthcare by eliminating unnecessary complexity, increasing administrative efficiency, and improving price transparency. That is why it has issued a series of executive orders directing federal agencies to reduce administrative burden, promote regulatory transparency, and advance policies that strengthen Medicare’s fiscal sustainability.

Executive Order 14192, “Unleashing Prosperity Through Deregulation,” or the “10-for-1 Deregulatory” Executive Order, directs agencies to eliminate outdated or unduly burdensome requirements to reduce the overall regulatory burden on the economy.² Executive Order 14273, “Lowering Drug Prices by Once Again Putting Americans First,” further directs the Department of Health and Human Services to implement the IRA’s negotiation program in a manner that improves cost savings and transparency and

² Federal Register, Executive Order 14192, “Unleashing Prosperity Through Deregulation.” Available at: <https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation>

seeks broad policy recommendations that “promote a more competitive, efficient, transparent, and resilient pharmaceutical value chain that delivers lower drug prices for Americans.”³

B. The Rebate Process Creates Uncertainty and Administrative Complexity

Under the manufacturer-preferred system of rebates, pharmacies and providers have no assurance on how or when they will be reimbursed. CMS’s program guidance established a Medicare Transaction Facilitator to serve as the primary infrastructure for effectuating the discounts.⁴ CMS also plans to create a payment module to provide a clearinghouse that manufacturers *may* use to provide rebates to dispensing entities, but right now, manufacturers are *not required* to use the yet-to-be-built payment module. Manufacturers will establish their own systems, rules, and processes for every Medicare negotiated medication they manufacture.⁵ By permitting manufacturers to either (1) use the CMS payment module for rebates or (2) develop bespoke rebate mechanisms outside of the CMS system, manufacturers will wield immense control over the process. And one thing is certain, whatever process manufacturers use will shift the administrative burden to providers and CMS itself.

If that sounds like regulations on regulations, that’s because it effectively is. Manufacturers will impose complex and burdensome red tape on pharmacies and providers that undermine the IRA’s objectives at every turn. That also means that CMS’s oversight responsibilities will multiply. The agency will need to evaluate and track numerous and varying rebate frameworks across all selected drugs and all participating manufacturers. This duplication of effort is unnecessary and avoidable. It adds compliance risk, consumes federal resources, and detracts from CMS’s ability to focus on programmatic integrity and beneficiary outcomes.

C. CMS’s Regulatory Relief RFI Recognized the Excessive Burden on Providers

CMS’s Medicare Regulatory Relief Request for Information (RFI), issued in furtherance of Executive Order 14192, explicitly sought stakeholder input on deregulation to reduce *provider burden*, streamline compliance obligations, and prioritize policies that enable providers to focus on care delivery rather than administrative complexity.⁶ The RFI recognized that policies which “require duplicative processes” or “impose excessive operational costs” can drive providers away from federal programs and ultimately undermine patient access and health equity. The manufacturer-preferred system of rebates exemplifies exactly the kind of system CMS identified as problematic in its RFI. It creates variation where uniformity is possible and risks not only increasing overhead costs but also deterring provider participation.

³ Federal Register, Executive Order 14273, “Lowering Drug Prices by Once Again Putting Americans First.” Available at: <https://www.federalregister.gov/documents/2025/04/18/2025-06837/lowering-drug-prices-by-once-again-putting-americans-first>

⁴ Section 40.4, [Medicare Drug Price Negotiation Program Final Guidance for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027](#)

⁵ Section 40.4.3, Medicare Drug Price Negotiation Program Final Guidance for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027

⁶ CMS, “Unleashing Prosperity Through Deregulation of the Medicare Program (Executive Order 14192)- Request for Information.” Available at: <https://www.cms.gov/medicare-regulatory-relief-rfi>

D. Prospective Discounts Are the Deregulatory, Transparent Alternative

A **prospective discount requirement**, by contrast, will eliminate dozens of redundant processes, streamline regulatory oversight, and ensure the negotiated prices are administered uniformly and transparently. CMS should take this opportunity to realign its implementation with the administration's regulatory and policy objectives.

III. An Upfront Discount Process is Needed to Ensure the IRA's Drug Price Negotiation Program Achieves the Full Range of Benefits Congress Intended

A. The IRA's Drug Pricing Goals are Dependent on Dispenser Participation

The IRA's drug pricing provisions reflect a congressional mandate to improve drug price affordability for Medicare beneficiaries and the federal government. The statute is intended to reduce out-of-pocket costs and overall program spending, increase transparency in drug pricing, and ensure Medicare beneficiaries have access to affordable therapies. To achieve its goals, the IRA's negotiation program depends on widespread dispenser participation so that beneficiaries can access negotiated prices through the existing healthcare delivery system without disruption or provider attrition. As CMS itself has noted in program guidance, implementing a timely, administrable, and sustainable mechanism to deliver the MFP to end users is critical to avoiding access barriers.⁷ This model presumes seamless integration of the negotiated pricing for all stakeholders.

B. The Rebate Model Threatens Dispenser Participation and Patient Access

The manufacturer-preferred system of rebates frustrates that design. Allowing manufacturers to satisfy their statutory obligations through retrospective rebates introduces a fragmented, administratively complex process that delays application of the negotiated price and forces dispensers to assume up-front costs. Rather than a single, streamlined approach, the rebate model generates dozens of manufacturer-specific payment procedures, each with its own reporting requirements, timeframes, and reimbursement pathways. That is nothing but additional red tape designed to increase complexity and will result in decreased provider participation.

In contrast, a **standardized, prospective discount model** will preserve beneficiary access, limit administrative burden, and promote statutory compliance—aligning implementation with the law's underlying structure and intent.

The IRA's primary drug pricing policy objective is to provide access to affordable prescription drugs to Medicare beneficiaries. As the agency has noted, "[t]he law provides meaningful financial relief for millions of people with Medicare by improving access to affordable treatments and strengthening Medicare."⁸ But allowing manufacturers to require that dispensing entities seek retrospective

⁷ Section 40.4, Medicare Drug Price Negotiation Program Final Guidance for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027

⁸ CMS, "Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026." Available at: <https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026>

reimbursement to recover discounts jeopardizes beneficiary access to these affordable drug prices. The retrospective rebate approach imposes a financial and operational burden on dispensing providers that is incompatible with the goals of the IRA.

The manufacturer-preferred system of rebates drives down provider participation, particularly among rural, safety-net, and community-based providers operating on thin margins. Inconsistent reimbursement timelines jeopardize liquidity and introduce substantial financial risk. For smaller providers, that risk is too great to bear.

A recent analysis published by the National Community Pharmacists Association (NCPA) demonstrates the significant financial risk facing pharmacies under the manufacturer-preferred system of rebates, including payment delays resulting in \$11,000 weekly cashflow loss and \$43,000 annual revenue loss.⁹ Perhaps most concerning, a survey of NCPA members found that 93.2% of independent pharmacists are considering not stocking, or have already decided not to stock, one or more of the first ten Part D drugs selected for price setting.¹⁰ Those decisions are the logical consequence of CMS guidance prioritizing manufacturers where the IRA does not. And ultimately, Medicare beneficiaries will be denied the IRA's full benefit.

Conclusion

The manufacturer-preferred system of rebates jeopardizes provider stability, undermines patient access, and exceeds the agency's statutory authority. The IRA does not authorize CMS to allow manufacturers to shift the cost burden of the negotiated prices to dispensers.

Allowing manufacturers to effectuate negotiated pricing through a rebate rather than a singular **manufacturer-provided upfront discounted price** contradicts not only the plain text and structure of the IRA, but also with the administration's broader policy priorities, including regulatory simplification under the Executive Order 14192 and the commitment to a transparent and efficient prescription drug value chain set forth in President Trump's Executive Order 14273. An upfront discount represents the default method under comparable federal programs, aligns with the IRA's legislative design, eliminates excessive administrative processes, supports provider participation, and ensures the sustainability of the negotiation program.

ASHP, HOPA, NPhA, and state pharmacy associations across the country strongly urge CMS to revise its guidance and require a uniform, prospective discount model.

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.

The Hematology/Oncology Pharmacy Association (HOPA) supports hematology/oncology pharmacy professionals and promotes the role of the pharmacist in collaborative cancer care. Founded in 2004,

⁹ NCPA. (January 2025). *Unpacking the Financial Impacts of Medicare Drug Price Negotiation Analysis on Pharmacy Cash Flows*. Available at:

¹⁰ NCPA. (January 2025). Report for January 2025 Survey of Independent Pharmacy Owners/Managers. Available at: https://ncpa.org/sites/default/files/2025-01/1.27.2025-FinalExecSummary.NCPA_.MemberSurvey.pdf

HOPA provides crucial education, networking, and advancement opportunities frequently sought by pharmacists, pharmacy interns, residents, fellows, students, technicians, researchers, and administrators who specialize in hematology/oncology pharmacy.

The National Pharmaceutical Association (NPhA), established in 1947, is dedicated to representing the views and ideals of minority pharmacists on critical issues affecting healthcare and pharmacy, promoting racial and health equity, as well as advancing the standards of pharmaceutical care among all practitioners.

Collectively, our members are on the front lines of delivering affordable and clinically appropriate medication to the American people.

We stand ready to support CMS in effectuating this policy shift and ensuring the successful implementation of the IRA's reforms, as well as the administration's drug pricing policy goals. Please do not hesitate to contact Jillanne Schulte Wall at 301-664-8698 or jschulte@ashp.org if we can provide any further information or assist the agency in any way.

Sincerely,

American Society of Health-System Pharmacists
Hematology/Oncology Pharmacy Association
National Pharmaceutical Association
Alabama Society of Health-System Pharmacists
Arizona Pharmacy Association
Arkansas Association of Health System Pharmacists
California Society of Health System Pharmacists
Colegio de Farmaceuticos de Puerto Rico
Colorado Pharmacists Society
Connecticut Society of Health System Pharmacists (CSHP)
Delaware Society of Health-System Pharmacists
Georgia Society of Health-System Pharmacists
Idaho Society of Health-System Pharmacy
Illinois Council of Health-System Pharmacists
Iowa Pharmacy Association
Indiana Pharmacy Association
Kansas Council of Health System Pharmacy
Kentucky Society of Health-System Pharmacists
Louisiana Society of Health-System Pharmacists
Maryland Society of Health-System Pharmacy
Massachusetts Society of Health System Pharmacy
Michigan Society of Health-System Pharmacists
Minnesota Society of Health-System Pharmacists
Missouri Society of Health System Pharmacists

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Nebraska Pharmacists Association

Nevada Society of Health System Pharmacists

Nevada Society of Health-System Pharmacists

New Hampshire Society of Health-System Pharmacists

New Jersey Society of Health-System Pharmacy

New York State Council of Health-system Pharmacists

North Carolina Association of Pharmacists

Norton Healthcare

Ohio Society of Health-System Pharmacy

Oregon Society of Health-System Pharmacists

Pharmacy Society of Wisconsin

South Dakota Pharmacists Association

Tennessee Pharmacists Association

Texas Society of Health-System Pharmacy

Virginia Society of Health-System Pharmacists

Washington State Pharmacy Association

West Virginia Society of Health System Pharmacists

Wyoming Society of Health-System Pharmacy

cc:

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