



GUIDE

HRSA's 340B Rebate Model Pilot Program

Your guide to understanding what a covered entity needs to know before the Pilot takes effect on January 1, 2027.

On August 3, 2026, HRSA introduced the most significant change to 340B's price mechanism since the program's inception in 1992. Under the 340B Rebate Model Pilot Program, qualifying manufacturers can deliver 340B pricing through a rebate paid after a drug is dispensed, rather than through a discount applied before purchase.

That structural shift sets off a practical chain of consequences. New deadlines govern how quickly a rebate turns into cash. Those deadlines depend on data a covered entity has never had to send to a manufacturer before. Sending that data reliably is a distinct operational challenge from simply possessing it. And once a claim is submitted, it can still come back denied, with a real financial consequence attached. Each piece builds on the last, starting with the mechanism itself.

This guide covers what that shift means for a covered entity's operations and where it creates friction between covered entities and manufacturers. It also covers what a covered entity needs to resolve before the Pilot takes effect on January 1, 2027.

The Shift: From Discount to Rebate

Discount

Under 340B's current model, a covered entity dispenses drugs from a "neutral inventory" not yet designated as 340B or non-340B. Software reviews each dispense and determines 340B eligibility. When enough eligible dispenses accumulate to reach a full package, the covered entity purchases a matching quantity at the discounted ceiling price. The discount applies retroactively, but the purchase itself still happens at the discounted price.

Rebate

The rebate model reverses this sequence for a defined set of drugs. In the Pilot Program, a covered entity orders through its wholesaler account at wholesale acquisition cost rather than the 340B ceiling price. The entity then dispenses the drugs, submits claims data to the manufacturer, and receives a rebate for the difference between what it paid and the ceiling price. Each unit dispensed triggers its own rebate, without waiting to meet a package-level threshold. This structure makes rebate payments more frequent and predictable.



In the current model, the discount happens at the register. In the new model, it happens after a claim submission. This distinction underpins everything else in this guide. Once payment depends on a claim rather than a purchase, the relationship between timing, data, and risk changes, starting with how quickly that claim turns into cash

The Clock: Deadlines That Turn Claims into Cash

The cycle begins the moment a drug is dispensed. From there, the Pilot runs on a small set of fixed deadlines that determine how quickly a rebate turns into cash.

45 CALENDAR DAYS

The window to submit claims data from the date of dispense.

10 CALENDAR DAYS

The window for a manufacturer to pay or deny a submission, restarting if the submission comes back incomplete

90 CALENDAR DAYS

The notice a manufacturer must give covered entities before its plan takes effect.

15-DAY GRACE PERIOD

A one-time window to claim a rebate on leftover dispenses awaiting replenishment, capped at two packages.



Together, this cycle asks a covered entity to capture each dispense event accurately and submit the associated claims data within the 45-day window. It also asks the entity to track whether the resulting rebate arrives within the 10-day window that follows. Each deadline depends on a covered entity's ability to produce specific data on demand, which raises the next question: what data does the Pilot require, and where does it come from?



The Data: What Has to Move, and Where It Breaks Down

Within the current model, covered entities use claims-level data internally to determine 340B eligibility. That data is not routinely sent to a manufacturer as part of a transaction. This changes under the rebate model. Starting January 1, 2027, covered entities must submit claims-level data to the manufacturer for every dispense of a Pilot drug, and the manufacturer pays the rebate only after it validates that submission.

For the Pilot Program, HRSA has limited this requirement to a defined set of pharmacy and medical claims fields.

PHARMACY CLAIMS FIELDS

- Date of Service
- Date Prescribed
- Rx number
- Fill number
- NDC-11
- Quantity Dispensed
- Prescriber ID
- Service Provider ID
- 340B ID
- RX BIN
- RX PCN

MEDICAL CLAIMS FIELDS

- Date of Service
- Claim Line Number
- Claim Number
- Unit of Measure
- NDC-11
- Quantity
- Rendering Physician ID
- Service Provider ID
- 340B ID
- Health Plan Name
- Health Plan ID
- Health Plan ID Qualifier

EXCLUDED FIELDS

- Purchasing data
- Encounter-level clinical documentation
- Direct patient identifiers



Most of this data already exists within a covered entity's systems, generated in the ordinary course of billing Medicare, Medicaid, and commercial payers. The harder question is whether an entity can actually assemble and transmit that data as a single submission. Covered entities commonly store pharmacy claims data and medical claims data on separate internal systems that do not connect, and the Pilot requires a way to compile both and send them to a manufacturer together. That requirement exposes a real administrative and technological gap.

Closing this gap depends largely on a covered entity's TPA capabilities. According to HRSA, at least 53 TPAs can already send pharmacy claims data to a rebate processing platform used by manufacturers, so pharmacy claims submission already works for much of the market. Medical claims submission is a different story. Many TPAs have never pulled medical claims data, let alone connected it to a manufacturer-facing platform.

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A covered entity evaluating any TPA, including PharmaForce, should verify readiness through direct questions. Useful questions include:

Has the vendor actually pulled medical claims data before?

Does it already connect to the billing systems where that data lives?

Has its software been built to the Pilot's exact field requirements?



The Risk: When Rebates Get Denied

A denial carries significant weight under the Pilot's new price mechanism. By the time a covered entity submits a rebate claim, it has already paid full wholesale acquisition cost for the drug. A denial means the covered entity absorbs the entire gap between WAC and the 340B ceiling price for that unit, having paid full price with no return on that dispense.

In Section VIII of its notice, [HRSA outlined](#) a closed list of reasons a manufacturer cannot use to deny a rebate claim and withhold payment:

- Concerns about a covered entity's 340B eligibility.
- Concerns about drug diversion.
- Concerns about a Medicaid duplicate discount.
- A perceived shortfall in wholesale acquisition cost purchases to support the claim.

A manufacturer with any of these concerns must raise them directly with HRSA's Office of Pharmacy Affairs, or pursue them through the 340B Program's existing audit and Administrative Dispute Resolution process. A manufacturer cannot resolve these particular concerns simply by denying the claim.





HRSA did not provide an equivalent closed list of reasons a claim can be denied. Its notice gives two examples instead. The first is nonduplication with the Maximum Fair Price. If a Medicare beneficiary already received a selected drug at the MFP, the manufacturer can deny a 340B rebate claim on that same unit, since paying both would violate the statute's nonduplication rule. The second is a duplicate rebate on the same claim, where a rebate has already been paid to another covered entity for the same underlying transaction.

These are only two examples among an open-ended set. HRSA's structure is bound only by a documentation requirement, which gives manufacturers room to develop denial reasons beyond what the notice specifically describes.

To keep this in check, HRSA intends to monitor denial patterns across the Pilot. If covered entities report a manufacturer denying claims without acceptable justification, HRSA can review a sample of disputed transactions over a defined period. Where a significant share of that sample shows unjustified denials, HRSA can begin removal proceedings against that manufacturer. The underlying dispute over how much proof a manufacturer actually owes remains open.

The Scope: How Much of Your Program This Touches

The rebate mechanism applies only to drugs that appear on the CMS Medicare Drug Price Negotiation Selected Drug List for initial price applicability years 2026 and 2027, during those drugs' specific price applicability periods. HRSA states that these drugs represented less than 5.5 percent of total 340B sales based on 2025 data, which means more than 94 percent of a typical covered entity's 340B purchasing continues under the familiar upfront discount model through at least 2027.

The Pilot is voluntary for manufacturers, though mandatory for covered entities once a plan is approved. A manufacturer with an eligible drug on the selected list chooses whether to submit a rebate plan to HRSA. Once HRSA approves that plan, participation becomes mandatory for every covered entity that acquires that manufacturer's selected drug, and a covered entity cannot opt out of the rebate mechanism for that drug afterward.

HRSA has also signaled that it intends to expand this scope over time. It describes the Pilot as a way to generate operational evidence before considering broader application of the rebate model to additional drugs.



The Readiness Test: What to Ask Before January 2027

Covered entities benefit from starting preparation well ahead of the effective date. Doing so early means understanding where the rebate model intersects with existing operations and closing gaps before claims move through the new process. Five clusters of questions cover most of what matters.

EXPOSURE AND DATA

Which manufacturers and drugs create rebate exposure? Can existing systems produce every required field accurately within the 45-day window, without relying on a new manual workaround?

WORKFLOW AND OWNERSHIP

Who owns submission, monitoring, denial management, resubmission, and reconciliation once a claim leaves the building?

FINANCIAL EXPOSURE

How much working capital could remain tied up while rebates are pending, and what is the plan if a manufacturer pays late or denies a claim?

VENDOR ACCOUNTABILITY

What is a TPA actually responsible for, and what stays with the internal team? Has the vendor tested medical claims submission against a real manufacturer platform?

CONTINGENCY

What happens when a claim is incomplete, denied, delayed, or disputed, and who is accountable for resolving it?

A useful test traces the full rebate lifecycle end to end: affected dispense, 340B eligibility, required data, claim submission, submission status, manufacturer response, rebate payment or denial, reconciliation, and resolution. A gap at any point in that chain is worth closing now.

The Bottom Line

This Pilot matters beyond its current scope because HRSA built it to expand if it works. A rebate model that today touches less than 6 percent of 340B purchasing is, by HRSA's own framing, a test run for a mechanism it may extend further once it has evidence from this first year. How the rebate calculation works, how the payment cycle runs, what data it requires, and where the risk of denial sits will matter to a covered entity's finances before January 2027, regardless of how far the scope eventually reaches.

PharmaForce has already built the capabilities the Pilot requires. The platform pulls medical claims data and integrates directly with the systems needed to source it, closing a gap most of the market has yet to address.



Ready to Talk Rebates?

See how PharmaForce can help your organization simplify rebate submissions, manage rejections, track payments, and reconcile rebates in one connected workflow.



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