

Purpose: This tool outlines the compliance requirements for manufacturers participating in the 340B Drug Pricing Program (“340B Program”).

Background: As a condition of participating in the [Medicaid Drug Rebate Program \(MDRP\)](#), a manufacturer must enter into a pharmaceutical pricing agreement (PPA) with the Secretary of Health and Human Services, which also obligates the manufacturer to participate in the 340B Drug Pricing Program. Manufacturers must participate in MDRP for their drug product(s) to be reimbursed by CMS under Medicaid or Medicare Part B. By signing a PPA, a manufacturer agrees to offer its covered outpatient drugs to covered entities at or below the 340B ceiling price if the drugs are made available to other purchasers at any price.

[Section 340B of the Public Health Services Act](#) (“340B Statute”) and the [340B Ceiling Price and Manufacturer Civil Monetary Penalties Regulation](#) (“CMP Final Rule”) outline the compliance requirements for manufacturers participating in the 340B Program. The Health Services and Resources Administration (HRSA) within the Department of Health and Human Services (HHS) is charged with administering the 340B Program. HRSA ensures 340B Program integrity by outlining its requirements for manufacturers and conducting audits.

[HRSA requires manufacturers to:](#)

- Sign a [PPA](#) and [PPA addendum](#)
- Register with the [340B Office of Pharmacy Affairs Information System](#) (340B OPAIS) and routinely verify that the manufacturer’s information is up to date
- Submit quarterly pricing data in 340B OPAIS (refer to “[Reporting the 340B Ceiling Price](#)” on page 3)
- Comply with all **340B Program Requirements for Manufacturers**

340B Program Requirements for Manufacturers: As outlined in the 340B Statute and CMP Final Rule, manufacturers participating in the 340B Program are required to:

- **Calculate and report the 340B ceiling price each quarter to HHS (via 340B OPAIS).**
 - For newly launched products, for which a provisional 340B ceiling price is used, calculate and make available the actual 340B ceiling price no later than the fourth quarter of sales in the market.
- **Charge no more than the 340B ceiling price for covered outpatient drugs to covered entities.**
- **Restate incorrect 340B prices and issue refunds for overcharges.**
 - For newly launched products, offer refunds to covered entities for the difference between the provisional and actual 340B ceiling prices within 120 days of determination of an overcharge.
- **Undergo HRSA audits to ensure compliance with 340B Program requirements.**

Implications of Noncompliance: Manufacturers that knowingly and intentionally overcharge covered entities for covered outpatient drugs may be subject to civil monetary penalties (CMPs) for each instance of overcharge. Manufacturers are responsible for the conduct of their business and distribution partners to ensure that the 340B ceiling price is offered.

Calculating the 340B Ceiling Price: The 340B ceiling price calculation is performed quarterly and is based on sales transaction data that are reported to the Centers for Medicare and Medicaid Services (CMS). The 340B ceiling price is calculated at the smallest unit of measure of a covered outpatient drug. The 340B ceiling price is subsequently multiplied by the package size (PS) and case package size (CSP) to arrive at the package

adjusted price. Section 10.10(a) of the CMP Final Rule clarified and finalized the method for calculating the 340B ceiling price in alignment with Section 340B(a)(1) of the Public Health Services Act.

340B Ceiling Price = Average Manufacturer Price (AMP) *minus* Unit Rebate Amount (URA)

Package Adjusted Price = (AMP – URA) × PS × CSP

1. **Calculating Average Manufacturer Price (AMP):** Manufacturers calculate AMP on both a monthly and a quarterly basis and report these values to CMS. The AMP for the preceding calendar quarter is used for the purposes of the 340B ceiling price calculation.
 - a. **Standard AMP** applies for purchases made by wholesalers for drugs distributed to “retail community pharmacies” (RCPs) or purchases made directly from the manufacturer by RCPs.
 - **5i AMP** applies for purchases made by wholesalers for drugs that are not generally dispensed through an RCP (i.e., drugs that are inhaled, infused, instilled, implanted, or injected) and for purchases made directly from the manufacturer by physicians, pharmacy benefit managers (PBMs), or hospitals.
2. **Calculating Unit Rebate Amount (URA):** CMS calculates the URA on a quarterly basis. The URA consists of two components that are calculated at the unit level: a basic rebate and an inflation rebate.

Unit Rebate Amount (URA) = Basic Rebate *plus* Inflation Rebate

- a. The basic rebate is calculated for all covered outpatient drugs, whereas the inflation rebate applies only when a drug product’s price increases faster than the rate of inflation as measured by the Consumer Price Index for all Urban Consumers (CPI-U). The basic and inflation rebate calculations are based on the classification of the drug product:

Classification	Basic Rebate	Inflation Rebate
Single-source or innovator products (i.e., brand products)	<i>Greater of:</i> AMP* × 23.1% (statutory discount) OR AMP* <i>minus</i> BP	Current quarter AMP <i>minus</i> inflation-adjusted baseline AMP**
Clotting factors or drugs approved exclusively for pediatric indications	<i>Greater of:</i> AMP* × 17.1% (statutory discount) OR AMP* <i>minus</i> BP	
Multiple-source or non-innovator products (i.e., generic products)	AMP* × 13% (statutory discount)	Current quarter AMP <i>minus</i> inflation-adjusted baseline AMP***

***Standard AMP or 5i AMP**, as applicable

****Inflation-adjusted AMP** = Baseline AMP $\times \left(\frac{\text{CPI-U of month prior to current quarter}}{\text{CPI-U of month prior to baseline quarter}} \right)$

*****Inflation-adjusted AMP** = Baseline AMP $\times \left(\frac{\text{CPI-U of month prior to current quarter}}{\text{CPI-U of last month in baseline quarter}} \right)$

Calculating the Provisional 340B Ceiling Price: For newly launched products, the 340B ceiling price is estimated as the launch WAC price minus the applicable statutory discount percentage. This is known as the **provisional 340B ceiling price**.

Provisional 340B Ceiling Price = Wholesale Acquisition Cost (WAC) *minus* Statutory Discount

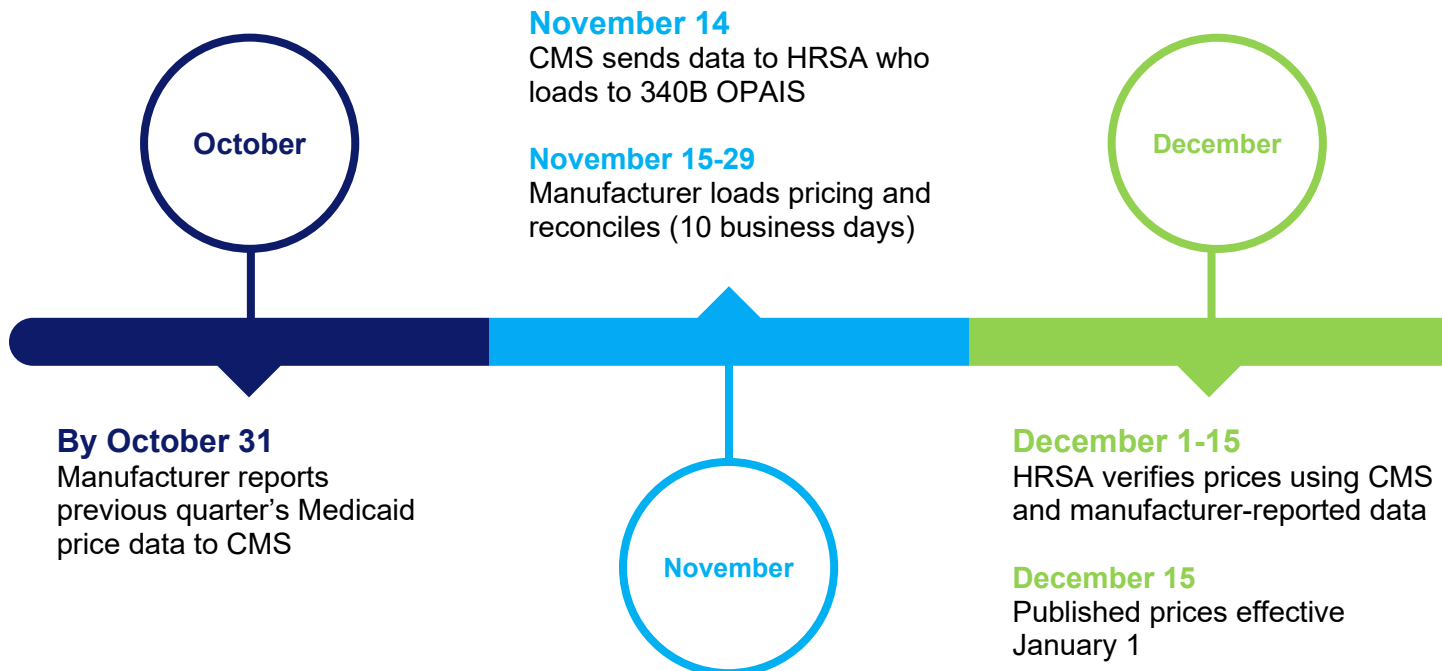
1. **Identifying Wholesale Acquisition Cost (WAC):** The WAC is the price paid by a wholesaler (or direct purchaser) in the United States for drugs purchased from the drug's manufacturer or supplier.
2. **Calculating Statutory Discount:** The statutory discount is the minimum rebate amount that is paid on each unit of a covered outpatient drug. The statutory discount varies based on the classification of the drug product:
 - a. **Single-source or innovator products** (i.e., brand products): 23.1%
 - b. **Clotting factors or drugs approved exclusively for pediatric indications:** 17.1%
 - c. **Multiple-source or non-innovator products** (i.e., generic products): 13%

Reporting the 340B Ceiling Price: Manufacturers are required to report sales data for a particular quarter (say, Q1) to CMS within 30 days after the start of the following quarter (Q2). During Q2, manufacturers use Q1 pricing data to calculate the 340B ceiling price that becomes effective for Q3. During the second month of Q2, manufacturers load and reconcile the 340B ceiling price information into [340B OPAIS](#). Refer to the [340B OPAIS Online Help for Manufacturer Users](#) webpage for information on how to create an account and load pricing information. See "**Examples of 340B Ceiling Price Reporting**" on the following page.

Examples of 340B Ceiling Price Reporting



The following is a more detailed timeline of manufacturer, CMS, and HRSA activities during the quarter following the sales quarter (i.e., Q2, dates are subject to change):



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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