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340B Rebates 2.0: HRSA Revives Its Pilot Program — and Sets Up a Collision Course With Congress

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VIEWPOINT TOPICS

- Health Care

The Trump administration advances a claims-based rebate model for select 340B drugs as a new bipartisan Senate bill would block it, forcing health systems to track three reform paths at once.

On July 31, 2026, the Health Resources and Services Administration (HRSA) announced a revised 340B Rebate Model Pilot Program, followed on August 3, 2026, by a formal Federal Register notice putting the details into effect. It is the agency's second attempt in just over a year to shift a subset of 340B drugs from upfront discounts to retrospective manufacturer rebates — and it lands squarely in the middle of the legislative reform fight we flagged in our **July 1, 2026, alert** on Senator Cassidy's 340B Drug Pricing Integrity and Affordability for Patients Act discussion draft.

Below we review what has changed in the revised pilot, how industry has reacted, and, critically, how **a brand-new bipartisan Senate bill** introduced just days later is now positioned to override the administration's approach entirely. For health systems, the upshot is that 340B reform is no longer a single storyline. It is three of them, moving on three different clocks.

Background: From a Vacated Pilot to "Rebates 2.0"

HRSA's first attempt at a rebate model, announced in July 2025, approved nine manufacturer plans covering ten high-utilization, Medicare-negotiated drugs for a January 1, 2026, effective date. The American Hospital Association (AHA) and the Maine Hospital Association sued before launch, arguing HRSA had violated the Administrative Procedure Act in developing the program. A federal court in Maine blocked the pilot, the First Circuit upheld the injunction, HHS declined to continue defending the original design, and the district court formally vacated the pilot and remanded it to the agency in February 2026.

HRSA did not abandon the concept. In February 2026, it issued a Request for Information (RFI) that closed in April and drew more than 2,400 public comments from hospitals, health centers, manufacturers, pharmacies, and patient advocates. Around the same time, the D.C. Circuit's decision in *Novartis v. Kennedy* confirmed that a rebate model is permissible under the 340B statute, but only with HRSA approval — reinforcing both the agency's authority and its intent to try again. The RFI process culminated in the **August 3, 2026, Federal Register notice** announcing the revised Pilot Program.

What's New — and What's Not — in the Revised Pilot

The core mechanism has shifted in a way health systems should understand precisely. Rather than receiving the 340B ceiling price up front, participating covered entities will purchase affected drugs at wholesale acquisition cost (WAC) and then submit claims to the manufacturer for a rebate equal to the difference between WAC and the 340B ceiling price. Key operational details include:

- Scope: The Pilot covers drugs selected under the Medicare Drug Price Negotiation Program for both Initial Price Applicability Year (IPAY) 2026 and IPAY 2027 — a broader universe than the original 2025 version, though still a narrow slice of total 340B purchasing.
- Timeline: Manufacturers seeking to participate must submit rebate plans to HRSA by August 24, 2026, and HRSA expects to issue approvals by September 24, 2026. Approved plans must give covered entities at least 90 days' notice before implementation and the Pilot itself launches January 1, 2027, running for at least one year.

- Manufacturer Commitment: Participating manufacturers must commit to the Pilot for a minimum of one year and must bear the cost of the rebate technology platform covered entities will use to submit claims data.
- Claims Cycle: Covered entities are expected to be able to submit claims within roughly 45 days of dispensing. Manufacturers must issue rebates on complete claims within 10 calendar days, and rebates must be paid on a per-prescription basis rather than bundled and delayed.
- Dispute and Integrity Provisions: Manufacturers must document and report denied claims, including the basis for denial, and submit rebate and purchase data to HRSA. The agency will monitor manufacturer compliance and has committed to publishing a claims-dispute pathway for providers by January 30, 2027.
- No Categorical Carve-outs: The Pilot contains no blanket exemption for critical access hospitals, federally qualified health centers (FQHCs), rural hospitals, rural referral centers, sole community hospitals, children's hospitals, cancer hospitals, or disproportionate share hospitals. Once a manufacturer's plan applies to a selected drug, the rebate process applies across all covered-entity types. Any hardship relief would have to come through plan-specific exceptions raised with HRSA or the manufacturer.

HRSA has been direct about rejecting the administrative-burden concerns that sank the first version of the rebate pilot. The agency's notice states that it considered providers' reliance interests and concluded they do not outweigh the benefits of moving forward, and that it does not expect the Pilot to meaningfully increase administrative burden or destabilize covered entities' cash flow, a characterization hospital groups sharply dispute.

Congress Answers Back: The SUSTAIN 340B Act

On August 5, 2026 — just days after HRSA's Federal Register notice — the Senate 340B Bipartisan Working Group (Sens. Jerry Moran, Tammy Baldwin, Shelley Moore Capito, Tim Kaine, John Boozman and John Hickenlooper) introduced the Supporting Underserved and Strengthening Transparency, Accountability and Integrity Now and for the Future of 340B Act, or the **SUSTAIN 340B Act**. Unlike **Chairman Cassidy's discussion draft**, which would let covered entities choose among a discount, a rebate, or a government-operated claims repository, the SUSTAIN 340B Act takes direct aim at HRSA's regulatory approach.

- It would preserve the traditional point-of-purchase discount model as the default and sunset HRSA's Rebate Model Pilot Program within one year of enactment.
- In place of manufacturer rebates, it would establish an independent, third-party data clearinghouse to coordinate claims data between covered entities and manufacturers and to identify duplicate discounts — the same integrity concern HRSA cites as its rationale for the rebate model.
- It would codify covered entities' ability to use contract pharmacies, while layering in new registration and audit requirements — a materially different approach than the discussion draft's proposed five-pharmacy cap.
- It would add new compliance, reporting, and transparency obligations for covered entities and proposes a 340B user fee program to help fund HRSA oversight, an idea previously floated by both Republican and Democratic administrations.

The Working Group has existed for more than a decade and includes members generally supportive of preserving the 340B program's core benefits, which distinguishes the SUSTAIN 340B Act's framing from both HRSA's rebate-first approach and the more provider-restrictive elements of the Cassidy draft. AHA has welcomed the bill's direction, a marked contrast to its response to both the rebate Pilot and, in part, to the Cassidy draft.

Three Reform Tracks, One Compliance Clock

Health systems are now tracking three distinct efforts that could each reshape 340B, on three different timelines:

- Track 1 — HRSA's Rebate Model Pilot: a live regulatory action with binding near-term deadlines (manufacturer plans due August 24, 2026; approvals expected by September 24, 2026; launch January 1, 2027) that will proceed unless a court intervenes again or Congress acts first.
- Track 2 — The Cassidy discussion draft: still a discussion draft, not introduced legislation, with a stakeholder comment period running through August 28, 2026, and a design that would let covered entities choose their preferred discount mechanism.
- Track 3 — The SUSTAIN 340B Act: newly introduced legislation that would affirmatively block the rebate model HRSA is currently implementing and replace it with a clearinghouse approach.

These tracks are not aligned. HRSA’s deadlines will continue while Congress deliberates, so health systems cannot wait for clarity. Meanwhile, SUSTAIN 340B’s one-year sunset could render Pilot systems temporary — or make them the foundation of a longer-term model.

Key Takeaways for Health Systems

As HRSA and Congress move on overlapping but divergent timelines, health systems should begin preparing for multiple potential implementation scenarios.

We recommend the following steps:

- Assess Program Exposure: Cross-reference 340B purchasing activity against the IPAY 2026 and IPAY 2027 Medicare-negotiated drug lists to identify products that could fall within approved manufacturer rebate plans.
- Evaluate Cash-Flow Implications: Coordinate with finance and pharmacy leadership to quantify the working-capital impact of purchasing at WAC and receiving retrospective, claims-based rebates, including under the Pilot's 10-day repayment standard.
- Strengthen Claims Readiness: Confirm that internal systems can generate standardized claims submissions within required timeframes and reconcile manufacturer rebate activity on a per-prescription basis.
- Plan for Broad Applicability: Rural hospitals, CAHs, FQHCs, and other safety-net providers should prepare for inclusion under approved manufacturer plans and identify any potential hardship arguments before implementation begins.
- Monitor HRSA Approval Timing: The expected September 24 approval date will clarify which manufacturers and products are in scope and trigger the 90-day implementation notice period.
- Engage Across Legislative and Regulatory Channels: Submit comments on the Cassidy discussion draft before the August 28, 2026, deadline while tracking the SUSTAIN 340B Act's committee path, as each proposal reflects a materially different policy framework for the program.

Fifteen years without a statutory update, a vacated regulatory pilot, a revived one, a sweeping committee discussion draft, and now a competing bipartisan bill — all within a matter of weeks signal that 2026 may finally be the year 340B reform moves from talk to action. Which version of reform prevails is still very much an open question. What is no longer in question is that health systems need to be positioned for more than one outcome.

ML Strategies is actively monitoring both the HRSA Rebate Model Pilot Program and Congressional 340B reform efforts.

Authors

Traci L. Vitek, Senior Vice President

Traci L. Vitek, Senior Vice President at ML Strategies in Washington, DC, advises clients on federal health care policy, legislative strategy, and executive branch engagement.

Theresa Carnegie

Theresa C. Carnegie is a Mintz attorney who advises health care clients on a wide array of transactional, regulatory, compliance, fraud and abuse matters, and health law issues. She counsels health plans, pharmacy benefit managers, pharmacies, device manufacturers, and distributors.