



Health Resources and Services Administration

Request for Information: 340B Rebate Model Pilot Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice, request for Information.

SUMMARY: The Health Resources and Services Administration (HRSA) administers section 340B of the Public Health Service Act (PHS Act), referred to as the “340B Drug Pricing Program” or the “340B Program.” HRSA is issuing this Request for Information (RFI) to gather input from interested parties regarding the potential use of rebates to effectuate the ceiling price under the 340B Program, including the standards and procedures that should govern the approval of manufacturer rebate plans and the impacts on all stakeholders.

This RFI seeks comments on whether HRSA should implement a rebate model under the 340B Program and how best to operationalize any such rebate framework for stakeholders. The information collected through this RFI will assist HRSA in evaluating the operational, financial, and access to drugs for patients of a rebate model on covered entities, manufacturers, and other stakeholders across the drug supply chain.

DATES: Comments on this notice should be received no later than **March 19, 2026**.

ADDRESSES: Electronic comments should be submitted through the *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the instructions on the website for submitting comments. Include the HHS Docket No. HRSA-2026-03042 in your comments. All comments received will be posted without change to: <http://www.regulations.gov>. Please do not include any personally identifiable or confidential business information you do not want publicly disclosed. Any proprietary information on comments will not be publicly posted.

We encourage commenters to include supporting facts, research, and evidence in their comments. When doing so, commenters are encouraged to provide citations to the published

materials referenced, including active hyperlinks. Likewise, commenters who reference materials which have not been published are encouraged to upload relevant data collection instruments, data sets, and detailed findings as a part of their comment. Providing such citations and documentation will assist us in analyzing the comments.

FOR FURTHER INFORMATION CONTACT: Chantelle Britton, Director, Office of Pharmacy Affairs (OPA), Office of Special Health Initiatives, HRSA, 5600 Fishers Lane, Mail Stop 10W29, Rockville, MD 20857; email: 340Bpricing@hrsa.gov; telephone: 301-594-4353.

SUPPLEMENTARY INFORMATION:

I. Background

Section 340B of the PHS Act entitled “Limitation on Prices of Drugs Purchased by Covered Entities,” was created under section 602 of Public Law 102–585, the “Veterans Health Care Act of 1992,” and codified at 42 U.S.C. § 256b. The 340B Program is intended to enable covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” H.R. Rep. No. 102–384(II), at 12 (1992). The Secretary of Health and Human Services (Secretary) has delegated the authority to administer the 340B Program to the HRSA Administrator, who in turn delegated this authority to the Office of Pharmacy Affairs, within HRSA, which oversees the 340B Program. Eligible covered entity types are defined in section 340B(a)(4) of the PHS Act, as amended. Section 340B(a)(1) of the PHS Act instructs HHS to enter into pharmaceutical pricing agreementsⁱ with manufacturers of covered outpatient drugs. Currently, there are approximately 14,000 covered entities participating in the Program and 800 drug manufacturers. In 2024 covered entities purchased \$81.4 Billion of covered outpatient drugs under the Program. Under section 1927(a)(5)(A) of the Social Security Act, a manufacturer must enter into an agreement with the Secretary that complies with section 340B of the PHS Act “[i]n order for payment to be available under section 1903(a) or under part B of title XVIII of the Social Security Act for covered outpatient drugs of a manufacturer.” When a drug manufacturer signs a pharmaceutical pricing

agreement, it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed statutorily defined 340B ceiling prices. 340B ceiling prices are based on quarterly pricing reports that manufacturers provide to the Secretary through the Centers for Medicare & Medicaid Services (CMS) and are calculated and verified by HRSA.

In 2024, HRSA began receiving inquiries directly from manufacturers seeking to unilaterally implement different proposed rebate models for the 340B Program, which manufacturers stated was, primarily to limit the availability to maximum fair price (MFP) to 340B covered entities consistent with the nonduplication provision of the Medicare Drug Price Negotiation Programⁱⁱ (MDPNP) and to facilitate other aims such as the prevention of 340B-Medicaid duplicate discounts and diversion. While the manufacturers' different proposals varied in terms of their scope and how they would be operationalized, the proposals all required that, under a rebate model, a covered entity would order the drug at a higher price and would then receive a rebate that reflects the difference between that higher initial price and the discounted 340B price, a departure from the way that the 340B Program has traditionally operated as an upfront discount program (i.e., a covered entity receives the discounted 340B price at the time of purchase).

Section 340B(a)(1) of the PHS Act states, “[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for [certain] covered outpatient drugs ... purchased by a covered entity ... does not exceed [designated prices].” In response to manufacturers’ inquiries, HRSA made clear that implementing a rebate model proposal without prior Secretarial approval would violate section 340B(a)(1) of the PHS Act.

In light of the significant feedback received both from manufacturers and covered entities, and Congressional concern regarding the shift from an upfront discount to a rebate model, HRSA became interested in testing the merits and shortcomings of a rebate model,

including whether it would be beneficial to manufacturers participating in the MDPNP as well as to 340B program integrity efforts relating to the prevention of 340B Medicaid duplicate discounts and diversion. HRSA sought a balanced and measured approach to allow eligible manufacturers to implement rebate models, at the Secretary's direction and discretion, within certain parameters that would cause minimal impact on 340B covered entities.

Therefore, on August 1, 2025, HRSA published a Federal Register notice titled "340B Program Notice: Application Process for the 340B Rebate Model Pilot Program," 90 Fed. Reg. 36,163 (August 1, 2025). Recognizing that a rebate model would shift how the 340B Program has operated for over 30 years, HRSA invited manufacturers that met specific criteria to voluntarily participate in the 340B Rebate Model Pilot Program. A technical correction extended the public comment period to September 8, 2025, 90 Fed. Reg. 38,165 (August 7, 2025). HRSA received 1,243 public comments from stakeholders, including covered entity and manufacturer trade organizations, individual covered entities, and pharmaceutical manufacturers.

Covered entities filed suit on December 1, 2025, to enjoin implementation of the rebate pilot. In accordance with the December 29, 2025, order of the U.S. District Court for the District of Maine in *American Hospital Association et al. v. Kennedy et al.*, No. 25-cv-600 (D. Me.), HRSA paused implementation of the 340B Rebate Model Pilot Program for all covered entities and the nine manufacturers approved to participate in the pilot.

HRSA is now requesting comments from stakeholders to further evaluate the potential benefits and costs of a rebate model, among other topics. HRSA is issuing this RFI to seek comments from stakeholders across the continuum of the drug supply chain in order to gather information on how a rebate model would impact covered entities, manufacturers, wholesalers, State Medicaid Agencies, pharmacies, the Federal Government, and other stakeholder groups. By issuing this RFI, HRSA is undertaking a methodical and deliberate approach to assess whether to implement a potential 340B Rebate Model Pilot Program consistent with its statutory

authority. Likewise, HRSA commits to analyzing the comments received prior to pursuing the implementation of a potential 340B Rebate Model Pilot Program.

HRSA is inviting comments on a range of issues, including:

- administrative, operational, financial, and medication access concerns in connection with rebate models;
- reliance interests in continuing to obtain the 340B ceiling prices through upfront discounts and whether such reliance interests are reasonable in light of the Secretary's express statutory authority to provide for discounts via "rebate or discount;"
- potential cash-flow impacts; and
- proposed alternatives and scope-limiting measures to inform a rebate pilot design, including safeguards to promote the integrity of the 340B Program, and avoid duplicate discounts, as well as consistency with the MDPNP nonduplication provision.

In addition, HRSA seeks input on how to:

- appropriately balance stakeholder concerns regarding implementation of a rebate model against the agency's goal of testing rebates in the 340B Program;
- gather empirical data on the effectuation of the ceiling price through use of rebates;
- generate data relevant to other Federal health care programs, including the MDPNP; and
- improve transparency and inform future policy decisions.

With the information collected from this RFI, HRSA will evaluate if a potential 340B Rebate Model Pilot Program is in the public's interest and, if so, determine a viable implementation strategy, consistent with the 340B statute.

II. Request for Comments

The purpose of this RFI is to obtain information and public comments on the standards and procedures by which HRSA should consider implementation of a rebate model under the 340B Program. All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received:

<http://www.regulations.gov>. Follow the search instructions on that website to view public comments. HRSA will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. HRSA continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

HRSA is seeking input to ensure that it considers all aspects of the problem and to ensure a fair and transparent comment process for all stakeholders. HRSA invites comments on all aspects of a rebate pilot program implementation under the 340B Program, but specifically seeks comments on the targeted areas below:

1. COSTS TO COVERED ENTITIES

- a. Current Administrative Costs Under the Upfront 340B Discount

- i. Provide the total number of 340B transactions processed by your organization during the most recent fiscal year.
 - ii. Describe your current administrative costs, including costs to third parties (e.g., contract pharmacies) related to 340B Program operations and compliance.
 - iii. Identify any key cost drivers (e.g., staffing, IT systems, third-party vendors, compliance activities, labor hours) for current administrative costs.

b. Administrative Costs Under a Potential 340B Rebate Model Pilot Program

- i. Estimate the incremental administrative and operational costs your organization would incur under a 340B Model Rebate Pilot Program, distinguishing between one-time startup costs and ongoing costs. These figures can be measured in terms of hours to complete the activities or in dollar amounts in the aggregate. In addition, the estimation can include administrative and operational costs associated with filing rebate requests for the drugs selected for MFP under MDPNP.
- ii. Describe the methodology and assumptions used to develop these estimates.
- iii. Specify the activities or functions these incremental costs would cover (e.g., claims processing, data submission, reconciliation, audit support) and what, if any, effect the change of some drugs to a rebate model would have on current administrative costs under the upfront 340B discount.
- iv. If a potential 340B Rebate Model Pilot Program were structured so as to offset these administrative and operational costs, how could that be achieved and how could such an offset be accurately quantified?
- v. Comment on the impact of these incremental costs under your current operations.

c. Staffing Impacts Under a Potential 340B Rebate Model Pilot Program

- i. Indicate whether implementation of a potential 340B Rebate Model Pilot Program would require additional full-time employees or would cause current medical provider full-time employees to reallocate work

hours from medical care to perform administrative functions

(quantifying wherever possible).

- ii. If yes, identify the anticipated number of additional full-time employees; describe their roles, responsibilities, and functions; and indicate whether the FTEs would be temporary or permanent.

d. Systems and Infrastructure for Implementation of a Potential 340B Rebate Model Pilot Program

- i. Describe any new or modified IT systems, software, or data infrastructure that would be required to implement a potential 340B Rebate Model Pilot Program.
- ii. Provide estimated costs for system development, procurement, maintenance, or integration that would be required to implement a potential 340B Rebate Model Pilot Program and specify whether any such costs would be one-time or recurring.

e. Other Anticipated Costs or Impacts of a Potential 340B Rebate Model Pilot Program

- i. Discretely identify any additional costs to your organization associated with implementation of a potential 340B Rebate Model Pilot Program not otherwise captured above (e.g., legal review, training, consulting services, reduction in services offered, and specify whether these costs are one-time or recurring.
- ii. Identify any organization-specific factors that could impact your organization's ability to participate in a potential 340B Rebate Model Pilot Program (e.g., rural, small business, community health center).
- iii. Identify any specific impacts on access to drugs for patients that may occur as a result of a potential 340B Rebate Model Pilot Program.

2. PAYMENT TIMING AND POTENTIAL CASH FLOW IMPACTS FOR COVERED ENTITIES

- a. Describe with specificity whether payment timing (e.g., within ten calendar days of submission of a complete claim) under a potential 340B Rebate Model Pilot Program would affect your cash flow, including any financial risks to your organization.
- b. Describe the typical payment terms under your current wholesaler contracts for 340B drugs, including the number of days allowed for payment, and whether those payment terms differ for non-340B drugs.
 - i. Identify any prompt payment incentives or discounts currently offered by drug wholesalers for early payment and the timeframes associated with those incentives.
 - ii. State the average number of calendar days within which your organization typically remits payment under these contracts.
- c. Describe with specificity whether a rebate-based payment model would alter payment timing compared to current drug wholesaler arrangements, and indicate whether alternative payment arrangements could mitigate any potential impacts of such a rebate-based payment.
- d. A potential 340B Rebate Model Pilot Program could require that all rebates be paid to the covered entity (or denied, with documentation in support) within 10 calendar days of data submission. Describe ways that a potential 340B Rebate Model Pilot Program could be structured to ensure that manufacturers adhere to such a requirement.
- e. Describe other ways that a potential 340B Rebate Model Pilot Program could be structured to address payment timing and potential cashflow impacts for covered entities.

3. REBATE DENIALS

- a. Under a potential 340B Rebate Model Pilot Program the acceptable grounds for a manufacturer denial of a covered entity rebate request could be limited (for example, limited to denials where a 340B rebate was provided to another covered entity on the same claim) and the manufacturer could be required to provide the covered entity with the rationale and specific documentation for reasons claims are denied. Explain whether your organization believes more specific guardrails should be built into a potential 340B Rebate Model Pilot Program to ensure that denials are limited to appropriate circumstances.
- b. Describe what (if any) standard process elements should be required for rebate denials under a potential 340B Rebate Model Pilot Program, including template forms and timeline for adjudications of improper denials.

4. DATA COLLECTION BY COVERED ENTITIES

- a. Describe how your organization currently collects, maintains, and retains data related to 340B Program participation, including whether third-party vendors are used to carry out some or all of these activities.
- b. Identify current measures to ensure data accuracy, completeness, and consistency (e.g., validation checks, reconciliations, audits).
- c. Describe whether a potential 340B Rebate Model Pilot Program would change current data collection activities and whether any such changes would be one-time or ongoing.
- d. Describe the specific pharmacy and medical claims data elements that should comprise a potential 340B Rebate Model Pilot Program (at both contract pharmacies and in-house pharmacies); whether such data elements are currently available or are readily available; the source(s) for such data; and whether such data is already being furnished to existing third parties.

- e. Provide any recommendations for ensuring a potential 340B Rebate Model Pilot Program has the appropriate guardrails in place to mitigate any privacy and security concerns related to patient information and data submission, including any agreements that may be required by third parties.

5. MANUFACTURER EFFORTS TO AVOID DUPLICATE DISCOUNTS

- a. Describe your organization's practices and procedures prior to January 1, 2026, to avoid paying both 340B discounts and Medicaid rebates on the same drug dispense, including data collection and record-maintenance practices.
- b. Describe any operational or administrative changes implemented by your organization since January 1, 2026, to avoid paying 340B discounts on drug dispenses subject to a MFP under the MDPNP, including any changes to data collection or record-maintenance practices.
- c. Describe your organization's experience since January 1, 2026, with identifying drug dispenses to a covered entity for which your organization did not provide access to the MFP under the non-duplication provisions of the MDPNP.
- d. Identify any challenges encountered (e.g., data availability, claim identification, timing mismatches) in identifying potential duplicate discounts under 340B and CMS payment programs (e.g., Medicare and Medicaid).
- e. Identify the minimum data elements you believe are necessary for a manufacturer to identify potential duplicate discounts under 340B and CMS payment programs and the potential for the 340B Rebate Model Pilot Program to be an additional or alternative source for those data elements.

6. REQUIRED REPORTING

- a. What specific data should manufacturers be required to submit (and to what frequency) for HRSA's review to ensure compliance with a potential 340B Rebate Model Pilot Program?
 - b. What specific manufacturer data should HRSA share publicly (and to what frequency) as a potential 340B Rebate Model Pilot Program progresses?
 - c. What should be the frequency and duration of manufacturer data to support the assessment of a potential 340B Rebate Model Pilot Program?
7. 340B PROGRAM INTEGRITY AND OTHER POTENTIAL BENEFITS OF A REBATE PILOT
- a. Explain whether and how a potential 340B Rebate Model Pilot Program would affect the integrity of the 340B program.
 - b. Explain whether a rebate-based model would:
 - i. Assist manufacturers in their efforts to avoid paying duplicate discounts under 340B and CMS payment programs;
 - ii. Reduce diversion or improper claims; and
 - iii. Increase pricing transparency across stakeholders.
 - c. Provide any recommendations for improving data collection and reporting to strengthen the 340B Program's integrity while minimizing administrative burden.
 - d. Describe any other potential benefits (e.g., transparency, audit compliance) of a 340B Rebate Model Pilot Program to participants in the 340B Program and to what extent these benefits outweigh any potential costs.

III. Collection of Information Requirements

Please note, this is an RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the ***Federal Register*** or other

publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA. The paperwork burden associated with a potential 340B Rebate Model Pilot program shall be accounted for under an information collection request submitted to OMB and approved in keeping with the PRA prior to pursuing the implementation of a potential 340B Rebate Model Pilot.

This RFI is issued solely for information and planning purposes; it does not constitute a request for proposals, applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, HRSA is not seeking proposals through this RFI and will not accept unsolicited proposals. Respondents are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. In addition, HRSA will not respond to questions related to policy issues outside of the scope of a potential 340B Rebate Model Pilot Program raised in this RFI.

HRSA will actively consider all input as we develop future policy. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, HRSA shall publicly post the public comments received in their entirety.

Thomas J. Engels,

Administrator.

ⁱ OMB Number: 0915-0327

ⁱⁱ Maximum Fair Price refers to the negotiated price under the Medicare Drug Price Negotiation Program (Negotiation Program). See 42 U.S.C. §§ 1320f(c)(2). Under the MDPNP “nonduplication” provision, manufacturers that agree to a maximum fair price are not required to provide a covered entity access to the negotiated maximum fair price under that agreement if the drug is also subject to a 340B agreement and the 340B ceiling price is lower than the maximum fair price. 42 U.S.C. § 1320f-2(d).