PUBLICATION

HRSA Announces 340B Rebate Pilot Program

Authors: Gregory M. Fliszar, Alissa D. Fleming, Katherine A. Denney
August 12, 2025

Structure & Timing of the Pilot Program

On August 1, 2025, the Health Resources and Services Administration (HRSA), administrator of the 340B Drug Pricing Program, announced its voluntary 340B Rebate Model Pilot Program in a Notice and set forth next steps for drug manufacturers to apply to participate in the program. The program will run for at least one year and will be limited to a specific set of drugs that are part of the Medicare Drug Price Negotiation Program. These drugs will include a number of drugs, including those used to treat conditions such as diabetes and heart failure. Drug manufacturers have until September 15, 2025, to apply to participate in the pilot rebate program. Each drug manufacturer must include a plan for how it will implement the rebate program in its application. These applications will be reviewed and approvals issued by October 1, 2025, for a January 1, 2026, effective date. While the program is voluntary for pharmaceutical manufacturers, 340B covered entities will have to participate in the program. The OPA may consider expanding the rebate pilot program to other drugs purchased under the 340B program following the initial pilot program and feedback from stakeholders.

Introduction of Critical Safeguards for Evaluation

HRSA and the Office of Pharmacy Affairs (OPA) are requiring drug manufacturers to include several significant safeguards designed to protect covered entities from significant delays and other fraudulent behavior in their proposals submitted for consideration by OPA. These safeguards include:

1. Assurances that all costs for data submission through an Information Technology (IT) platform will be borne by the manufacturer, and no additional administrative costs of running the rebate model shall be passed onto the covered entities.
2. 60 calendar days' notice to covered entities and other impacted stakeholders before implementation of a rebate model, with instructions for registering for any IT platforms.
3. Maintenance of existing distribution mechanisms to ensure purchases flow through the existing infrastructure.
4. Technical assistance/customer service component to the plan.
5. Assurances from any IT platform that the data is secure and protected and collection of the data is limited to the elements listed below that are necessary for providing 340B rebates.
6. Assurances that the IT platform has mechanisms in place to protect patient identifying information.
7. Data submission and reporting mechanism for covered entities' data for up to 45 calendar days from the date of dispense, which allows for submission of extenuating circumstances and other exceptions.
8. Specification of whether rebates are paid at the package level or at the unit level.
9. Assurances that all rebates are paid to the covered entity (or denied, with documentation in support) within 10 calendar days of data submission.
10. Assurances that all data requested as part of the plan is limited to only the following readily available pharmacy claim fields:

Date of Service

Date Prescribed

RX number

Fill Number

11 Digit National Drug Code (NDC)

Quantity Dispensed

Prescriber ID

Service Provider ID

340B ID

Rx Bank Identification Number (BIN)

Rx Processor Control Number (PCN)

Potential Impact on 340B Providers

Although this is only a pilot program, it may have a significant impact on 340B covered entities. Instead of receiving discounts up front, 340B providers will have to purchase drugs included in the pilot program at full price and then later apply for a rebate. This delay in payment and the added administrative costs to comply with the rebate program may be difficult for many safety net providers to absorb. The administrative costs will be in addition to those already being expended in managing the traditional 340B program for all other 340B drugs not included in the pilot. One of the purported purposes of the pilot is to determine the potential impact of a rebate model on 340B covered entities from both a cost and fairness perspective, as manufacturers will have more discretion – following the sale of the drug – to issue a rebate.

The Notice states that "OPA will consider comments received but is under no obligation to respond to or act on the comments." Comments to the pilot program must be submitted by September 8, 2025, to the Federal eRulemaking Portal.

The pilot program is just one measure that has been taken in the last several months that signals a future, potentially significant change for the 340B Program. For additional information on the current state of affairs for the 340B Program, please contact Greg Fliszar, Alissa D. Fleming, Katherine Denney, or any member of the Baker Donelson Health Law Team.