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Client Alert: 340B Year in Review: Rebates Return, Congress Turns, and the States Keep Fighting

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For 340B covered entities, 2026 was defined by one issue: rebates. The Health Resources and Services Administration's (HRSA) first attempt at a rebate pilot was blocked in court, but HRSA has since relaunched a revised pilot that takes effect January 1, 2027. Federally qualified health centers (FQHCs), Ryan White clinics, and safety-net hospitals should plan now for paying full price up front on certain drugs and waiting for rebates, while watching Congress, the courts, and the states for relief. Below are the key developments and what they mean for you.

1. The Rebate Pilot: Blocked in 2026, Revived for 2027

In July 2025, HRSA announced a voluntary rebate pilot for drugs subject to Medicare price negotiation, to begin January 1, 2026. On December 29, 2025, the U.S. District Court for the District of Maine preliminarily enjoined the pilot nationwide in a lawsuit brought by the American Hospital Association (AHA), citing deficiencies in the administrative record. After the First Circuit refused to stay the injunction, the United States Department of Health and Human Services (HHS) dismissed its appeal and withdrew the pilot, and on February 10, 2026, the court vacated it. Importantly, the court stated that HRSA "is empowered by statute" to use rebates, meaning HRSA lost on process, not on authority.

HRSA then rebuilt the record. Its February 2026 Request for Information drew more than 2,400 comments (comments closed April 20, 2026), and on August 3, 2026, HRSA published a revised pilot covering drugs selected for Medicare negotiated prices in 2026 and 2027, which HRSA says represent less than 5.5 percent of total 340B sales. On October 1, 2026, HRSA approved 10 manufacturers covering 21 drugs, all on the

Beacon platform. HRSA's first-year evaluation is due April 30, 2028.

How it works for covered entities:

- Purchase covered drugs at wholesale acquisition cost.
- Submit claims data to the manufacturer platform.
- Receive a rebate for the difference between the price paid and the 340B ceiling price.

This creates cash-flow pressure, particularly for grant-funded FQHCs and Ryan White clinics. On October 9, 2026, the AHA, the Maine Hospital Association, and four hospitals filed a new suit challenging the revised pilot, supported by an amicus brief from America's Essential Hospitals, 340B Health, Association of American Medical Colleges (AAMC), and the Children's Hospital Association. That case is the only realistic path to stopping the pilot before launch; a ruling is pending.

2. Other Federal Developments

- **Manufacturer-imposed rebates rejected.** On July 21, 2026, the D.C. Circuit held that manufacturers cannot impose rebate models on their own; HRSA approval is required.
- **Medicare payment cuts.** Centers for Medicare & Medicaid Services (CMS) 2027 outpatient rule reduces Medicare payments for 340B drugs, a hospital-specific concern.
- **Tighter manufacturer restrictions.** Contract pharmacy and claims-data restrictions continue to expand. Johnson & Johnson now requires in-house claims data and has extended its contract pharmacy restrictions to federal grantees, including Ryan White clinics.

3. Congress: Many Bills, Limited Time

Ryan White clinics, health centers, and safety-net hospitals are united in opposing the rebate model and have endorsed the bipartisan 340B Rebate Model Delay Act.

Key proposals currently alive in Congress include:

Bill	What it does on rebates	Note for covered entities
340B Rebate Model Delay Act (H.R. 10770)	Requires upfront discounts Jan. 1, 2027–Dec. 31, 2028; bars federal funds for the pilot	Bipartisan, single-issue bill
Community Health Center Drug Pricing Protection Act (H.R. 7391)	Bars pay-first, rebate-later arrangements	FQHCs only; standalone Ryan White clinics not covered
Safety Net Provider Drug Pricing Protection Act (H.R. 10919)	Permanently bars pay-first, rebate-later arrangements	Covers Ryan White grantees, FQHCs, critical access hospitals, sole community hospitals and others
PROTECT 340B Act of 2026 (H.R. 10937)	Requires HHS to terminate the pilot before launch	Also bars Pharmacy Benefit Manager (PBM) and insurer discrimination
SUSTAIN 340B Act (S. 5244)	Ends the pilot one year after enactment	Codifies contract pharmacy use; patient definition; child site rules
SECURE 340B Act (H.R. 9599)	Bars rebate models for four years	Unlimited contract pharmacies; reporting; medical-debt limits

Bill	What it does on rebates	Note for covered entities
340B ACCESS Act (H.R. 5256)	Creates a claims clearinghouse	Would preempt state contract pharmacy protection laws

Democrats won both chambers in the midterms, but without a veto-proof majority, and the 120th Congress convenes January 3, 2027—two days after the pilot starts. Lame-duck odds for 340B legislation are extremely low, and all pending bills expire with the 119th Congress. The most realistic relief is a 2027 appropriations rider modeled on the Delay Act's funding ban, which would still require the President's signature. New majorities can also hold oversight hearings as HRSA evaluates the pilot. Because courts have recognized HHS's statutory authority to use rebates, HRSA retains the initiative unless Congress acts.

4. The States: A Deepening Circuit Split

More than 20 states now have contract pharmacy protection laws, and newer laws also restrict manufacturer claims-data demands. The Fifth Circuit has upheld Louisiana's (July 6, 2026) and Mississippi's laws, and the Eighth Circuit has upheld Arkansas Act 1103. In the Fourth Circuit, a panel found the West Virginia and Maryland laws likely preempted; the full court reheard the case on October 27, 2026, and a decision is pending. Colorado's law has survived three challenges, and active litigation is underway in Oregon, Hawaii, Washington, Oklahoma, and Maine. The Arkansas Attorney General is also suing manufacturers over contract pharmacy restrictions. With a Seventh Circuit appeal involving Lilly pending, Supreme Court review is expected.

Key Dates

Date	Event
Nov. 30, 2026	CMS deadline to publish 2028 negotiated prices, including Biktarvy
Through Jan. 2, 2027	Lame-duck window for action on the Delay Act
Jan. 1, 2027	Revised rebate pilot takes effect
Jan. 3, 2027	120th Congress convenes under Democratic control
Early 2027	CMS announces 20 drugs selected for 2029 prices
Pending	Maine ruling on revised pilot; full Fourth Circuit; Seventh Circuit (Lilly)
Apr. 30, 2028	HRSA first-year pilot evaluation due

What Covered Entities Should Do Now

- Identify which of the 21 pilot drugs you purchase and model the cash-flow impact of paying wholesale acquisition cost before rebates arrive.
- Prepare your systems and staff for claims-data submission through the Beacon platform, and track rebate timing and any denials.
- Review contract pharmacy arrangements against current manufacturer restrictions, including new restrictions on federal grantees such as Ryan White clinics.
- Monitor state law developments and litigation affecting contract pharmacy and claims-data protections in your states.
- Engage in advocacy: support appropriations-based relief in 2027 and urge HRSA and the new congressional majorities to commit that the pilot will not expand to 2028 drugs before its evaluation is complete.

Shumaker health care lawyer Daphne Kackloudis can answer your questions about how these developments affect your organization. Please contact your Shumaker relationship attorney.

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