LEGAL UPDATES

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HHS Unveils 340B Drug Rebate Pilot Program

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340B Drug Pricing Program

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On July 31, 2025, the U.S. Department of Health and Human Services (HHS) announced that it will conduct a pilot program testing out a rebate model for 340B drug purchases. Under the program, drug manufacturers will be allowed to require safety-net hospitals and clinics to purchase select 340B drugs at full price and then submit claims data to receive manufacturer rebates after dispensation. The pilot program is limited to drugs listed on the Centers for Medicare and Medicaid Services (CMS) Medicare Drug Price Negotiation Selected Drug List and is subject to proposed safeguards and requirements. Covered entities, drug manufacturers, contract pharmacies, and the public can comment on the proposal on or before September 2, 2025.

Background

The 340B Drug Pricing Program allows eligible safety net providers (i.e., covered entities) to purchase covered outpatient drugs at steep discounts. Drug manufacturers have recently sought to implement a post-sale rebate model, which would require covered entities to purchase 340B drugs at the wholesale acquisition cost then apply for rebates after dispensing products to an eligible patient. Such efforts have led to ongoing litigation over whether HHS authorization is required for what amounts to a substantial reshaping of the current system, with two federal district courts affirming that pharmaceutical manufacturers must obtain HHS approval. This pilot program aims to provide HHS with real-world data on the effects of a post-sale rebate model for 340B Program participants and stakeholders.

Key features of the 340B Rebate Model Pilot Program

340B Rebate Model Pilot Program structure and scope

Transition from up-front discounts to a post-sale rebate: Traditionally, covered entities receive upfront discounts when purchasing covered outpatient drugs through the 340B Program. Under the pilot, these entities will pay the wholesale acquisition cost for select drugs and subsequently receive a rebate from the manufacturer equal to the difference between the purchase price and the 340B ceiling price.

Limited initial scope: The pilot is initially restricted to drugs (NDC-11s) included on the CMS Medicare Drug Price Negotiation Selected Drug List, regardless of payor. The first phase targets manufacturers with Medicare Drug Price Negotiation Program (MDPNP) Agreements for price applicability year 2026. The Health Resources and Service Administration (HRSA) has indicated that it may choose to expand the list of drugs eligible for rebates beyond those initially included following its evaluation of the pilot program.

Implementation timeline: Manufacturer plans must be submitted to HRSA by September 15, 2025. HRSA will notify approved manufacturers by October 15, 2025, with the pilot set to begin January 1, 2026. Manufacturers must obtain HRSA approval before implementation.

340B Rebate Model Pilot Program criteria: general requirements

Manufacturers must pay all IT and administrative costs related to data submission. Costs cannot be passed on to covered entities.

Covered entities and stakeholders must receive at least 60 days' advance notice before the rebate model begins, along with clear instructions for registration.

Covered entities must be able to continue purchasing eligible drugs through their existing 340B distribution channels.

Manufacturers must provide responsive technical support and customer service through both the IT platform and a dedicated contact.

The IT platform must ensure data security and restrict data collection to only what is necessary for rebate processing.

All patient-identifiable information must be handled in compliance with HIPAA and other applicable privacy laws.

340B Rebate Model Pilot Program criteria: reporting requirements

Covered entities have 45 days post-dispense to submit rebate claims, with flexibility for special cases.

IT systems must filter for only required data and provide real-time claim status updates.

Manufacturers must regularly report to HHS's Office of Pharmacy Affairs (OPA) on rebate activity, including claim processing times, delays, denials, and other relevant metrics.

340B Rebate Model Pilot Program criteria: rebate requirements

Manufacturers must specify whether rebates will be paid per package or per unit.

Rebates must be issued, or denials with supporting documentation provided, within 10 days of claim submission.

Rebates cannot be denied due to concerns about diversion or Medicaid duplicate discounts. Such issues must be addressed through statutory audit or dispute resolution processes, and any denials must be fully documented.

Rebates are limited to qualifying sales of drugs listed under the MDPNP, regardless of payor.

340B Rebate Model Pilot Program criteria: data submission

Data requested is limited to only the following readily available pharmacy claim fields: service/prescription dates, RX/fill numbers, 11-digit NDC, quantity, prescriber/provider IDs, 340B ID, and claim processing numbers (BIN/PCN).

What this means to you

In response to this initial notice, stakeholders have until September 2, 2025, to submit comments to HHS. Manufacturers are required to submit plans to participate in the pilot by September 15, 2025. The short turnaround between the comment due date and manufacturer application date suggests that HHS is seeking comments to inform the future of the pilot program and will be evaluating applications based on the criteria outlined in the notice. Stakeholders, including manufacturers and covered entities, are encouraged to monitor ongoing developments and consider submitting feedback to HHS.

Contact us

For more information or assistance in preparing comments, evaluating the impact of the pilot program, or navigating compliance strategies, please contact Renee Zerbonia, Robert Hess, Kristina Abdalla, or your Husch Blackwell attorney.