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Vizient Office of Public Policy and Government Relations

340B Program Notice: Application Process for the 340B Rebate Model Pilot Program

August 5, 2025

Background & Summary

On July 31, the Health Resources & Services Administration (HRSA) Office of Pharmacy Affairs (OPA) issued a notice to announce an application process for the 340B Rebate Model Pilot Program and a request for public comment (hereinafter "Notice"). In the Notice, HRSA provides information regarding a new pilot program where qualifying drug manufacturers can effectuate the 340B ceiling price on select drugs to all covered entities (CEs) through a retrospective rebate versus an up-front discount. Manufacturers with Medicare Drug Price Negotiation Program (MDPNP) Agreements for initial price applicability year (IPAY) 2026 may submit plans to OPA for review, with model expansion possible after the pilot is assessed.

While the Notice is effective immediately, OPA is accepting comments until September 2, 2025, and manufacturers may start to submit applications on September 15, 2025, with approvals made by October 15, 2025 and the 340B Rebate Model Pilot Program beginning on January 1, 2026.

340B Rebate Model Pilot Program Framework

In response to inquiries from manufacturers related to different proposed rebate[1] models for the 340B Drug Pricing Program (e.g., to address 340B and Maximum Fair Price (MFP) deduplication and prevention of 340B Medicaid duplicate discounts and diversion), OPA invites certain drug manufacturers to apply to participate in a voluntary pilot, the 340B Rebate Model Pilot Program, for a minimum of one year.

Scope of Drugs and Manufacturers

The scope of drugs that may be included in the model will be limited to the National Drug Code (NDC)-11s included on the Centers for Medicare and Medicaid Services (CMS) Medicare Drug Price Negotiation Program (MDPNP) Selected Drug List, regardless of payer. Manufacturers must have agreements with CMS for IPAY 2026 to participate in the 340B Rebate Model Pilot Program. OPA indicates that it may announce a call for plans from manufacturers with MDPNP agreements for other applicability years, at a later time.

Key Dates

OPA indicates that manufacturer plans for participation in the 340B Rebate Model Pilot Program should be submitted to 340BPricing@hrsa.gov no later than September 15, 2025. Approvals will be made by October 15, 2025, for a January 1, 2026, effective date. In addition, OPA clarifies that manufacturers may not implement plans without first receiving approval.

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[1] A "rebate" for purposes of this pilot program, means a reimbursement made from the manufacturer to the covered entity in the amount of the standard acquisition cost (i.e., wholesale acquisition cost) of a covered outpatient drug less the statutory 340B ceiling price as defined at section 340B(a)(1) of the Public Health Service Act (PHSA).

Manufacturer Plans

OPA specifies the criteria (i.e., General Requirements, Reporting Requirements, Rebates and Data) that should be included in manufacturer plans, which are not to exceed 1000 words. In addition, OPA indicates that plans that exceed or go beyond these criteria should include detailed justification and will be subject to additional review by OPA prior to implementation. OPA also indicates that it reserves the right to revoke approval of a manufacturer plan at any time if a manufacturer is not in compliance with the criteria outlined in the "Rebate Model Pilot Program Criteria".

Plan Criteria	Detailed Criteria
General Requirements	- Include assurances that all costs for data submission through an Information Technology (IT) platform be borne by the manufacturer and no additional administrative costs of running the rebate model shall be passed onto the CEs - Allow for: • 60 calendar days notice to CEs and other impacted stakeholders before implementation of a rebate model, with instructions for registering for any IT platforms. • Allow for CEs to order the selected drugs under existing distribution mechanisms (e.g., 340B wholesaler accounts with pre-rebate prices loaded) to ensure purchases flow through existing infrastructure. - Provide a technical assistance/customer service component and ensure that opportunities to engage with the manufacturer in good faith regarding questions or concerns are made available to CEs through both the IT platform and a point of contact at the manufacturer. - Ensure that the IT platform has: • Assurances in place to ensure 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.[2] • Mechanisms in place to protect patient identifying information, which is required to be maintained in a manner consistent with the Health Insurance Portability and Accountability Act of 1996 and any other applicable privacy and data security laws.
Reporting Requirements	- Ensure that: • CEs are allowed to submit and report data (as detailed below) for up to 45 calendar days from date of dispense, with allowances for extenuating circumstances and other exceptions, including adjustments when a 340B status change occurs on a claim. • The IT platform will have the capacity to receive data that will filter and use only the data required to effectuate the rebate[3] • The IT platform will have the capability to provide real-time reconciliation reports for CEs to be informed of the rebate status of submitted claims. - Agree to provide OPA with periodic reports consistent with the information outlined in the Notice, in a format and manner specified by OPA (instructions forthcoming).[4]
Rebates	- Specify if rebates are paid at the package level, or at the unit level. - Ensure that: • All rebates are paid to the covered entity (or denied, with documentation in support) within 10 calendar days of data submission.

[2] As pursuant to section 340B(a)(1) of the PHSA.
[3] For example, if drugs other than selected drugs under the MDPNP are submitted, the platform will be able to identify and discard unneeded data.
[4] Such reports should detail data on purchases provided through rebates, information related to claim delays and denials, and other information that may evaluate the effectiveness of the rebate model.

	• 340B rebates are not denied based on compliance concerns with diversion or Medicaid duplicate discounts[5], and provide rationale and specific documentation for reasons claims are denied[6]. • 340B rebates are only paid on sales of drugs selected under the MDPNP, regardless of payer.
Data	All data requested as part of the Plan should be limited to following pharmacy claim fields:
	- Date of service - Date prescribed - Rx Number - Fill number - 11-digit NDC - Quantity Dispensed - Prescriber ID - Service Provider ID - 340B ID - Rx Bank Identification Number (BIN) - Rx Processor Control Number (PCN)

Questions for Feedback

OPA seeks comments, including supporting data and sources, on all aspects of the 340B Rebate Model Pilot Program and for the following questions:

- Are there any additional flexibilities to maximize efficiency and efficacy for participating manufacturers that should be considered in the pilot design?
- Are there any additional safeguards to mitigate adverse, unintended impacts for CEs that should be considered in the pilot design?
- Are there any additional data or reporting elements that should be required to improve implementation and evaluation of the pilot?
- Are there any potential implementation issues not yet sufficiently accounted for in the pilot design (e.g., logistical or administrative burdens)?

What's Next?

As noted above, the Notice is effective immediately and OPA is accepting comments until August 30, 2025. Manufacturers may start to submit applications on September 15, 2025, with approvals being made by October 15, 2025 for manufacturers participating in the 340B Rebate Model Pilot Program. CEs and other impacted stakeholders should anticipate receiving notice 60 calendar days before implementation of the 340B Rebate Model Pilot Program with instructions for registering for an IT platform. In addition, OPA will also assess the pilot and additional opportunities for stakeholder feedback will be provided in the future.

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued client feedback on this Notice. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this Notice – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, Vice President, Regulatory Affairs and Public Policy, in Vizient's Washington, D.C. office.

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[5] Pursuant to sections 340B(a)(5)(A) and (B) of the Public Health Service Act

[6] For example, deduplication for MFP or 340B rebate provided to another covered entity on the same claim). As provided in the notice, if a manufacturer has concerns regarding diversion or Medicaid duplicate discounts, the manufacturer should raise those concerns directly with OPA or utilize the 340B statutory mechanisms, such as audits and administrative dispute resolution (ADR), for addressing such issues. CEs are also afforded opportunities to raise concerns with OPA if there are issues with rebate delays and denials, or any other administrative or logistical issues emerging through implementation of the rebate model.