340B Rebate Model Pilot Program

The 340B Drug Pricing Program was enacted in 1992 as a mechanism to financially assist certain hospitals (covered entities) that care for low-income or uninsured patients. These entities receive discounts on all eligible covered outpatient drugs. The program has expanded substantially over the years, with the number of covered entities growing by **174% between 2013 and 2023**, and 340B Program sales growing from **$53.7B to $66.4B (+23.4%) between 2022 and 2023**.[1] Due to pushback by pharmaceutical manufacturers, a new program is being piloted by the Health Resources and Services Administration (HRSA).

Existing model vs. Rebate Pilot at a glance

Under the existing program, manufacturers provide up-front discounts to covered entities at the point of purchase. The pilot instead effectuates the 340B ceiling price through a back-end rebate on a limited set of medications. The two approaches compare as follows:

Feature	Existing 340B Program	New 340B Rebate Pilot
Pricing mechanism	Up-front discount applied at the point of purchase	Back-end rebate paid within 10 days after data submission to manufacturer
Price paid at purchase	Discounted 340B ceiling price (at least 23.1% off branded drugs)	Full wholesale acquisition cost (WAC), later rebated down to the ceiling price
Cash flow timing	Savings realized immediately; working capital preserved	Capital tied up until the rebate is received
Drugs covered	All eligible covered outpatient drugs	Limited set of ~25 Medicare-negotiation drugs (IPAY 2026-2027), about 5.5% of 2025's 340B sales[1]
Data & administration	Minimal claims-level data sharing	Standardized claims data submitted to manufacturers to trigger each rebate
Oversight & transparency	Limited transaction-level visibility for manufacturers	Manufacturers validate claims before paying, adding transaction-level visibility
Participation	Required of manufacturers participating in the Medicaid Drug Rebate Program	Voluntary pathway for qualifying manufacturers
Status & timeline	In effect since 1992	Pilot launches Jan 1, 2027; runs at least one year, HRSA report due Apr 30, 2028

Strategic implications for the 340B Rebate Pilot Program

Participating manufacturers can validate claims before rebates are paid, introducing a new level of transactional transparency. This should help to reduce duplicate or inappropriate claims.

A 340B entity's experience with rebate payment may become a differentiator for manufacturers.

340B entities may prefer the up-front discounts from products that are not participating in the model. It may also introduce longer-term cash flow constraints for covered entities.

Significant data infrastructure is required by both the covered entities and the manufacturers to submit claims data, validate, and process claims to issue rebates within relatively tight timelines.

[1] https://www.federalregister.gov/documents/2026/08/03/2026-15633/notice-regarding-340b-rebate-model-pilot-program

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