



September 8, 2025

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: Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998)

Dear Administrator Engels:

On behalf of our 60,000 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) notice regarding the 340B Rebate Model Pilot Program (the "pilot program" or "model").

ASHP opposes the imposition of any rebate model in the 340B program. Payment under the 340B program has always been prospective.¹ Shifting to a rebate model, even for a small number of drugs, is legally dubious and creates serious risks to a high-functioning program and the patient services that it supports. We continue to 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 Drug Pricing Program. As detailed in the attached memo to the Centers for Medicare and Medicaid Services (CMS), clear legal authority exists for implementing a prospective payment for IRA negotiated price drugs, negating manufacturer arguments for 340B rebates.² As outlined in the memo, requiring a retrospective rebate will result in huge costs for covered entities by requiring them to purchase medications at the Wholesale Acquisition Cost rather than the 340B price and then float that cost until (and if) they receive reimbursement via rebate. HRSA's pilot program accelerates the timeline for these costs with almost no notice to covered entities despite the major budgetary impact.

Further, the unnecessary rush to implement this program – with a mere week between the comment due date and the manufacturer application due date – creates additional risk. If this pilot program must be implemented, it is critical that it includes safeguards for covered entities and the 340B program. To

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).

² See Attachment 1.

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accomplish this (short of abandoning the pilot, which we continue to urge), HRSA will need to make a number of changes to the pilot program proposal.

The 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. Specifically, if this damaging and unnecessary pilot must be implemented, the following safeguards must be incorporated:

- Provide a Guarantee of Full Cost Coverage for Covered Entities: We recognize and appreciate HRSA's 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 pilot proposal includes no mechanism for accounting for these costs, which will include new costs for third party administrators (TPAs), staff time for managing 340B program changes, and potential legal costs associated with addressing denials or claims disputes. Operating what amounts to a secondary 340B program (e.g., for the drugs subject to the rebate model) will create significant financial strain at a time when many covered entities, particularly rural providers, face major financial headwinds. We respectfully request HRSA create a clear mechanism by which covered entities can submit costs and request reimbursement for all costs associated with this pilot program.
- Ensure Prompt Payment and Impose Penalties for Manufacturer Noncompliance: To ensure that the 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. While we appreciate the clarification in the [Frequently Asked Questions](#) (FAQ) document regarding how HRSA defines noncompliance (i.e., the 10 day window for rebate payment after claims submission), the FAQ still lacks sufficient specificity. HRSA should enumerate clear requirements for prompt payment (including, but not limited to, delayed rebate payment, improper claims denial, etc.) for manufacturers with stringent penalties for noncompliance. Specifically, we agree with the American Hospital Association's comments that 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 (10 day) window outlined in the FAQ.

HRSA must also clarify when and how manufacturers can delay or deny claims. HRSA notes that under the pilot, claims cannot be "denied based on compliance concerns with diversion or Medicaid duplicate discounts." However, there is no additional detail regarding permissible grounds for denial or what might flag a manufacturer's pattern of delay or denial as suspicious. For instance, HRSA must clarify that manufacturers cannot use their own unilateral limits on covered entities (e.g., contract pharmacy restrictions) to deny claims.

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We recognize that HRSA is attempting to provide flexibility within the pilot program, but doing so opens the door to manufacturer abuse of a rebate program they alone demanded. To minimize administrative burden, HRSA should create a standard form for claims denial that would require detailed information regarding a delay or denial sufficient to allow the covered entity to challenge it. At minimum, this would require a dedicated manufacturer point-of-contact and supporting documentation for the claims delay and/or denial. This process must also be coupled with concrete timelines for resolution.

Further, to best ensure prompt payment, HRSA must clarify how claims disputes will be resolved. As HRSA is aware, the 340B administrative dispute resolution (ADR) process has been troubled, and given the additional costs at issue in the pilot, it is imperative that the dispute resolution process is efficient and fair. The existing ADR process is slow and not nearly nimble enough 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 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 proposes to allow each manufacturer to establish its own bespoke program to implement the pilot program. This permissive structure means that covered entities may be faced with multiple data platforms and processes for rebate submission, including variation in data fields required. 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 breaches (e.g., 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 would 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. Although HRSA indicates that it will be reviewing the “merits and shortcomings” of a 340B rebate model, it has proposed no objective metrics to gauge success. Further, the FAQ makes clear that the

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agency is willing to move beyond IRA negotiated price drugs, stating it “may consider expanding the rebate pilot to other drugs purchased under the 340B Program that have not been selected for negotiation.” The fact that this determination is largely premised on manufacturer feedback is alarming.

The consequences of such a fundamental and wholly unnecessary shift in the 340B program should be clearly documented. When evaluating the 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.

ASHP appreciates the opportunity to offer our input and suggestions on the 340B Rebate Model Pilot Program. We urge HRSA to abandon the pilot program until it 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 leeway to dictate 340B programmatic requirements is legally questionable and certainly inadvisable. We urge HRSA to reconsider the model pilot. 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,

A handwritten signature in black ink that reads "Jillanne Schulte Wall". The signature is written in a cursive, slightly slanted style.

Jillanne Schulte Wall, J.D.
Senior Director, Health & Regulatory Policy

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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.”³

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

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>

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members are on the front lines of delivering affordable and clinically appropriate medication to the 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.

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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.

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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.⁴ 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.”⁵

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.⁶ CMS also plans to create a payment

⁴ 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>

⁵ 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>

⁶ 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](#)

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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.⁷ 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 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.⁸ 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.

⁷ 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](#)

⁸ 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>

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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 Maximum Fair Price to end users is critical to avoiding access barriers.⁹ 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."¹⁰ But allowing manufacturers to require that dispensing entities seek retrospective reimbursement to recover discounts jeopardizes beneficiary access to these affordable drug prices. The

⁹ 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](#)

¹⁰ 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>

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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.¹¹ 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.¹² 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

¹¹ NCPA. (January 2025). *Unpacking the Financial Impacts of Medicare Drug Price Negotiation Analysis on Pharmacy Cash Flows*. Available at:

¹² 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

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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,

A handwritten signature in black ink that reads "Jillanne Schulte Wall". The signature is written in a cursive, slightly slanted style.

Jillanne Schulte Wall, J.D.
Senior Director, Health & Regulatory Policy

cc:

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