HRSA Releases Application Process for the 340B Rebate Model Pilot Program and Request for Public Comment

HRSA released a *voluntary* 340B Rebate Model Program on July 31, 2025, that will be effective immediately however, the agency is requesting comments on the program. Click here for the guidance document and here for the press release from HRSA.

Certain drug manufacturers, that meet certain criteria, will be invited to apply for participation in a voluntary 340B Rebate Model Pilot Program for a minimum of 1 year. The drugs available for the new program will be limited to a select group of drugs included on the CMS Medicare Drug Price Negotiation Selected Drug List.

Manufacturers must send plans for participation by Sept. 15th, with approvals being made by Oct. 15th, for a start date of Jan. 1, 2026.

The following is the criteria that Rebate Models must follow to be considered:

General Requirements

1. Plan should 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 covered entities.
2. Plan should allow for 60 calendar days' notice to covered entities and other impacted stakeholders before implementation of a rebate model, with instructions for registering for any IT platforms.
3. Plan should allow for covered entities 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.
4. Plan should 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 covered entities through both the IT platform and a point of contact at the manufacturer.
5. Plan should 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 pursuant to section 340B(a)(1) of the PHSA.
6. Plan should ensure that the IT platform has 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

7. Plan should ensure that covered entities 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.
8. Plan should ensure that the IT platform will have the capacity to receive data that will filter and use only the data required to effectuate the rebate (e.g., if drugs other than selected drugs

under the MDPNP are submitted, the platform will be able to identify and discard unneeded data).

9. Plan should ensure that the IT platform will have the capability to provide real-time reconciliation reports for covered entities to be informed of the rebate status of submitted claims.
10. A manufacturer should agree to provide OPA with periodic reports consistent with the information outlined in this Notice, in a format and manner specified by OPA (instructions forthcoming). 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.

Rebates

11. Plan should specify if rebates are paid at the package level, or at the unit level.
12. Plan should ensure that all rebates are paid to the covered entity (or denied, with documentation in support) within 10 calendar days of data submission.
13. Plan should ensure that 340B rebates are not denied based on compliance concerns with diversion or Medicaid duplicate discounts, pursuant to sections 340B(a)(5)(A) and (B) of the Public Health Service Act and should provide for rationale and specific documentation for reasons claims are denied (e.g., deduplication for MFP or 340B rebate provided to another covered entity on the same claim). 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. Covered entities 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.
14. Plan should ensure that 340B rebates are only paid on sales of drugs selected under the MDPNP, regardless of payer.

Data

15. All data requested as part of the Plan should be limited to only the following readily available pharmacy claim fields:
    a. Date of Service
    b. Date Prescribed
    c. RX number
    d. Fill Number
    e. 11 Digit National Drug Code (NDC)
    f. Quantity Dispensed
    g. Prescriber ID
    h. Service Provider ID
    i. 340B ID
    j. Rx Bank Identification Number (BIN)
    k. Rx Processor Control Number (PCN)