



September 3, 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: HRSA-2025-14998 – Application process for the 340B Rebate Model Pilot Program

Dear Administrator Engels,

On behalf of the 101 Iowa hospitals participating in the 340B Drug Pricing Program, the Iowa Hospital Association writes to express our strong concerns regarding the proposed 340B Rebate Model Pilot Program and its application process. While we appreciate HRSA's interest in exploring alternative pricing mechanisms, we believe the rebate model represents a fundamental departure from the principles and statutory framework that have guided the 340B Program for more than three decades. As raised by hospitals in pending litigation related to manufacturer 340B rebate proposals, we believe 340B rebate models are unlawful per se and HRSA lacks authority to approve rebate plans. Nevertheless, if courts find that HRSA may approve a rebate plan, we believe that HRSA's previous decisions to require preapproval were lawful and appropriate, and we are providing the following comment with respect to the types of rebate models HRSA may permit.

The longstanding upfront discount model has enabled hospitals to stretch scarce federal resources to provide essential services to underserved communities. In Iowa, savings from the 340B program has supported access to critical services such as behavioral health, maternal care, oncology, and mobile health clinics in rural areas. The proposed rebate model, by contrast, threatens to destabilize this critical infrastructure by imposing severe financial and administrative burdens on hospitals, particularly those operating on thin margins.

Under the rebate model, hospitals would be required to pay the full wholesale acquisition cost (WAC) for drugs upfront, often at prices exponentially higher than the 340B rate. For example, the WAC for Stelara exceeds \$14,000 per fill, while Enbrel costs over \$7,000. Even a short delay in reimbursement can jeopardize a hospital's ability to meet bond covenants, maintain cash reserves for emergencies, and continue providing community benefits. These financial pressures are compounded by the administrative complexity of managing multiple rebate processes across different manufacturers, each with its own IT platform and data requirements.

Moreover, the legal foundation for this pilot program is deeply flawed. The Department of Health and Human Services has long recognized upfront discounts as the only lawful mechanism for

providing 340B pricing. HRSA itself has stated that any rebate model requires Secretarial approval, which has not been granted in cases such as Johnson & Johnson's unilateral implementation. The courts have affirmed that private enforcement of 340B requirements is impermissible, yet the rebate model effectively delegates oversight to drug manufacturers—contravening both the letter and spirit of the law.

The narrative advanced by the pharmaceutical industry—that rebate models are necessary to address program integrity concerns—is not supported by evidence. HRSA's own audit data show that hospitals have significantly improved compliance, with findings of diversion and duplicate discounts declining by 62% between FY 2018 and FY 2022. In contrast, 60% of audited drug companies had adverse findings, and 75% were required to repay hospitals. HRSA audits hospitals at ten times the rate it audits manufacturers, underscoring the need for greater scrutiny of industry practices, not additional burdens on providers.

If HRSA proceeds with the pilot program, it must implement robust safeguards to protect hospitals and patients. Drug companies must be required to cover all administrative costs associated with the rebate model, including staffing, legal expenses, and third-party administrator fees. A centralized, neutral data platform should be established to streamline submissions and prevent misuse of hospital data. Enforcement mechanisms must include civil monetary penalties and interest for delayed or denied rebates, and a dedicated dispute resolution process must be created to ensure timely adjudication of claims.

Furthermore, HRSA must clarify that drug companies cannot deny rebates based on unilateral contract pharmacy restrictions, which have already caused significant harm to 340B hospitals. Any denial of a rebate must be accompanied by detailed documentation, including a narrative explanation, supporting data, and a point of contact for follow-up. Finally, HRSA must define clear metrics for evaluating the success of the pilot program, including the financial impact on hospitals and the extent to which patient care is affected.

In conclusion, any changes to the 340B Program's structure must be grounded in sound policy, legal authority, and a commitment to preserving access to care. The proposed rebate model fails to meet these standards. We urge HRSA to reconsider its approach and work collaboratively with stakeholders to strengthen—not weaken—the 340B Program.

Thank you for your attention to this matter. We welcome the opportunity to discuss these concerns further and assist in developing policies that support hospitals and the patients they serve.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris Mitchell".

Chris Mitchell
President/CEO
Iowa Hospital Association