

# 340B OPAIS

## *340B OPAIS User Guide for Covered Entity Users*

Office of Pharmacy Affairs 340B OPAIS  
U.S. Department of Health and Human Services



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**All screen shots displayed in the user guides were based on public information at a point in time and may no longer be accurate.**

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# GETTING STARTED

## Introduction

HRSAs Office of Pharmacy Affairs (OPA) administers the 340B Drug Pricing Program established by Section 340B of the Public Health Service Act (PHSA). Manufacturers participating in Medicaid enter into an agreement with Health and Human Services (HHS) under which they cannot charge covered entities a price that exceeds the 340B ceiling price. It also requires that the Government inform drug manufacturers and State Medicaid agencies of the identity of these entities. In addition, it requires that the Government inform drug manufacturers and State Medicaid agencies of the identity of these entities. The 340B registration and pricing databases collectively known as the 340B Office of Pharmacy Affairs Information System (340B OPAIS) has been created to meet these requirements.

The 340B OPAIS public access system allows manufacturers and wholesalers to verify that an organization requesting 340B pricing is an active participant in the 340B program. New registrations from eligible organizations and their contracted pharmacy partners are accepted at published intervals (currently the first two weeks of every quarter). Registration records are reviewed/validated by OPA staff and approved entities may begin accessing program discounts at the start of the next quarter; once approved participants must recertify their continued eligibility and compliance annually.

The 340B OPAIS pricing module is the sole official federal source for 340B ceiling prices; it calculates those prices based on information supplied by pharmaceutical manufacturers, the Centers for Medicare and Medicaid Services (CMS), and a commercial data broker. The calculated prices are considered non-public information due to the proprietary nature of some of the underlying data. Calculated ceiling prices can only be viewed by selected OPA staff and authorized staff at manufactures/covered entities currently participating in the 340B Program with secure access.

Only authorized users can access the internal sites of the Pricing and Registration modules. Public information contained within the registration module is accessible to the public via the application.

## What You Can Do

### What You Can Do

Capability	Description
<b>Look Up Drug Ceiling Prices</b>	AOs and PCs are able to look up drug ceiling prices and save favorite NDCs for future reference.

## Revision History

Below is a table documenting the revision history of OPAIS Pricing Online Help for Covered Entity Users.

The Revision History includes the release number, release date, and summary of changes made.

Online Help / User Guide	Release #	Release Date	Summary of Changes
340B OPAIS Pricing Online Help for Covered Entity Users	10.1	02/28/2024	■ Pricing Help created

# DATA TABLES

## Sorting Data Tables

All tables in the 340B application can be sorted to make the data displayed more manageable.

1. The first time you click a column heading, the column will be highlighted and the table will be sorted in ascending order (lowest to highest) based on the values in that column. A small upward-pointing arrow icon will appear in the heading.

All	340B ID	Entity Type	Name	Sub Name	Address	City	Sorted in ascending order by date	State	Start Date	Term Date	Edit Date
	DSH010033	DSH	UNIVERSITY OF ALABAMA HOSPITAL		619 S. 19th Street	BIRMINGHAM		AL	12/01/1992		08/13/2015
	DSH010087	DSH	UNIVERSITY OF SOUTH ALABAMA MEDICAL CTR		2451 FILLINGIM STREET	MOBILE		AL	10/01/2003		10/15/2015
	DSH010092	DSH	DCH REGIONAL MEDICAL CENTER		809 UNIVERSITY BOULEVARD EAST	TUSCALOOSA		AL	01/01/2004		08/20/2015
	DSH010099	DSH	D.W. MCMILLAN MEMORIAL HOSPITAL		1301 BELLEVILLE AVENUE	BREWTON		AL	07/01/2004		08/20/2015
	DSH010109	DSH	PICKENS COUNTY HEALTH CARE AUTHORITY		241 ROBERT K WILSON DRIVE	CARROLLTON		AL	07/01/2004		09/04/2015
	DSH010029C	DSH	EAST ALABAMA MEDICAL CENTER	AUBURN DIAGNOSTIC IMAGING	1527 PROFESSIONAL PARKWAY	AUBURN		AL	10/01/2004		08/18/2015
	DSH010029	DSH	EAST ALABAMA MEDICAL CENTER		2000 PEPPERELL PARKWAY	OPELIKA		AL	10/01/2004		08/18/2015
	DSH010029A	DSH	EAST ALABAMA MEDICAL CENTER	MEDICAL ARTS DIAGNOSTICS	121 NORTH 20TH STREET, BUILDING 17	OPELIKA		AL	10/01/2004		08/18/2015

2. The second time you click the column heading, the table will be sorted in descending order (highest to lowest) based on the values in that column. A small downward-pointing arrow icon will appear in the heading.

All	340B ID	Entity Type	Name	Sub Name	Address	City	Sorted in descending order by date	State	Start Date	Term Date	Edit Date
	ONLINE_REG_58	DSH	CHEROKEE MEDICAL CENTER		100 NORTHWOOD DRIVE	CENTRE		AL	07/01/2016		06/27/2016
	DSH010007	DSH	MIZELL MEMORIAL HOSPITAL		702 MAIN STREET	OPP		AL	04/01/2016		03/02/2016
	DSH010113A	DSH	MOBILE INFIRMARY MEDICAL CENTER	Infirmary Eastern Shore / Outpatient Surgery	7101 U.S. Highway 90	Daphne		AL	01/01/2016		10/26/2015
	DSH010113C	DSH	MOBILE INFIRMARY MEDICAL CENTER	Infusion Center	1721 Springhill Avenue	Mobile		AL	01/01/2016		10/26/2015
	DSH010113B	DSH	MOBILE INFIRMARY MEDICAL CENTER	Heart Failure Clinic	3 Mobile Infirmary Circle	Mobile		AL	01/01/2016		10/26/2015
	DSH010095	DSH	HALE COUNTY HOSPITAL		508 GREENE STREET	GREENSBORO		AL	01/01/2016		10/26/2015
	DSH010138	DSH	HILL HOSPITAL OF SUMTER COUNTY		751 DERBY DRIVE	YORK		AL	01/01/2016		11/19/2015

- The third time you click the column heading, the table will be returned to its original sort order and the highlighting and arrow icon will be removed.

## Filtering Data Tables

All tables in the 340B application can be filtered using one or more columns to make the data displayed more manageable.

340B ID	Entity Type	Name	Sub Name	Address	City	State	Start Date	Term Date	Edit Date
CAN100079-15	CAN	UNIVERSITY OF MIAMI HOSPITAL	UMHC: Radiology Oncology	1192 E. Newport Center Dr.			04/01/2015		
CAN100079-27	CAN	UNIVERSITY OF MIAMI HOSPITAL	UMHC: Interventional Radiology	1150 NW 14th Street Miami FL 33136			04/01/2015		
DSH050327AA	DSH	LOMA LINDA UNIVERSITY MEDICAL CENTER	SH ANGIO INTERVENTIONAL RADIOLOGY	26780 BARTON ROAD			10/01/2014		
DSH050327K	DSH	LOMA LINDA UNIVERSITY MEDICAL CENTER	LOMA LINDA UNIVERSITY MEDICAL CENTER	11370 ANDERSON ST			10/01/2014		
DSH050327P	DSH	LOMA LINDA UNIVERSITY MEDICAL CENTER	LOMA LINDA UNIVERSITY MEDICAL CTR - EC Radiology	25333 BARTON RD			10/01/2014		
DSH050327Z	DSH	LOMA LINDA UNIVERSITY MEDICAL CENTER	SH DIAGNOSTIC RADIOLOGY	26780 BARTON ROAD			10/01/2014		
DSH050599BW	DSH	UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER	PET Radiology Clinic (ACC)	4860 Y Street,			10/01/2014		
DSH060024AA	DSH	UNIVERSITY OF COLORADO HOSPITAL	Magnetic Resonance Radiology Lone Tree	9548 Park Meadows Drive	Lone Tree	CO	04/01/2014		08/18/2015
DSH060024AB	DSH	UNIVERSITY OF COLORADO HOSPITAL	CT Scan Radiology Lone Tree	9548 Park Meadows Drive	Lone Tree	CO	04/01/2014		08/18/2015
DSH060024AC	DSH	UNIVERSITY OF COLORADO HOSPITAL	Radiology Diagnostic PET/CT Lone Tree	9548 Park Meadows Drive	Lone Tree	CO	04/01/2014		08/18/2015

### Filtering Text Columns

- Type the text to be used as a filter in the text box below the column heading.
- Click the funnel-shaped filter icon (🔍) and select one of the following:
  - NoFilter** – Clear existing text and redisplay results.
  - Contains** – Display only results that *contain* the filter text.
  - EqualTo** – Display only results that *exactly* match the filter text.
  - NotEqualTo** – Display only results that *do not* match the filter text.
  - IsEmpty** – Display only results where the column is empty.
  - NotIsEmpty** – Display only results where the column *is not* empty.
- The filtered table will show only those records with text that matches the filter.

### Filtering Date Columns

- Use the calendar widget to select the date.
- Click the funnel-shaped filter icon (🔍) and select one of the following:
  - NoFilter** – Clear existing date and redisplay results.
  - EqualTo** – Display only results that *exactly* match the filter date.
  - NotEqualTo** – Display only results that *do not* match the filter date.



- **GreaterThan** – Display only results with dates that are *after* the filter date.
  - **LessThan** – Display only results with dates that are *before* the filter date.
3. The table will show only those records with dates that match the filter.

## Resizing Data Tables

You can change the number of rows displayed per page for any 340B data table.

1. Type the number of rows you want to view per page.

**Note:** If you specify a number greater than the total number of rows in the table, the system will set the page size to match the maximum number of rows.

2. Click the **Change** button. The data table will be resized to display the number of rows you specified.

## Page Navigation in Data Tables

The pagination controls appear above and/or below all data tables. The number of pages is determined by the page size setting.

- The first two buttons let you jump to the first page or to the previous page.
- Clicking a page number (1, 2, 3, etc.) lets you to jump to a particular page.
- Clicking the ellipsis (...) button displays the next 10 pages.
- The last two buttons let you jump to the next page or to the last page.
- Typing a page number and clicking the **Go** button lets you jump to a particular page.

# CEILING PRICE LOOKUP

1. To look up ceiling prices, click **Pricing** in the “What Would You Like to Do?” section or click the **Pricing** tab on the menu bar of the 340B OPAIS home page



2. Upon selecting the Pricing function, the system will prompt you to log in and authenticate again to gain access to the Pricing data.
3. Upon a successful login, the system displays the **Ceiling Price** page. This table can be sorted and filtered to make the data displayed more manageable. For more information, refer to Data Tables.

<input type="checkbox"/> Only Favorites <a href="#">Edit Favorites</a>					
National Drug Code	Product Name	Manufacturer Name	Market Date	Ceiling Price	Flag
69978414101	FentMago11	TM1 Inc	01/01/2005	\$83.91	c
69978418005	FentMago06	TM1 Inc	01/01/2005	\$3,589.51	i
69978418030	FentMago01	TM1 Inc	01/01/2005	\$7,341.10	i
69978418101	FentMago02	TM1 Inc	01/01/2005	\$7,341.10	*, i
69978418107	FentMago07	TM1 Inc	01/01/2005	\$1,795.32	
69978418211	FentMago03	TM1 Inc	01/01/2005	\$1,217.55	*, i
69978418289	FentMago08	TM1 Inc	01/01/2005	\$1,091.53	
69978418302	FentMago04	TM1 Inc	01/01/2005	\$8,079.10	i
69978418382	FentMago09	TM1 Inc	01/01/2005	\$1,540.47	*
69978418403	FentMago05	TM1 Inc	01/01/2005	\$1,725.82	i

(\*) The 340B ceiling price for this product was calculated by HRSA solely based on CMS data.  
 (\*\*) The 340B ceiling price for this product was calculated solely based on data submitted by the manufacturer.  
 (\*\*\*) The 340B Ceiling Price was adjusted by HRSA after review/adjudication of all available data.  
 (\*\*\*\*) The Product has New Drug Price Estimate.

(i) This NDC is an inner NDC and may not be available for individual sale; therefore no package adjusted price is available  
 (c) This is the corrected price for this quarter

Important: HRSA 340B OPAIS does not contain a comprehensive list of covered outpatient drugs (CODs) in the 340B Drug Pricing Program. Manufacturers are obligated to extend the 340B ceiling price for all their products that meet the definition of CODs (per Section 1927 of Social Security Act), including those not listed in this database.

### Ceiling Price Lookup Controls

Control	Description
<b>Only Favorites</b>	<ul style="list-style-type: none"> <li>When this checkbox is selected, the page displays only the National Drug Codes (NDCs) you have defined as favorites.</li> <li>When this checkbox is not selected, the page displays the default ceiling price search results.</li> </ul>
<b>Edit Favorites</b>	Clicking this button displays a pop-up window to let you enter a list of favorite NDCs.
<b>National Drug Code</b>	Select a link in the National Drug Codes column to view the Product Detail page for that NDC.
<b>Ceiling Price</b>	Calculated by subtracting the unit rebate amount (URA) from the average manufacturer price (AMP) for the smallest unit of measure of each covered outpatient drug (as identified by the product's 11-digit NDC).
<b>Package Adjusted Price</b>	Calculated by multiplying the Ceiling Price amount by the drug's Package Size (PS), the number of billing units in the labeled quantity, and by the Case Pack Size (CSP), the number of salable units in the shipping container.

### Ceiling Price Lookup Controls (continued)

Control	Description
<b>Flag</b>	<p>The asterisks in the <b>Flag</b> column indicate that HRSA had only one source of information for determining the 340B ceiling price. The full meaning for the asterisks is shown at the bottom of the page:</p> <p><b>(*) The 340B ceiling price for this product was calculated by HRSA solely based on CMS data. The Manufacturer did not submit 340B pricing data to HRSA for ceiling price comparison.</b> HRSA publishes the 340B ceiling price without comparing it to the manufacturer's data in situations where the manufacturer has not uploaded their quarterly pricing data to the 340B OPAIS Pricing Application or has missed the submission period.</p> <p><b>(**) The 340B ceiling price for this product was calculated by HRSA solely based on using only data submitted by the manufacturer. No CMS pricing data was available for ceiling price comparison.</b> HRSA publishes the 340B ceiling price without comparing it with the AMP and URA data points received from CMS in situations where the manufacturer does not participate in the Medicaid Drug Rebate Program and CMS has no quarterly pricing data to report for the specified product</p> <p><b>(***) The 340B ceiling price was adjusted by HRSA after review/adjudication of all available data.</b> HRSA publishes the 340B ceiling price after the data points were adjusted by HRSA during review/adjudication.</p> <p><b>(****) The product is a New Drug Price Estimate.</b> HRSA publishes the 340B ceiling price for the product that has been marked as a New Drug Price Estimate.</p> <p><b>(c)</b> – This is the corrected price for this quarter</p>

## Add NDC to Favorites

Upon clicking the **Edit Favorites** button, a pop-up window is displayed to let you add NDCs to your favorites list.

☐ Only Favorites Edit Favorites  
 Enter NDCs to Perform Search  
  
 The search NDCs must be comma separated or new line separated, Invalid entries will be ignored.  

Search
Close

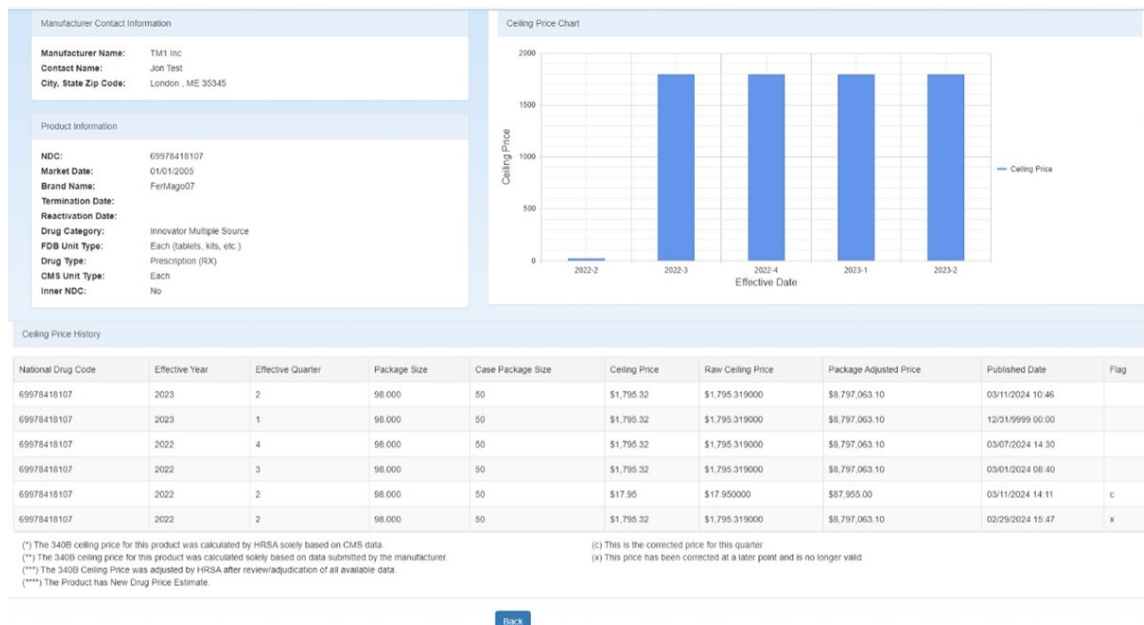
National Drug Code	Product Name	Manufacturer Name	Market Date	Ceiling Price	Package Adjusted Price	Flag
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
00042000101	Sample HCL (generic name) 50mg tab	EASTON	01/01/2005	\$5.88		*
00042000201	Sample HCL (generic name) 50mg tab	EASTON	01/01/2005	\$5.88		*
00042000301	Sample HCL (generic name) 50mg tab	EASTON	01/01/2005	\$5.88		*
00042000401	Sample HCL (generic name) 50mg tab	EASTON	01/01/2005	\$5.88		*
00042000501	Sample HCL (generic name) 50mg tab	EASTON	01/01/2005	\$5.88		*
00042000601	Sample HCL (generic name) 50mg tab	EASTON	01/01/2005	\$5.88		*

### Add NDC to Favorites Controls

Control	Description
<b>Enter NDCs to Perform Search</b>	Type or paste one or more NDCs. <ul style="list-style-type: none"> <li>Multiple NDCs must be separated by commas or new line breaks.</li> <li>Invalid entries will be ignored.</li> </ul>
<b>Search</b>	Clicking this button closes the pop-up window and displays the <b>Ceiling Price</b> page with the <b>Only Favorites</b> checkbox selected and only your favorites displayed.
<b>Close</b>	Clicking this button closes the pop-up window without saving any changes you made and displays the <b>Ceiling Price</b> page with the <b>Only Favorites</b> box unchecked and all NDCs displayed.

## NDC Product Details

Upon clicking an NDC on the **Ceiling Price** page, the **Product Details** page is displayed.



- The left side of the page shows the **Manufacturer Contact Information** and **Product Information**.
  - The **Manufacturer Contact Information** section shows the manufacturer name, contact name and email address, and the manufacturer's city, state, and ZIP code.
  - The **Product Information** section shows the National Drug Code (NDC), market date, brand name, termination date (if applicable), drug category, FDB unit type, drug type, and CMS unit type.
- The right side of the page contains the Ceiling Price Chart showing the ceiling price by effective year and quarter. The associated information is listed in grid format below the chart, including NDC, effective date ceiling price (AMP – URA), package adjusted price (ceiling price multiplied by the drug's package size and case package size).
  - **Note:** The asterisks (\*\*\*\*) in the **Flag** column denote that the product is a New Drug Price Estimate
- Hover over a bar in the ceiling price chart to view the associated price.
- **Note:** The following Flags denote that there has been a price correction: **(c)** – This is the corrected price for this quarter. **(x)** – This price has been corrected at a later point and is no longer valid.
- Click the **Back** button to return to the **Ceiling Price** page.

# LINKS AND CODES

This chapter provides links to external resources and explains 340B OPAIS codes and acronyms.

## External Links

The following are links to external web sites.

### HRSA Frequently Asked Questions (FAQs)

- <https://www.hrsa.gov/opa/faqs/>

### 340B Eligibility

- <https://www.hrsa.gov/opa/eligibility-and-registration/index.html>

### 340B Registration

- <https://www.hrsa.gov/opa/registration/index.html>

### 340B Program Updates

- <https://www.hrsa.gov/opa/updates/program-updates.html>

### 340B Annual Recertification

- <https://www.hrsa.gov/opa/recertification/recertification.html>

### Medicaid Duplicate Discount Prohibition

- <https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion/index.html>

### 340B Orphan Drugs

- <https://www.hrsa.gov/opa/program-requirements/orphan-drug-exclusion/index.html>

## Hospital Registration Instructions (PDF)

- <https://www.hrsa.gov/sites/default/files/opa/files/hospitalreginfo.pdf>

## Contract Pharmacy Guidelines (PDF)

- <https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf>

## 340B Program Acronyms for Covered Entity Types and/or Grantees

Code	Entity Type/Grantee
340S	<b>School Based Program (Healthy Schools, Healthy Communities)</b> – now combined in CH category
BL	<b>Black Lung Clinics Program</b> One of the categories of non-hospital covered entities that are eligible to participate in the 340B Program. Black lung clinics receive funding from the HRSA Black Lung Clinic Program to seek out coal miners, whether they are currently involved in mining or not, and provide services to them and their families, regardless of their ability to pay. Services may be provided either directly by grantees or through formal arrangements with appropriate health care providers, such as Federally Qualified Health Centers, hospitals, state health departments, mobile vans and clinics. The Black Lung Clinic Program is authorized by Section 427 (a) of the Black Lung Benefits Act (30 USCS§901).
CAH	<b>Critical Access Hospital (CAH)</b> Critical Access Hospitals are designated by the Centers for Medicare and Medicaid Services. The defining legislation is Section 1820 (c)(2) of the Social Security Act. To be eligible to participate in the 340B Drug Pricing Program, Critical Access Hospitals must meet the requirements of section 340B(a)(4)(L)(i) of the Public Health Service Act.



Code	Entity Type/Grantee
<b>CAN</b>	<b>Free Standing Cancer Hospital (CAN)</b> One of the categories of hospital covered entities that are eligible to participate in the 340B Program. Freestanding Cancer Hospitals are independent, non-profit hospitals that treat patients with cancer. For-profit hospitals are not eligible to participate in the 340B program. To be eligible to participate in the 340B Drug Pricing Program, Freestanding Cancer Hospitals must either: (1) have a disproportionate share adjustment percentage greater than 11.75% for the most-recently filed cost report; or (2) be eligible under a separate indigent care calculation that meets specific criteria including location in an urban area, 100 or more beds and net inpatient care revenues (excluding Medicare) for indigent care of more than 30% of net during the cost reporting period in which the discharges occur. This indigent care revenue must come from state and local government sources and Medicaid.
<b>CE</b>	<b>Covered Entity (CE)</b> Section 340B(a)(4) of the Public Health Service Act specifies which covered entities are eligible to participate in the 340B Drug Program. These include qualifying hospitals, Federal grantees from HRSA, the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services' Office of Population Affairs, and the Indian Health Service. Covered entities include six categories of hospitals and 11 categories of non-hospitals.
<b>CH</b>	<b>HRSA-Funded Health Center(CH)</b> Combines Community Health Centers, School Based Programs, Health Care for the Homeless Programs, Migrant Health Programs, and Public Housing Primary Care Programs entity types.
<b>CMS</b>	<b>Centers for Medicare &amp; Medicaid Services</b> Centers for Medicare and Medicaid Services, the federal agency within Health and Human Services (HHS) that administers the Medicare and Medicaid programs, including the Medicaid drug rebate program and the Medicare Part D prescription drug benefit.
<b>CP</b>	<b>Contract Pharmacy (CP)</b> A pharmacy that enters into an agreement with a covered entity to provide services to the covered entity's patients, including dispensing entity-owned 340B drugs. Contract pharmacies must register for the 340B Program and be listed on the 340B OPAIS prior to dispensing 340B drugs on a covered entity's behalf. In addition, a contract pharmacy must have a written, signed contract pharmacy agreement in place with the covered entity prior to registering that pharmacy with the 340B Program. HRSA recommends that the written agreement include all essential elements of the contract pharmacy guidelines (75 Fed. Reg. 10272 (March 5, 2010). Failure to have the contract pharmacy correctly listed in the 340B OPAIS may be cause for removal of the contract pharmacy from the 340B Program.

Code	Entity Type/Grantee
<b>DSH</b>	<b>Disproportionate Share Hospital (DSH)</b> One of the categories of hospitals that are eligible to participate in the 340B Program. Disproportionate Share Hospitals serve a significantly disproportionate number of low-income patients and receive payments from the Centers for Medicaid and Medicare Services to cover the costs of providing care to uninsured patients. Disproportionate share hospitals are defined in Section 1886(d)(1)(B) of the Social Security Act. To be eligible to participate in the 340B Program, disproportionate share hospitals must meet the requirements of section 340B(a)(4)(L) of the Public Health Service Act.
<b>DSH %</b>	<b>Disproportionate Share Adjustment Percentage</b>
<b>EIN</b>	<b>Employer Identification Number</b>
<b>FP</b>	<b>Family Planning – Title X (FP)</b> One of the categories of non-hospitals that are eligible to participate in the 340B Program. Title X family planning clinics receive funding from the Title X Family Planning Program to provide contraceptive services, counseling, and reproductive health-related preventive services, with priority given to low-income people. Title X family planning clinics must apply for the 340B program through their grantee organization. Title V (state-funded) family planning clinics are not eligible for the 340B program. (includes only Title X funded)
<b>FQHCLA</b>	<b>Health Center Program Look-Alike</b> One of the categories of non -hospital covered entities that participate in the 340B program. FQHC look-alikes are community-based health care providers that meet the requirements of the HRSA Health Center Program but do not receive Health Center Program funding.
<b>FQHC638</b>	<b>Tribal Contract/Compact with IHS (P.L. 93-638)</b> One of the categories of non-hospital covered entity groups that are eligible to participate in the 340B Program. Tribal Contract or Compact Health Centers (also called a 638 contract or compact) are operated by Tribes or Tribal organizations and Urban Indian Health Centers are outpatient health care programs and facilities that specialize in caring for American Indians and Alaska natives. They are operated under the Indian Self-Determination Act. To be eligible to participate in the 340B Drug Pricing Program, these health centers must be operated by programs funded under P.L. 93-638 or 25 USCS §1651.
<b>HCRIS</b>	<b>Healthcare Cost Report Information System</b> Healthcare Cost Report Information System – HCRIS contains annual reports submitted by healthcare providers to Medicare. It provides information to CMS that assists with the annual settlement summary between CMS and healthcare providers.
<b>HIPAA</b>	<b>Health Insurance Portability and Accountability Act (HIPAA)</b> A U.S. law designed to provide privacy standards to protect patients' medical records and other health information provided to health plans, doctors, hospitals, and other health care providers.

Code	Entity Type/Grantee
<b>HM</b>	<b>Comprehensive Hemophilia Treatment Center (HTC)</b> One of the categories of non-hospital covered entities that are eligible to participate in the 340B Program. Hemophilia Treatment Centers (HTC) that receive HRSA grant funding are expected to provide optimal care using a multi-disciplinary team approach that provides accessible, family-centered, continuous, comprehensive, coordinated, and culturally effective care for individuals with hemophilia and other bleeding disorders. The program is authorized under section 501(a)(2) of the Social Security Act. Non-hospital CEs of this type are identified by the prefix "HM" in the 340B ID.
<b>HO</b>	<b>Health Care for the Homeless Program</b> – now combined in CH category
<b>HV</b>	<b>Ryan White Part C (formerly Title III)</b> One of the categories of non-hospital covered entities that receive federal funding to provide HIV/AIDS treatment and related services to people living with HIV/AIDS who are uninsured or under-insured. In addition, the funding is used for technical assistance, clinical training, and the development of innovative models of care. The Ryan White HIV/AIDS Program is authorized by Title XXVI of the Public Health Service Act.
<b>HRSA</b>	<b>Health Resources and Services Administration (HRSA)</b> An agency of the U.S. Department of Health and Human Services, HRSA is the primary federal agency for improving access to health care services for people who are uninsured, isolated, or medically vulnerable.
<b>MFR</b>	<b>Manufacturer (MFR)</b> As defined in section 1927(k)(5) of the Social Security Act, manufacturers include all entities engaged in (1) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products or (2) the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. A manufacturer must hold legal title to or possession of the NDC number for the covered outpatient drug. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under state law. "Manufacturer" includes entities that sell outpatient drugs to covered entities, whether or not the manufacturer participates in the Medicaid rebate program.
<b>MH</b>	<b>Migrant Health Program</b> – now combined in CH category
<b>MPN</b>	<b>Medicare Provider Number (MPN)</b>
<b>NH</b>	<b>Native Hawaiian Health Care Program</b> Non-hospital covered entities that participate in the 340B program and receive Native Hawaiian Health Care Systems Program funding through the HRSA Health Center Program appropriation to provide medical and enabling services to Native Hawaiians.
<b>NPI</b>	<b>National Provider Identifier (NPI)</b>
<b>OPA</b>	<b>Office of Pharmacy Affairs (OPA)</b> The HRSA office responsible for administering the 340B program.

Code	Entity Type/Grantee
<b>PED</b>	<b>Children's Hospital</b> One of the categories of hospitals that are eligible to participate in the 340B Program. Nonprofit hospitals that serve individuals through the age of 18 years of age and have a CMS-issued 3300 Series Medicare Provider Number to designate them as Medicare certified children's hospitals. Children's hospitals must meet certain requirements, including a DSH adjustment percentage greater than 11.75% and compliance with the GPO Prohibition, to be eligible to participate in the 340B program.
<b>PH</b>	<b>Public Housing Primary Care Program</b> – now combined in CH category
<b>RRC</b>	<b>Rural Referral Center (RRC)</b> One of the categories of hospital covered entities that are eligible to participate in the 340B Program. Rural Referral Centers are high-volume acute-care rural hospitals that treat a large number of complicated cases. Hospitals classified as Rural Referral Centers may be eligible to participate in the 340B Drug Pricing Program if they have a disproportionate share adjustment percentage equal to or greater than 8 percent for the most recently filed Medicare cost report and meet the requirements of section 340B(a)(4)(L)(i) of the Public Health Service Act.
<b>RWI</b>	<b>Ryan White Part A (formerly Title I)</b> One of the categories of non-hospital covered entities that receive federal funding to provide HIV/AIDS treatment and related services to people living with HIV/AIDS who are uninsured or under-insured. In addition, the funding is used for technical assistance, clinical training, and the development of innovative models of care. The Ryan White HIV/AIDS Program is authorized by Title XXVI of the Public Health Service Act.
<b>RWII</b>	<b>Ryan White Part B (formerly Title II)</b> One of the categories of non-hospital covered entities that receive federal funding to provide HIV/AIDS treatment and related services to people living with HIV/AIDS who are uninsured or under-insured. In addition, the funding is used for technical assistance, clinical training, and the development of innovative models of care. The Ryan White HIV/AIDS Program is authorized by Title XXVI of the Public Health Service Act.
<b>RWIIIR</b>	<b>Ryan White Part B (formerly Title II) ADAP Rebate Option</b> One of the categories of non-hospital covered entities that receive federal funding to provide HIV/AIDS treatment and related services to people living with HIV/AIDS who are uninsured or under-insured. In addition, the funding is used for technical assistance, clinical training, and the development of innovative models of care. The Ryan White HIV/AIDS Program is authorized by Title XXVI of the Public Health Service Act.

Code	Entity Type/Grantee
<b>RWIID</b>	<b>Ryan White Part B (formerly Title II) ADAP Direct Purchase</b> One of the categories of non-hospital covered entities that receive federal funding to provide HIV/AIDS treatment and related services to people living with HIV/AIDS who are uninsured or under-insured. In addition, the funding is used for technical assistance, clinical training, and the development of innovative models of care. The Ryan White HIV/AIDS Program is authorized by Title XXVI of the Public Health Service Act.
<b>RW4</b>	<b>Ryan White Part D (formerly Title IV)</b> One of the categories of non-hospital covered entities that receive federal funding to provide HIV/AIDS treatment and related services to people living with HIV/AIDS who are uninsured or under-insured. In addition, the funding is used for technical assistance, clinical training, and the development of innovative models of care. The Ryan White HIV/AIDS Program is authorized by Title XXVI of the Public Health Service Act.
<b>SCH</b>	<b>Sole Community Hospital (SCH)</b> One of the categories of hospital covered entities that are eligible to participate in the 340B Program. Sole Community Hospitals are designated by the Centers for Medicare and Medicaid Services. To be eligible to participate in the 340B Drug Pricing Program, Sole Community Hospitals must also have a disproportionate share adjustment percentage equal to or greater than 8 percent for the most-recently filed Medicare Cost Report and meet the requirements of Section 340B(a)(4)(L)(i) of the Public Health Service Act.
<b>SPNS</b>	<b>Ryan White Part F (formerly Special Projects of National Significance)</b> One of the categories of non-hospital covered entities that receive federal funding to provide HIV/AIDS treatment and related services to people living with HIV/AIDS who are uninsured or under-insured. In addition, the funding is used for technical assistance, clinical training, and the development of innovative models of care. The Ryan White HIV/AIDS Program is authorized by Title XXVI of the Public Health Service Act.
<b>STD</b>	<b>Sexually Transmitted Diseases</b> One of the categories of non -hospital covered entities that diagnose and treat sexually transmitted diseases and receive funding from their state and local health departments through the Sexually Transmitted Disease Control Program administered by the Centers for Disease Control and Prevention. STD clinics must apply for the 340B program through their state program director.
<b>TB</b>	<b>Tuberculosis</b> One of the categories of non-hospital covered entities that are eligible to participate in the 340B Program. These entities receive funding from their state tuberculosis control offices to prevent, diagnose and treat tuberculosis. The Centers for Disease Control and Prevention administers the program.

Code	Entity Type/Grantee
UI	<b>Urban Indian (UI) Health Center</b> One of the categories of non-hospital covered entities that are eligible to participate in the 340B Program. Urban Indian Health Centers are designated Federally Qualified Health Centers that provide comprehensive primary care and related services to American Indians and Alaska Natives. The facilities are owned or leased by Urban Indian organizations and receive grant and contract funding through Title V of the Indian Health Care Improvement Act. To be eligible to participate in the 340B Drug Pricing Program, these health centers must be operated by programs funded under P.L. 93-638 or 25 USCS §1651.

# 340B GLOSSARY

## 3

### 340B ID

A unique identification number assigned by OPA to each covered entity parent or child site (e.g., child site, subdivisions, or sub-grantees).

### 340B OPAIS

The 340B Office of Pharmacy Affairs Information System (OPAIS) is a collection of information submitted by covered entities, contract pharmacies, and manufacturers maintained and verified by HRSA's Office of Pharmacy Affairs (OPA).

### 340B Prime Vendor Program

Section 340B(a)(8) of the Public Health Service Act requires HHS to create a Prime Vendor Program (PVP) to develop, maintain and coordinate a program capable of distribution, facilitation, and other activities in support of the 340B Program. The PVP is a voluntary program for 340B covered entities and serves its participants by negotiating sub-340B pricing on pharmaceuticals, establishing distribution solutions and networks that improve access to affordable medications, and providing other value-added products and services. All covered entities may participate in the PVP, including hospitals that are prohibited from purchasing in a group purchasing arrangement.

### 340B Program

The federal drug discount program authorized under section 340B of the Public Health Service Act and established by Congress under the Veterans Health Care Act of 1992 (Public Law 102-585, codified at 42 USC § 256b). The 340B program requires drug manufacturers to enter into pharmaceutical pricing agreements with the HHS Secretary, under which manufacturers agree not to sell covered outpatient drugs to covered entities above 340B ceiling prices.

**A****Authorizing Official (AO)**

An external user for a covered entity or manufacturer who is able to attest to any changes to an entity.

**B****Billing Address**

An address verified as belonging to the covered entity that is used for billing purposes. A billing address is not required to be a physical address; it can be a P.O. box or other mailing address.

**Black Lung Clinics Program**

One of the categories of non-hospital covered entities that are eligible to participate in the 340B Program. Black lung clinics receive funding from the HRSA Black Lung Clinic Program to seek out coal miners, whether they are currently involved in mining or not, and provide services to them and their families, regardless of their ability to pay. Services may be provided either directly by grantees or through formal arrangements with appropriate health care providers, such as Federally Qualified Health Centers, hospitals, state health departments, mobile vans and clinics. The Black Lung Clinic Program is authorized by Section 427(a) of the Black Lung Benefits Act (30 USCS§901).

**C****CAPTCHA**

Acronym for "Completely Automated Public Turing test to tell Computers and Humans Apart," a type of challenge-response test used in computing to determine whether or not the user is human.

**Carve-In**

Section 340b(a)(5)(A)(i) of the Public Health Service Act prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must have mechanisms in place to prevent



duplicate discounts. Carving-in describes a covered entity's decision to use 340B drugs for its Medicaid patients. Upon enrollment in the 340B Program, covered entities that decide to carve-in must provide their Medicaid provider number or National Provider Identifier (NPI) at the time they enroll. OPA lists this information in a Medicaid Exclusion File posted on its website. Having this information in the file indicates to the states and manufacturers which drugs are not subject to Medicaid rebates, and helps ensure the prevention of duplicate discounts, as prohibited by statute. Covered entities are required to ensure that information in the file is accurate each quarter and at the time of annual recertification.

### Carve-Out

Section 340b(a)(5)(A)(i) of the Public Health Service Act prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must have mechanisms in place to prevent duplicate discounts. Carving-out describes a covered entity's decision to not use 340B drugs for any of its Medicaid patients. For covered entities that opt to carve-out, ALL drugs billed under that Medicaid provider number/NPI must be purchased outside the 340B Program, and that Medicaid provider number/NPI should not be listed in the HRSA Medicaid Exclusion File.

### Ceiling Price

Manufacturers who participate in the Medicaid Drug Rebate Program (MDRP) enter into an agreement with the Secretary of Health and Human Services under which the manufacturer must agree to charge a price no greater than the statutory pricing formula (340B ceiling price) when selling covered outpatient drugs to 340B covered entities. In order to calculate the 340B ceiling price, the Unit Rebate Amount (URA) is subtracted from the Average Manufacturer Price (AMP) for the smallest unit of measure [340B Ceiling Price = (AMP – URA)]. Under section 340B(a) of the Public Health Service Act (PHSA), the 340B ceiling price is calculated by subtracting the unit rebate amount (URA) from the average manufacturer price (AMP) for the smallest unit of measure of each covered outpatient drug (as identified by the product's 11-digit National Drug Code (NDC). To ensure that the final price is operational in the marketplace, HRSA then multiplies this amount by drug's package size (PS), defined as the number of billing units in the labeled quantity from which the pharmacist dispenses, and the case pack size (CSP), defined as the number of salable units in the shipping container [340B Ceiling Price = (AMP-URA) x PS x CSP].

### **Change Request (CR)**

An online process that allows covered entities and manufacturers to update their existing information in the 340B application.

### **Child Site**

A hospital clinic/department/offsite facility that is eligible to participate in the 340B Program because it is an integral part of a hospital that participates in the program, as evidenced by the fact that it is reimbursable on the hospital's Medicare cost report. OPA requires that a covered entity register as child sites all offsite clinics, departments, and services where 340B drugs are purchased or used, regardless of whether they are in the same building. Offsite generally means a location has a separate physical address than the hospital parent site and is not located within the main hospital. A hospital does not need to register outpatient clinics, departments, or services located within the entity's main hospital but may do so if they appear on a reimbursable line of a hospital's most recently filed cost report.

### **Children's Hospital (PED)**

One of the categories of hospitals that are eligible to participate in the 340B Program. Non-profit hospitals that serve individuals through the age of 18 years of age and have a CMS-issued 3300 Series Medicare Provider Number to designate them as Medicare certified children's hospitals. Children's hospitals must meet certain requirements, including a DSH adjustment percentage greater than 11.75% and compliance with the GPO Prohibition, to be eligible to participate in the 340B program.

### **CMS**

Centers for Medicare and Medicaid Services, the federal agency within Health and Human Services (HHS) that administers the Medicare and Medicaid programs, including the Medicaid drug rebate program and the Medicare Part D prescription drug benefit.

### **Consolidated Health Center Program (CH)**

Combines Community Health Centers, School Based Programs, Health Care for the Homeless Programs, Migrant Health Programs, and Public Housing Primary Care Programs entity types.

### **Contract Pharmacy (CP)**

A pharmacy that enters into an agreement with a covered entity to provide services to the covered entity's patients, including dispensing entity-owned 340B drugs. Contract pharmacies must register for the 340B Program and be listed on the 340B OPAIS prior to dispensing 340B drugs on a covered entity's behalf. In addition, a contract pharmacy must have a written, signed contract pharmacy agreement in place with the covered entity prior to registering that pharmacy with the 340B Program. HRSA recommends that the written agreement include all essential elements of the contract pharmacy guidelines (75 Fed. Reg. 10272 (March 5, 2010)). Failure to have the contract pharmacy correctly listed in the 340B OPAIS may be cause for removal of the contract pharmacy from the 340B Program.

### **Control Type per HCRIS**

Indicates the nature of the organization that operates a provider of services. Proprietary operations (control types 3–6) are not eligible for participation in the 340B Program.

### **Covered Entity (CE)**

Section 340B(a)(4) of the Public Health Service Act specifies which covered entities are eligible to participate in the 340B Drug Program. These include qualifying hospitals, Federal grantees from HRSA, the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services' Office of Population Affairs, and the Indian Health Service. Covered entities include six categories of hospitals and 11 categories of non-hospitals.

### **Critical Access Hospital (CAH)**

Critical Access Hospitals are designated by the Centers for Medicare and Medicaid Services. The defining legislation is Section 1820(c)(2) of the Social Security Act. To be eligible to participate in the 340B Drug Pricing Program, Critical Access Hospitals must meet the requirements of section 340B(a)(4)(L)(i) of the Public Health Service Act.

### **CSP**

Defines the size of the cases for an NDC (i.e., if a case of a dozen bottles of 100 pills, CSP = 12).

**D****DEA Number**

A registration number assigned to health care providers by the U.S. Drug Enforcement Administration, allowing them to write prescriptions for controlled substances. Legally, the DEA number is solely to be used for tracking controlled substances. However, it is often used as a unique general "prescriber number" for anyone who can prescribe medication.

**Disproportionate Share Adjustment Percentage (DSH%)**

An adjustment applied to hospitals that treat a high percentage of low-income patients, resulting in an additional payment to those hospitals. Factors included in this adjustment are the sum of the ratios of Medicare Part A Supplemental Security Income (SSI) patient days to total Medicare patient days and Medicaid patient days to total patient days in the hospital. 340B covered entity hospitals must meet a certain threshold for DSH percentage (greater than 11.75% for DSH, PED, and CAN; greater than or equal to 8% for RRC and SCH)

**Disproportionate Share Hospital (DSH)**

One of the categories of hospitals that are eligible to participate in the 340B Program. Disproportionate Share Hospitals serve a significantly disproportionate number of low-income patients and receive payments from the Centers for Medicaid and Medicare Services to cover the costs of providing care to uninsured patients. Disproportionate share hospitals are defined in Section 1886(d)(1)(B) of the Social Security Act. To be eligible to participate in the 340B Program, disproportionate share hospitals must meet the requirements of section 340B(a)(4)(L) of the Public Health Service Act.

**Duplicate Discount**

Section 340B(a)(5)(A)(i) of the Public Health Service Act prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must have mechanisms in place to prevent duplicate discounts. Upon enrollment in the 340B Program, covered entities must determine whether they will use 340B drugs for their Medicaid patients (carve-in) or whether they will purchase drugs for their Medicaid patients through other mechanisms (carve-out) in order to comply with the duplicate discount prohibition.

**E****Edit Date**

The 340B OPAIS uses the term "edit date" to denote the date that a 340B entity's information was edited. Edits can occur at any time.

**Employer Identification Number (EIN)**

A nine-digit number assigned by the U.S. Internal Revenue Service (also known as a Federal Tax Identification Number) used to identify a business entity for tax purposes.

**External User**

Non-HRSA user who has created an account. External users may or may not have any associations with a covered entity or a manufacturer. External users must follow a two-step authentication process to log into the system.

**F****Family Planning – Title X (FP)**

One of the categories of non-hospitals that are eligible to participate in the 340B Program. Title X family planning clinics receive funding from the Title X Family Planning Program to provide contraceptive services, counseling, and reproductive health-related preventive services, with priority given to low-income people. Title X family planning clinics must apply for the 340B program through their grantee organization. Title V (state-funded) family planning clinics are not eligible for the 340B program.

**Federally Qualified Health Center**

One of the categories of non-hospitals that are eligible to participate in the 340B Program. Federally Qualified Health Centers are community-based health care providers that receive funds from the HRSA Health Center Program to provide primary care services in underserved areas. They must meet a stringent set of requirements, including providing care on a sliding fee scale based on ability to pay and operating under a governing board that includes patients. Federally Qualified Health Centers may be Community Health Centers, Migrant Health Centers, Health Care for the Homeless, and Health Centers for Residents of Public Housing.

### **Federally Qualified Health Center Look-Alike (FQHCLA)**

One of the categories of non-hospital covered entities that participate in the 340B program. FQHC look-alikes are community-based health care providers that meet the requirements of the HRSA Health Center Program but do not receive Health Center Program funding.

### **Filing Date**

The date when the Cost Center report was filed (required field for all hospital registrations). This date must be (1) greater than the cost reporting period end date, (2) not older than a year, and (3) not a future date.

### **Free Standing Cancer Hospital (CAN)**

One of the categories of hospital covered entities that are eligible to participate in the 340B Program. Freestanding Cancer Hospitals are independent, non-profit hospitals that treat patients with cancer. For-profit hospitals are not eligible to participate in the 340B program. To be eligible to participate in the 340B Drug Pricing Program, Freestanding Cancer Hospitals must either: (1) have a disproportionate share adjustment percentage greater than 11.75% for the most-recently filed cost report; or (2) be eligible under a separate indigent care calculation that meets specific criteria including location in an urban area, 100 or more beds and net inpatient care revenues (excluding Medicare) for indigent care of more than 30% of net during the cost reporting period in which the discharges occur. This indigent care revenue must come from state and local government sources and Medicaid.

## **G**

### **Grant**

Financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

### **Group Purchasing Organization (GPO)**

Disproportionate share hospitals (DSH), children's hospitals, and free-standing cancer hospitals participating in the 340B Program under 42 U.S.C. 256b(a)(4)(L) and (M) are subject to section 340B(a)(4)(L)(iii), which states that in order to participate in the 340B Program, these entities may not "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement." Upon enrollment, the covered entity's AO

attests that the hospital will comply with the GPO Prohibition. This applies to the hospital as of the date of listing on the 340B OPAIS. The hospital AO attests to compliance with the GPO Prohibition during the annual recertification.

## H

### HCRIS

Healthcare Cost Report Information System – HCRIS contains annual reports submitted by healthcare providers to Medicare. It provides information to CMS that assists with the annual settlement summary between CMS and healthcare providers.

### Health Resources and Services Administration (HRSA)

An agency of the U.S. Department of Health and Human Services, HRSA is the primary federal agency for improving access to health care services for people who are uninsured, isolated, or medically vulnerable.

### Hospital Classification

Eligible hospitals must be (1) owned or operated by a state or local government, (2) private, non-profit hospital with state/local government contract, or (3) public or private non-profit hospital granted governmental powers. For-profit organizations are ineligible for participation in the 340B Program.

## I

### In-house Pharmacy

A pharmacy that is owned by and is a legal part of a 340B entity. Typically, in-house pharmacies are listed as shipping addresses of the entity and the entity owns the pharmacy license.

## L

### Labeler Code (NDC Number)

For 340B purposes, the portion of the 10-digit NDC number assigned by the FDA to identify a specific manufacturer. A given corporate entity may own multiple labeler codes.

**M****Manufacturer (MFR)**

As defined in section 1927(k)(5) of the Social Security Act, manufacturers include all entities engaged in (1) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products or (2) the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. A manufacturer must hold legal title to or possession of the NDC number for the covered outpatient drug. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under state law. "Manufacturer" includes entities that sell outpatient drugs to covered entities, whether or not the manufacturer participates in the Medicaid rebate program.

**Medicaid Drug Rebate Program (MDRP)**

The Medicaid Drug Rebate Program is a program that includes CMS, state Medicaid agencies, and participating drug manufacturers that helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients.

**Medicaid Exclusion File (MEF)**

The Medicaid Exclusion File (MEF) lists covered entities that have decided to use 340B drugs for their Medicaid patients and to bill Medicaid for those drugs (carve-in). When covered entities choose to carve-in for Medicaid, they must provide the HRSA Office of Pharmacy Affairs with the Medicaid Provider Number/NPI used to bill Medicaid. These provider identifiers are listed in the MEF. Having this information in the MEF indicates to the states and manufacturers which drugs are not subject to Medicaid rebates, and helps ensure the prevention of duplicate discounts, as prohibited by the 340B statute. Covered entities are required to ensure that information in the MEF is accurate each quarter and at the time of annual recertification.

**Medicare Provider Number (MPN)**

The identification number of an institutional provider certified by the Centers for Medicare and Medicaid Services (CMS) to provide services to beneficiaries.



**N****National Provider Identifier (NPI)**

A unique 10-digit identification number for covered health care providers. Health care providers, all health plans, and health care clearinghouses must use the NPIs in the administrative and financial transactions adopted under HIPAA.

**Native Hawaiian Health Centers (NH)**

Non-hospital covered entities that participate in the 340B program and receive Native Hawaiian Health Care Systems Program funding through the HRSA Health Center Program appropriation to provide medical and enabling services to Native Hawaiians.

**NDC**

A unique 11-digit, 3-segment code numeric identifier assigned to each medication listed under Section 510 of the US Federal Food, Drug, and Cosmetic Act. The segments identify the labeler or vendor, product (within the scope of the labeler), and trade package (of this product). The first segment (4 or 5 digits) is assigned by the Food and Drug Administration (FDA). The second segment (3 or 4 digits) identifies a specific strength, dosage form, and formulation for a particular firm. The third segment (1 or 2 digits) identifies package forms and sizes.

**O****Office of Pharmacy Affairs (OPA)**

The HRSA office responsible for administering the 340B program.

**P****Parent Entity**

The main hospital facility of a covered entity that is eligible to use 340B drugs by virtue of enrollment in the 340B program. In contrast, hospital outpatient clinics/departments/services that have a different street address than the entity's main facility and are located outside the four walls of the main hospital, which are commonly called

"child sites," must be separately registered with OPA before they can begin using 340B drugs.

### **Participant**

A registered entity or facility in the 340B program.

### **Password Reset**

Changing of a password due to an expired or forgotten password at login.

### **PC**

External user who is designated as a Primary Contact for an entity. This user can enter registrations and update entity information. This user can enter registrations, and update entity information. Any changes to an entity performed by the PC user must be attested to by the AO for that entity.

### **PS**

Defines the size of a single package for an NDC (i.e., if a case of a dozen bottles of 100 pills, PS = 100).

### **Public User**

A user who either does not have an account or is not logged in for a covered entity.

## **R**

### **Recertification**

340B covered entities must annually recertify their eligibility to remain in the 340B Program and continue purchasing covered outpatient drugs at discounted 340B prices. As part of this process, the Authorizing Official of each 340B covered entity certifies basic information about the entity and its 340B compliance. Covered entities with inaccurate information in the 340B OPAIS run a high risk of being removed from the program.

### **Rural Referral Center (RRC)**

One of the categories of hospital covered entities that are eligible to participate in the 340B Program. Rural Referral Centers are high-volume acute-care rural hospitals that treat a

large number of complicated cases. Hospitals classified as Rural Referral Centers may be eligible to participate in the 340B Drug Pricing Program if they have a disproportionate share adjustment percentage equal to or greater than 8 percent for the most recently filed Medicare cost report and meet the requirements of section 340B(a)(4)(L)(i) of the Public Health Service Act.

### **Ryan White Program Grantees**

One of the categories of non-hospital covered entities that receive federal funding to provide HIV/AIDS treatment and related services to people living with HIV/AIDS who are uninsured or under-insured. In addition, the funding is used for technical assistance, clinical training, and the development of innovative models of care. The Ryan White HIV/AIDS Program is authorized by Title XXVI of the Public Health Service Act.

## **S**

### **Sexually Transmitted Diseases (STD) Clinic**

One of the categories of non -hospital covered entities that diagnose and treat sexually transmitted diseases and receive funding from their state and local health departments through the Sexually Transmitted Disease Control Program administered by the Centers for Disease Control and Prevention. STD clinics must apply for the 340B program through their state program director.

### **Shipping Address**

An address authorized to receive 340B drugs on behalf of a covered entity parent or child site and registered as such on the 340B OPAIS. Because pharmacies are not permitted to be registered as covered entity sites, they may be listed as shipping addresses of the parent entity or a registered outpatient child site, depending on the locations served by the pharmacy. When registering a new covered entity or a new outpatient facility online, the entity has a choice of listing shipping addresses under either the main entity's registration or the offsite facility's registration. Listing shipping addresses permits all parties to know where 340B drugs may be delivered by the manufacturer and wholesaler. Pharmacies that support multiple outpatient facilities should be listed as shipping addresses under the parent entity.

### **Sole Community Hospital (SCH)**

One of the categories of hospital covered entities that are eligible to participate in the 340B Program. Sole Community Hospitals are designated by the Centers for Medicare and Medicaid Services. To be eligible to participate in the 340B Drug Pricing Program, Sole Community Hospitals must also have a disproportionate share adjustment percentage equal to or greater than 8 percent for the most-recently filed Medicare Cost Report and meet the requirements of Section 340B(a)(4)(L)(i) of the Public Health Service Act.

### **Start Date**

Denotes an entity's start date in the 340B program. Entity start dates are updated quarterly.

## **T**

### **Termination Date**

The date in the 340B OPAIS on which a provider's participation in the 340B program is terminated. After its termination date, a provider can no longer purchase 340B drugs. OPA updates termination dates on a quarterly basis.

### **Tribal Contract/Compact with HIS (P.L. 93-638)**

One of the categories of non-hospital covered entity groups that are eligible to participate in the 340B Program. Tribal Contract or Compact Health Centers (also called a 638 contract or compact) are operated by Tribes or Tribal organizations and Urban Indian Health Centers are outpatient health care programs and facilities that specialize in caring for American Indians and Alaska natives. They are operated under the Indian Self-Determination Act. To be eligible to participate in the 340B Drug Pricing Program, these health centers must be operated by programs funded under P.L. 93-638 or 25 USCS §1651.

### **Tuberculosis (TB) Clinic**

One of the categories of non-hospital covered entities that are eligible to participate in the 340B Program. These entities receive funding from their state tuberculosis control offices to prevent, diagnose and treat tuberculosis. The Centers for Disease Control and Prevention administers the program.

**U****URA**

The CMS Medicaid Drug Rebate (MDR) system performs the URA calculation using the drug manufacturer's pricing. The specific methodology used is determined by law and depends upon the drug's classification. Drug manufacturers remain responsible for correctly calculating the URA for their covered outpatient drugs.

**Urban Indian (UI)**

One of the categories of non-hospital covered entities that are eligible to participate in the 340B Program. Urban Indian Health Centers are designated Federally Qualified Health Centers that provide comprehensive primary care and related services to American Indians and Alaska Natives. The facilities are owned or leased by Urban Indian organizations and receive grant and contract funding through Title V of the Indian Health Care Improvement Act. To be eligible to participate in the 340B Drug Pricing Program, these health centers must be operated by programs funded under P.L. 93-638 or 25 USCS §1651.

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