**Purpose:** This document provides information on what to report to the Health Resources and Services Administration (HRSA) when a 340B price is unavailable for a covered outpatient drug.

**Instructions:** Enter data in each field that describe the entity’s experience with the unavailable 340B price(s). Before completing and submitting the form, covered entities are encouraged to contact the wholesaler and manufacturer directly to determine the reason for the unavailability to better equip HRSA in understanding the circumstance. HRSA follows up on all allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. OPA might reach out for additional clarifying information. If additional information is needed from manufacturers, it may extend the time for follow-up with the entity. If the form is unable to capture all details, **please attach additional documentation as necessary. The completed form should be emailed to HRSA at:** **340Bpricing@hrsa.gov**

Disclosure options:

1. **My signature below serves as consent for HRSA to disclose contact information to the manufacturer(s) in question, if necessary, so the covered entity can be contacted to help resolve the issue in question.**

|  |  |
| --- | --- |
| *Contact’s Name:* |  |
| *Phone Number:* |  |
| *Email Address:* |  |
| *Printed Name of Submitter:* |  |
| *Date:* |  |
| *Submitter’s Signature:* |  |

1. ** Check this box if the covered entity does not want to be disclosed to the manufacturer(s).**

|  |  |  |
| --- | --- | --- |
| **Field** | **Description** | **Enter Data Here** |
| Entity Information | Enter covered entity information | Entity Name: |  |
| 340B ID: |  |
| Address: |  |
| Contact Name: |  |
| Contact Phone #: |  |
| Contact Email: |  |
| Date of Submission: |  |
| Product Information | Enter information about the unavailable drug product | NDC | Drug Name & Strength | Manufacturer |
|  |  |  |
| Manufacturer/ Wholesaler Communications | **Attach a copy of communications with manufacturer and/or wholesaler and the response/reason for lack of price availability** | Name of wholesaler or distributor: |  |
| Reason given for lack of 340B availability and communication to the entity: | Reason for lack of 340B availability (circle response)1. Drug shortage
2. Limited distribution plan
3. Other
 |
| Describe lack of 340B availability: |

|  |  |  |
| --- | --- | --- |
| **Field** | **Description** | **Enter Data Here** |
| 340B Price Unavailable | Enter the calendar date (MM/DD/YYYY) or approximate date when the lack of a 340B price was first observed. Enter NEVER if the 340B price has never been available. |  |
| Last 340B Purchase Date | Enter the calendar data (MM/DD/YYYY) or approximate date when the product was last available for purchase or purchased by your entity. Enter NEVER if the 340B price has never been available. |  |
| Non-340B Account Availability | Identify which non-340B accounts have current drug availability (put “N/A” if your entity does not have access to the listed account) | Available on **non-GPO**/**WAC** account?1. Yes
2. No
3. N/A
 | Available on **GPO** account?1. Yes
2. No
3. N/A
 |
|  |  |
| Non-340B Account Purchases  | Identify which non-340B accounts were used to purchase drug in place of 340B account due to unavailability (put “N/A if your entity does not have access to the listed account) | Purchased on **non-GPO/WAC** account?1. Yes
2. No
3. N/A

Timeframe of purchases (MM/DD/YY) | Purchased on **GPO** account?1. Yes
2. No
3. N/A

Timeframe of purchases |
| *DSH/CAN/PED Hospitals only*If a GPO account was used to purchase drug, explain process to exhaust all measures for obtaining drug at a non-GPO price | Describe: |
| Other/Special Limitations | Describe any other scenarios impacting your ability to purchase the drug at 340B price due to a special limitationExample: the product is available only via a specialty pharmacy | Describe: |

**Additional comments:**

*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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