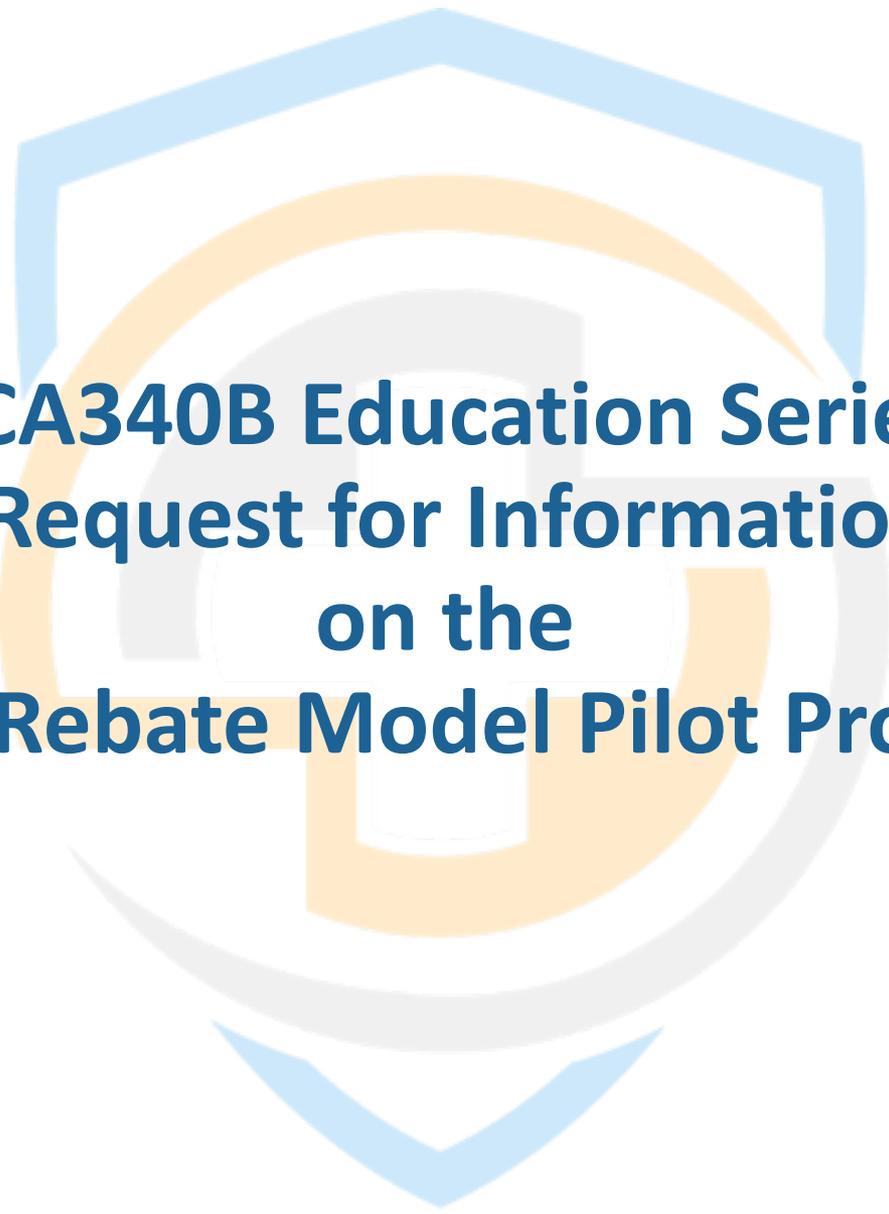




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"You are never wrong, if you do the right thing."



**GCA340B Education Series:
HRSA Request for Information (RFI)
on the
340B Rebate Model Pilot Program**

2/25/2026

Helpful Hints

- Deadline: RFI Responses must be submitted by **April 20, 2026**
- Let your voice be heard!
 - Provide a response on the Federal Registry site
 - Helpful verbiage on slide 6 could provide a starting point to work from in creating a response
- Make it Personal!
 - Estimate Potential Financial Impacts....
 - Purchasing drugs at WAC vs 340B Cost
 - Additional staff that could be required to meet the IT/data submission requirements or to complete the reconciliation process for the backend manufacturer rebates
 - Estimate time lost to complete the additional administrative burden being placed solely on the shoulders of the CEs....
 - Time taken away from direct patient care
 - Time taken away from community outreach efforts
 - Estimate programs and number of patients affected by cash flow impact....
 - Inability to fund copay assistance programs for uninsured and underinsured patients
 - Inability to fund community outreach efforts such as free testing services
 - Touch on key topics and real-world consequences!
 - Centralizing significant 340B Program authority in the hands of the pharmaceutical manufacturers gives them unilateral authority and disproportionate control over program interpretation, data adjudication, and enforcement decisions
 - Manufacturer data submission requirements that conflict with the established 340B logic model
 - Lack of meaningful provider-level validation creates unnecessary risk and could lead to misdirected rebates
 - Introduction of operational uncertainty and significant financial risk
 - Already operating on extremely thin margins? Could a rebate model lead to reducing services or closing your CE altogether?

Where Can I Submit Information?

1) Go Directly to the Federal Register

<https://www.federalregister.gov/documents/2026/02/17/2026-03042/request-for-information-340b-rebate-model-pilot-program>

Comments can be entered via free text or uploaded as a file.

The screenshot shows the Federal Register website interface. At the top, there are navigation links for Sections, Browse, Search, Reader Aids, and My FR. The main header includes the Federal Register logo and the text 'The Daily Journal of the United States Government'. Below the header, a blue bar indicates a 'Notice' for the 'Request for Information: 340B Rebate Model Pilot Program'. A sub-header states 'A Notice by the Health Resources and Services Administration on 02/17/2026'. A message indicates 'This document has a comment period that ends in 22 days. (03/19/2026)'. A red circle highlights a green button labeled 'SUBMIT A PUBLIC COMMENT'. Below this, it says '14 comments received. View posted comments'. On the left, a sidebar menu lists options like PDF, Document Details, Document Dates, Table of Contents, Public Comments, Regulations.gov Data, Sharing, Print, Document Statistics, Other Formats, and Public Inspection. The main content area shows 'PUBLISHED DOCUMENT: 2026-03042 (11 FR 7287)' and 'DOCUMENT HEADINGS' for the Department of Health and Human Services, Health Resources and Services Administration. It includes sections for AGENCY, ACTION (Notice, request for information), SUMMARY (The Health Resources and Services Administration (HSA) administers section 340B of the Public Health Service Act (PHS Act), referred to as the "340B Drug Pricing Program" or the "340B Program." HSA 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 HSA 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 HSA 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.), and DATES. At the bottom, it says 'Comments on this notice should be received no later than March 19, 2026.'

The screenshot shows the Regulations.gov website interface for the 'Request for Information: 340B Rebate Model Pilot Program'. At the top, there is the Federal Register logo and the text 'The Daily Journal of the United States Government'. Below the header, a blue bar indicates a 'Notice' for the 'Request for Information: 340B Rebate Model Pilot Program'. A sub-header states 'A Notice by the Health Resources and Services Administration on 02/17/2026'. A message indicates 'You are submitting an official comment to Regulations.gov. Comments are due 03/19/2026 at 11:59 pm EST.' Below this, there is a 'Thank you for taking the time to create a comment. Your input is important.' section. A red circle highlights the 'Comment' text box. Below the text box, there is a red circle around the 'Upload File(s)' button. To the right of the 'Upload File(s)' button is a '+ Add a file' button with a note: 'Note: You can attach your comment as a file and/or attach supporting documents to your comment. Attachment Requirements.' Below the text box and file upload area, there is an 'Email' field with a note: 'This will NOT be posted on regulations.gov'. Below the email field, there is a checkbox for 'I'd like to receive email confirmation of submission and tracking number?'. Below the checkbox, there is a 'Tell us about yourself! I am...' section with three radio buttons: 'An Individual', 'An Organization', and 'Anonymous'. Below the radio buttons, there is a red circle around a note: 'Do not file a document into an official docket. Any person information included in your comment text and/or uploaded attachments may be publicly available on the web.' Below the note, there is a checkbox for 'I read and understand the statement above.' At the bottom, there are two buttons: 'SUBMIT COMMENT' and 'Preview Comment'.

Where Can I Submit Information?

2) Get to the Federal Register via HRSA.gov

<https://www.hrsa.gov/opa/340b-model-pilot-program>

Click on the “Request for Information: 340 Rebate Model Pilot Program” link
(highlighted in below screenshot)

[Home](#) » [340B Drug Pricing Program](#) » 340B Rebate Model Pilot Program

340B Drug Pricing Program

Contract Pharmacy Services

Educational Resources

Eligibility

Registration

Program Requirements

Duplicate Discount Prohibition

Orphan Drugs

Program Integrity

Recertification

Self-Disclosures

Manufacturer Notices to Covered
Entities

340B Rebate Model Pilot Program

On February 10, 2026, in *American Hospital Association et al. v. Kennedy et al.*, No. 25-cv-600 (D. Me.), the U.S. District Court for the District of Maine vacated and remanded to HHS the 340B Rebate Model Pilot Program Application Notice, 90 Fed. Reg. 36,163 (Aug. 1, 2025), the Corrected 340B Rebate Model Pilot Program Application Notice, 90 Fed. Reg. 38,165 (Aug. 7, 2025), and the approvals of applications from drug manufacturers submitted pursuant to those notices (announced between October 30 and November 14, 2025).

HHS is reconsidering whether to implement a 340B Rebate Model Pilot Program consistent with its statutory authority. HRSA is issuing a 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. For more information on how to submit a response to the RFI by the April 20, 2026 deadline, please visit [Request for Information: 340B Rebate Model Pilot Program](#).

Date Last Reviewed: February 2026

Sample Response Verbiage for HRSA RFI on 340B Rebate Model Pilot Program



My name is [your name], and I am a [role: patient/provider/community member/etc.] in [city/state]. I am writing to express deep concern about the proposed shift to a rebate model within the 340B Program. From my perspective and experience, such a change would cause significant harm to safety-net hospitals and the vulnerable patient populations they serve.

For decades, the 340B Program has enabled providers to deliver sustained, high-quality care—particularly in underserved communities. Many safety-net hospitals already operate on extremely thin margins, and a rebate-based structure would jeopardize their financial viability. Some may ultimately be forced to reduce services or close altogether. If HRSA, HHS, CMS, and pharmaceutical manufacturers were truly prioritizing patient access and community health, a rebate model would not be under consideration.

There are already clear indications that manufacturers intend to leverage questionable practices under a 340B rebate model. A prominent example is their push to require invoice-level detail at the point of data submission. This demand fundamentally conflicts with the established logic and operational cycle of 340B replenishment, in which purchasing and utilization are intentionally decoupled. By insisting on a documentation standard that does not reflect how the 340B Program is designed to operate, manufacturers are effectively trying to rewrite the rules governing 340B interactions – creating administrative hurdles that fall disproportionately on covered entities and undermine the program’s core purpose.

Compounding this issue is the lack of meaningful provider-level validation, despite the model’s requirement to submit provider NPI data. Without safeguards to ensure that the provider information aligns with the entity submitting the data, the system creates an unnecessary and entirely avoidable risk: rebates could be misdirected and paid to the wrong party, even in cases of unintentional error.

These concerns represent only a fraction of the broader risks inherent in a rebate-based model. Such a framework centralizes significant authority in the hands of pharmaceutical manufacturers, granting them unilateral authority and disproportionate control over program interpretation, data adjudication, and enforcement decisions. This imbalance not only undermines the statutory intent of the 340B Program, it increases the likelihood of lost 340B savings while leaving covered entities vulnerable to opaque decision-making and inconsistent standards.

Ultimately, the rebate model introduces operational uncertainty, administrative inefficiency, and significant financial risk – while simultaneously weakening support for the very services the 340B Program was created to sustain. These essential services include ensuring access to medications and essential medical care for uninsured and underinsured patients, maintaining the financial stability of safety-net hospitals, and supporting community outreach efforts that protect public health, promote disease prevention, reduce disease transmission, and keep people engaged in ongoing care.

To echo 340B Health President and CEO Maureen Testoni “The 340B Program’s upfront discount structure provides hospitals with predictability and stability, enabling them to stretch scarce resources to meet community needs. A rebate approach reverses that payment model by requiring hospitals to pay full price upfront and wait for reimbursement. That shift would disrupt cash flow, increase administrative burdens and introduce uncertainty that many safety-net hospitals cannot absorb.”

I urge policymakers to consider the real-world consequences of a rebate-based model and to protect the integrity of the 340B Program for the communities that depend on it.

We're Here to Help!

Zack Schiffer

Senior Project Manager

845.797.5746 (M)

zack.schiffer@gca340b.com

Anja Wilkinson

Director of Implementation and Compliance

918.231.6358

anja.wilkinson@gca340b.com

Brandi Lawson-Garlutzo

Operations Specialist

623.229.9477

brandi.lawson-garlutzo@gca340b.com

www.gca340b.com