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340B Rebate Model Pilot Program—Medicaid implications and considerations: An issue brief

What state Medicaid programs should know and do ahead of the January 2026 launch

Laura Kasamis, PharmD
Jennifer Prather, PharmD
Jim Davidson, PharmD, MBA

Introduction

The 340B Drug Pricing Program, administered by the Health Resources and Services Administration (HRSA), requires drug manufacturers participating in Medicaid to offer covered outpatient drugs to eligible safety net providers, known as covered entities, at a significantly reduced price known as the 340B ceiling price. While the intent of the 340B program is to enable covered entities to "stretch scarce federal resources to reach more eligible patients and provide more comprehensive services,"[1] concerns have been raised related to ambiguity in the program and a lack of oversight to ensure the program is achieving its original intent.[2]

Amid ongoing litigation[3] and increasing complexity in federal drug pricing, including the introduction of Medicare maximum fair prices (MFPs) under the Inflation Reduction Act and longstanding issues around duplicate discounts with Medicaid, HRSA is launching a 340B Rebate Model Pilot Program to address concerns raised by both covered entities and manufacturers. Rather than purchasing drugs at a discounted 340B price, covered entities would pay the full price upfront and later receive a rebate reflecting the difference between the higher initial price and the 340B price. This is a major shift in the 340B program, which has operated as an upfront discount model for over 30 years.[4]

KEY DETAILS OF THE 340B REBATE MODEL PILOT PROGRAM

Anticipated effective date: January 1, 2026

Eligibility and scope: Open only to select drug manufacturers for drugs on the CMS Medicare Drug Price Negotiation Selected Drug List for year 2026. These drugs include:

- Eliquis
- Enbrel
- Entresto
- Farxiga
- Fiasp/NovoLog
- Imbruvica
- Januvia
- Jardiance
- Stelara
- Xarelto

The initial 10 drugs selected are applicable for the rebate program via both pharmacy point-of-sale claims as well as the physician-administered setting.

Participation and duration: The manufacturers of these 10 drugs may voluntarily apply to enroll in the pilot program, which will operate for a minimum of one year.

Rebate timing: Covered entities are required to submit 340B-eligible drug data to manufacturers within 45 calendar days, and manufacturers must issue the corresponding rebate payment within 10 calendar days of receiving the data.

1. Draper, D.A. (July 18, 2017). Update on agency efforts to improve 340B Program oversight. Government Accountability Office. Retrieved October 21, 2025, from https://www.gao.gov/assets/gao-17-749t.pdf.
2. Rogers, H.-A. (October 14, 2022). Overview of the 340B Drug Discount Program. Congressional Research Service. Retrieved October 21, 2025, from https://www.congress.gov/crs-product/IF12232.
3. Rogers, H.-A. (September 10, 2025). The 340B Drug Discount Program: Litigation topics and trends. Retrieved October 21, 2025, from https://www.congress.gov/crs_external_products/R/PDF/R48696/R48696.1.pdf.
4. Federal Register. (August 1, 2025). Notices. Vol. 90, No. 146. Retrieved October 21, 2025, from https://www.govinfo.gov/content/pkg/FR-2025-08-01/pdf/2025-14619.pdf.

State Medicaid program readiness considerations for the 340B Rebate Model Pilot Program

Review existing 340B policies to evaluate the current 340B pharmacy and medical billing guidance for consistency with the 340B rebate model, including claim identification, submission of acquisition cost, and reimbursement. States that require billing at 340B acquisition cost versus the 340B ceiling price may need to update policies to define or clarify acquisition cost to ensure the higher upfront purchase price is not submitted.

Clarify the definition of "acquisition cost" to ensure alignment between state policy, provider understanding, and the 340B rebate model. HRSA addresses acquisition cost in their published FAQs, noting that while the upfront drug purchase will occur at wholesale acquisition cost (WAC), the cost of the 340B drug is expected to be the 340B ceiling price once the rebate is paid. Further, HRSA states 340B covered entities have access to view the 340B ceiling prices and should work with state Medicaid agencies to determine billing best practices.[5]

Assess state plan language to evaluate if updates are needed for changes resulting from the 340B rebate model. 340B reimbursement methodologies must be defined in the state plan and remain consistent with actual acquisition cost requirements of the CMS Covered Outpatient Drugs final rule.[6]

Evaluate rebate processes and coordination to identify how the 340B rebate model will interface with traditional rebate workflows, including duplicate discount prevention. Duplicate discounts occur when a manufacturer provides both a 340B discount—either upfront or through rebate—to a covered entity and a Medicaid rebate on the same drug claim. This risk remains present under both the traditional 340B model and the rebate-based model, regardless of how the 340B drug is reimbursed. States must continue to ensure robust mechanisms are in place to identify and exclude 340B claims from Medicaid rebate invoicing to maintain compliance.

Analyze administrative burden and system impacts to identify system or operational changes needed to support implementation of the 340B rebate model. This may include claims data tracking, claim edits, or reporting capabilities. As with any policy change, ongoing monitoring is critical to ensuring provider compliance with updated 340B billing requirements.

Perform a comprehensive delivery system review to evaluate and identify impacts. While exclusion of 340B claims from Medicaid rebate invoicing is required under both fee-for-service (FFS) and managed care delivery systems, 340B billing policies may vary. In some states, 340B billing requirements apply only to FFS claims, while others extend the same policies to managed care. States that align 340B policies across both delivery systems must ensure managed care plans are informed and compliant with updated billing guidance. Even where managed care is not subject to the same 340B billing rules, communication is recommended to promote awareness.

Engage and communicate with 340B covered entities to proactively share policy changes and ensure provider understanding of updated 340B billing and reimbursement expectations.

Monitor pilot program developments and post-launch updates to track HRSA and CMS guidance, manufacturer participation, and operational experiences before and after the pilot's anticipated January 1, 2026, launch.[7]

5. Health Resources and Services Administration. (August 2025). 340B Rebate Model Pilot Program FAQ. Retrieved October 21, 2025, from https://www.hrsa.gov/opa/340b-model-pilot-program.
6. Centers for Medicare and Medicaid Services. (January 21, 2016). Covered Outpatient Drugs final rule with comment (CMS-2345-FC). CMS. Retrieved October 21, 2025, from https://www.cms.gov/newsroom/fact-sheets/covered-outpatient-drugs-final-rule-comment-cms-2345-fc.
7. Health Resources and Services Administration. (July 31, 2025). HRSA announces application process for the 340B Rebate Model Pilot Program and request for public comment. Retrieved October 21, 2025, from https://www.hrsa.gov/about/news/press-releases/rebate-model-pilot-program.

Final thoughts for state Medicaid agencies before the 340B Rebate Pilot Program begins

In closing, with the anticipated January 2026 launch of the 340B Rebate Model Pilot Program rapidly approaching, state Medicaid agencies must ensure they are prepared to manage the operational, financial, and compliance implications of this significant change. While the pilot is initially limited in scope, its outcomes may shape broader changes to the 340B program and Medicaid drug reimbursement strategies in the future. States that take early, coordinated steps to review policies, engage stakeholders, and monitor implementation will be better positioned to maintain compliance, reduce disruption, and avoid unintended financial consequences.

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CONTACT

Laura Kasamis, PharmD
laura.kasamis@milliman.com

Jennifer Prather, PharmD
jennifer.prather@milliman.com

Jim Davidson, PharmD, MBA
jim.davidson@milliman.com