Purpose: The purpose of the Glossary of 340B Terms guide is to define common terms used in the 340B Program.

Term	Definition
340B ceiling price	The maximum price drug manufacturers can charge for a 340B-purchased drug. **340B Ceiling Price =** Generic: • AMP – URA Brand: • AMP – (AMP – best price) (if lower than AMP – URA) • If AMP is rising faster that the rate of inflation, an additional discount is owed: AMP current – (CPI – U current/CPI – U baseline) × AMP baseline URAs: • Brand-name drugs ([single source] and [innovator]) = 23.1% • Generic drugs (non-innovator multiple source drugs [N]) = 13% • Hemophilia and pediatric drugs = 17.1%
340B covered entity (CE)	340B covered entities are facilities/programs that are listed in the 340B statute as eligible to purchase drugs through the 340B Program and appear on 340B OPAIS.
340B covered outpatient drug (COD)	A covered outpatient drug, defined in section 1927(k) of the Social Security Act (SSA), is summarized as: *An FDA-approved prescription drug, an over-the-counter (OTC) drug that is written on a prescription, a biological product that can be dispensed only by a prescription (other than a vaccine), or FDA-approved insulin.*
340B Drug Pricing Program (340B Program)	Section 340B of the Public Health Service (PHS) Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign a pharmaceutical pricing agreement (PPA) with the Secretary of Health and Human Services. This agreement limits the price that manufacturers may charge certain covered entities for covered outpatient drugs. The resulting program is the 340B Drug Pricing Program.
340B-eligible patient	In summary, an individual is a "patient" of a covered entity (with the exception of state-operated or -funded AIDS drug purchasing assistance programs) only if: 1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; 2. 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; and 3. 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 entity for purposes of 340B 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. An individual registered in a state-operated AIDS drug purchasing assistance program receiving financial assistance under Title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible by the state program.

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 (published by HRSA)	HRSA's list of orphan drug designations used by 340B stakeholders to ensure compliance with the Orphan Drug Exclusion. The list is updated quarterly and is based on the list of orphan drug designations provided by the U.S. FDA, Office of Orphan Products Development. Covered entities may need to conduct additional analyses of the drugs provided on HRSA's list to determine the appropriate drugs to exclude for 340B Program purposes. The list is posted at http://www.hrsa.gov/opa/programrequirements/orphandrugexclusion/index.html.
340B Prime Vendor Program (PVP)	HRSA is required by the 340B statute to establish a prime vendor program. This program is responsible for securing sub-ceiling discounts on outpatient drugs and discounts on other pharmacy-related products and services for participating 340B entities. The current 340B Prime Vendor Program (PVP) is managed by Apexus, through a contract awarded by HRSA. Apexus serves participants in three primary roles: 1. Negotiates sub-ceiling 340B pricing on branded and generic pharmaceuticals 2. Establishes distribution solutions and networks that improve access to affordable medications 3. Provides other value-added pharmacy-related products and services to its participants
5i drugs	5i drugs are drugs that are inhaled, infused, instilled, implanted, or injectable. This definition is pending a proposed CMS rule, and there may be an alternate AMP calculation for these drugs.
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 a policy release regarding 340B and ACOs.
Actual acquisition cost (AAC)	The net cost of a drug paid by a pharmacy. AAC may vary by container size and whether the drug was purchased from a manufacturer or wholesaler. AAC typically includes discounts, rebates, chargebacks, and other price adjustments, but excludes dispensing fees. States may define AAC differently for purposes of Medicaid reimbursement, and some states ask entities to determine or reimburse using an "estimated acquisition cost."
AMP true-up	An 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 at the incorrect price.
Apexus	Currently contracted as HRSA's 340B Prime Vendor. Apexus has its own board of directors, including representatives from covered entity organizations and industry experts. The organization is self-funded through nominal administration fees from its contracted suppliers and is responsible for meeting the contractual requirements of the 340B Prime Vendor agreement. The current agreement expires in 2019.
Apexus Generics Portfolio (AGP)	Apexus Generic Portfolio Pricing is available in the 340B account and the non-GPO/WAC account. The AGP is subcontracted to wholesalers and extended to Apexus participants.
Apexus PVP sub-340B	Apexus PVP sub-340B pricing reflects pricing that is negotiated by Apexus with branded and/or generic manufacturers offering sub-340B pricing.

Term	Definition
Apexus 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 such as vaccines, blood glucose monitoring supplies, prescription vials and labels, and discounts on service contracts such as pharmacy automation hardware and software.
Average manufacturer price (AMP)	AMP is the average unit price paid in the United States to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt-pay discounts (excluding direct sales to hospitals and health maintenance organizations, and to wholesalers where the drug is relabeled under the distributor's National Drug Code [NDC] number). Originally created as a benchmark by Congress to aid in calculating Medicaid rebates, several legislative changes have recently affected the definition of AMP. A CMS proposed rule that addresses the AMP definition is pending. Because 340B is calculated based on AMP, changes in this proposed rule will result in changes to the 340B Program. The base AMP is the calculated AMP for the first full quarter after the market date of the drug.
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)	AWP is a 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.
Banking	Banking occurs when an entity was initially registered in 340B OPAIS as participating, but for a period of time did not place 340B purchases. At some point later in time, the entity places large 340B replenishment orders based on 340B "banked" orders that theoretically could have been placed previously, but were not. HRSA has not authorized the use of a credit–rebill, banking, or similar process to re-characterize previous transactions. Covered entities participating in the 340B Program are responsible for requesting 340B pricing at the time of the original purchase. If a covered entity wishes to reclassify a previous purchase as 340B, the entity should first notify manufacturers and ensure that all processes are fully transparent, with a clear audit trail that reflects the actual timing and facts underlying a transaction. The covered entity retains responsibility for ensuring full compliance and integrity of its use of the 340B Program.
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.
Bundled sales	An arrangement, regardless of physical packaging, under which the rebate, discount, or other price concession is conditioned on the purchase of the same drug, drugs of different types (that is, at the nine-digit NDC level), or another product or some other performance requirement. Examples of such performance requirements include the achievement of market share, inclusion or tier placement on a formulary, or the resulting discounts or other price concessions being greater than those that would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.

Term	Definition
Carve-out/carve-in	See *Medicaid carve-out/Medicaid carve-in*.
Centers for Medicare and Medicaid Services (CMS)	The federal agency charged with implementing and overseeing the Medicare and Medicaid programs.
Chargeback	A chargeback is 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), but sell to 340B entities at the contracted 340B price, which is much less. The wholesaler submits a chargeback request to the manufacturer to account for the difference.
Children's hospital (PED)	These nonprofit hospitals serve individuals under 19 years old 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.
Consumer Price Index-Urban (CPI-U)	The Consumer Price Index-Urban (CPI-U) is 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 for 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 must list the contract pharmacy on 340B OPAIS during a quarterly registration period. Typically, a bill-to (entity)/ship-to (pharmacy) arrangement is used.
Corporate integrity agreement (CIA)	OIG negotiates CIAs with health care providers and other entities as part of the settlement of federal health care program investigations arising under a variety of civil false claims statutes. Drug manufacturers sometimes enter into CIAs as a result of pricing calculation settlements.
Covered outpatient drug (COD)	An FDA-approved prescription drug, an over the-counter (OTC) drug that is written on a prescription, or a biological product that can be dispensed only by a prescription (other than a vaccine) or FDA-approved insulin. The 340B statute uses the definition of covered outpatient drug found here: https://www.ssa.gov/OP_Home/ssact/title19/1927.htm.
Critical access hospital (CAH)	A critical access hospital is 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 those of 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, including abiding by the Orphan Drug Prohibition. CAHs are not subject to the 340B Program's GPO Prohibition.
Deficit Reduction Act, 2005 (DRA)	This federal legislation permitted manufacturers to include certain sales to 340B entities as nominal prices, and initially conferred 340B eligibility for children's hospitals.
Dispensing fee	A dispensing fee is 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*.

Term	Definition
Disproportionate share hospital (DSH)	Disproportionate share hospitals 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% to be 340B eligible.
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 amount 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	A duplicate discount, prohibited by the 340B statute, occurs when manufacturers both provide a 340B discount on a drug AND pay a Medicaid rebate to the state on the same drug.
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.
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 are using EAC (plus a dispensing fee) as a basis for establishing reimbursement, especially for 340B entities. 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.
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)	The federal supply schedule 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.
Free-standing cancer hospital (CAN)	A free-standing cancer hospital (CAN) is 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 and Orphan Drug Prohibition.
Government Accountability Office (GAO)	The U.S. Government Accountability Office (GAO) is an independent nonpartisan agency that works for Congress. Often called the “congressional watchdog,” GAO investigates how the federal government spends taxpayer dollars.
GPO Prohibition	The GPO Prohibition, per 340B statute, prohibits 340B participating disproportionate share hospitals (DSH), children’s hospitals (PED), and free-standing cancer hospitals (CAN) from obtaining covered outpatient drugs through group purchasing organizations (GPOs). Upon enrollment, an entity official signs a form attesting 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 Policy Release about GPO was posted by HRSA in February 2013.

Term	Definition
Group purchasing organization (GPO)	A group purchasing organization is 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. The PVP portfolio is not considered a GPO.
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 alpha-numeric 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)	The Health Insurance Portability and Accountability Act is 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.
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. Comprising five bureaus and ten offices, HRSA provides leadership and financial support to health care providers in every state and U.S. territory. The Office of Pharmacy Affairs (OPA), the office responsible for administering the 340B Program, falls under the Healthcare Systems Bureau within HRSA.
HRSA 340B Database	*see 340B OPAIS*
In-house pharmacy	A pharmacy that is owned by, and a legal part of, the 340B entity. Typically, in-house pharmacies are listed as shipping addresses of the entity and the entity owns the pharmacy license.
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 ftp://ftp.hrsa.gov/bphc/pdf/opa/pricingagreement.pdf.
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).

Term	Definition
Medicaid carve-in	340B entities may elect to use drugs purchased at 340B prices to bill for Medicaid patients. This activity is termed a "Medicaid carve-in." If an entity chooses to use 340B drugs to bill Medicaid, it must indicate this on the Medicaid Exclusion File and list the appropriate Medicaid provider numbers or NPIs. Entities must inform HRSA whether they are carving in or out.
Medicaid carve-out	340B entities may elect to use non-340B drugs to bill for Medicaid patients. This activity is termed a "Medicaid carve-out." Entities may choose to do this so they can receive fair Medicaid reimbursement (many states reimburse entities that use 340B for Medicaid patients on a cost + dispensing fee basis, as the dispensing fee is often not high enough to cover costs). Entities must inform HRSA whether they are carving in or out through the Medicaid Exclusion File.
Medicaid Exclusion File	HRSA established the Medicaid Exclusion File to help support program integrity regarding the statutory prohibition of duplicate discounts. The Medicaid Exclusion File is maintained on the HRSA 340B website and contains the National Provider Identification (NPI) number or Medicaid provider number of entities that use 340B discounted drugs to bill Medicaid for their patients. Entities are expected to provide updated information to HRSA for incorporation into the Medicaid Exclusion File. The covered entity should be billing according to their designation on the Exclusion File. The covered entity should immediately inform HRSA of any changes. The Medicaid Exclusion File is used as follows: • All entities must inform HRSA whether they will use 340B drugs to bill for Medicaid patients. • Entities using 340B purchased drugs for Medicaid patients must inform HRSA of their NPI/Medicaid provider number(s). • Medicaid agencies use the Medicaid Exclusion File to identify the NPI or Medicaid provider number of the entities purchasing at 340B prices. • The state Medicaid agency excludes from its rebate requests to manufacturers all claims associated with entities whose NPIs/Medicaid provider numbers are listed in the Medicaid Exclusion File. • Manufacturers use the Medicaid Exclusion File to verify denial of rebate payment on claims associated with entities purchasing at 340B prices.
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 and Medicaid Extenders Act, 2010	This federal legislation clarified that children's hospitals should continue to receive 340B prices on orphan drugs.
Medicare DSH adjustment percentage	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.
Medicare Modernization Act, 2003 (MMA)	This federal legislation made it easier for rural hospitals to meet one requirement for 340B eligibility (reaching the 11.75% DSH adjustment threshold).
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.

Term	Definition
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)	The National Provider Identifier (NPI) is a unique 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. The NPI is a 10-position, intelligence-free numeric identifier (10-digit number).
Nominal price	A nominal price is any price less than 10% of the AMP in the same quarter for which the AMP is calculated. Only nominal price sales to 340B entities and other safety net providers, as specified by CMS, are excluded from the calculation of: • Average sales price (ASP) • Best price (BP) • Average manufacturer price (AMP)
Non-federal average manufacturer price (non-FAMP)	Non-federal average manufacturer price is 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.
Non-innovator multiple source drug	A non-innovator multiple source drug is a drug that is not originally marketed under an original new drug application, and whose therapeutic equivalent is available from multiple sources.
Office of Pharmacy Affairs (OPA)	The Office of Pharmacy Affairs (OPA) is the HRSA office responsible for administering the 340B Program.
Office of Inspector General (OIG), Department of Health and Human Services	The Office of Inspector General is 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.
Office of Regional Operations (ORO), Health Resources and Services Administration	The Office of Regional Operations (ORO) works through HRSA's 10 regional offices to improve health care systems and America's health care safety net, increase access to quality care, reduce disparities, and advance public health. The ORO conducts 340B audits, with oversight by HRSA.

Term	Definition
Orphan Drug Act (ODA)	The 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. On October 14, 2015, the U.S. District Court for the District of Columbia vacated HRSA's Orphan Drug Interpretive Rule. Access the court ruling.
Orphan drug "approved"	An orphan-designated product is considered "approved" by the U.S. Food and Drug Administration (FDA) Office of Orphan Products Development (OOPD) if it has received marketing approval for an indication that falls within the designated disease or condition.
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	As part of the Affordable Care Act, designated orphan drugs were excluded from the definition of covered outpatient drug for critical access hospitals (CAH), rural referral centers (RRC), sole community hospitals (SCH), and free-standing cancer hospitals (CAN); these entities cannot purchase designated orphan drugs at 340B prices. An interpretive rule, issued in July 2014, clarifies how this section (340Be) will be implemented in these entity types only.
Orphan drug "opt in"	340B hospitals subject to the Orphan Drug Exclusion may choose to purchase orphan drugs used for a non-orphan indication under the 340B Program, or "opt in." If they make this choice, they are required to maintain audible records to demonstrate compliance with the Orphan Drug Exclusion.
Orphan drug "opt out"	340B hospitals subject to the Orphan Drug Exclusion that cannot or do not wish to maintain auditable records regarding compliance with the Orphan Drug Exclusion may "opt out." If they make this choice, they will purchase all orphan drugs outside the 340B program, regardless of the indication for which the drug is used.
Orphan drug "sponsor"	The party that owns or has assigned rights to an orphan drug designation granted by the FDA. Sponsors 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.
Orphan drug "withdrawn"	An orphan-designated drug with marketing approval may have its marketing approval withdrawn for the designated use.
Outpatient clinic	To purchase/use 340B drugs, a hospital outpatient clinic must: • Be an integral part of a 340B eligible hospital. • Appear as a reimbursable clinic above line 96 on Worksheet A of the hospital's most recently filed Medicare cost report.* • Have patients that meet the criteria in the 340B patient definition guideline. • Submit to HRSA the most recently filed cost report to verify clinic eligibility. • Be listed on 340B OPAIS as eligible to participate. *Special requirements may apply to certain children's hospitals (PED).

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 (PAPs)	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 price	A term used to describe the price that results when the calculation for a 340B price yields zero. The manufacturers have been instructed to charge a "penny" for the smallest unit of measure of the product (often per tablet or per package). HRSA has published a policy release clarifying its penny pricing policy.
Pharmaceutical pricing agreement (PPA)	This agreement is required for manufacturers that have executed a Medicaid rebate agreement with CMS and voluntary for those who do not have a current Medicaid rebate agreement. The pharmaceutical pricing agreement must be signed by a corporate officer of the company (e.g., president, chief executive officer, or general counsel; signatures by vice presidents or directors of sales or marketing will not be accepted). 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. 340B entities often use a PBM in multiple contract pharmacies, but the use of a PBM is not required.
Pharmacy services administrative organization (PSAO)	A group that functions as a "negotiator" with payers for payment rates for covered entity groups.
Physician-administered drugs	Drugs administered directly by a physician or a physician designee to a patient. This may occur in 340B entities such as federally qualified health centers (FQHCs), or it may occur in an outpatient clinic setting of a hospital.
Private label product	Private label products are typically those 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 just labeled under the offered company's own branding.

Term	Definition
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.
Provider transaction access number (PTAN)	A PTAN is a Medicare-only number issued to providers by Medicare administrative contractors (MACs) upon enrollment to Medicare. When a MAC approves enrollment and issues an approval letter, the letter will contain the PTAN assigned to the provider. The NPI and the PTAN are related to each other for Medicare purposes. A provider must have one NPI and will have one, or more, PTAN(s) related to it in the Medicare system, representing the provider's enrollment. If the provider has relationships with one or more medical groups or practices or with multiple Medicare contractors, separate PTANS are generally assigned. Together, the NPI and PTAN identify the provider, or supplier in the Medicare program.
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. Covered entities with inaccurate information in 340B OPAIS run a high risk of being removed from the program.
Reclassification	Reclassification (sometimes also called re-characterization) occurs when a credit–rebill process is used to reclassify information about a transaction after it initially occurred. Examples of reclassified information might include the purchasing contract used or the time of dispensing. HRSA has not authorized the use of a credit–rebill, banking, or similar process to re-characterize previous transactions. Covered entities participating in the 340B Program are responsible for requesting 340B pricing at the time of the original purchase. If a covered entity wishes to reclassify a previous purchase as 340B, covered entities should first notify manufacturers and ensure that all processes are fully transparent, with a clear audit trail that reflects the actual timing and facts underlying a transaction. The covered entity retains responsibility for ensuring full compliance and integrity of its use of the 340B Program.
Replenishment (340B outpatient drug)	340B outpatient drug replenishment occurs when a non-340B drug is initially dispensed to a 340B eligible patient, and an entity later replaces the non-340B dispensed drug with 340B purchased inventory. The replaced inventory, although it was purchased at 340B prices, is no longer considered 340B inventory, as the title passes to the pharmacy after purchase.
Rural referral center (RRC)	A Medicare participating acute care hospital is classified as an RRC if it is located in a rural area and it meets specific criteria.
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, and the like.
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).
Social Security Act, 1935 (SSA)	This federal legislation defines many key terms that apply to the 340B Program, including covered outpatient drug and covered entity types (e.g., FQHC and different hospitals such as DSH, CAH, SCH).

Term	Definition
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.
Split-billing software	Split-billing software is used in settings in which a 340B entity uses multiple wholesaler contracts for drug purchasing. This software helps the entity track and separate ("split") the 340B-eligible dispensations from the non-340B dispensations, and ultimately builds purchase orders based on varied information.
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 program policies or operational approach, states send 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.
Telepharmacy	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. As of this date, the entity may no longer purchase 340B or use drugs. Termination dates are updated on a quarterly basis.
Unit rebate amount (URA)	CMS computes this amount and state Medicaid programs apply utilization information to it in order to invoice drug manufacturers for rebates.
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.