April 20, 2026

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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 – HHS Docket No. HRSA-2026-03042

Dear Administrator Engels:

The National Association of Specialty Pharmacy (NASP) submits these comments in response to the Health Resources and Services Administration's (HRSA) Request for Information (RFI) published in the Federal Register on February 17, 2026, regarding the potential implementation of a rebate model under the 340B Drug Pricing Program (HHS Docket No. HRSA-2026-03042; 91 Fed. Reg. 7287).

NASP is the national professional association representing the full spectrum of specialty pharmacy stakeholders, including specialty pharmacies operating within 340B covered entities and specialty pharmacies serving as 340B contract pharmacies. NASP's membership also includes pharmaceutical manufacturers who participate in the 340B program. We are mindful of the legitimate interests of all stakeholders in this process and offer these comments with the shared goal of a 340B program that is well-functioning, transparent, and sustainable for every participant in the supply chain.

NASP respectfully urges HRSA to decline to implement a rebate model under the 340B program. As detailed below, a rebate model is expected to impose severe and unjustifiable cash flow burdens on 340B covered entities operating specialty pharmacies; creating dangerous delays in patient access to high-cost specialty medications; undermining the foundational statutory purpose of the 340B program; and departing from more than 30 years of consistent agency practice in a manner inconsistent with the program's statutory framework. If HRSA nonetheless determines to pursue a rebate pilot, NASP urges the agency to adopt robust safeguards

specifically calibrated to the unique operational and financial realities of specialty pharmacy practice.

Background: The 340B Program and the Specialty Pharmacy Context

Since its enactment, the 340B Drug Pricing Program has required participating manufacturers to sell covered outpatient drugs to eligible covered entities at or below the statutory ceiling price. The program's legislative history is clear and unambiguous: its purpose is to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

For more than three decades, HRSA has implemented this statutory purpose through a consistent upfront discount model—covered entities purchase drugs at the 340B ceiling price at the time of sale, without the financial burden of fronting full wholesale acquisition cost (WAC) and awaiting reimbursement. This upfront discount model has been integral to how covered entities plan operations, manage cash flow, and fulfill their safety-net missions.

Specialty pharmacy plays a central and expanding role within the 340B program. Complex specialty drugs—those treating cancer, autoimmune conditions, rare diseases, hepatitis C, HIV, and other complex conditions—represent the majority of 340B drug spending, even though specialty prescriptions account for a small fraction of total prescription volume. For hospitals with specialty pharmacies, the 340B discount on specialty drugs can generate significant savings. These savings are reinvested directly into expanded patient services, uncompensated care, clinical staffing, and community health programs.

NASP is aware that manufacturers have sought to implement rebate models to address concerns including duplicate discounts and the nonduplication provision under the Medicare Drug Price Negotiation Program (MDPNP). NASP acknowledges these as legitimate operational concerns that deserve a well-designed policy response. However, the rebate model as proposed—requiring covered entities to purchase drugs at WAC and await manufacturer-controlled rebate payments—is not a proportionate or operationally sound solution, particularly for high-cost specialty medications.

I. The Rebate Model Would Impose Severe and Unsustainable Cash Flow Burdens—Particularly for High-Cost Specialty Drugs

NASP's most fundamental concern with any 340B rebate model is its impact on covered entity cash flow, which is especially acute in the specialty drug context. Under a rebate model, a covered entity would be required to purchase specialty drugs at WAC—which for high-cost specialty medications can range from tens of thousands to hundreds of thousands of dollars per course of therapy—and wait for the manufacturer to process and pay a rebate equal to the difference between WAC and the 340B ceiling price. During this period, the covered entity is effectively providing an interest-free loan to the manufacturer.

The magnitude of this burden has been documented by 340B Health, whose 2025 national survey[1] found that under a rebate model applied to specialty drugs, the average annual "float" per disproportionate-share hospital would be $72.2 million.

These figures reflect a program limited to 10 to 25 drugs selected under the Medicare Drug Price Negotiation Program (MDPNP). If the rebate model were expanded more broadly—which HRSA has signaled as a potential future direction—the cash flow disruption for covered entities with specialty pharmacies would be exponentially greater. Specialty pharmacies within hospital systems commonly dispense dozens to hundreds of specialty products. The prospect of funding WAC-level upfront purchases for a broad range of specialty drugs, while waiting for manufacturer-controlled rebate timelines, would fundamentally destabilize specialty pharmacy operations within 340B covered entities.

340B Health's survey[2] further found that 93 percent of hospitals would face challenges maintaining current levels of uncompensated care; 92 percent would be forced to reduce the free and discounted drugs they provide through their pharmacies; and 77 percent could be forced to close programs entirely if such financial burdens were applied broadly. These are not abstract projections—they reflect the on-the-ground financial realities of hospitals and specialty pharmacies operating on thin margins in service to vulnerable populations.

The rebate model also has the potential to create a dangerous mismatch between payer reimbursement cycles and manufacturer rebate timelines. Health-system pharmacies typically receive reimbursement from insurers 14–45 days after claim submission. If manufacturer rebates are delayed and/or denied - the covered entity is forced to absorb the difference between WAC acquisition cost and payer reimbursement for extended periods. For high-cost specialty drugs where payer reimbursement may be below WAC (e.g., Medicaid, Medicare Part B), this creates a net cash loss on every dispense until the rebate is received, if it is received at all.

NASP urges HRSA to specifically address the following cash flow questions in any rebate pilot design: (a) the guaranteed maximum timeline within which manufacturers must pay rebates after dispense; (b) the financial consequences—including automatic interest charges—if manufacturers fail to pay timely; (c) the prohibition on manufacturers leveraging the rebate process to unilaterally deny or delay otherwise valid 340B claims; and (d) interim bridge financing mechanisms or other safeguards to prevent covered entities from being forced to choose between program participation and operational solvency.

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[1] 340B Health, Survey of 340B Hospitals on Financial and Operational Impacts of Drugmaker Rebate Proposals (Feb-Mar 2025); https://www.340bhealth.org/members/research/reports/.

[2] Ibid.

Many health-system specialty pharmacies use 340B savings to offer deeply discounted or free medications to uninsured and underinsured patients at the point of sale. Under the current upfront discount model, a specialty pharmacy can acquire high-cost oncology and other specialty medications at the 340B ceiling price, often a fraction of the wholesale acquisition cost, and offer those medications to cash-paying patients at or near the discounted acquisition cost. This point-of-sale assistance makes the difference between access and abandonment for financially vulnerable patients.

Under a rebate model, the pharmacy must acquire those same drugs at full WAC and cannot offer a meaningful discount until the manufacturer rebate is received weeks or months later, if at all. The pharmacy cannot afford to dispense a high-cost specialty medication to an uninsured patient at a loss and then wait an indefinite period for rebate reimbursement. This structural change eliminates the financial basis for point-of-sale patient assistance programs and forces vulnerable patients to either pay full WAC, delay therapy, or forgo treatment entirely. For patients facing cancer, transplant rejection, or other life-threatening conditions, such delays are not merely inconvenient, they can be clinically catastrophic.

II. The Rebate Model Threatens Timely Patient Access to Specialty Drugs

Access to high-cost specialty drugs is time-sensitive in ways that distinguish specialty pharmacy from conventional dispensing. Patients receiving oncology agents, immunosuppressants for transplant, biologics for autoimmune disease, or antiretrovirals for HIV cannot afford delays in therapy initiation or continuation. The cash flow disruptions described in Section I translate directly into access barriers: covered entities facing unsustainable upfront purchase costs may restrict their specialty pharmacy formularies, limit the volume of specialty drugs on hand, or cease dispensing certain products entirely.

Contract pharmacies face even more acute access risks. Under the existing upfront discount model, many 340B contract specialty pharmacies can offer point-of-sale discounts to cash-paying patients based on the 340B acquisition cost advantage. Under a rebate model, contract pharmacies would be required to dispense drugs at WAC while awaiting a rebate paid not to the contract pharmacy but to the covered entity. This structural mismatch eliminates the financial basis for point-of-sale discounts to cash-paying patients at contract pharmacies—directly undermining patient access for the most economically vulnerable individuals served by the 340B program.

NASP is particularly concerned that the rebate model, as proposed for MDPNP-negotiated drugs, targets precisely the high-cost specialty products for which the 340B discount provides the greatest benefit to patients and providers. The drugs selected for the initial pilot, including oncology agents, anticoagulants, and biologics are among the most costly and clinically critical specialty therapies. Imposing a rebate model on these drugs first concentrates the cash flow and access risks in the most operationally sensitive product categories.

HRSA's own stated commitment to evaluating "access to drugs for patients" as part of this RFI reinforces the centrality of this concern. NASP urges HRSA to require, as a threshold condition before any rebate pilot, a comprehensive and independently validated assessment of the downstream patient access impacts for specialty drugs dispensed through covered entity specialty pharmacies and 340B contract specialty pharmacies.

III. The Rebate Model Raises Serious Statutory and Regulatory Concerns

Section 340B(a)(1) of the Public Health Service Act (42 U.S.C. § 256b(a)(1)) requires the Secretary to enter into agreements with manufacturers under which "the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed" the applicable ceiling price. The statute's parenthetical—"taking into account any rebate or discount, as provided by the Secretary"—acknowledges that the ceiling price may be effectuated through various mechanisms. However, that parenthetical does not authorize the Secretary to implement any mechanism without regard to the program's core purpose, its legislative history, or more than 30 years of consistent agency practice.

Since the 340B program's inception, HRSA has consistently required that the discount be provided to covered entities at the point of sale—an upfront discount. HRSA's own prior guidance[3], including statements made in direct response to manufacturer inquiries in 2024, confirmed that unilateral manufacturer implementation of a rebate model "without prior Secretarial approval would violate section 340B(a)(1) of the PHS Act." The agency has now proposed to do precisely what it previously characterized as a statutory violation.

The U.S. District Court for the District of Maine's December 29, 2025, preliminary injunction in *American Hospital Association et al. v. Kennedy et al.* (No. 25-cv-600) found that HRSA's original rebate pilot program reflected a "departure from [HRSA's] decades-long practice of requiring upfront discounts on 340B eligible drugs" and that HRSA "failed to follow the APA's basic blueprint." The court further found "fatal" HRSA's failure to evaluate the costs and benefits of the rebate model or to weigh covered entities' decades of reliance on the upfront discount structure. The February 10, 2026, order[4] vacating and remanding the pilot program confirms that a rebate model cannot be lawfully implemented without a thorough, transparent, and procedurally proper rulemaking process.

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[3] U.S. Department of Health, Health Resources and Services Administration (HRSA;, *340B Rebate Model Pilot Program*; 90 Fed. Reg. 146 (August 1, 2025). https://www.govinfo.gov/content/pkg/FR-2025-08-01/pdf/2025-14619.pdf

[4] *American Hospital Association et al. v. Kennedy et al.*, No. 2:25-cv-00600-LEW (D. Me. Feb. 10, 2026) (Order on Motion to Vacate and Remand).

The legislative history of the 340B statute underscores the upfront discount model's centrality to the program's purpose. The program was designed to preserve for safety-net providers the

ability to "stretch scarce federal resources." A rebate model that requires covered entities to deploy those scarce resources to fund WAC-level upfront drug purchases—and to spend additional resources on administrative compliance, staffing, and IT infrastructure—directly inverts the program's purpose. It transforms covered entities from beneficiaries of the program into temporary creditors of pharmaceutical manufacturers.

The American Hospital Association has estimated[5] that compliance with a rebate model for just 10 drugs would require, on average, nearly two full-time employees per hospital—amounting to approximately 11.2 million burden hours across over 2,700 340B hospitals, at an estimated aggregate cost of more than $400 million annually. HRSA's own burden estimates confirm the disproportionate impact: covered entities would bear more than 5,000 times the annualized burden hours imposed on manufacturers.

NASP respectfully submits that deploying 340B program savings on administrative compliance with a manufacturer-controlled rebate process rather than on patient services is manifestly counter to the program's purpose. While NASP does not support a rebate model, if HRSA were to proceed, it would be necessary to ensure that any rebate model must, at minimum, fully account for and offset these costs, provide independent adjudication of rebate denials, and include enforceable timelines and financial penalties for delayed payments.

IV. Specific Responses to Selected RFI Questions

A. Administrative and Operational Costs (RFI Section 1)

Specialty pharmacies within 340B covered entities may face substantial incremental administrative and operational costs under a rebate model, if it the model was not run out of a single platform across manufacturers. Separate submissions would require a pharmacy to submit claims-level data to multiple separate manufacturer platforms—each with its own formats, timelines, and adjudication criteria—would require new IT integrations, additional pharmacy staff, and revised dispensing workflows. These costs are particularly burdensome for specialty pharmacies, which already operate under complex compliance environments addressing state licensure, JCAHO and other accreditations, PBM contract requirements, and HRSA 340B program integrity rules simultaneously.

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[5] American Hospital Association, Comment Letter to HRSA; The 340B Rebate Model Pilot Program (Information Collection Request), at 2–3 (Sept. 30, 2025); https://www.aha.org/lettercomment/2025-09-30-aha-letter-hrsa-re-340b-rebate-model-pilot-program.

- NASP recommends that HRSA require any rebate pilot to standardize the data submission format and platform across all participating manufacturers, to prevent the compounding burden of multiple incompatible systems.
- HRSA should require manufacturers to bear the costs of platform development, integration, and ongoing maintenance, and to provide covered entities with direct technical support at no charge.
- Any startup timeline must provide covered entities no less than 12 months from final program design to implementation, to allow for IT development, staff training, and contract renegotiation.

B. Payment Timing and Cash Flow (RFI Section 2)

The cash flow impact of a rebate model on specialty pharmacy operations cannot be overstated. Specialty drugs dispensed through 340B covered entity pharmacies frequently carry WAC prices of $10,000 to $50,000 per month or more per patient. Under a rebate model, the covered entity would be required to purchase these drugs at WAC—potentially weeks before any rebate payment is received. Wholesalers often offer prompt-pay and pre-pay discounts which most hospitals take advantage of, paying in less than 30-days to allows for greater cost of goods discounts. However, standard wholesaler payment terms for specialty drugs are typically 30 days from invoice, but rebate payment timelines under the proposed model could extend 30 to 90 days or more from date of dispense, creating a compounding cash flow deficit.

- NASP strongly supports a guaranteed maximum 10-calendar-day rebate payment timeline from data submission, as referenced in RFI Section 2(d), but notes that the 10-day clock must begin from dispense, not from covered entity submission, to prevent manufacturers from delaying the trigger date.
- HRSA should require manufacturers to pay interest on rebates not paid within the mandated timeline, at a rate equal to the Federal short-term rate plus 3 percentage points, consistent with IRS underpayment interest standards.
- HRSA should evaluate and publish data on actual rebate payment timelines experienced in any pilot, disaggregated by drug and manufacturer, to enable meaningful assessment of cash flow impacts.

C. Rebate Denials (RFI Section 3)

NASP is deeply concerned that a rebate model would enable manufacturers to unilaterally impose their own interpretation of 340B patient eligibility through selective rebate denials, effectively circumventing HRSA's statutory authority to administer the program. Under the current upfront discount model, manufacturers cannot deny discounts based on individual patient determinations. Under a rebate model, manufacturers would gain transaction-level visibility and could deny rebates based on their own, potentially more restrictive, definitions of patient eligibility, such as requiring specific types of clinical relationships, excluding patients

referred from community providers, rejecting contract pharmacy arrangements, or imposing documentation requirements beyond HRSA's standards.

This would create inconsistent, manufacturer-specific eligibility criteria that vary by drug and undermine the uniform national program Congress established. Covered entities would face impossible choices between restricting patient access based on manufacturer preferences or risking non-payment after dispensing.

NASP urges HRSA to explicitly prohibit manufacturers from denying rebates based on patient eligibility interpretations that differ from official HRSA guidance, and to require that covered entities' good-faith patient eligibility determinations are presumptively valid unless the manufacturer can demonstrate clear non-compliance with specific HRSA regulatory requirements.

- Permissible grounds for denial must be narrowly defined in advance by HRSA, not by individual manufacturers, and limited solely to objective, documentable criteria.
- HRSA must establish an independent adjudication process for denied claims, with binding resolution timelines and enforceable remedies.
- Manufacturers must bear the administrative burden of identifying improper claims, not covered entities; the default presumption must favor rebate payment pending resolution of any dispute.

D. Patient Access to Drugs (RFI Section 1(e)(iii))

NASP specifically urges HRSA to require a comprehensive pre-implementation patient access assessment for any rebate pilot. Such assessment should evaluate: (1) the impact on covered entities' ability to maintain specialty drug formulary breadth; (2) the effect on point-of-sale discount programs for uninsured and underinsured patients at contract specialty pharmacies; (3) the potential for specialty drug therapy delays attributable to covered entity cash flow constraints; and (4) the disproportionate impact on rural and underserved populations served by safety-net specialty pharmacy programs.

V. Recommended Alternatives to Achieve Shared Program Integrity Goals

NASP recognizes that the concerns motivating manufacturer interest in rebate models particularly duplicate discounts and the MDPNP nonduplication provision are legitimate and warrant a well-designed policy response. NASP respectfully proposes the following alternatives that would advance program integrity without the cash flow, access, and administrative harms associated with a rebate model:

- Enhanced claims-level data sharing**:** HRSA should work with covered entities, contract pharmacies, TPAs, and manufacturers to develop a standardized, real-time claims data exchange framework that enables manufacturer identification of 340B-eligible claims without requiring a rebate payment structure.

- Medicaid duplicate discount prevention technology**:** Investment in improved data matching between 340B claims and Medicaid managed care encounter data would more directly address the duplicate discount problem without restructuring the entire payment architecture.
- MDPNP nonduplication safe harbors**:** HRSA and CMS should work jointly to develop a targeted, operationally feasible framework specifically for addressing the 340B/MFP nonduplication provision for MDPNP-negotiated drugs, rather than importing the rebate model into all 340B transactions.
- Eliminate specialty drugs/pharmacies from participation: if an initial pilot is pursued, it should be restricted to non-specialty medications with predictable utilization patterns, lower per-unit costs, and lesser patient access risks. Specialty drugs must be explicitly excluded from any initial rebate pilot, with a separate, specialty-specific assessment conducted before any expansion to this category.

Conclusion

NASP respectfully urges HRSA to decline to implement a 340B rebate model pilot at this time. The cash flow disruption, patient access risks, statutory concerns, and administrative burdens associated with a rebate model are particularly severe in the specialty pharmacy context and are not outweighed by the program integrity benefits that could be achieved through less disruptive means. The 340B program has served covered entities and their patients effectively for more than 30 years through the upfront discount model; that model should be preserved and strengthened.

If HRSA ultimately determines that a rebate pilot is warranted, NASP urges the agency to: (1) complete a full notice-and-comment rulemaking before implementation; (2) exclude specialty drugs from any initial pilot scope; (3) mandate standardized, manufacturer-funded data platforms; (4) guarantee rebate payment timelines enforceable by independent adjudication; (5) fully offset all incremental covered entity costs; and (6) conduct a robust pre- and post-implementation assessment of patient access outcomes.

NASP appreciates HRSA's expressed commitment to a "methodical and deliberate approach" and strongly cautions against fast implementation of any rebate pilot. We are available to provide additional information or technical assistance as HRSA evaluates the path forward. For additional information please contact me at sheila.arquette@naspnet.org.

Respectfully submitted,

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