



HRSA 340B Rebate Model Pilot Program: How It Is Expected to Work

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Overview. The Health Resources and Services Administration (HRSA) has established a revised 340B Rebate Model Pilot Program that would allow qualifying manufacturers to provide the statutory 340B ceiling price through a retrospective rebate rather than an upfront discount for a limited set of covered outpatient drugs. The revised Pilot is scheduled to take effect January 1, 2027 for approved manufacturers and eligible drugs.

Which drugs are affected. The Pilot is limited to selected drugs under the Medicare Drug Price Negotiation Program for the 2026 and 2027 initial price applicability years, during their applicable pricing periods. Manufacturer participation is voluntary, but once HRSA approves a manufacturer rebate plan, covered entities purchasing the affected drugs would operate under that approved rebate process.

How the transaction would work. For affected drugs, the covered entity would generally purchase the product at the higher wholesale acquisition cost (WAC), rather than receiving the 340B price at the point of purchase. After the drug is dispensed or administered to a 340B-eligible patient, the covered entity or its vendor would submit specified pharmacy or medical claims data through the manufacturer's approved electronic platform. Covered entities must generally have at least 45 calendar days from the date of dispense to submit the information.

Rebate calculation and payment. The manufacturer would calculate the rebate so that the covered entity's net acquisition cost equals the applicable 340B ceiling price. Rebates must be calculated at the individual-unit level. Once a complete claim is received, the manufacturer must generally pay the rebate or provide a documented denial within 10 calendar days; if information is incomplete, the payment clock restarts after the missing information is supplied.

Data and denial safeguards. HRSA limits the information manufacturers may require to standardized transaction-level pharmacy or medical claims fields and does not permit broad demands for additional purchasing records, encounter data, invoice-level information, or direct patient identifiers as a condition of payment. Manufacturers also may not deny rebates simply because they independently believe diversion or Medicaid duplicate-discount rules were violated; those concerns generally must be addressed through HRSA's existing compliance, audit, or dispute processes.

Hospital implications. The central concern for 340B hospitals is cash flow: hospitals would pay substantially more upfront for affected drugs and recover the 340B benefit only after claims validation. This may increase working-capital needs, administrative costs, and dependence on manufacturer-controlled systems. HRSA has sought to reduce those burdens through the 10-day payment requirement, unit-level rebates, and limits on required data. Commenters nevertheless warned that upfront acquisition costs for some drugs could rise dramatically.

References

1. HRSA, "HRSA Announces Revised 340B Rebate Model Pilot Program to Strengthen Care in Rural and Medically Underserved Communities," July 31, 2026. <https://www.hrsa.gov/about/news/press-releases/revised-340b-program-2026>
2. HRSA, "340B Rebate Model Pilot Program," Office of Pharmacy Affairs, reviewed July 2026. <https://www.hrsa.gov/opa/340b-model-pilot-program>
3. Health Resources and Services Administration, "Notice Regarding 340B Rebate Model Pilot Program," Federal Register notice, July 31, 2026. <https://public-inspection.federalregister.gov/2026-15633.pdf>
4. HRSA, "Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation," 2026. <https://public-inspection.federalregister.gov/2026-11989.pdf>