

The transition to rebate-based 340B pricing introduces new considerations for medication purchasing, claims submission, cash flow and financial reconciliation.

For covered entities preparing for the 340B Rebate Model Pilot Program, readiness requires coordination across pharmacy, finance, revenue cycle, IT and operations. This checklist helps teams evaluate preparedness, identify gaps and establish accountability across the rebate process.

How to use this checklist

Review each readiness area with the appropriate stakeholders. Select a status, document supporting evidence or gaps, and assign an owner and next action. Mark an item Ready when the applicable checks have been documented and verified. Prioritize gaps that could affect submissions, rebate payments or financial performance.

Organization: _____

Review Date: _____

Review Lead: _____

1. Information

Do teams have complete and reliable information to support rebate submissions?

- Confirm affected drugs, National Drug Codes (NDCs), transaction dates and submission requirements against current HRSA-approved manufacturer plans.
- Verify completeness, accuracy and accessibility of required pharmacy and medical claims data.
- Confirm submission processes use only HRSA-approved data fields.
- Identify information gaps and assign responsibility for resolving them.

Owner: _____

Status:

☐ Ready

☐ In progress

☐ Not Started

☐ Not Applicable

Evidence/Gap and Next Action: _____

2. Ownership

Who is accountable for each stage of the rebate process?

- Assign primary owners and backups for data preparation, submissions, payment monitoring, reconciliation and exception resolution.
- Confirm responsibilities and handoffs across pharmacy, finance, revenue cycle, IT and operations.
- Clarify roles and dependencies involving third-party administrators, technology providers and external partners.

Owner:

Status:

☐

Ready

☐

In progress

☐

Not Started

☐

Not Applicable

Evidence/Gap and Next Action:

3. Policies and Partner Agreements

Do existing policies and agreements support rebate-based operations?

- Review and update 340B policies and procedures, where appropriate, to reflect approved rebate model requirements.
- Evaluate pharmacy services agreements and third-party administrator arrangements to determine whether changes are needed.
- Confirm responsibilities for data sharing, rebate administration, payment monitoring and dispute resolution.
- Review applicable contract pharmacy arrangements for potential operational and financial implications.

Owner:

Status:

☐

Ready

☐

In progress

☐

Not Started

☐

Not Applicable

Evidence/Gap and Next Action:

4. Purchasing

Are purchasing and inventory processes prepared for rebate-based pricing?

- Review 340B purchasing accounts and wholesaler price files to confirm appropriate WAC pricing for affected drugs.
- Assess purchasing, inventory and replenishment workflows, including the transition of existing inventory and unreplenished accumulations.
- Confirm how purchase and dispensing information will be connected to support rebate eligibility and financial reconciliation.
- Evaluate applicable DSCSA obligations and identify purchasing or inventory dependencies that may require attention.

Owner:

Status:

☐

Ready

☐

In progress

☐

Not Started

☐

Not Applicable

Evidence/Gap and Next Action:

5. Workflow

Can teams follow a rebate transaction from identification through resolution?

- Map each stage, from identifying and validating eligible transactions through submission, response, payment and closeout.
- Confirm manufacturer-specific submission requirements and deadlines, including the minimum 45-calendar-day submission window provided under the pilot.
- Establish procedures for corrections, resubmissions, reversals and transaction adjustments.
- Identify manual steps, system dependencies and potential sources of delay.

Owner:

Status:

☐

Ready

☐

In progress

☐

Not Started

☐

Not Applicable

Evidence/Gap and Next Action:

6. Rebate payment and cash flow

Are payment expectations and potential financial exposure understood?

- Confirm expected rebate calculations, payment methods and routing by covered entity or 340B ID.
- Verify banking and electronic payment arrangements, where required.
- Establish a process to monitor rebate payments against the pilot's 10-calendar-day payment requirement, accounting for incomplete submissions that require resubmission.
- Assess potential cash-flow implications of upfront purchases and delayed or denied rebates.
- Coordinate with finance to establish working-capital expectations, inform budgeting decisions, determine the appropriate accrual of anticipated rebate payments and establish appropriate contingencies.

Owner:

Status:

☐

Ready

☐

In progress

☐

Not Started

☐

Not Applicable

Evidence/Gap and Next Action:

7. Visibility

Can teams track affected transactions through rebate payment?

- Establish consistent identifiers to connect purchasing activity, eligible transactions, submissions, responses and payments.
- Maintain a shared view of submitted, pending, paid, denied and overdue rebate requests.
- Track expected rebate amounts, outstanding balances, aging and assigned owners.
- Confirm pharmacy and finance teams have access to the information needed to identify unresolved activity and potential financial exposure.

Owner:

Status:

☐

Ready

☐

In progress

☐

Not Started

☐

Not Applicable

Evidence/Gap and Next Action:

8. Reconciliation

Can teams explain differences between expected and actual rebate payments?

- Define how expected rebates will be matched to payments, recorded in financial systems and reviewed regularly.
- Establish procedures for investigating missing, partial, duplicate or unmatched payments.
- Review how rebate adjustments, denials and unresolved balances affect financial reporting.
- Evaluate contract pharmacy settlement processes, where applicable, including the treatment of rebate-related adjustments or denials.
- Retain supporting documentation through investigation and resolution.

Owner:

Status:

☐ Ready ☐ In progress ☐ Not Started ☐ Not Applicable

Evidence/Gap and Next Action:

9. Exceptions and Good Faith Inquiry (GFI)

What happens when a submission, determination or payment requires further action?

- Establish procedures for identifying and addressing incomplete submissions, rejections, delayed payments and disputed rebate determinations.
- Define how teams initiate, document and respond to good-faith inquiries with manufacturers and rebate platform providers.
- Confirm documentation requirements, response timelines, contacts and escalation procedures, including reporting unresolved issues to HRSA when appropriate.
- Establish an internal process to evaluate and manage financial exposure associated with delayed or denied rebates.

Owner:

Status:

☐ Ready ☐ In progress ☐ Not Started ☐ Not Applicable

Evidence/Gap and Next Action:

10. Operational readiness

Have the people, systems and processes needed to support rebate operations been verified?

- Confirm platform registration, user access, staffing, training, backup coverage and partner responsibilities.
- Validate required data exchanges and test submission, payment monitoring and reconciliation workflows where testing is available.
- Review exception-handling and escalation procedures, including good-faith inquiries and resubmissions.
- Document untested processes, outstanding dependencies and contingency plans.
- Confirm legal and compliance approval of participation, including review and acceptance of applicable platform terms and conditions.
- Obtain cross-functional readiness approval and establish a process to monitor changes to approved manufacturer plans.
- Retain supporting documentation through investigation and resolution.

Owner:

Status:

☐

Ready

☐

In progress

☐

Not Started

☐

Not Applicable

Evidence/Gap and Next Action:

Turn readiness findings into action

Use the completed checklist to identify where processes, information or accountability gaps could affect rebate activity and financial outcomes. Prioritize issues that could block submissions, delay payments or leave financial exposure unresolved. Assign owners, establish due dates and review progress across affected teams.

Priority Gaps and Actions:

Next Review Date:

Planning basis

HRSA's revised 340B Rebate Model Pilot Program identifies January 1, 2027, as the effective date for selected drugs under approved manufacturer rebate plans. Covered entities should consult current HRSA guidance, individual manufacturer plans and subsequent updates when evaluating readiness.

This checklist supports operational and financial planning. It does not establish or certify regulatory compliance.

Sources

HRSA Notice Regarding 340B Rebate Model Pilot Program, August 3, 2026 (91 FR 48883)

<https://www.federalregister.gov/d/2026-15633>

HRSA 340B Rebate Model Pilot Program — Approved Manufacturer Plans and FAQs

<https://www.hrsa.gov/opa/340b-model-pilot-program>