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HRSA Revives 340B Rebate Model Pilot Program For 2027

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On August 3, 2026, the Health Resources and Services Administration (HRSA) published a Federal Register notice announcing a revised 340B Rebate Model Pilot Program (Pilot). The latest Pilot follows manufacturer attempts to unilaterally establish rebate programs and a previous 2025 pilot proposal by HRSA—both of which stalled due to litigation. The new notice reintroduces a rebate mechanism for a limited set of drugs, responds at length to more than 2,400 comments submitted in response to HRSA's February 2026 Request for Information (RFI), and sets a compressed timeline for manufacturer submissions for programs to start effective January 1, 2027.

Background

In 2024, several drug manufacturers proposed implementing the 340B discount via after-the-fact rebates instead of up-front purchase discounts. HRSA opposed it, arguing that rebate proposals could only be implemented with its approval. Litigation followed and the federal District Court for the District of Columbia and Court of Appeals for the D.C. Circuit both agreed that HRSA is required to provide for a rebate mechanism before manufacturers can implement it.

While the litigation over the manufacturers' attempt to unilaterally implement a rebate mechanism proceeded, HRSA separately proposed a rebate mechanism that would have gone into effect as of January 1, 2026. However, hospital groups challenged the proposal, and the federal District Court for Maine subsequently enjoined its enforcement, finding that HRSA's rollout likely violated the Administrative Procedure Act because the agency had not adequately explained the reasons for the rebate proposal. The Court of Appeals for the First Circuit declined to stay that injunction. HRSA ultimately withdrew its original rebate proposal.

On February 17, 2026, HRSA published a new RFI seeking broader stakeholder input to inform a new rebate proposal. The August 3, 2026, notice is HRSA's response to that RFI.

Key Features of the Revised Pilot

Scope and eligibility

The Pilot is limited to drugs included on the Centers for Medicare and Medicaid Services (CMS) Medicare Drug Price Negotiation Selected Drug List for initial price applicability years 2026 and 2027.

Manufacturer plans must be submitted to HRSA by August 24, 2026, with approvals expected by September 24, 2026, for a January 1, 2027, effective date.

Rebate mechanics

Rebates must equal WAC minus the 340B ceiling price based on the date of dispense (not the purchase date) and must be paid at the unit level.

Manufacturers must allow covered entities at least 45 days from the date of dispense to submit data and pay rebates (or issue a documented denial) within 10 calendar days of a complete claim submission.

Rebates may not be denied based on diversion, Medicaid duplicate discount concerns, or perceived insufficient WAC purchases; manufacturers must instead pursue such concerns through audits or the statutory administrative dispute resolution (ADR) process.

Data

Data collection remains limited to specific standardized pharmacy and medical claims fields (e.g., date of service, NDC-11, quantity dispensed, prescriber ID, 340B ID, RX BIN/PCN); purchasing data, encounter data, and patient-level clinical information are excluded at this time.

Manufacturers must bear all IT platform costs and ensure the platform can filter, secure, and limit data to only what is necessary to effectuate the rebate.

Oversight and enforcement

HRSA reserves the right to revoke a manufacturer's approval if it does not comply with the criteria outlined in the Notice or its approved manufacturer plan. HRSA noted it intends to monitor

manufacturer compliance with payment and denial timelines and may remove a manufacturer from the Pilot for repeated noncompliance (for example, if 5% or more of a sample of transactions show unjustified delays or denials).

HRSA intends to make a defined pathway for covered entities to challenge denials and to provide supporting tools on its website within 30 days of the Pilot's effective date.

HRSA intends to issue an evaluation of the first year of Pilot operations by April 30, 2028.

HRSA's Response to the Court Decisions Over the 2025 Rebate Proposal

The bulk of the new notice responds to deficiencies identified in the litigation over HRSA's previous rebate mechanism proposal. Unlike the 2025 notice, which HRSA issued with what the court called a "threadbare" administrative record, the new notice discusses at length the program history, HRSA's justifications for adopting a rebate mechanism, reliance interests, alternatives, and HRSA's evaluation of stakeholder comments and reservations.

What This Means for You

Given the litigation history, we expect covered entity stakeholders to closely scrutinize HRSA's reasoning, and further legal challenges are possible. The extensive discussion in the Notice appears calculated to address the procedural defects that prevented the 2025 notice from being implemented.

Manufacturers with active selected drugs have a short window to prepare and submit rebate plans by August 24, 2026. Once approved, manufacturers must provide covered entities and other impacted stakeholders at least 90 calendar days' advance notice before the January 1, 2027, effective date, and must commit to a minimum one-year participation period.

Covered entities should begin evaluating cash-flow, accumulator, and billing system impacts now, and prepare for planned implementation of manufacturer rebate programs as of the January 1, 2027, effective date. Many covered entities have conducted assessments in response to previous proposals. Those assessments should be refreshed to reflect the scope and parameters of the latest proposal.

Stakeholders should continue to monitor HRSA's website for the manufacturer plan approvals expected by September 24, 2026, and for any interim guidance issued before the January 1, 2027, effective date.

Contact Us

If you have questions about this legal update or how the revised 340B Rebate Model Pilot Program may affect your organization, please contact Kristina Abdalla, Robert Hess, Renee Zerbonia, or your Husch Blackwell attorney.