ML STRATEGIES

340B Rebate Pilot — The Clock Starts Now

October 07, 2026 | Blog | By **Traci L. Vitek**, **Emmett R. Jamieson**, **Theresa Carnegie**

VIEWPOINT TOPICS

- Health Care

On October 1, the Health Resources and Services Administration (HRSA) **published 10 approved rebate plans** covering 18 Medicare-negotiated drugs, setting a January 1, 2027, start. As we warned in **The 340B Squeeze** (September 28), this is the first of three federal pricing changes that will land on a single outpatient claim. Health systems have about one quarter to get ready, and litigation could still change the picture.

What Happened

- **Plans approved**: Ten manufacturers, covering Eliquis, Farxiga, Jardiance, Tradjenta, Januvia, Janumet, Imbruvica, Pomalyst, Ibrance, Breo Ellipta, Trelegy Ellipta, Enbrel, Otezla, Ofev, Linzess, Vraylar, Xtandi and Austedo (including XR versions). All selected Second Sight Solutions' Beacon Channel Management to administer their plans.
- **Notice clock**: Manufacturers must give covered entities at least 90 days' notice, so notices for a January 1 launch are due by about October 3.
- **CMS data**: CMS launched a voluntary 340B Part D claims data repository and has proposed making submissions mandatory starting January 1, 2027.
- **Mostly Part D, for now**: The list is weighted to retail Part D drugs. HRSA has not extended the pilot to Part B infused drugs, but its reasoning already covers them.
- **Litigation**: HRSA's first attempt was blocked by a federal judge after hospital lawsuits. The American Hospital Association (AHA) says it is "considering all available options to prevent this flawed program from going into effect." Expect injunction requests before January.

How The Pilot Works

Providers keep buying pilot drugs through their existing 340B wholesaler account, now at wholesale acquisition cost (WAC), and receive the 340B discount as a rebate once a complete, claim-level submission is verified. Providers should not buy pilot drugs through any other account (WAC-only or GPO) if they intend to seek a rebate. HRSA's goal is to verify eligibility up front rather than through costly after-the-fact audits and disputes. HRSA will publish interim summaries and a final evaluation by April 30, 2028.

Where The Sides Stand

Manufacturers say the model brings transparency and prevents duplicate discounts across 340B and Medicaid or Medicare. **Providers**, led by the AHA, warn of billions in administrative cost, cash-flow strain and the risk that manufacturers delay or withhold rebates. Congress is also in play, through Chairman Cassidy's **discussion draft** and the bipartisan **SUSTAIN 340B Act**.

Health Systems: Readiness is Critical

Academic medical centers and large systems must prepare for these changes. Our **September 28 analysis** sets out the internal readiness steps. October 1 adds three more:

- **Plan for two outcomes**. A court order could pause the pilot, or notices could arrive on schedule and the pilot could proceed. Build both plans now so a ruling doesn't leave you improvising in December.
- **Lock down purchasing**. Rebates are available only on drugs bought through the 340B wholesaler account. Make sure no pilot drug is ordered through a WAC-only or GPO account, whether by a pharmacy, a clinic or an automated reorder.
- **Decide on CMS's data repository**. Submissions are voluntary now and proposed to be mandatory January 1. Decide whether to submit early and test your data before the mandate.

October 1 turned a policy debate into a deadline. Health systems that act this quarter will be best positioned to protect their margins and to shape what comes next.

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.



Emmett R. Jamieson, Senior Manager of Legislative Affairs and Government Relations

Emmett is a Senior Manager of Legislative Affairs and Government Relations at ML Strategies in Washington, DC. He helps clients navigate federal policymaking, track legislative developments, and engage with policymakers and other stakeholders.

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.