HRSA invites comments on all aspects of a rebate pilot program for all stakeholders but is specifically seeking comments on:

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 the current administrative costs under the 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 by 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 Coss 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

Payment Timing and Potential Cash Flow Impacts for Covered Entities

a. Describe with specificity whether payment timing (e.g., within then calendar says 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 payments, 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 payments 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

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 manufacture 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

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 contact 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

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 frug 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

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 manufacture 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?

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