

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA



Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary to provide additional details (examples: screen shot of wholesaler catalog showing that 340B pricing is not available or lack of product availability; reports of eligible dispensations from third party vendor software that cannot be replenished; note: do not include PHI in documentation submitted to HRSA).** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Entity Background Information						
Entity Name: _____				340B ID: _____		
Table 1: Unavailable at 340B Price						
AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.						
Please list the product(s) affected in the table below:						
11-digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
Regarding the purchase and distribution processes, please answer yes or no to the following:						
▪ This drug is commonly referred to as a specialty drug				<input type="checkbox"/> Yes	<input type="checkbox"/> No	
▪ The issue reported is limited to a contract pharmacy purchase				<input type="checkbox"/> Yes	<input type="checkbox"/> No	
▪ If shortage-related, is this a recurrent/intermittent availability issue?				<input type="checkbox"/> Yes	<input type="checkbox"/> No	
▪ If shortage-related, is this due to (please specify)				<input type="checkbox"/> local	<input type="checkbox"/> regional	<input type="checkbox"/> national <input type="checkbox"/> global
Reason for lack of 340B access (<i>check all that apply</i>):						
<input type="checkbox"/> Unavailable for purchase by covered entity						
<input type="checkbox"/> Unavailable for purchase by covered entity through contract pharmacy						
<input type="checkbox"/> Drug subject to limited distribution or specialty pharmacy plan						
<input type="checkbox"/> Other (<i>please describe</i>): _____						
<input type="checkbox"/> Unknown						

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Check steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation <https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data> and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.

- For price unavailable due to shortage, check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA: Confirmed shortage issues by reviewing validated resources*
- Contacted wholesaler and/or manufacturer to confirm unavailability
- For hospitals subject to Group Purchasing Organization (GPO) Prohibition:** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

Date issue first observed: _____

Date drug last available at 340B price (enter NEVER if has never been available): _____

IMPACT TO COVERED ENTITY: Describe operational and administrative burden as well as financial impact to covered entity and patients as a result of restrictions or price unavailable.) Additional information may also be submitted as an attachment.

*Recommended Drug shortage resources: FDA: <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>
ASHP: <https://www.ashp.org/drug-shortages/current-shortages> Wholesaler catalog information

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Table 2: Incorrect 340B Price

Pricing Issue: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (<https://340bopais.hrsa.gov/manufacturerearch>), and check the Medicaid Drug Rebate Program labeler code (<https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data>)

Note: For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term “covered outpatient drug” does not include orphan drugs

- Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
 - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
 - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
 - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
 - Adjust the purchase price for your wholesaler distribution charge/markdown
- Attempted to work with the entity’s wholesaler and directly with the manufacturer to resolve the pricing issue
- Other (*please describe issue*): _____

Price paid by the covered entity (including package size): _____

Date issue first observed: _____

Date product last available at correct price (enter NEVER if has never been available): _____

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): _____ **Phone:** _____

Email Address: _____

Contact Role/Organization: _____

Contact Signature: _____ **Date:** _____

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

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