August 25, 2025

Chantelle Britton
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

Re: Comments on 340B Rebate Model Pilot Program (Notice published July 31, 2025); Docket HRSA-2025-0001-0001

Dear Ms. Britton:

On behalf of the Arizona Hospital and Healthcare Association (AzHHA) and our more than 80 hospital, healthcare, and affiliated health system members, we are submitting the following comments on the Health Resources and Services Administration (HRSA) notice announcing the new 340B Rebate Model Pilot Program. We believe that rebate models are inconsistent with the 340B statute and that allowing them would be a fundamental and detrimental shift in the 340B Program, which for over 30 years has successfully allowed covered entities to stretch limited resources and better serve low-income and uninsured patients. However, we recognize HRSA's stated intent to test whether any such approach could operate fairly and transparently, and we believe it is critical to ensure that hospital and patient interests are protected should the pilot move forward. With this in mind, we are submitting the following comments to highlight shortcomings of the proposed pilot and recommend safeguards that HRSA should adopt to minimize harm to covered entities and the communities they serve.

REBATE MODELS ARE INCONSISTENT WITH THE 340B STATUTE

AzHHA has consistently argued in amicus briefs filed in federal courts that manufacturer-imposed rebate models are fundamentally inconsistent with the 340B statute and therefore unlawful. The statute requires that covered entities must be able to purchase outpatient drugs at or below the 340B ceiling price at the time of sale. Rebate models invert this structure by forcing hospitals to purchase at inflated market prices and then await a discretionary rebate from the manufacturer. This delay not only undermines the statutory requirement of an up-front discount but also shifts financial risk and administrative burden onto hospitals, in direct conflict with Congress's intent to enable safety-net providers to stretch scarce federal resources.

While we are disappointed that HRSA has chosen to advance a rebate model pilot program, we are engaging constructively in the rulemaking process to ensure that hospital concerns are addressed. To that end, AzHHA is submitting this comment letter that recommends specific improvements to the program, including extending timelines to allow meaningful stakeholder engagement, requiring manufacturers to bear the full costs of IT and administrative systems, streamlining data requirements to minimize hospital burden, imposing strict penalties for delays or unjustified rebate denials, and ensuring transparency by publishing all approved rebate model terms. These recommendations are intended to mitigate the most harmful aspects of rebate structures and safeguard hospital resources should the pilot move forward.

HRSA SHOULD EXTEND THE COMMENT PERIOD TO ALLOW FOR MEANINGFUL ENGAGEMENT

AzHHA is not alone among hospitals, pharmacies, and other stakeholder groups in strongly recommending an extension of HRSA's deadlines to allow meaningful substantive review and input on this seismic policy shift. Current deadlines—with public comment due by September 8, manufacturer applications by September 15, and pilot approval by October 15—are extremely compressed. We urge HRSA to extend the deadlines to create a more thoughtful and transparent process.

HRSA SHOULD MITIGATE CASH FLOW CHALLENGES AND ADMINISTRATIVE BURDENS FOR COVERED ENTITIES

A rebate model would require hospitals to purchase drugs at full Wholesale Acquisition Cost (WAC), perhaps weeks or months before the drug is dispensed, then await reimbursement. This shifts the financial risk to hospitals and creates significant cash flow issues. This is exceptionally burdensome for small, rural, and safety-net providers with little to no profit margins. While drug manufacturers argue that rebate systems provide compliance clarity, burden-shifting to hospitals undermines the core 340B mission to empower safety-net providers. HRSA should implement all possible safeguards to protect 340B hospitals and limit negative financial repercussions resulting from this policy.

Additionally, the notice does not clearly require drug manufacturers to bear the costs that covered entities will incur in adopting IT systems necessary to implement a rebate program. The notice also does not require manufacturers to utilize a particular IT platform, suggesting that covered entities will be required to make different submissions to different platforms. We urge HRSA to make clear that hospitals are not required to divert scarce operational and patient care resources to support a rebate model, and that all drug manufacturers must use the same IT platform to minimize administrative burden on covered entities.

HRSA MUST ENSURE PRESERVATION OF THE 340B PROGRAM MISSION

Decades of research confirm that 340B-generated revenue enables hospitals and clinics to deliver expanded services, improve medication adherence, and subsidize care for underserved populations. Delays and disruptions in reimbursements will tie up vital funds that currently support patient programs, uncompensated care, and expanded services. To mitigate these effects and protect providers' financial stability, we strongly recommend that HRSA implement strict penalties for delays and unjustified denials.

HRSA SHOULD PUBLISH ALL APPROVED REBATE MODEL TERMS

To preserve accountability and protect covered entities, HRSA should commit to publishing the full terms of all approved rebate models in a publicly accessible format. Hospitals cannot effectively evaluate the impact of different rebate structures if the details are kept confidential between manufacturers and the agency. Public disclosure of model terms—including eligibility requirements, data submission obligations, timelines for rebate remittance, and standards for dispute resolution—would create a level playing field, deter discriminatory practices, and

provide covered entities with the information needed to plan for potential financial and operational impacts. Transparency is essential not only to uphold fairness but also to prevent manufacturers from adopting overly complex or burdensome requirements that undermine the statutory purpose of the 340B program.

SUMMARY OF RECOMMENDATIONS FOR PILOT PROGRAM IMPLEMENTATION

Therefore, to ensure the pilot program informs policy without harming covered entities, we urge HRSA to:

- **Extend timelines** to allow meaningful stakeholder engagement;
- **Require manufacturers to bear the costs** of IT and administrative systems and keep hospitals' data requirements streamlined;
- **Implement strict penalties** for delays and unjustified denials of rebate remittance; and
- **Ensure transparency** by publishing all approved rebate model terms.

CONCLUSION

The 340B program plays a vital role in supporting vulnerable communities, and we believe its success depends on manufacturers honoring the statute's requirement to provide up-front discounts rather than imposing rebate mechanisms. While we are concerned that HRSA is advancing this rebate pilot program, we recognize the agency's intent to study this approach in a limited, controlled setting. Any such effort must be carefully designed to ensure transparency, minimize administrative burdens, and prevent the shifting of costs or risks onto safety-net providers. AzHHA stands ready to provide further input as HRSA evaluates this program and will continue to advocate vigorously for the integrity of the 340B Program on behalf of our more than 80 hospital and healthcare members and the communities they serve.

We appreciate your consideration of these comments.

Sincerely,

Helena Whitney
Senior Vice President of Policy and Advocacy
Arizona Hospital & Healthcare Association