April 20, 2026

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20852

Re: Request for Information: 340B Rebate Model Pilot Program (HRSA–2026–03042)

Dear Administrator Engels:

On behalf of our over 65,000 pharmacist, pharmacy technician, and pharmacy student members practicing in all settings across the United States, the American Society of Health-System Pharmacists (ASHP) appreciates the opportunity to comment on the Health Resources and Services Administration's (HRSA) request for information (RFI) regarding the 340B Rebate Model Pilot Program (the "pilot program" or "model").

ASHP continues to oppose the imposition of any rebate model in the 340B Drug Pricing Program. Payment under the 340B program has always been prospective.[1] Shifting to a rebate model, even for a small number of drugs, creates serious risks to a high-functioning program and the patient services that it supports. We believe that manufacturers are using the implementation of the Inflation Reduction Act (IRA) negotiated drug pricing framework as an improper justification for seeking rebates in the 340B program. Structuring both the 340B program and the IRA negotiated pricing programs as prospective discounts would make them more efficient, more consistent with congressional intent, and less prone to manufacture abuse.

1. **HRSA Must Consider Alternatives to a Rebate Model.**

Although we appreciate HRSA's efforts to collect detailed feedback on a rebate model, HRSA must consider alternatives. From its inception, the 340B program has operated as an upfront discount. Covered entities have relied on that program design for almost 40 years, setting up care models around it that have greatly expanded patient access to care services. Although the previously proposed rebate model pilot was explicitly not premised on addressing duplicate discounts, they are a chief manufacturer complaint and almost certainly underpin the manufacturer push for a refund model. However, covered

[1] *See* 58 Fed. Reg. 27289, 27291 (May 7, 1993); *see also* 63 Fed. Reg. 35239 (June 29, 1998)(allowing a sole exception to the prospective discount for AIDs programs that are structured differently than other covered entities).

entities do not have a program integrity problem — ample safeguards already exist to address duplicate discounts, including HRSA and manufacturer audits.

If HRSA determines that these mechanisms are inadequate, a claims clearinghouse run by an independent third party could help mitigate manufacturer concerns about duplicate discounts while preserving prospective discounts. Under this arrangement, 340B covered entities would continue to receive the upfront 340B price, with any reconciliation post-payment, thereby ensuring that manufacturers bear the costs. This option would also obviate the need for manufacturer-imposed claims data requirements (e.g., the recent Eli Lilly and Novo Nordisk policies that attempt to unilaterally impose extra-statutory program requirements).

As the IRA rollout demonstrates, when pharmaceutical manufacturers are given too much control over the design and implementation of a program, they will choose to delay payment obligations through a drawn-out rebate scheme— leaving health care providers and their patients to suffer. Although HRSA has no authority over the MFP process, we understand that the agency is coordinating closely with CMS. We continue to urge CMS to reconsider its administratively burdensome and unworkable rebate model and institute an upfront discount (see Attachment 1). We urge HRSA to look at the unsuccessful rollout of the IRA rebate process and rethink the imposition of a rebate model for the 340B program. Both IRA Medicare discounts and 340B would be administratively simpler and less prone to manufacturer abuse if implemented as prospective discounts.

II. Rebate Models Unnecessarily Increase Costs and Siphon Healthcare System Resources.

If HRSA moves ahead with a rebate model over covered entities' objections and in spite of evidence that a rebate model will undermine program efficacy, any model must be piloted on a small scale (i.e., voluntarily and not nationwide) and must be carefully tailored and implemented to avoid causing additional damage to providers and their patients. Any pilot program must include safeguards for covered entities and the 340B program. To accomplish this (short of abandoning the efforts to implement a rebate model, which we continue to urge), HRSA will need to provide the following guarantees to covered entities:

- HRSA Retains Authority for the Program: Any pilot program must ensure that no authority over program administration is ceded to manufacturers. Ongoing manufacturer efforts to systematically undercut the 340B program highlight the need to close any potential loopholes that could be used to damage the program.

- Provide a Guarantee of Full Cost Coverage for Covered Entities: We recognize and appreciate HRSA's previous statement that plans must assure that "no additional administrative costs of running the rebate model shall be passed on to covered entities." However, assurances alone are insufficient. The previous pilot proposal included no mechanism to account for these expenses, which include costs associated with third party administrators, financing, staff time to manage 340B program changes, and potential legal fees to address denials or claims disputes. Operating what amounts to a secondary 340B program for drugs subject to the rebate model will create

significant financial strain at a time when many covered entities, particularly rural providers, face major financial challenges.

The rollout of the Maximum Fair Price (MFP) rebates under the IRA illustrates the problems created by a rebate model. Hospitals and health systems are seeing delayed rebate and claims payments, forcing them to float purchasing and administrative costs. Our members are reporting that they are currently waiting on, collectively, millions of dollars in rebates for just the first three months of IRA. These unpaid rebate claims are in addition the costs of purchasing the drugs at a higher price (WAC versus 340B). Further, because claims issues are reported to both CMS and the manufacturers, and each claim must be reported separately, organizations must reconfigure workflows and add FTEs to cover management of the rebates.

Manufacturers had almost total control over how the IRA systems were configured and yet now argue they are unworkable and require this ancillary 340B rebate model. Members have reported numerous problems with the MFP rebates, including mismatched data fields, requests for invoice pricing for all purchases (not just 340B inventory), and a lack of responsiveness from both CMS and certain manufacturers regarding these issues. Allowing manufacturers to expand these problems into the 340B environment is both unnecessary and fiscally irresponsible, especially considering the existence of a much simpler, cost-effective option — the third-party clearinghouse.

Although manufacturers argue that including only IRA drugs in a pilot limits costs, hospitals will see costs across all non-340B drugs as well because they must account for two separate reimbursement processes (pilot drugs versus non-pilot 340B drugs). For any rebate pilot, HRSA must create a clear mechanism by which covered entities can submit costs and request reimbursement for <u>all</u> new administrative and operational costs associated with any rebate pilot.

- <u>Ensure Prompt Payment and Impose Penalties for Manufacturer Noncompliance</u>: To ensure that any pilot program is not subject to abuse, penalties for manufacturer noncompliance must be meaningful. This will require a clear definition of noncompliance with civil monetary penalties attached. HRSA must enumerate clear requirements for manufacturers to issue prompt payments (including, but not limited to, delayed rebate payments and improper claims denials), with stringent penalties for noncompliance. Specifically, HRSA should exercise its authority under (d)(1)(B)(vi) of the 340B statute and impose civil monetary penalties (CMP) for each instance of non-compliance, with interest accruing on rebates not paid within the prompt payment window.

  HRSA must also clarify that manufacturers have no authority to delay or deny claims. Current experience with the MFN rebate process underscores the importance of agency oversight of claims denial. At present, hospitals and other providers have reported a pattern of manufacturer noncompliance with the IRA's prompt payment requirements. Many hospitals are sitting on backlogs of 3 or more months' worth of unpaid rebates — in some cases, up to 50 – 70% of rebates from certain manufacturers. Rebate payment is then conditioned on access to invoice pricing or other claims data that should not have to be provided.

Hospitals have been further frustrated by the Beacon platform, which generates canned responses to queries regarding unpaid rebates, thereby requiring extensive human intervention to simply determine the reasons for the claim rejection. This creates a troubling precedent for the expansion of a rebate into 340B, which would greatly magnify the already significant costs of managing the IRA MFP process. Again, this could be avoided by implementing a third-party clearinghouse and maintaining upfront payment.

To best ensure prompt payment, HRSA must clarify how it will resolve claims disputes. As HRSA is aware, the 340B administrative dispute resolution (ADR) process has been troubled. Given the financial stakes of the pilot, the dispute resolution process must be efficient and fair. The existing ADR process is slow and ill-equipped to address the rebate issues likely to arise under the pilot. We urge HRSA to establish a separate dispute resolution process that will allow covered entity claims to be fast-tracked. This must include, at minimum, a dedicated HRSA ombudsman or point-of-contact, as well as concrete, enforceable timelines for resolution. Further, manufacturers must be required to cover the legal fees and other administrative costs associated with delayed rebates or improper denials.

- Establish a Consistent Process for Claims Submission: HRSA must prohibit manufacturers from dictating the implementation of a rebate pilot. Such a permissive structure exposes covered entities to multiple data platforms and processes for rebate submission, including variation in required data fields. This is particularly problematic because some covered entities lack access to BIN and PCN data that could be required by a manufacturer. Because manufacturers can also create bespoke systems for IRA negotiated drug pricing effectuation, this raises the possibility of layering a second set of manufacturer- or drug-specific systems on covered entities. This will further increase administrative costs even beyond what we have noted above. Further, it creates serious concerns about maintaining data integrity and security, especially given recent healthcare data breaches like the one at Change Healthcare.

  To reduce administrative burden, HRSA should require the use of a single neutral third-party platform for data submission. This entity should have no affiliation with manufacturers (e.g., a platform such as Kalderos/Truzo should not be permitted). Doing so would offer far more control over data security standards, while providing a firewall against manufacturer incursion into sensitive claims data.

- Provide Objective Program Metrics: As noted above, we believe that opening the door to a rebate model will damage the 340B program, harming patients across the country. There must be objective metrics to gauge success, particularly, as if indicated in previous communications, HRSA intends to consider expanding any pilot. The fact that this determination could be largely premised on manufacturer feedback without fully engaging covered entities is alarming.

  The consequences of such a fundamental and wholly unnecessary shift in the 340B program should be clearly documented. When evaluating any pilot for continuation, HRSA must consider the total additional costs of the program to covered entities and measure the negative

consequences for patients. At minimum, the standards by which the program is evaluated should be publicly available and subject to notice and comment.

We appreciate the opportunity to offer our feedback on the RFI. ASHP urges HRSA to abandon the pilot program in favor of other practical, less damaging options. No pilot program should be proposed until HRSA has time to adequately address stakeholder feedback and fully gauge the potential damage to covered entities and their patients from such a precipitous and catastrophic policy shift. Allowing manufacturers to dictate 340B programmatic requirements is misguided. We look forward to working with HRSA to identify practical policy solutions that protect the 340B program and the patients it serves. 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.
Senior Director, Health & Regulatory Policy

ASHP comments re: HRSA 340B Rebate Pilot

April 20, 2026

Attachment 1: ASHP Memo to CMS re: IRA Negotiated Drug Pricing Framework

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 mounting crisis facing Americans. That is why it has made reform in this area a priority. One of its chief reforms has been to ensure affordable therapies that Americans in every zip code can access. The American Society of Health-System Pharmacists (ASHP) is committed to the same reform the Administration has been working so hard to implement.

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" 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 seeking policy recommendations to "promote a more competitive, efficient, transparent, and resilient pharmaceutical value chain that delivers lower drug prices for Americans."[2]

The ASHP shares those goals. 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. Its members are on the front lines of delivering affordable and clinically appropriate medication to the

[2] 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

American people. This makes ASHP well positioned to address the reforms that Congress and the Administration have tasked CMS with implementing.

Unfortunately, pharmaceutical manufacturers have halted that progress in its tracks. They have lobbied hard for a negotiation program that leaves manufacturers in control of honoring the Maximum Fair Price. Under the manufacturer-preferred system, manufacturers can force pharmacies and other providers to pay far more than the Maximum Fair Price 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, timing, pseudo-regulatory fiat. This is in direct conflict with President Trump's order to make the IRA's drug pricing transparent. By the time pharmacies realize the increasingly illusory benefits of the IRA's negotiation program, the damage is done, and the force of the reforms has been largely lost.

ASHP submits 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. 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 Maximum Fair Prices 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' 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.

ASHP comments re: HRSA 340B Rebate Pilot

April 20, 2026

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 Maximum Fair Price

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 a "Maximum Fair Price" 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 Maximum Fair Prices: 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. But 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 Maximum Fair Price.

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 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** here as well. 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, obliges agencies to eliminate outdated or unduly burdensome requirements reduce the overall regulatory burden on the economy.[3] Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First," further directs HHS to implement the IRA's negotiation program in a manner that improves cost savings and transparency and seeks broad policy recommendations that "promote a more competitive, efficient, transparent, and resilient pharmaceutical value chain that delivers lower drug prices for Americans."[4]

B. The Rebate Process Creates Uncertainty and Administrative Complexity

Under the manufacturer-preferred system of rebates, pharmacies 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.[5] 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.[6] 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 yield immense

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[3] 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

[4] 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

[5] 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

[6] 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

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 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.[7] 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.

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

[7] 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

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 Maximum Fair Price to end users is critical to avoiding access barriers.[8] 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."[9] But allowing manufacturers to require that dispensing entities seek retrospective 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

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[8] 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

[9] 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

payment delays resulting in $11,000 weekly cashflow loss and $43,000 annual revenue loss.[10] Perhaps most concerningly, a survey of NCPA members found that 93.2 percent 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.[11] Those decisions are the logical consequence of 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 strongly urges CMS to revise its guidance and require a uniform, prospective discount model. ASHP stands 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 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.
Senior Director, Health & Regulatory Policy

cc:

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

[11] 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

ASHP comments re: HRSA 340B Rebate Pilot

April 20, 2026

Stephanie Carlton, Chief of Staff

Centers for Medicare & Medicaid Services

John Brooks, Deputy Administrator and Chief Policy and Regulatory Officer

Centers for Medicare & Medicaid Services

Chris Klomp, Deputy Administrator and Director of the Center for Medicare

Centers for Medicare & Medicaid Services