



HRSA's 340B Rebate Model Pilot Program

KEY DATES

- **July 31, 2025:** HRSA announced the rebate model, to start Jan. 1, 2026
- **Oct. 30, 2025:** HRSA announced eight manufacturers to participate in 340B rebate model pilot
- **Dec. 29, 2025:** A federal court issued a preliminary injunction halting the pilot
- **Feb. 2026:** HRSA indicated it will essentially withdraw the pilot
- **Feb.-June 2026:** HRSA issued notices and information collection requests on a new 340B Rebate Model Pilot Program
- **July 31, 2026:** HRSA published a notice establishing a revised pilot program
- **Aug. 24, 2026:** Rebate model plans due from manufacturers interested in participating
- **Sep. 24, 2026:** HRSA to approve manufacturer plans
- **Jan. 1, 2027:** Start date of the revised pilot program

HRSA [issued](#) a revised **340B Rebate Model Pilot Program** on July 31, 2026, under which participating manufacturers will provide covered entities (CEs) rebates after 340B drugs are dispensed to eligible patients.

Participants:

- On the company side, eligibility is limited to manufacturers and products with Medicare-negotiated maximum fair prices for **initial price applicability years (IPAY) 2026 and 2027**.
- Company participation is **voluntary**.
- **All covered entities** are required to participate under approved rebate plans.

Rebate Model Premise:

- CEs will buy covered outpatient drugs through existing distribution channels at **wholesale cost**.
- CEs have **45 days** post-dispensation of a covered outpatient drug to send specific claims-level data to manufacturers.
- Manufacturers have **10 days** after data submission to provide rebates to CEs, where the rebate is equal to the wholesale acquisition cost minus the 340B price.



Key Takeaways

- **Hospitals are largely opposed to the pilot**, with some [arguing](#) HRSA ignored comments regarding administrative burdens and patient harms.
- The **number of eligible drugs and manufacturers increased** from 10 drugs and 8 companies to 25 drugs and 13 companies. All companies eligible for the first version of the pilot had their rebate model plans approved, but it remains to be seen whether all eligible companies & products will again be included.