340B Glossary of Terms

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

TERM	DEFINITIONS
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 Drug= 17.1%
340B Covered Entity (CE)	340B covered entities are facilities/programs listed in the 340B Statute as eligible to purchase drugs through the 340B Program and appear on the Office of Pharmacy Affairs Database.
340B Covered Outpatient Drug (COD)	A covered outpatient drug, defined in 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 or 340B Program	Section 340B of the Public Health Service Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign an agreement with the Secretary of Health and Human Services. This agreement limits the price manufacturers may charge certain covered entities for covered outpatient drugs. The resulting program is called the 340B Program.

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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; and 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 which 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.
340B ID	A unique identification number provided by the OPA to identify a 340B eligible entity on the 340B Database. This 340B ID is used to purchase 340B drugs.
340B Network	For purposes of 340B, a network consists of at least two separate entities (with unique 340B IDs) that are listed in the 340B Database and have received an Alternative Method Demonstration Project approval from OPA. Upon approval, networks will be permitted to purchase 340B drugs and dispense these drugs (using a single inventory) to network 340B eligible patients. A network will designate a lead entity.

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340B Prime Vendor Program (PVP)	Health Resources and Services Administration (HRSA) is required by the 340B statute to establish a prime vendor program (PVP). This PVP 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, who 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 both 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. OPA 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 or not 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.

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Apexus	A non-for profit entity which is currently contracted as HRSA's 340B prime vendor. Apexus has its own board of directors represented by 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 2014.
Apexus Generics Portfolio (AGP)	The Apexus Generics Portfolio offers discounts on non-contract items for which entities currently pay wholesaler acquisition cost (WAC) pricing. Apexus provides its AGP for outpatient covered and non-covered drugs; this portfolio provides discounted contract pricing which has no reference to the 340B ceiling pricing, although it can be lower than 340B. It is subcontracted to wholesalers and extended to Apexus participants under the AGP.
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.
Apexus PVP Sub-WAC	Apexus PVP Sub-WAC contracted pricing allows entities to order covered outpatient drugs in situations that would otherwise require the entity to purchase at WAC pricing. This pricing is negotiated without regard to 340B Pricing, and use of this pricing is GPO Prohibition compliant. Pricing is negotiated for outpatient covered drugs at sub-WAC or GPO-similar.
Apexus Value Add	As HRSA's 340B Prime Vendor, Apexus is authorized to contract for other products and services required by the outpatient pharmacy environment. Other value add contracts are for non-covered drugs like vaccines, blood glucose monitoring supplies, prescription vials and labels, discounts on service contracts such as pharmacy automation hardware and software, etc.
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, 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 impacted the definition of AMP. A CMS proposed rule is pending that addresses the AMP definition. Because 340B is calculated based upon 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.

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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 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)	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. AWP 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 the 340B Database as participating, but for a period of time did not yet place any or all 340B purchases. At some point later in time, the entity places large 340B replenishment orders based upon 340B "banked" orders that theoretically could have been placed, but weren't placed. OPA has not authorized banking of 340B purchases in writing. OPA has suggested entities follow standard business practices when addressing other 340B processes with marketplace involvement (i.e. contract pharmacy auditing and ADAP rebate agreements). Such standard business practices should occur with full transparency to all parties involved, and would be consistent with the requirements of section 340B and all program guidance published in the Federal Register.
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	The 340B Database uses the "billing address" field to denote the address verified as belonging to the covered entity. Billing addresses are not required to be physical addresses and can be a P.O. Box or other mailing address.

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Bundled Sales	An arrangement, regardless of physical packaging, under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level), or another product or some other performance requirement. Example of such performance requirements include: the achievement of market share, inclusion or tier placement on a formulary, or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.
Carve-out	(See Medicaid Carve-out)
Centers for Medicare & 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 (PEDS)	These non-profit hospitals serve individuals under 19 years old and have a CMS-issued 3300 Series Medicare Provider Number to designate them as a Medicare certified children's hospital. Children's Hospitals must meet certain requirements, including a DSH Adjustment Percentage > 11.75%, and compliance with the GPO Prohibition, in order 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. In order to engage in contract pharmacy services, the entity and pharmacy(ies) must have a written contract that aligns with the compliance elements listed in guidance, and must list the contract pharmacy on the 340B Database. Typically a bill-to (entity)/ship-to (pharmacy) arrangement is used.

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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.
Critical Access Hospital (CAH)	A Critical Access Hospital (CAH) 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 that of acute care hospitals, and must meet certain criteria to be designated as a CAH. 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 (i.e., ASP, AMP, AWP, WAC, AAC, etc.) plus a dispensing fee.
Disproportionate Share Adjustment (DSH Rate)	See Medicare DSH Adjustment Percentage
Disproportionate Share Hospital (DSH)	Disproportionate Share Hospitals (DSH) receive adjustment payments to provide additional help to those hospitals that serve a significantly disproportionate number of low-income patients. 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 Percent >11.75% in order 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 lesser amount than what that 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).

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Duplicate Discount	A duplicate discount, prohibited by 340B statute, occurs when manufacturers provide both a **340B discount on a drug** AND pay a **Medicaid rebate** to the State on the same drug. A duplicate discount would occur if an up-front **340B discount** and back-end **Medicaid rebate** were provided on the same drug/drug claim. 340B covered entities are prohibited from causing a duplicate discount to occur.
Edit Date	The 340B Database uses the term "edit date" to denote the date that a 340B entity's information was edited. Edits to the 340B Database can occur at anytime.
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 Estimated Acquisition Cost (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 by 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 healthcare services — Veteran's Affairs (VA), Department of Defense (DoD), Indian Health Services (IHS), Public Health Services (PHS), and the Coast Guard. The Federal Ceiling Price (FCP) is effective for a calendar year, or that portion of a calendar year in which the covered drug is marketed.
Federal Supply Schedule (FSS)	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 (DoD), Bureau of Prisons (BoP), Indian Health Services (IHS), Public Health Services (PHS), some State Veterans Homes, etc.
Free Standing Cancer Hospital (CAN)	Free-Standing Cancer Hospitals (CAN) are nonprofit entities that are financially and administratively independent (not a part of a larger institution.) CAN hospitals are exempt from Medicare's prospective payment system. For 340B purposes, a CAN hospital 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.

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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. Upon enrollment, an entity official signs a form attesting that the hospital will comply with the GPO Prohibition, and it applies to the hospital as of the date of listing on the OPA website. Upon recertification of information on the 340B Database, the hospital official attests to compliance with the GPO Prohibition. A Policy Release about GPO was posted by OPA in FEB 2013.
Group Purchasing Organization (GPO)	A Group Purchasing Organization (GPO) 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, and 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 Apexus 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 each other via computer. Health Industry Numbers (HINs) are a randomly assigned, nine-character, alpha-numeric identifier. HINs are issued by the Health Industry Business Communications Council (HIBCC). Drug wholesalers and manufacturers typically use HINs to identify entities.
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 six 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, is part of HRSA.
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.
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 new drug application shall be included as an innovator multiple source drug when the drug product meets this definition.

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Manufacturer	A 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 (BP) 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 (i.e., prices to the Indian Health Service (IHS), Department of Veterans Affairs (VA), Department of Defense (DoD), the Public Health Service (PHS), 340B covered entities, Federal Supply Schedule, state pharmaceutical assistance programs, depot prices, and nominal pricing to covered entities).
Medicaid Carve-Out	340B entities may elect to purchase drugs for Medicaid patients on a non-340B contract. This activity is termed a "Medicaid carve-out." Entities may choose to do this in order to 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 OPA whether they are carving in or out.

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Medicaid Exclusion File	OPA 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 OPA website and contains the National Provider Identification (NPI) Number or Medicaid Provider Number of those entities which dispense 340B discounted drugs to a Medicaid patient and bill Medicaid. Entities are expected to provide timely and accurate information to OPA 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 OPA of any changes. The Medicaid Exclusion File is used as follows: • Entities using 340B purchased drugs for Medicaid patients must inform OPA 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 NPI/Medicaid Provider Number 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 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 which 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; i.e., >11.75% for DSH, PEDs,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: inpatient and outpatient. Often these are surgery centers, cardiac cath labs, infusion centers, ER, etc.

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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. 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. It 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 percent 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 (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 (Non-FAMP) 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 drugs is a drug that is not an innovator multiple source drug.
Office of Pharmacy Affairs (OPA)	The Office of Pharmacy Affairs (OPA) is the Office responsible for administering the 340B Program and is part of HRSA.

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Office of the Inspector General, Department of Health and Human Services (OIG)	The Office of Inspector General (OIG) 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, 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; and • Keeps the Secretary and the 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 ten 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 OPA.
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 product to treat the rare disease or condition 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. The Affordable Care Act designated newly eligible 340B entities (Critical Access Hospitals (CAH), Rural Referral Centers (RRC), Sole Community Hospitals (SCH), and Free-Standing Cancer Hospitals (CAN)), and restricted them from purchasing orphan designated drugs at 340B prices. In 7/2013, the Office of Pharmacy Affairs (OPA) issued a final rule which details how the orphan drug exclusion is implemented for the 340B Program.

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Orphan Drug "Approved"	An orphan-designated product is considered "approved" by the US 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.
340B Orphan Drug List (published by HRSA/OPA)	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 US 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
Orphan Drug "Opt-In"	340B hospitals subject to the Orphan Drug Exclusion that purchase orphan drugs used for a non-orphan indication under the 340B Program and maintain auditable 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 and will purchase all orphan drugs outside of the 340B Program, regardless of the indication for which the drug is used, and will not use a Group Purchasing Organization (GPO) to purchase those drugs if the hospital is a free-standing cancer hospital.
Orphan Drug "Sponsor"	The party that owns or has assigned rights to an orphan drug designation granted by 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.

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Outpatient Clinic	In order to purchase/use 340B drugs, a hospital outpatient clinic must: • Be listed on the 340B Database as eligible to participate; • Be an integral part of a 340B eligible hospital; • Have patients that meet the criteria in the 340B Patient Definition Guideline; • Submit to OPA the most recently filed cost report to verify clinic eligibility.
Patient Assistance Programs (PAPs)	Programs whereby 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 impacted 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 Freestanding Cancer Centers (CAN). • Required OPA 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 Accounting 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). OPA has published a policy release clarifying its penny pricing policy.

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Pharmaceutical Pricing Agreement (PPA)	This agreement is required for manufacturers who 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 (PPA) must be signed by a corporate officer of the company (e.g., President, Chief Executive Officer, or General Counsel – signatures by Vice President or Director 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 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.
Physician–Administered Drugs	Drugs administered directly by a physician or a physician designee to a patient. This may occur in 340B entities such as Federal Qualified Health Centers (FQHCs), or it may occur in an outpatient clinic setting of a hospital.
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.
Recertification	HRSA's Office of Pharmacy Affairs (OPA) is required by statute to conduct annual recertification of participating 340B covered entities' information listed in the 340B Database. As part of this process, an authorizing official from each 340B entity certifies basic information about the entity and its 340B compliance with OPA. Covered entities with inaccurate information in the 340B Database run a high risk of being removed from the program.

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Reclassification	Reclassification (sometimes also called recharacterization) occurs when a credit-rebill process is used to reclassify information about a transaction after it initially occurred. Examples of information reclassified might include the purchasing contract used or the time of dispensing. OPA has not authorized reclassification in writing. OPA has suggested entities follow standard business practices when addressing other 340B processes with marketplace involvement (i.e. contract pharmacy auditing and ADAP rebate agreements). Such standard business practices should occur with full transparency to all parties involved, and would be consistent with the requirements of section 340B and all program guidance published in the Federal Register.
Replenishment	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 a RRC if it is located in a rural area and it meets specific criteria.
Shipping Address	The 340B Database 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.
Single Source Drug	A covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA), 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 340B program, including covered outpatient drug, as well as covered entity types (i.e., FQHC, different hospitals such as DSH, CAH, SCH, etc.)

340B Glossary of Terms

TERM	DEFINITIONS
Sole Community Hospital (SCH)	A hospital paid under the Medicare Acute Care Hospital Inpatient Prospective Payment System (IPPS) is eligible to be classified as a 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 where 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	The 340B Database uses the term "start date" to denote an entity's start date in the 340B program. Entity start dates are updated quarterly.
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 located remotely from a physical pharmacy.
Termination Date	The 340B Database 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*. Apexus negotiates favorable rates on vendor services, and a list is available here. Some examples of organizations that fall into this category include: • Pharmacy benefit management • Contract pharmacy solutions • Split-billing software • In-clinic medication dispensing • Outpatient pharmacy management software • Overcharge recovery, etc.

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TERM	DEFINITIONS
Wholesale Acquisition Cost (WAC)	The price paid by a wholesaler (or direct purchasers) 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 within a particular state.

This tool, written to align with OPA policy, is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by the Office of Pharmacy Affairs 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 each stakeholder to include legal counsel as part of their program integrity efforts.