



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, HHS Docket No. HRSA-2026-03042***

Dear Administrator Engels:

On behalf of the 99 Iowa hospitals participating in the 340B Drug Pricing Program, including critical access hospitals, disproportionate share hospitals (DSHs), and sole community hospitals, the Iowa Hospital Association (IHA) respectfully submits these comments in response to the Health Resources and Services Administration's (HRSA's) Request for Information (RFI) regarding a potential 340B Rebate Model Pilot Program.

IHA strongly opposes implementation of a rebate-based model and urges HRSA to abandon the rebate model. As a matter of both health care policy and federal administrative law, a rebate model applied to the Program represents a fundamental inconsistency with Section 340B, lacks evidentiary support, disregards covered entities' substantial reliance interests, and would impose significant financial and operational harms on 340B providers.

### **Iowa Hospitals' Financial Realities Heighten Policy and Legal Risks**

Iowa's 340B hospitals operate in an exceptionally constrained financial environment, making reliance on the upfront 340B discount model unreasonable. State-specific data demonstrates that even modest disruptions to cash flow and increases in administrative costs would impose disproportionate harm on Iowa providers and their patients.

Between 2023 and 2025, Iowa hospital drug costs increased by approximately 42 percent, substantially outpacing general inflation. Outpatient pharmaceuticals, particularly oncology, infusion, and specialty drugs, are among the most volatile and highest cost inputs in hospital operations. Immediate 340B price reductions allow hospitals to secure these therapies without advancing capital or assuming repayment risk. A rebate model requiring 340B hospitals to purchase drugs at full wholesale acquisition cost (WAC) and await reimbursement would materially shift financial risk to covered entities and introduce uncertainty into clinical and operational decision-making.

Liquidity considerations further amplify these concerns. While composite financial metrics may suggest

adequacy at a system level, such averages obscure wide variation among individual hospitals, particularly rural facilities. In Iowa, where Medicare and Medicaid together account for nearly 60 percent of hospital payer mix, predictable 340B savings function as a critical offset to historically low Medicare and Medicaid reimbursement rates. From a legal perspective, 340B hospitals' longstanding dependence on this predictable framework is not incidental; it is a reliance interest that HRSA must consider and weigh before pursuing any materially disruptive policy change.

### **The Upfront Discount Model Is Grounded in the Statutory Scheme**

As a condition of participating in Medicaid and Medicare Part B, Section 340B requires manufacturers to "offer" covered outpatient drugs to eligible covered entities at or below a defined ceiling price. HRSA has implemented this requirement for more than three decades through upfront discounts at the point of sale.

This approach reflects more than HRSA's preference or historical inertia. It is consistent with Congress's intent to enable 340B hospitals to stretch scarce federal resources and directly supports immediate patient access to high cost outpatient medications. Importantly, HRSA has not identified a statutory ambiguity or systemic failure that would necessitate discarding this framework. Absent such findings, a structural redesign of how statutory discounts are delivered raises fundamental questions of statutory interpretation and exceeds the bounds of reasoned policy adjustment.

### **A Rebate Model Raises Clear Statutory Authority Concerns**

Nothing in 42 U.S.C. § 256b authorizes HRSA to require 340B hospitals to finance manufacturer discounts or to substitute post-purchase rebates for the statutorily contemplated ceiling-price mechanism. A rebate model would materially alter the allocation of obligations by shifting timing, liquidity, and repayment risk from manufacturers to hospitals.

Agencies may not reorganize statutory schemes simply because an alternative approach is administratively appealing or responsive to stakeholder pressure. Courts have repeatedly held that agencies may not rewrite statutes based on policy judgment alone. By requiring hospitals to advance funds and pursue reimbursement, a rebate model would invert Section 340B's statutory structure and create obligations for covered entities that the statute does not impose.

### **The Administrative Procedure Act (APA) Requires a Reasoned Explanation and Consideration of Reliance Interests**

Under the APA, HRSA's action may not be arbitrary or capricious. That means when HRSA proposes to depart from a longstanding implementation framework—as here—it must do more than assert potential benefits; it must confront the factual record supporting the existing approach, explain why that approach is now inadequate, and meaningfully address the reliance interests it has created.

340B hospitals have structured pharmacy operations, compliance systems, contractual relationships, and patient service models around HRSA's consistent application of upfront discounts. These reliance interests are significant, well-documented, and legally cognizable. A policy change that imposes materially greater financial and administrative burdens, without evidence of systemic Program failure, would be difficult to reconcile with the APA's requirement that agencies account for reliance and explain why disruption is justified.

## **Administrative Burden and Program Integrity Considerations**

A rebate model would impose new and ongoing administrative requirements, including claim-level rebate submission, reconciliation, dispute resolution, and expanded compliance oversight across multiple manufacturers with varying standards. These burdens would divert limited hospital resources away from patient care and toward administrative activity.

Critically, HRSA has not demonstrated that the Program's integrity tools are insufficient. Current mechanisms, including audits, the 340B ESP, Medicaid exclusion files, and manufacturer chargeback systems, already address diversion and duplicate discount concerns. The APA requires agencies to consider reasonable alternatives before adopting more burdensome regulatory approaches. Failure to do so would further undermine the legal defensibility of a rebate model.

## **Patient Access and Downstream Impacts Must Be Considered**

The predictable policy consequences of a rebate model—liquidity strain, increased administrative cost, staffing diversion, and delayed reimbursement—would directly affect hospitals' ability to deliver charity care, maintain patient support programs, and invest in oncology, behavioral health, outpatient, and rural services. These downstream effects on statutory beneficiaries are a legally relevant aspect of the policy decision before HRSA.

Agency action is arbitrary when it fails to consider important aspects of the problem, including foreseeable impacts on access to care for vulnerable populations. Any evaluation of a rebate approach must therefore fully account for these patient level consequences.

For these reasons, IHA and Iowa's 340B hospitals strongly urge HRSA to end efforts around any 340B Rebate Model Pilot Program and to preserve the upfront discount framework Congress established, and that has effectively supported patient care for decades.

Should HRSA continue to explore a rebate-based approach, HRSA must clearly identify the statutory authority supporting such a model and proceed only through the APA's notice-and-comment procedure. Any rebate model should require manufacturers to bear all associated administrative and operational costs, establish enforceable reimbursement timelines and binding dispute-resolution mechanisms, and fully account for 340B hospitals' longstanding reliance interests and patient care impacts.

Thank you for your time and consideration. We look forward to continued engagement with HRSA to ensure the 340B Program remains lawful, stable, and effective in supporting care for Iowa's most vulnerable communities.

Sincerely,



Chris Mitchell  
President/CEO  
Iowa Hospital Association