

340 B Basics

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340 B Statute

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- Section 602 of Public Law 102-585, the “Veterans Health Care Act of 1992,” enacted section 340B of the PHSA, “Limitation on Prices of Drugs Purchased by Covered Entities,” codified at 42 U.S.C. 256b.
- The 340B Program permits covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” H.R. REP. No. 102-384(II), at 12 (1992).

340 B Statue cont.

- Section 340B of the PHSA instructs HHS to enter into a pharmaceutical pricing agreement (PPA) with certain drug manufacturers.
- When a drug manufacturer signs a PPA, it is opting into the 340B Program and it agrees to the statutory requirement that the prices charged for covered outpatient drugs to covered entities will not exceed defined 340B ceiling prices, which are based on quarterly pricing data obtained from the Centers for Medicare & Medicaid Services (CMS).

340 B Ceiling Price

The 340B ceiling price for a covered outpatient drug is equal to the Average Manufacturer Price (AMP) from the preceding calendar quarter for the smallest unit of measure minus the Unit Rebate Amount (URA).

$$\text{Ceiling Price} = \text{AMP} - \text{URA}$$

340 B Statute cont.

Participating covered entities report savings that range between 25-50% of Average Wholesale Price (AWP) for covered outpatient drugs as a result of 340B discounts.

340 B Stakeholders

- Covered Entities
- Contract Pharmacies
- Eligible patients
- Federal and State Government
- HRSA (OPA)
- HRSA (HIV/HAB)
- Manufacturers
- Pharmacy Benefits Managers
- Wholesalers/Distributors

340 B Eligibility

340 B Eligible Covered Entity

Federal Grantees

- Hemophilia Treatment Center
- Federally Qualified Health Centers/ Look A-likes
- **Ryan White HIV/AIDS Program authorized by Title XXVI of the Public Health Service Act**
- Sexually Transmitted Disease/Tuberculosis
- Title X Family Planning
- Urban/ 638 Health Center
- Native Hawaiian Health Centers

Non- Federal Grantees

- Critical Access Hospitals
- Disproportionate Share Hospitals
- Rural Referral Centers
- Sole Community Hospitals
- Children's Hospitals
- Free Standing Cancer Hospitals

340 B Patient Definition

- HRSA's **patient definition** guidance states the individual must receive 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 (61 Fed. Reg. 55156 (October 24, 1996)).
- HRSA's **patient definition** guidance also states that an individual will not be considered a 'patient' of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting (61 Fed. Reg. 55156, 55158 Oct. 24, 1996.)

340 B Registration

Registration Periods

- October 1-15,
- January 1-15,
- April 1-15,
- July 1-15

Grantee Periods

- The Notice of Funding Opportunity (NOFO) number at the time of registration and
- The date range of their NOFO funding.

340 B Covered Drugs

- (A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act);
- (B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section

340 B Requirements

Program Requirements

- Prohibit duplicate discounts
- Prohibit the resale of drugs
- Auditing
- Additional Sanctions for non-compliance
- Recertification

Contract Pharmacy Requirements

- 340B Registration
- Covered entities that utilize contract pharmacies must register each pharmacy.
- Must have a contract in place prior to registration.
- Register during the quarter of open registration.
- Information must be accurate.

340 B Program Monitoring

- **The Covered Entity is ultimately responsible for ensuring program integrity as well as prevention of diversion and duplicate discounts.**
- **Annual recertification**
- **Policies and Procedures**
- **Prevent diversion and duplicate discounts**
 - Prescription cannot be Medicaid eligible
- **Prepare for program audits**
 - Virtual inventory reports
 - Dispensing reports
 - Wholesaler replenishment (invoices)
 - Program income detail

340 B Prime Vendor



QUESTIONS?

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