COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

HRSA'S REVISED 340B REBATE MODEL PILOT

A Targeted Fix for a Real Problem: Duplicate Discounts

HHS released a revised 340B Rebate Model Pilot Program that reduces waste and ensures accurate payment for drugs, as the Inflation Reduction Act requires. CAHC supports the pilot program because it will lead to improved transparency and lower costs for patients.

340B is a Safety Net Program

The 340B Drug Pricing Program is a federal program created in 1992 under the Veterans Health Care Act. It requires drug manufacturers that want their outpatient drugs covered by Medicaid and Medicare Part B to sign an agreement with HHS to sell those drugs at a discounted ceiling price to certain safety-net providers, known as covered entities.

- The manufacturer sells the drug to the covered entity at the discounted ceiling price rather than the commercial price.
- Historically this has been an upfront discount: the entity either buys directly at the lower price or, more commonly today, uses a replenishment model, dispensing from regular-price inventory, identifying which dispenses went to 340B-eligible patients, then buying a matching quantity at the discounted price to restock.
- Since the Affordable Care Act, the number of covered entities and the value of discounts have increased dramatically and are rarely passed onto patients.[i]

Duplicate discounts are a real cost

- A duplicate discount occurs when the same unit of a drug is discounted twice under two federal programs that are supposed to be mutually exclusive. The 340B statute bars a covered entity from taking the 340B discount on a unit also subject to a Medicaid rebate. HRSA built the Medicaid Exclusion File (MEF) in 1993[ii] to keep the two separate, but it was designed for a far smaller program. HHS's Office of Inspector General and GAO have both flagged this as a persistent weak spot, especially for Medicaid managed care claims.[iii]
- Manufacturer and industry commenters cited estimates that duplicate discounts may affect up to a quarter of all 340B transactions and represent tens of billions of dollars annually across Medicaid, Medicare, and the new IRA drug-negotiation program.

The pilot is narrow, proven, and cash-flow protected

- The IRA created a newer version of the same problem: the law bars stacking the negotiated maximum fair price (MFP) and the 340B ceiling price (section 1320f-2(d) already requires that MFP and 340B pricing not be cumulative[iv]). But HRSA and manufacturers lack timely, claims-level data on which units already received the lower price, forcing retrospective pay-and-chase reconciliation.
- The rebate model fixes this by tying the discount to a validated claim before payment, rather than untangling who discounted what after the money has moved.
- It applies only to drugs on the CMS Medicare Drug Price Negotiation Selected Drug List for 2026 and 2027, less than 5.5 percent of total 340B sales. The other 94.5 percent stays on the current upfront-discount model.
- HRSA built in real protections: a mandatory 10-calendar-day rebate payment window, unit-level (not full-package) processing, and a 15-day inventory grace period. Independent analyses from IQVIA and 3 Axis Advisors found rebate models can match or improve cash flow relative to current replenishment models, particularly for contract pharmacies.[v]

To Get a 340B Discount, Entities Must Be Transparent

- Validating claims data before payment instead of after-the-fact 'pay-and-chase' audits is how most health claims are processed today.
- The Pilot changes only the mechanism and timing of the 340B discount. It does not alter the discount, who gets it, or patient eligibility. Summary of the Pilot

The 340B Rebate Model Pilot Program

Rather than receiving the 340B discount up front, covered entities pay wholesale acquisition cost (WAC) for a drug, dispense the drug, then submit a claim to the manufacturer for a rebate equal to the difference between WAC and the 340B ceiling price.

- Manufacturers must pay within 10 calendar days of a complete claim and must bear the cost of the rebate-processing IT platform.
- The covered universe is the IRA-negotiated maximum fair prices selected drugs for initial price applicability years (IPAY) 2026 and 2027, during their price applicability periods.
- This expands the original 2025 pilot, which covered only the 10 IPAY 2026 drugs, to add the 15 IPAY 2027 drugs, provided a manufacturer applies and is approved.
    - IPAY 2026 drugs (10): Eliquis, Jardiance, Xarelto, Januvia, Farxiga, Entresto, Enbrel, Imbruvica, Stelara, and NovoLog/Fiasp. Conditions include atrial fibrillation and blood clots, diabetes, heart failure, rheumatoid arthritis and psoriasis, and blood cancers.
    - IPAY 2027 drugs (15): Ozempic, Rybelsus, Wegovy; Trelegy Ellipta; Xtandi; Pomalyst: Kaposi; Ibrance; Ofev; Linzess; Calquence; Austedo, Austedo XR; Breo Ellipta; Tradjenta; Xifaxan; Vraylar; Janumet, Janumet XR; Otezla. Conditions include cancer, cardiovascular, type 2 diabetes, psoriasis/psoriatic arthritis/Behcet's, bipolar/depression/schizophrenia, and COPD.
- By limiting the rebate model to this list, HRSA is testing whether claims-level rebate data can solve the MFP/340B deduplication problem specifically, rather than converting the entire $100 billion-plus[vi] 340B program to rebates. The set is large enough (25 drugs spanning diabetes and obesity, oncology, and respiratory products) to generate real operational data, but small enough (under 5.5 percent of 340B sales) to avoid disrupting covered entities, especially rural and safety-net providers.

THE BOTTOM LINE

A program that has nearly doubled in three years needs modern tools to police duplicate discounts. HRSA's revised Pilot is narrow, tested, and cash-flow protected. Congress gave the Secretary this authority in 1992, and CAHC agrees it is time to use it.

Source: HRSA, Notice Regarding 340B Rebate Model Pilot Program, Fed. Reg. 2026-15633 (Aug. 3, 2026).

[i] https://schaeffer.usc.edu/research/misaligned-incentives-340b/
[ii] https://www.hrsa.gov/opa/updates/2015-october
[iii] https://www.gao.gov/assets/gao-20-212.pdf
[iv] https://www.law.cornell.edu/uscode/text/42/1320f-2
[v] https://www.iqvia.com/locations/united-states/library/white-papers/how-will-a-rebate-model-impact-cash-flow-in-the-340b-drug-pricing-program
[vi] https://www.hrsa.gov/opa/updates/2025-340b-covered-entity-purchases