

# Now & Next

## Healthcare Alert

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### New for 2026 — 340B Rebate Model Pilot Program

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Mandatory 340B rebate model starts Jan 2026. Learn what covered entities must do to stay compliant and manage rebate claims effectively.



#### What's the impact?

- Beginning January 1, 2026, covered entities purchasing certain drugs included in the 340B Rebate Model Pilot Program will be charged the wholesale acquisition cost and will be eligible to receive a manufacturer rebate after dispensing the drug to an eligible patient.
- The Model Pilot Program is mandatory for covered entities, so they should review and adjust their current operational systems to address the submission of rebate claims, track rebates, and manage denials.

In August 2025, the Health Resources and Services Administration's Office of Pharmacy Affairs (OPA) [announced a 340B Rebate Model Pilot Program \(Model Pilot Program\)](#) for manufacturers meeting defined participation criteria. In October, after a period of public comment and review of manufacturer applications, OPA approved nine manufacturer plans to participate in the Model

Pilot Program. Eight of the approved plans will take effect on January 1, 2026, and the ninth will begin April 1, 2026.

On December 4, 2025, OPA held a [webinar](#) to inform participants about the Model Pilot Program's claims submission process, OPA's monitoring of compliance, and OPA's approach to evaluating the Pilot's effectiveness.

## Model Pilot Program process

Historically, drug manufacturers have been required to provide upfront discounted prices on covered outpatient drugs to 340B-covered entities. Under the Model Pilot Program, however, covered entities must purchase certain drugs at the wholesale acquisition cost (WAC) and submit claims for a rebate after the drugs are dispensed. OPA has posted a list of the affected drugs and approved manufacturer plans on the [340B Rebate Model Pilot Program website](#).

Beginning January 1, 2026, covered entities will be expected to order Model Pilot Program drugs through their 340B wholesaler accounts. For the subset of drugs included in the Model Pilot Program, manufacturers will load WAC pricing into the covered entities' 340B accounts so wholesalers charge WAC at the time of purchase, rather than a discounted price. All participating manufacturers will use the [Beacon platform](#) as their IT vendor in the Model Pilot Program.

To receive a rebate, covered entities must submit a rebate claim on the Beacon IT platform within 45 days of dispensing or administering the WAC-priced product to an eligible 340B patient. The platform will transmit the data to the manufacturer for review, and the manufacturer will approve or deny the rebate request. Rebates will be calculated as WAC minus the 340B ceiling price on the date of service. Covered entities should expect rebates to be paid within 10 calendar days of data submission. Once paid, the effective acquisition cost will reflect the 340B price. As the Model Pilot Program progresses, OPA will evaluate whether to incorporate certain purchase data in the claim submission process.

## Rebate denials and disputes

Manufacturers may not deny rebates based solely on general compliance concerns, such as suspected diversion or Medicaid duplicate discounts. However, manufacturers may deny rebate requests in certain cases. For example, if the Maximum Fair Price (MFP) is lower than the 340B ceiling price, the manufacturer may deny the 340B rebate because it is only required to pay the lesser of the MFP or 340B ceiling price. In addition, the manufacturer may deny a rebate request if a duplicate rebate claim has already been paid to another covered entity.

If a claim is denied, the manufacturer must provide clear, specific, and documented justification. Covered entities that do not receive rebates within 10 days after submitting complete and accurate data should first contact the manufacturer and the IT platform vendor to report their

concerns. If the covered entity still does not receive a rebate after attempting to resolve the issue with the manufacturer, HRSA indicated it should email [340BPricing@hrsa.gov](mailto:340BPricing@hrsa.gov) with its concern.

## Compliance and monitoring

OPA will assess manufacturer and covered entity compliance through data reporting and audits. Covered entities are expected to maintain auditable records supporting WAC purchases, patient eligibility, claims submissions, and rebate receipts. OPA will solicit routine feedback and provide collection tools to evaluate how the Model Pilot Program functions in practice. OPA will be collecting ongoing questions and updates, so covered entities should consult the OPA website FAQs for the latest information.

## Non-Model Pilot Program drugs

OPA also confirmed that covered entities will continue to receive upfront 340B discounts on all other covered outpatient drugs not included in the Model Pilot Program.

Although a legal challenge has been initiated, covered entities need to take steps to comply with the requirements of the Pilot Program as of January 1, 2026.

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