



340 B Statue

- 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 <u>42 U.S.C. 256b</u>.
- 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).

DC HEALTH

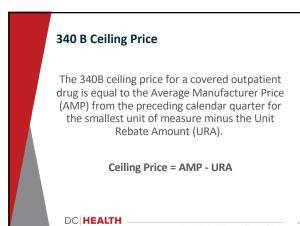
Copyright 2020 DC Health | Government of the District of Colum

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).

Copyright 2020 DC Health | Government of the District of Columbia

DC HEALTH



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.

DC **HEALTH**

340 B Stakeholders

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

DC **HEALTH**



Copyright 2020 DC Health / Go

340 B Eligible Covered Entity

Federal Grantees

Non- Federal GranteesCritical Access Hospitals

- 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 PlanningUrban/ 638 Health Center
- Native Hawaiian Health Centers

DC **HEALTH**

- Disproportionate Share HospitalsRural Referral Centers
- Sole Community Hospitals
- Children's Hospitals
- Free Standing Cancer Hospitals

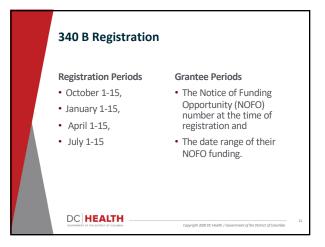
Copyright 2020 DC Health | Government of the District of Colu

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 selfadministration or administration in the home setting (61 Fed. Reg. 55156, 55158 Oct. 24, 1996.)

Copyright 2020 DC Health | Government of the District of Columbic

DC HEALTH

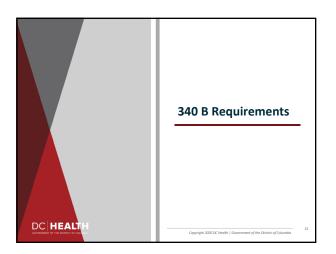


340 B Covered Drugs

 (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

DC **HEALTH**

Copyright 2020 DC Health | Government of the District of Colum





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.
- Register during the quarter of open registration.
- Information <u>must</u> be accurate.

Copyright 2020 DC Health |

• Must have a contract in place prior to registration.

DC HEALTH -

