

# 340B Drug Program

## Key Terms

### 340B Covered Entity (CE)

Only nonprofit health care organizations that have certain Federal designations or receive funding from specific Federal programs are eligible organizations (covered entities) that can register, be enrolled and purchase discounted drugs through the 340B Program. These include Federally Qualified Health Centers, Ryan White HIV/AIDS Program grantees, and certain types of hospitals and specialized clinics. Eligible covered entities can be found in the HRSA 340B database.

**Note:** Covered entities must recertify their eligibility every year and provide notification to the Office of Pharmacy Affairs if a change in eligibility occurs.

### 340B Covered Outpatient Drug (COD)

Drugs purchased through the 340B Program must be limited to outpatient use and provided to eligible patients. Generally, the 340B Program covers the following outpatient drugs:

- ◆ FDA-approved prescription drugs;
- ◆ Over-the-counter (OTC) drugs written on a prescription;
- ◆ Biological products that can be dispensed only by a prescription (other than vaccines);
- ◆ FDA-approved insulin

### 340B Drug Pricing Program

The 340B Drug Pricing Program requires drug manufacturers who opt-into the program, to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices. The intent of this Federal program is that it enables covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

### 340B Eligible Patient

To be eligible to receive 340B-purchased drugs, patients must receive health care services other than drugs from the 340B covered entity. The only exception is patients of State-operated or –funded AIDS drug purchasing assistance programs. To stay current on patient eligibility, check at <http://www.hrsa.gov/opa/eligibilityandregistration/index.html>

### 340B ID

HRSA provides a unique identification number to identify a 340B-eligible entity on the 340B Database. This unique identifier is used to purchase 340B drugs.

**340B Prime Vendor Program (PVP)**

The 340B statute requires HRSA to establish a prime vendor program whose responsibilities include securing sub-ceiling discounts on outpatient drugs as well as other pharmacy-related products and services on behalf of participating entities. The current PVP is managed by Apexus. More information specific to their services can be found at <https://www.apexus.com>.

**Accountable Care Organization (ACO)**

An accountable care organization (ACO) is a healthcare organization characterized by a payment and care delivery model that seeks to tie provider reimbursements to quality metrics and reductions in the total cost of care for an assigned population of patients. According to the [Centers for Medicare and Medicaid Services \(CMS\)](#), an ACO is "an organization of health care providers that agrees to be accountable for the quality, cost, and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it."

**Actual Acquisition Cost (AAC)**

The total price a pharmacy pays for the product it dispenses which may vary according to whether it is purchased direct versus wholesale, the volume of purchases made, incentives or special deals offered and the type of pharmacy.

**Average Manufacturer Price (AMP)**

Average manufacturer price (AMP) means the average price paid by wholesalers to manufacturers for drugs distributed to retail pharmacy class of trade. AMP helps in determining Medicaid drug rebate liabilities.

**Average Wholesale Price (AWP)**

In the United States the Average Wholesale Price (AWP) is a prescription drugs term referring to the average price at which drugs are purchased at the wholesale level. The term was originally intended to convey real pricing information to third-party payors, including government prescription drug programs.

**Best Price (BP)**

The lowest price available to any wholesaler, retailer, provider, health maintenance organization (HMO), nonprofit entity, or the government. BP excludes prices to the Indian Health Service (IHS), Department of Veterans Affairs (DVA), Department of Defense (DoD), the Public Health Service (PHS), 340B covered entities, Federal Supply Schedule (FSS) and State pharmaceutical assistance programs, depot prices, and nominal pricing. BP includes cash discounts, free goods that are contingent upon purchase, volume discounts, and rebates.

**Big 4**

The four largest purchasers of pharmaceuticals within the Federal government include: Department of Veterans Affairs (VA), Department of Defense (DoD), Public Health Service (PHS), and Coast Guard. These four Federal agencies have the right to purchase their pharmaceuticals from the Federal Supply Schedule (FSS) like every other Federal agency.

**Comprehensive Hemophilia Treatment Centers (HTC)**

This is an example of non-hospital covered entities that participate in the 340B program. HTCs are specialized treatment centers that receive funding from the Centers for Disease Control and Prevention to provide complete hemophilia services through multidisciplinary teams that focus on preventing complications of the disease.

**Contract Pharmacy**

An arrangement through which a covered entity may contract with an outside pharmacy to provide comprehensive pharmacy services utilizing medications purchased under 340B.

**Critical Access Hospital (CAH)**

Is a designated limited-service hospital located in a rural area. Medicare pays CAHs for inpatient and outpatient services on the basis of their current Medicare-allowable costs or "cost-based reimbursement". Specific 340B eligibility criteria must be met to participate in the program, including accepting the orphan drug prohibition.

**Dispensing Fee**

The dispensing fee represents the charge for the professional services provided by the pharmacist when dispensing a prescription (including overhead expenses and profit). Medicaid and most direct pay insured prescription programs use dispensing fees to establish pharmacy payment for prescriptions. Dispensing fees do not include any payment for the drugs being dispensed. Under the new Medicare Law, pharmacy dispensing fees paid by Medicare under Part B are expected to grow depending on the complexity of the drug administration services involved.

**Disproportionate Share Hospital (DSH)**

A hospital with a disproportionately large share of low-income patients. Under Medicaid, States augment payment to these hospitals. Medicare inpatient hospital payments are also adjusted for this added burden.

**Federal Ceiling Price (FCP):**

The maximum price manufacturers can charge for FSS-listed brand name drugs to the Big 4: Veterans Affairs, Department of Defense, Public Health Service, and the Coast Guard.

**Group Purchasing Organization (GPO)**

A healthcare group purchasing organization (GPO) assists in promoting quality healthcare relief and assists diverse providers in effectively managing expenses. A GPO aggregates the purchasing volume of its members for various goods and services and develops contracts with suppliers through which members may buy at group price and terms if they choose to. GPOs typically provide contracted discounts on medical supplies, nutrition, pharmacy and laboratory.

**GPO Prohibition**

The GPO prohibition is a statutory requirement that applies to disproportionate share hospitals (DSH), children's hospitals (PED), and free-standing cancer hospitals (CAN). Upon registration for the 340B Program, these covered entity types must acknowledge that they understand the restriction with using a GPO for covered outpatient drugs, and during the 340B annual recertification process, they must attest to compliance with the GPO prohibition.

**Health Insurance Portability and Accountability Act (HIPAA)**

HIPAA (Health Insurance Portability and Accountability Act of 1996) is United States legislation that provides data privacy and security provisions for safeguarding medical information.

**Health Resources and Services Administration (HRSA)**

HRSA is an agency within the Department of Health and Human Services. Its mission is to improve and expand access to quality health care for all. HRSA assures the availability of quality health care to low income, uninsured, isolated, vulnerable and special needs populations and meets their unique health care needs. HRSA is organized into several Offices and five Bureaus (the Healthcare Systems Bureau, the Bureau of Primary Health Care, the Bureau of Health Professions, the HIV/AIDS Bureau, and the Maternal and Child Health Bureau).

**HRSA 340B Database**

Once a covered entity is enrolled in the 340B Program and included in the [covered entities database](#), it is the covered entity's responsibility to inform wholesalers and manufacturers of enrollment in order to purchase drugs at the 340B discounted price.

**In-house Pharmacy**

An in-House Pharmacy, is where the covered entity owns drugs, pharmacy and license; purchases drugs; is fiscally responsible for the pharmacy; and pays pharmacy staff.

**Manufacturers**

Manufacturers who participate in Medicaid are required under the 340B statute to enter into an agreement with the Secretary under which the manufacturer must agree to charge a price that will not exceed the amount determined under statute (ceiling price) when selling covered outpatient drugs to 340B covered entities. This agreement, known as the Pharmaceutical Pricing Agreement (PPA), must be signed by a manufacturer as a condition for participating in Medicaid. 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 manufacturer may not condition the offer of 340B discounts upon a covered entity's assurance of compliance with section 340B Program requirements.

<b>Medicaid Carve-in</b>	The term "carve-in" is used to describe a covered entity's decision to use 340B discounted drugs for its Medicaid patients that meet the 340B program's patient definition test.
<b>Medicaid Carve-out</b>	The term "carve-out" is used to describe a covered entity's decision not to use 340B discounted drugs for any of its Medicaid patients. Covered entities that choose to carve out fee-for-service Medicaid patients must inform OPA of this decision. A covered entity that chooses the "carve-out" option must purchase all covered outpatient drugs subject to Medicaid rebate outside the 340B program.
<b>Medicaid Exclusion File</b>	The Office of Pharmacy Affairs (OPA) created and maintains a database to ensure that manufacturers do not pay a rebate and a 340B discount on the same drug given to fee-for-service Medicaid patients. When a covered entity enrolls in the 340B program, they must inform OPA how they will administer or dispense drugs purchased at 340B price to its fee-for-service Medicaid beneficiaries
<b>Mixed Use Setting</b>	This refers to a hospital area that serves both outpatients and inpatients. Examples of mixed-use settings include emergency rooms, infusion centers, surgery centers and cardiac catheterization labs.
<b>Office of Pharmacy Affairs (OPA)</b>	The Office of Pharmacy Affairs (OPA) is the section within the Health Resources and Services Administration (HRSA) that administers the 340B Drug Pricing Program.
<b>Outpatient Clinic</b>	In order to purchase, administer or dispense 340B drugs, a hospital outpatient clinic must be an integral part of a 340B eligible hospital, have patients that meet the 340B patient definition guideline, be listed on the HRSA 340B Database as eligible, submit to HRSA the most recently filed cost report to verify clinic eligibility and be designated as a reimbursable clinic above line 96 on Worksheet A of the cost report.
<b>Pharmacy Benefit Manager (PBM)</b>	An organization that provides administrative services in processing and analyzing prescription claims for pharmacy benefit and coverage programs. PBM services can include contracting with a network of pharmacies; establishing payment levels for provider pharmacies; negotiating rebate arrangements; setting and managing formularies, preferred drug lists, and prior authorization programs; maintaining patient compliance programs; performing drug utilization review; and operating disease management programs. Many PBMs also operate mail order pharmacies or have arrangements to include prescription availability through mail order pharmacies. PBMs are expected to play a key role in managing pharmacy benefit plans in the Medicare drug program.

**Recertification**

As a participant in the 340B program, entities must review and update their information maintained in the 340B Database on an annual basis. Part of this recertification include statements related to compliance.

**Termination Date**

The date in the OPA database on which a provider's participation in the 340B program is terminated. Providers/entities can no longer purchase 340B drugs once a termination date has been established. OPA updates termination dates on a quarterly basis.

**Wholesale Acquisition Cost (WAC)**

This refers to the price paid by a wholesaler for drugs purchased from the wholesaler's supplier, typically the manufacturer of the drug. On financial statements, the total of these amounts equals the wholesaler's cost of goods sold. Disclosed in published compendia, listed WAC amounts may not reflect all available discounts. A few states use markups of WAC in setting Medicaid reimbursement.

**Wholesaler**

A wholesaler is an enterprise that purchases drugs from a supplier, typically through a manufacturer, for the purpose of distributing the drugs to pharmacies, hospitals, physicians and other purchasers that dispense and/or administer drugs to patients.

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**Wellpartner: Who We Are**

As your strategic partner, we're committed to providing a complete 340B service suite that creates value, and gets it right.

Wellpartner is the authority in 340B program management offering innovative technology and the broadest set of 340B services. By staying ahead of industry changes, Wellpartner provides a seamless, easy-to-use solution for covered entities currently or considering participating in the 340B Drug Program.

Our experience is your advantage. Our processes are finely-tuned towards achieving the best results for our customers, whether it is contracting, providing our fully accredited specialty pharmacy services, ensuring program compliance, aligning specialty network access, maximizing claims capture, or driving program value. Wellpartner is focused on excelling at these tasks, since we share the same goal as our covered entity customers — to preserve resources, in order to serve those who need it most.

**Wellpartner | When it matters most**

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