340B Glossary of Terms

Purpose: Define common terms used in the 340B Program.

Term	Definition
340B ceiling price	The maximum price drug manufacturers can charge a covered entity for a 340B-purchased covered outpatient drug. 340B Ceiling Price = Average Manufacturer Price (AMP) – Unit Rebate Amount (URA) Pursuant to section 340B(a)(1) of the Public Health Service Act and the 340B Ceiling Price and Civil Monetary Penalty final rule (82 Fed. Reg. 1210, January 5, 2017), the 340B ceiling price for a covered outpatient drug is equal to the average manufacturer price (AMP) from the preceding calendar quarter for the smallest unit of measure minus the unit rebate amount (URA). The 340B ceiling price is published in the 340B OPAIS Pricing component.
340B covered entity (CE)	A facility/program that is listed in the 340B statute as eligible to purchase drugs through the 340B Program and appears on 340B OPAIS.
340B Drug Pricing Program **(340B Program)**	The 340B Drug Pricing Program is a federal program that requires drug manufacturers participating in the Medicaid drug rebate program to provide covered outpatient drugs to enrolled "covered entities" at or below the statutorily defined ceiling price. This requirement is described in Section 340B of the Public Health Service Act and codified at 42 USC §256b. The purpose of the 340B Program is to permit covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). See http://www.hrsa.gov/opa/eligibilityandregistration/index.html for additional information and a complete list of covered entity types.
340B-eligible patient	An individual is a patient of a 340B covered entity (with the exception of state-operated or -funded AIDS drug purchasing assistance programs) if: • The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care. • The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity. • The individual receives a health care service or range of services from the covered entity that is consistent with the service or range of services for which grant funding or federally qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement. An individual will not be considered a patient of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting. Exception: Individuals registered in a state-operated or funded AIDS Drug Assistance Program (ADAP) that receives federal Ryan White funding ARE considered patients of the participant ADAP if so registered as eligible by the state program. For more information: Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility.

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340B Glossary of Terms

Term	Definition
340B ID	A unique identification number provided by HRSA to identify a 340B-eligible entity in 340B OPAIS. This 340B ID is used to purchase 340B drugs.
340B OPAIS	The 340B Office of Pharmacy Affairs Information System (OPAIS) provides access to covered entity and manufacturer records, user accounts, change requests, recertification, and registrations. This system increases the integrity and effectiveness of 340B stakeholder information and focuses on three key priorities: security, user accessibility, and accuracy.
340B Orphan Drug List	An orphan drug list can be downloaded from the FDA website. The following outlines how to create a list of currently designated orphan drug products from the Office of Orphan Products Development (OOPD) database: 1. Navigate to: FDA OOPD Database 2. Enter in the Search Results field: All designations 3. Enter in the Output Format: Download Excel File 4. Filter the Orphan Designation Status Column to include “Designated” and “Designated/Approved.”
340B Prime Vendor Program (PVP)	The Prime Vendor Program is managed by Apexus through an agreement with the Health Resources and Services Administration (HRSA), the federal government branch responsible for administering the 340B Drug Pricing Program. The PVP serves its participants in these primary roles: • Negotiating sub-340B pricing on pharmaceuticals • Establishing distribution solutions and networks that improve access to affordable medications • Stakeholder education through the 340B University programs • Providing other value-added products and services The PVP is a voluntary program for 340B covered entities. All covered entities may participate in the PVP. The PVP negotiates discounts for all participating entities.
340B selling price	The 340B selling price represents the price communicated to the PVP by a supplier or distributor, which may not match the 340B ceiling price as published by HRSA. HRSA’s 340B ceiling price for a covered outpatient drug, published quarterly in the 340B OPAIS Pricing component, is the source of truth and equal to the average manufacturer price (AMP) from the preceding calendar quarter for the smallest unit of measure minus the unit rebate amount (URA).
5i drugs	Drugs that are inhaled, infused, instilled, implanted, or injectable. 5i drugs are not formally defined in the Covered Outpatient Drugs (COD) Final Rule but 5i is widely adopted by many stakeholders as a convenient way to condense the list of the five specific drug types (see 447.507 of COD Final Rule).

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Term	Definition
Accountable care organizations (ACOs)	Groups of doctors, hospitals, and other health care providers that come together voluntarily to give coordinated high-quality care to their Medicare patients. The goal of coordinated care is to ensure that patients, especially the chronically ill, get the right care at the right time while avoiding unnecessary duplication of services and preventing medical errors. When an ACO succeeds in both delivering high-quality care and spending health care dollars more wisely, it will share in the savings it achieves for the Medicare program. HRSA has issued https://www.hrsa.gov/sites/default/files/hrsa/opa/accountable-care-05-23-2012.pdf regarding 340B and ACOs.
Actual acquisition cost (AAC)	CMS/HHS determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers as defined in the Covered Outpatient Drugs Final Rule.
Administrative dispute resolution (ADR)	Is a process required by statute requiring HHS to establish and implement a binding ADR process for certain disputes arising under the 340B Program. The ADR final rule (PDF) sets forth the requirements and procedures for the 340B Program's ADR process. The purpose of the ADR process is to resolve (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers and (2) claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHSA, that a covered entity has violated the prohibition on diversion or duplicate discounts. See https://www.hrsa.gov/opa/340b-administrative-dispute-resolution for additional information
AMP true-up	Occurs when manufacturers restate their reported AMP for a specific time period and then refund any difference to 340B participating entities that had made purchases above the ceiling price.
Apexus Generics Program (AGP) price	The AGP price represents the contracted price available to PVP participants on certain multi-sourced generic products. This price has been negotiated by the Prime Vendor with distributor partners, on behalf of 340B covered entities, and may be loaded in the 340B and/or WAC accounts. AGP contracting provides manufacturers with full price protections and contracting infrastructure to support covered entity compliance with the GPO Prohibition.
Associated site	"Associated site" is used by HRSA's 340B OPAIS to indicate sites that share grant numbers (Federally qualified health centers) or a designation number (federally qualified health center look-alikes). Before September 2017, these covered entity types had a parent-child relationship. The 340B ID numbers of these entity types will not be changing, only the terminology—from parent-child to "associated sites." No other type of covered entity will have the associated site terminology.
Average manufacturer price (AMP)	CMS has authority regarding AMP. AMP is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer. This definition applies to covered outpatient drugs of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act). See Covered Outpatient Drugs Final Rule.

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Term	Definition
Average sales price (ASP)	Originally created during drug pricing litigation to ensure accurate price reporting, ASP is the weighted average of all non-federal sales to wholesalers. ASP is net of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug product, regardless of whether it is paid to the wholesaler or the retailer. Excluded from ASP are sales that are excluded from the best price calculation. ASP is used as a basis of reimbursement for some Medicare Part B covered drugs and biologicals administered in hospital outpatient departments.
Average wholesale price (AWP)	Publicly available national average of list prices charged by wholesalers to pharmacies. AWP is not defined in legislation and does not account for discounts. It is sometimes referred to as a "sticker price," as it is not an actual price paid by most purchasers. AWP was once used as a primary basis of pharmacy reimbursement, but there is a trend moving away from this practice.
Best price (BP)	See *Medicaid best price.*
"Big 4"	The federal government's four largest purchasers of pharmaceuticals: Department of Veterans Affairs (VA), Department of Defense (DoD), Public Health Service (PHS), and Coast Guard.
Billing address	340B OPAIS uses the "billing address" field to denote the address verified as belonging to the covered entity. 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	Clinics that 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).
Carve-out/carve-in	See *Medicaid carve-out/carve-in.*
Centers for Medicare and Medicaid Services (CMS)	The federal agency charged with implementing and overseeing the Medicare and Medicaid programs.
Chargeback	The method wholesalers use to request reimbursement from manufacturers for 340B discounts provided to entities for 340B covered outpatient drugs. Wholesalers purchase drugs from the manufacturer at wholesale acquisition cost (WAC) and sell to 340B entities at the contracted 340B price, which is a lower price. The wholesaler submits a chargeback request to the manufacturer to account for the difference.
Children's hospital (PED)	These nonprofit hospitals serve individuals aged 18 or younger and have CMS-issued 3300 Series Medicare provider numbers to designate them as Medicare-certified children's hospitals. Children's hospitals must meet certain requirements, including a DSH adjustment percentage >11.75% and compliance with the GPO Prohibition, to be eligible to participate in the 340B Program.

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Term	Definition
Comprehensive hemophilia treatment centers	Hemophilia treatment centers (HTCs) that receive HRSA grant funding are expected to provide optimal care using a multidisciplinary 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.
Consumer Price Index–Urban (CPI-U)	A measure of the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services. CPI-U is used in determining whether or not to apply a penalty to the manufacturer affecting the 340B ceiling price for single-source and innovator multiple-source drugs.
Contract pharmacy	340B covered entities may contract with a pharmacy or pharmacies to provide services to the covered entity's patients, including the service of dispensing the entity-owned 340B drugs. To engage in a contract pharmacy arrangement, the entity and pharmacy (or pharmacies) must have a written contract that aligns with the compliance elements, listed in guidance, and list the contract pharmacy on 340B OPAIS during a quarterly registration period. Typically, a bill-to (entity)/ship-to (pharmacy) arrangement is used.
Covered entity (CE)	The term "covered entity" refers to a health care provider or organization that is eligible for the 340B Program per the 340B statute.
Covered outpatient drug (COD)	Defined in section 1927(k) of the Social Security Act (SSA). Manufacturers participating in the Medicaid Drug Rebate Program must also provide 340B pricing on all of their CODs to CEs. Check the labeler code on 340B OPAIS and the Medicaid Drug Rebate Program to help determine whether a drug is a covered outpatient drug in the Medicaid Drug Rebate Program and thus should have a 340B price. Covered entities should maintain auditable records and policies and procedures related to the definition of covered outpatient drug and the use of a GPO that is consistent with the 340B statute.
Critical access hospital (CAH)	A hospital certified to receive cost-based reimbursement from Medicare. This reimbursement is intended to improve the hospital's financial performance, thereby reducing hospital closures. CAHs are certified under different, more flexible Medicare conditions of participation (CoP) than acute care hospitals, and must meet certain criteria to be designated as CAHs. For the purposes of 340B, CAHs must meet specific 340B eligibility criteria.
Dispensing fee	The charge for the professional services provided in association with prescription dispensing. Most prescription payers reimburse on the basis of a benchmark of the drug cost (e.g., ASP, AMP, AWP, WAC, AAC) plus a dispensing fee.
Disproportionate share adjustment (DSH rate)	See *Medicare DSH adjustment percentage.*
Disproportionate share hospital (DSH)	Hospitals that serve a significantly disproportionate number of low-income patients; as such, they receive adjustment payments to provide additional help. The primary method of qualification is based on the sum of the percentage of Medicare inpatient days and the percentage of total patient days attributable to patients eligible for Medicaid but not eligible for Medicare Part A. Among other requirements, DSHs must have a DSH adjustment percentage >11.75% and meet certain criteria to be 340B eligible.

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Term	Definition
Disproportionate share hospital (DSH) inpatient pricing	The voluntary DSH inpatient contracts most GPOs offer their membership; the discount is usually ~2–3%. GPOs offer manufacturers this opportunity to put products on the DSH inpatient portfolio at a lower price than what the manufacturer has given the GPO (i.e., in the GPO acute care file/and/or for products that the manufacturer chooses not to contract under the GPO acute care file).
Duplicate discount	Prohibited by the 340B statute, a duplicate discount occurs when a covered entity obtains a 340B discount on a medication and a Medicaid agency obtains a discount in the form of a rebate from the manufacturer for the same medication.
Edit date	340B OPAIS uses the term “edit date” to denote the date that a 340B entity’s information was edited. Edits to 340B OPAIS can occur at any time.
Electronic Handbook (EHB)	A database that contains grant information for certain HRSA grantees. This is what HRSA uses to determine eligibility for certain entities.
Entity-owned pharmacy	A pharmacy that is owned by, and is a legal part of, the 340B entity. Typically, entity-owned pharmacies are listed as shipping addresses of the entity.
Estimated acquisition cost (EAC)	The estimation of the price typically paid by entities for a particular manufacturer’s drug, using the most commonly purchased package size. Some Medicaid agencies use EAC (plus a dispensing fee) as a basis for establishing reimbursement. The exact method of calculating or projecting EAC may vary in different states.
Federal ceiling price (FCP)	The maximum price that a manufacturer may charge for a covered drug sold to the “big 4” federal entities engaged in providing health care services—Veterans Affairs, Department of Defense, Public Health Service (including Indian Health Service), and the Coast Guard. The federal ceiling price is effective for a calendar year, or the portion of a calendar year in which the covered drug is marketed.
Federally qualified health center (FQHC)	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. FQHCs 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 (FQHC-LA)	Community-based health care providers that meet the requirements of the HRSA Health Center Program but do not receive Health Center Program funding. They provide primary care services in underserved areas, provide care on a sliding fee scale based on ability to pay, and operate under a governing board that includes patients.
Federal Register notice (FRN)	Notices about guidelines and regulations are published in the Federal Register, a federal journal publication; in some situations, comments on the document are requested.
Federal supply schedule (FSS)	Involves large contracts through which federal customers can acquire more than 4 million products and services directly from more than 8,000 commercial suppliers. Products include pharmaceuticals and medical equipment and supplies. These contracts are available for use by all government agencies, including, but not limited to, VA medical centers, Department of Defense, Bureau of Prisons, Indian Health Service, Public Health Service, and some state veterans’ homes.

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Term	Definition
Free-standing cancer hospital (CAN)	A nonprofit entity that is financially and administratively independent (not a part of a larger institution). CANs are exempt from Medicare's prospective payment system. For 340B purposes, a CAN must meet specific eligibility requirements, including a DSH adjustment percentage >11.75% and compliance with the GPO Prohibition. It is also subject to the orphan drug exclusion.
Government Accountability Office (GAO)	An independent nonpartisan agency that works for Congress. Often called the "congressional watchdog," GAO investigates how the federal government spends taxpayer dollars.
Group purchasing organization (GPO)	An organization created to leverage the purchasing power of entities to obtain discounts from vendors based on the collective buying power of the GPO members. GPOs are common in the drug industry; the GPO may set mandatory purchasing participation levels from its members or be completely voluntary. Certain 340B participating hospitals (disproportionate share hospitals [DSH], children's hospitals [PED], and free-standing cancer hospitals [CAN]) are prohibited from purchasing covered outpatient drugs from a GPO or GPO-like arrangement.
GPO Prohibition	Per 340B statute, 340B participating disproportionate share hospitals (DSH), children's hospitals (PED), and free-standing cancer hospitals (CAN) are prohibited from obtaining covered outpatient drugs through group purchasing organizations (GPOs). Upon enrollment, an entity official attests that the hospital will comply with the GPO Prohibition. This applies to the hospital as of the date of listing in 340B OPAIS. Upon recertification of information from 340B OPAIS, the hospital official attests to compliance with the GPO Prohibition. A GPO Prohibition Policy Release was posted by HRSA in 2013. The following examples are **not** GPO Prohibition compliant contracting practices: • An individual DSH/PED/CAN accessing contracts executed by an integrated delivery network (IDN) in which it is a member • A wholesaler's generic source program • A manufacturer extending a discounted price to a group of covered entities (subject to the GPO Prohibition) through a wholesaler, other third party, or group purchasing arrangement that is not supported by an individual contract between the 340B covered entity at the 340B ID level and the manufacturer. Such agreements should be reproducible for review during an audit of compliant 340B operations.
Health Industry Number (HIN)	A unique, universal identification number to be used by all trading partners when they communicate with one another via computer. HINs are randomly assigned nine-character alphanumeric identifiers that are issued by the Health Industry Business Communications Council (HIBCC). Drug wholesalers and manufacturers typically use HINs to identify entities.
Health Insurance Portability and Accountability Act (HIPAA)	A US 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.
Health Resources and Services Administration (HRSA)	An agency of the US 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. Comprising five bureaus and ten offices, HRSA provides leadership and financial support to health care providers in every state and US territory. The Office of Pharmacy Affairs (OPA), the office responsible for administering the 340B Program, falls under HRSA.

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Term	Definition
Hospital outpatient facility/site	An offsite hospital outpatient facility is eligible to be registered as a child site if it is listed as a reimbursable facility on the parent hospital's most recently filed Medicare cost report and has associated outpatient costs and charges. If the facility is a free-standing clinic of the hospital that submits its own cost reports using a different Medicare provider number (not under the covered entity's Medicare provider number) then it would NOT be eligible. Specific guidance on this topic was released in 1994. All clinics located offsite of the parent hospital, regardless of whether those clinics are in the same offsite building must register as child sites of the parent hospital if they choose to participate in the 340B Program. These clinics must be a reimbursable clinic of the hospital and have associated outpatient costs and charges to be able to register as child sites in 340B OPAIS. Click here for more information on hospital offsite outpatient facilities.
HRSA 340B OPAIS	See *340B OPAIS.*
In-house pharmacy	See *entity-owned pharmacy.*
Innovator multiple source drug	All covered outpatient drugs approved under a new drug application (NDA), product license approval (PLA), establishment license approval (ELA), or antibiotic drug approval (ADA). A covered outpatient drug marketed by a cross-licensed producer or distributor under the approved NDA shall be included as an innovator multiple source drug when the drug product meets this definition.
Manufacturer	The definition of "manufacturer" (for 340B purposes) includes all entities engaged in: 1. The production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; 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" also includes an entity, described in (1) or (2) above, that sells outpatient drugs to covered entities, whether or not the manufacturer participates in the Medicaid rebate program. For more information, visit https://www.hrsa.gov/opa/manufacturers/index.html.
Medicaid best price (BP)	Regarding the Medicaid Rebate Program, Medicaid best price is the lowest manufacturer price paid for a prescription drug, regardless of package size, by any purchaser. BP is reported to CMS and states, but otherwise is confidential. Included in BP are cash discounts, free goods that are contingent upon purchase, volume discounts, and rebates. Excluded from BP are prices paid by the federal government (e.g., prices to the "big 4," 340B covered entities, federal supply schedule, state pharmaceutical assistance programs, depot prices, and nominal pricing to covered entities).

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Term	Definition
Medicaid carve-in	340B entities may elect to bill Medicaid for drugs purchased at 340B prices. This activity is termed a "Medicaid carve-in." If an entity chooses to bill Medicaid fee-for-service (FFS) for 340B drugs, each covered entity site must answer "yes" the Medicaid billing question in 340B OPAIS, "At this site, will the covered entity bill Medicaid fee-for-service (FFS) for drugs purchased at 340B prices?" The site must also provide each Medicaid state it plans to bill, and the billing number(s) it will list on the bill to the state. Billing number(s) may include the billing provider's national provider identifier (NPI) only, state assigned Medicaid number only, or both NPI and state assigned Medicaid number. This information listed for each covered entity site (340B ID) in OPAIS is used to generate a quarterly Medicaid Exclusion File, which is the official data source used by stakeholders to determine which covered entity sites bill Medicaid for 340B drugs. In situations where an entity chooses to bill Medicaid managed care organizations (MCOs) for 340B drugs, HRSA encourages covered entities to work with states and their respective MCOs to develop strategies to prevent duplicate discounts. In some cases, states have placed certain requirements on covered entities regarding the prevention of duplicate discounts for drugs billed to MCOs.
Medicaid carve-out	To carve out Medicaid, a covered entity site does not provide drugs purchased at the 340B price to Medicaid patients. In 340B OPAIS, a covered entity site that plans to carve out Medicaid fee-for-service (FFS) should answer "no" to the question, "at this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices?" 340B drugs may not be used for Medicaid FFS patients at a contract pharmacy, absent an arrangement between the contract pharmacy, covered entity, and state Medicaid agency to prevent duplicate discounts. Any such arrangement shall be reported to the HRSA Office of Pharmacy Affairs by the covered entity. Once HRSA reviews and approves the arrangement, HRSA posts contract pharmacies that use 340B drugs for Medicaid FFS patients on the 340B OPAIS.
Medicaid Exclusion File (MEF)	The Medicaid Exclusion File was created to help support program integrity regarding the statutory prohibition of duplicate discounts and it serves as the official data source to determine whether 340B drugs are billed to Medicaid fee-for-service (FFS). The MEF does NOT apply to Medicaid managed care organizations (MCOs). The Medicaid Exclusion file is accessed by clicking the "Reports/Files" link on the homepage of the 340B Office of Pharmacy Affairs Information System (340B OPAIS), then selecting "Medicaid Exclusion Files." Entities are expected to provide updated Medicaid information on 340B OPAIS for incorporation into the MEF and bill Medicaid FFS according to its designation on the MEF. The covered entity should inform HRSA immediately of any changes to Medicaid FFS billing practices. The Medicaid Exclusion File is used by multiple stakeholders, such as: • Covered entities, designating whether they will bill Medicaid FFS for 340B drugs • State Medicaid agencies, to exclude 340B claims from their rebate requests to manufacturers • Manufacturers, to verify denial of payment of Medicaid rebates for 340B claims HRSA exports each covered entity site's Medicaid billing information from 340B OPAIS to generate the quarterly HRSA Medicaid Exclusion File (MEF). At 12:01am ET on the 16th day of the month prior to the start of each quarter, a snapshot of 340B OPAIS is taken.

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Term	Definition
Medicaid managed care organization (Medicaid MCO)	Managed care is a health care delivery system organized to manage cost, utilization, and quality. Medicaid managed care provides for the delivery of Medicaid health benefits and additional services through contracted arrangements between state Medicaid agencies and managed care organizations (MCOs) that accept a set per-member per-month (capitation) payment for these services. HRSA encourages covered entities to work with states and their respective MCOs to develop strategies to prevent duplicate discounts. In some cases, states have placed certain requirements on covered entities regarding the prevention of duplicate discounts for drugs billed to Medicaid MCOs.
Medicaid provider number (MPN)	An identifier issued to health care providers by CMS that allows the provider to bill Medicaid for medical services.
Medicaid rebate net price	The price for covered outpatient drugs paid by state Medicaid programs, including the manufacturer rebates received by the states.
Medicare DSH adjustment percentage (DSH %)	An adjustment applied to hospitals that treat a high percentage of low-income patients. This adjustment results in an additional payment to these 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 disproportionate share adjustment percentage: >11.75% for DSH, PED, and CAN, and ≥8% for RRC and SCH.
Mixed-use setting	A hospital area that serves a mixed patient type of both inpatients and outpatients. Often these are facilities such as surgery centers, cardiac catheter labs, infusion centers, and emergency departments or pharmacies serving these locations.
National Drug Code (NDC)	Drug products are identified and reported using a unique three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for human drugs. The FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory, which is currently updated semimonthly. The NDC is an 11-digit number; the first segment (5 digits) of the NDC indicates the manufacturer, the second segment (4 digits) indicates the drug product, and the third segment (2 digits) indicates the package size.
National Provider Identifier (NPI)	A unique 10-digit identification number for covered health care providers. Covered health care providers and all health plans and health care clearinghouses must use the NPIs in the administrative and financial transactions adopted under HIPAA.
Native Hawaiian Health Centers	Native Hawaiian Health Centers receive Native Hawaiian Health Care Systems Program funding (through the HRSA Health Center Program appropriation) to provide medical and enabling services to Native Hawaiians. Native Hawaiian Health Centers improve the health status of Native Hawaiians by providing access to health education, health promotion, and disease prevention services. Services provided include nutrition programs, screening and control of hypertension and diabetes, immunizations, and basic primary care services.
Non-federal average manufacturer price (non-FAMP)	The average price paid to a manufacturer by wholesalers for drugs distributed to non-federal purchasers. Non-FAMP is not publicly available. 340B and Prime Vendor sub-ceiling prices are excluded from a manufacturer's non-FAMP calculations.

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Term	Definition
Non-innovator multiple source drug	A drug that is not originally marketed under an original new drug application, and whose therapeutic equivalent is available from multiple sources.
Office of Inspector General (OIG), Department of Health and Human Services	An independent and objective oversight unit of the Department of Health and Human Services (HHS) to carry out the mission of promoting economy, efficiency, and effectiveness through the elimination of waste, abuse, and fraud. The OIG: • Conducts and supervises audits, investigations, and inspections. • Identifies systemic weaknesses giving rise to opportunities for fraud and abuse in HHS programs and operations and makes recommendations to prevent their recurrence. • Leads and coordinates activities to prevent and detect fraud and abuse in HHS programs and operations. • Detects wrongdoers and abusers of HHS programs and beneficiaries so appropriate remedies may be brought to bear. • Keeps the HHS Secretary and Congress fully and currently informed about problems and deficiencies in the administration of HHS programs. The OIG has issued several reports relating to 340B. Pursuant to a delegation of authority, the HHS Office of Inspector General (OIG) has the authority to impose civil monetary penalties (CMPs) using the definitions, standards, and procedures under 42 CFR Parts 1003 and 1005, as applicable. For additional information, see the delegation of authority Federal Register notice at https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31944.pdf (82 Fed Reg. 1356, January 5, 2017).
Office of Pharmacy Affairs (OPA)	The HRSA office responsible for administering the 340B Program.
Orphan Drug Act (ODA)	Provides for granting special status to a product to treat a rare disease or condition, upon request of a sponsor. The combination of the rare disease or condition *and* the product to treat it must meet certain criteria. This status is referred to as orphan designation. Orphan designation qualifies the sponsor of the product for the tax credit and marketing incentives of the ODA.
Orphan drug designation	The Orphan Drug Act (ODA) provides for granting special status to a drug or biological product (“drug”) to treat a rare disease or condition upon request of a sponsor. This status is referred to as orphan designation (or sometimes “orphan status”). For a drug to qualify for orphan designation, both the drug and the disease or condition must meet certain criteria specified in the ODA and FDA’s implementing regulations at 21 CFR Part 316.
Orphan drug exclusion	For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals participating in the 340B Program, the term “covered outpatient drug” does not include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition. Therefore, manufacturers are not required to provide orphan drugs to these covered entities under the 340B Program. A manufacturer may, at its sole discretion, offer discounts on orphan drugs to these hospitals.
Orphan drug “sponsor”	The party that owns or has assigned rights to an orphan drug designation granted by the FDA. A sponsor listed on the FDA orphan drug list may not be the current manufacturer for an orphan drug if ownership or rights have been subsequently transferred.

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Term	Definition
Own use	Purchases that reasonably may be regarded as being used by the hospital in the sense that such use is a part of and promotes the hospital's intended institutional operation in the care of persons who are its patients. Additional information is available from the advisory opinion here: https://www.ftc.gov/sites/default/files/attachments/price-discrimination-robinson-patman- violations/080213kaiser.pdf.
Patient assistance programs	Programs under which drug manufacturers provide free or greatly subsidized medications to patients in need of assistance.
Patient Protection and Affordable Care Act (PPACA), 2010	Federal legislation that affected the 340B Program in the following ways: • Expanded eligibility to include certain critical access hospitals (CAH), sole community hospitals (SCH), rural referral centers (RRC), and free-standing cancer centers (CAN). • Required HRSA to publish ceiling pricing and actual pricing data submitted by drug manufacturers. • Increased the Medicaid rebate percentage (from 15.1% to 23.1% for brand-name drugs; to 17.1% for clotting factors and pediatric drugs; and from 11% to 13% for generics). • Created integrity provisions for manufacturers, including the ability to impose fines on manufacturers for violations of 340B, increased price transparency, and new processes for dispute resolution and recovery of overcharges. • Created integrity provisions for entities, including civil penalties for providers knowingly violating the prohibition against diversion of 340B drugs. • Directed the Government Accountability Office (GAO) to prepare a 340B-related report to Congress.
Penny pricing	When the 340B ceiling price calculation results in an amount less than $0.01, the ceiling price will be $0.01. This policy was included in the 2017 Civil Monetary Penalties Regulation. A 340B ceiling price that equals or rounds to zero will be published in 340B OPAIS as $0.01 and the manufacturer must charge $0.01 per unit.
Pharmaceutical pricing agreement (PPA)	The 340B statute requires that the Secretary of Health and Human Services enter into a pharmaceutical pricing agreement (PPA) with each manufacturer of covered outpatient drugs in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under the statute (340B ceiling price). The PPA, and the subsequent PPA addendum, must be signed by a manufacturer as a condition for participating in the Medicaid program. Signing the PPA does not prohibit a manufacturer from charging a price for a covered outpatient drug that is lower than the 340B ceiling price. A PPA remains in effect until terminated by either the manufacturer or the secretary of HHS. It is not automatically terminated if a manufacturer terminates its Medicaid rebate agreement.
Pharmacy benefit manager (PBM)	An administrator of prescription drug programs. PBMs are responsible for processing and paying prescription drug claims, and often for developing and maintaining a formulary of drugs. PBMs also may contract with pharmacies and negotiate discounts and rebates with drug manufacturers.
Physician-administered drugs	Drugs administered directly by a physician or a physician designee to a patient during a clinic visit or encounter.

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Term	Definition
Private label product	Typically, products manufactured or provided by one company for offer to customers/ members under another company's (GPO) brand. These products are typically the same (chemically) as the manufacturer's labeled product, but are just labeled under the offered company's own branding.
Provider-based regulations or status	Medicare sets standards that "provider-based" departments or clinics must meet to enable the entity to bill Medicare a facility fee under the outpatient prospective payment system. Hospitals seek provider-based status for financial reasons.
PVP Medicaid State Profile Resource	To improve transparency and assist stakeholders with 340B compliance, the Prime Vendor has gathered 340B Medicaid information from multiple federal and state Medicaid sources and compiled them in one location. Access this valuable resource here: https://www.340bpvp.com/resource-center/medicaid/. Note: the information and data presented on this website are not endorsed by HRSA and are not dispositive in determining compliance with the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all applicable state and federal laws and regulations. Stakeholders are encouraged to contact the states to verify current policy/requirements.
PVP orphan drug price	The PVP orphan drug price represents the contracted price available to PVP participants subject to the orphan drug exclusion. This price has been negotiated by the Prime Vendor with the manufacturer, on behalf of 340B covered entities, and applies to orphan drugs in the 340B account.
PVP sub-340B price	The PVP sub-340B price represents the contracted pricing available to PVP participants that is below the statutory 340B ceiling price. This price has been negotiated by the Prime Vendor with the manufacturer on behalf of 340B covered entities.
PVP sub-WAC price	The PVP sub-WAC price represents the contracted pricing available to PVP participants that are subject to the GPO Prohibition and is below the wholesale acquisition cost (WAC). This price has been negotiated by the Prime Vendor with the manufacturer on behalf of 340B covered entities subject to the GPO Prohibition.
PVP value-added contracts	As HRSA's 340B Prime Vendor, Apexus is authorized to contract for other products and services required by the outpatient pharmacy environment. Other value-added contracts are for non-covered drugs including most vaccines, blood glucose monitoring supplies, and prescription vials and labels, and discounts on service contracts such as pharmacy automation hardware and software.
PVP value-added price	The PVP value-added price represents the contracted pricing available to PVP participants for products that are not covered outpatient drugs under the Medicaid Drug Rebate Program. This price may appear in the 340B and/or WAC accounts on certain vaccines, blood glucose monitoring supplies, and prescription vials and labels, among others.
Recertification	HRSA is required by statute to conduct annual recertification of participating 340B covered entities' information listed in 340B OPAIS. As part of this process, an authorizing official from each 340B entity certifies basic information about the entity and its 340B compliance.

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Term	Definition
Replenishment (340B outpatient drug)	340B drug replenishment occurs when a non-340B drug is dispensed to a 340B-eligible patient, and the entity later replaces the non-340B dispensed drug with a 340B purchased drug because of patient eligibility. Although the replacement drug was purchased at a 340B price, is no longer considered 340B inventory because it is replacing a non-340B drug dispensed to a 340B eligible patient. Replenishment models operate on a neutral inventory premise. The inventory that is purchased "replenishes" a dispensing/administration activity that already occurred in the past. When this reorder arrives in the pharmacy, it becomes neutral and that package can be dispensed to any patient. In essence, the arrival of the replenishment order turns the drug that was originally dispensed with neutral inventory to an actual 340B transaction. This leaves that neutral inventory to reside on the shelf for the next dispensation.
Rural referral center (RRC)	A Medicare-participating acute care hospital is classified as an RRC if it is located in a rural area and meets certain criteria.
Ryan White HIV/AIDS Program grantee	Ryan White HIV/AIDS Program grantees 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.
Sexually transmitted disease clinic	The US Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) oversees and funds the prevention of sexually transmitted diseases (STDs). Section 318 of the Public Health Service Act authorizes STD funding. Projects under Section 318 are awarded to state and local health departments and academic and public health organizations.
Shipping address	340B OPAIS uses the "shipping address" field to denote a location that may have 340B drugs shipped to it. This address must be a physical address (no P.O. boxes). A shipping address may include in-house pharmacies, entity-owned warehouses, central fill facilities, repackagers, etc. Contract pharmacies should not be listed as shipping addresses in 340B OPAIS.
Single source drug	A covered outpatient drug that is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application (NDA). It also includes a covered outpatient drug approved under a product license approval (PLA), establishment license approval (ELA), or antibiotic drug approval (ADA).
Sole community hospital (SCH)	A hospital paid under the Medicare Acute Care Hospital Inpatient Prospective Payment System (IPPS) is eligible to be classified as an SCH if it meets specific criteria determined by CMS. Typically, these hospitals furnish short-term, acute care, are paid under the Medicare Acute Care Hospital IPPS, are not critical access hospitals (CAH), and are not paid under any other Medicare prospective payment system.

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Term	Definition
Split-billing software	Split-billing software is voluntary and is often used to help covered entities manage a replenishment inventory model. The entity tracks data feeds (such as inpatient or outpatient status, patient and prescriber eligibility, clinic location, Medicaid status, drug identifier, and quantity dispensed) and loads these data points into split-billing software. This software uses logic based on configurations, chosen by the entity, to virtually separate 340B from non-340B transactions after they occur. The software then determines from which account each transaction should be reordered. The term "split-billing" is used to describe this software, which "splits" a purchase order into two or three different accounts (e.g., 340B, GPO, non-GPO/WAC). This software can help the entity place orders in appropriate accounts while maintaining auditable records of the accumulations and purchases.
Start date	340B OPAIS uses the term "start date" to denote an entity's start date in the 340B Program. Entity start dates are updated quarterly.
State plan amendment (SPA)	When a state is planning to make a change to its Medicaid or CHIP program policies or operational approach, it sends state plan amendments (SPAs) to the Centers for Medicare and Medicaid Services (CMS) for review and approval. States also submit SPAs to request permissible program changes, make corrections, or update their Medicaid or CHIP state plan with new information.
Telehealth	Telehealth is defined as the use of electronic information and telecommunication technologies to support long-distance clinical health care, patient and professional health-related education, health administration, and public health. See https://www.hrsa.gov/rural-health/topics/telehealth/what-is-telehealth for more information.
Telepharmacy	Involves the use of electronic information and communication technology to provide and support the delivery of pharmacy services (including drug product and professional pharmacist services) to locations that are remote from a physical pharmacy.
Termination date	340B OPAIS uses the term "termination date" to denote the date that the 340B entity is terminated from the 340B Program. The covered entity is no longer eligible to participate in the 340B Program on the day is terminated from the 340B Program or the day it becomes ineligible. The covered entity must stop purchasing, using, and administering 340B drugs once it is terminated from the 340B Program. Termination dates are updated on a quarterly basis.
Third-party administrator (TPA)	An organization that contracts with pharmacies and covered entities to help manage the operations of a contract pharmacy relationship. TPAs are responsible for determining 340B eligibility of prescriptions, processing and paying prescription drug claims, collecting revenue from payers, and tracking and ordering inventory for the covered entity. 340B entities often use a TPA in multiple contract pharmacy arrangements, but the use of a TPA is not required.
Title X family planning clinics	The Title X Family Planning program is authorized by Title X of the Public Health Service Act and is administered by the US Department of Health and Human Services' Office of Population Affairs. Title X family planning clinics receive funding from the Title X Family Planning Program to provide individuals with comprehensive family planning and preventative health services.

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Term	Definition
Tribal contract or compact health centers	Also called a 638 contract or compact, these sites are operated by Tribes or Tribal organizations. 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.
Tuberculosis clinics	The US Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) oversees and funds the prevention, diagnosis, and treatment of tuberculosis (TB). TB funding is authorized under Section 317E of the Public Health Service Act.
Unit rebate amount (URA)	CMS has authority over URA and computes this amount. State Medicaid programs apply utilization information to it in order to invoice drug manufacturers for rebates. Unit rebate amount is used in the 340B ceiling price calculation. URA Calculations **Brand:** Greater of (23.1% of AMP **or** AMP – best price) plus CPI-U adjustment **Generic/OTC:** 13% of AMP plus CPI-U adjustment **Blood Factors/Pediatric-only Indications:** Greater of (17.1% of AMP **or** AMP – best price) plus CPI-U adjustment
Urban Indian health center (UIHC)	Designated as federally qualified health centers, UIHCs 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.
Vendor	340B entities may elect to purchase services, designed to simplify or optimize 340B participation, from a variety of organizations, collectively called 340B vendors.
Wholesale acquisition cost (WAC)	The price paid by a wholesaler (or direct purchaser) in the United States for drugs purchased from the drug's manufacturer or supplier. Publicly available WAC lists do not represent actual transaction prices and do not include prompt pay or other discounts, rebates, or reductions in price.
Wholesaler	A drug wholesaler is an organization that provides drugs to entities, serving as the distributor between the drug manufacturer and the entity. Typically, states define the term "wholesaler," so exact definitions may vary from state to state.

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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