CLIENT ALERTS & INSIGHTS

HRSA's Revised 340B Rebate Pilot Drama

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Featured Practices: Healthcare, Medicare & Medicaid Reimbursement, Hospital & Health Systems

Featured Industries: Not-for-Profit

Key Takeaways

- The Health Resources and Services Administration's revised 340B Rebate Model Pilot would replace up-front discounts with post-purchase rebates for 21 drugs beginning January 1, 2027, requiring covered entities to pay full wholesale acquisition cost and submit claims data to recover the 340B discount.
- The Pilot is already facing legal and legislative challenges. Hospitals are again challenging HRSA's process and consideration of the financial and administrative burden on covered entities, while a bipartisan House bill seeks to delay implementation through 2028.
- Covered entities should prepare now for the potential operational and cash-flow effects of the Pilot, including claims-submission requirements, rebate timing and manufacturer-specific plans, while closely monitoring litigation that could affect whether or when the program takes effect.

Executive Summary

On October 1, 2026, the Health Resources and Services Administration (HRSA) approved plans for ten drug manufacturers, covering 21 drugs, to join a revised 340B Rebate Model Pilot Program (the Pilot) starting January 1, 2027.[1] Under the Pilot, covered entities eligible for 340B pricing under Section 340B of the Public Health Service Act, 42 U.S.C. § 256b (Section 340B), will pay the full wholesale acquisition cost (WAC) for these 21 drugs up front and then claim rebates equal to the 340B discount. This change reverses the up-front discount structure the 340B Program has used for more than 30 years.

This is HRSA's second attempt to implement a rebate model. A federal court in Maine preliminarily enjoined its first pilot in December 2025 until the First Circuit Court of Appeals denied a stay pending appeal, after which the government ultimately dropped its appeal and agreed to have the program set aside.[2] Before that, courts stopped several manufacturers from imposing rebate models on their own, most recently in *Novartis Pharmaceuticals Corp. v. Kennedy*, No. 25-5177 (D.C. Cir. July 21, 2026).

New lawsuit to block the Pilot.

On October 9, 2026, the American Hospital Association, the Maine Hospital Association and four safety-net hospitals sued in the U.S. District Court for the District of Maine to block the Pilot and asked for a temporary restraining order. They argue that the department of Health and Human Services (HHS) and HRSA did not adequately assess the administrative and cashflow strain the model places on safety-net providers.

Bill to delay the Pilot. On October 13-15, 2026, a bipartisan group of House members, Reps. Rob Bresnahan (R-PA), Debbie Dingell (D-MI), Tracey Mann (R-KS) and Lois Frankel (D-FL), introduced the 340B Rebate Model Delay Act (H.R. 10770). The bill would require manufacturers to keep providing up-front 340B discounts through December 31, 2028, and would bar federal funding to implement the Pilot.

Background: The Revised Pilot

Purpose and Scope

HRSA says the Pilot will improve transparency and program integrity. Under the current up-front discount model, HRSA has little visibility into individual 340B transactions, so compliance problems often only surface in later audits. Under the Pilot, the covered entity pays full price, submits claims data for each transaction and receives its rebate once the claim is verified. HRSA says this also helps manufacturers comply with the Inflation Reduction Act's nonduplication requirement, under which manufacturers must provide the lower of the 340B ceiling price or the Medicare maximum fair price, but not both on the same unit. The Pilot covers only the 21 approved drugs listed below, for a set period; all other drugs keep the up-front 340B discount.

Approved Manufacturers and Drugs

HRSA approved plans from ten manufacturers covering 21 drugs, a broader list than its first attempt (ten drugs from nine manufacturers). Most are high-volume, high-cost brand drugs for chronic conditions such as diabetes, cancer, and autoimmune disease.

How the Pilot Works

- **Purchasing.** Covered entities keep buying Pilot drugs through their existing 340B wholesaler account but now pay the full wholesale acquisition cost (WAC) instead of the discounted price. Drugs bought through WAC-only or group purchasing organization (GPO) accounts are not eligible for rebates.
- **Rebate amount.** Covered entities then submit claims data to obtain rebates equal to WAC minus the 340B ceiling price on the date of dispensing, paid per unit rather than per full package.
- **Timing.** Covered entities have 45 calendar days after dispensing to submit claims data, with limited exceptions set out in each manufacturer’s approved plan. Manufacturers then have 10 calendar days to pay, or to deny with supporting documentation. If a submission is returned as incomplete, the 10-day clock restarts.

- **Denials.** Manufacturers cannot deny a rebate because they suspect the entity is ineligible, the drug was diverted to ineligible patients, or Medicaid already received a discount, or because the entity made too few WAC purchases. Those concerns must go to HRSA or through the statutory audit and administrative dispute resolution (ADR) process.
- **Transition and evaluation.** To ease the switch, entities that previously used replenishment ordering can carry over up to two accumulated packages that have not yet been replenished, with a 15-day grace period. HRSA will publish interim summaries and a final evaluation of the Pilot by April 30, 2028.

Legal Risks and Prior Precedent

The Manufacturer Litigation: No Unilateral Right to Impose Rebates

Starting in mid-2024, Johnson & Johnson, Eli Lilly, Bristol Myers Squibb and Novartis each tried to replace up-front 340B pricing with rebates, citing duplicate discounts and other covered-entity noncompliance. HRSA said the Secretary had not approved any such model and warned J&J that going ahead could cost it its Pharmaceutical Pricing Agreement, and with it Medicaid and Medicare Part B coverage. The manufacturers and vendor Kalderos sued under the APA.

The manufacturers did not prevail at any level. In *Johnson & Johnson Health Care Systems Inc. v. Kennedy*, No. 24-3188 (D.D.C. June 27, 2025), the court held that the statute lets HRSA "provide" for discounts, rebates or both, so HRSA could require prior approval. Another district judge ruled the same way in the Lilly, BMS and Novartis cases. On appeal, the D.C. Circuit held that Section 340B "requires the Secretary to provide for a rebate mechanism before manufacturers may implement one" and places the Secretary "in the driver's seat." *Novartis*, slip op. at 3, 13-15. It warned against letting any manufacturer "experiment on all 340B hospitals and patients with whatever rebate model best suits its own interests." *Id.*

An important caveat. The D.C. Circuit also rejected the hospitals' argument that the statute bans rebates outright, holding that rebate models "can be" lawful. But it left open whether a particular model "might operate in a manner that runs afoul of the statute," and whether the Secretary should approve one and "with what limitations." *Id.* So challenges aimed at the Pilot's specific design remain open, even though the broadest argument is closed in the D.C. Circuit.

AHA v. Kennedy: HRSA's First Pilot Fails APA Review

HRSA announced its first pilot on July 31, 2025, and approved nine manufacturers to use rebates for ten drugs. The American Hospital Association, the Maine Hospital Association and several safety-net hospitals sued on December 1, 2025, arguing HRSA skipped the reasoned decision-making the APA requires. On December 29, 2025, Chief Judge Walker blocked the program, finding the hospitals likely to win. *Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-00600-LEW (D. Me. Dec. 29, 2025). The court found that:

- **HRSA ignored reliance on up-front discounts.** There was "no evidence in the administrative record" that HRSA considered how much hospitals depend on the 30-year-old model, which alone was fatal.
- **HRSA did not account for costs.** It had not resolved comments calling its $200 million compliance estimate too low or considered the cost of paying full price while awaiting rebates.
- **HRSA could not fix the record later.** The court refused to rely on a declaration written during the lawsuit; an agency must stand on the reasons it gave when it acted.
- **The harm was irreparable.** AHA members estimated $400 million in compliance costs that hospitals could not recover in an APA suit.

As the court put it, "Defendants cannot fly the plane before they build it." *Id.* The First Circuit refused to pause the ruling, and in February 2026 the government dropped its appeal and agreed to have the program set aside. Still, the court said HRSA "is empowered by statute" to use rebates and that a rebate model is not "impermissible." *Id.* HRSA lost because of how it built the program, not because it lacked authority.

Summary

The revised Pilot is the biggest structural change to the 340B Program in decades, and its legal footing is far from settled. It is broader than the pilot that failed and still faces hospital opposition, so it must clear the same scrutiny its predecessor could not.

The Benesch Healthcare team is tracking the Pilot and the legal and legislative developments that could affect its implementation. Our attorneys can help covered entities prepare for potential change with readiness assessments, manufacturer plan review, dispute strategy and compliance planning.

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[1] *340B Rebate Model Pilot Program*, Health Res. & Servs. Admin., https://www.hrsa.gov/opa/340b-model-pilot-program (last visited Oct. 6, 2026).

[2] *First Circuit Ends HHS Appeal of Enjoined 340B Rebate Model Pilot*, Am. Health L. Ass'n: Health L. Wkly. (Jan. 23, 2026), https://www.americanhealthlaw.org/content-library/health-law-weekly/2026/january/23/first-circuit-ends-hhs
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