340B Program
Fact Sheet

BACKGROUND

Enacted in 1992 by the Federal Government, the 340B Drug Pricing Program (340B Program) is intended to permit eligible safety net providers—known as a Covered Entity—“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)).

Under the 340B Program, Covered Entities obtain discounted prices for certain medications known as Covered Outpatient Drugs and provide them to an Eligible Patient regardless of the eligible patient’s health care payor source, unless that source is Medicaid.

FEDERAL OVERSIGHT

The 340B Program is operated by the Health Resources and Services Administration (HRSA) and is housed within the Office of Pharmacy Affairs (OPA) at HRSA.
KEY FEATURES

Covered Entity

The 340B Program provides discounts on outpatient medications to certain organizations known as a Covered Entity. As of 2014 more than 28,000 providers participated in the program as a Covered Entity. Organizations that are eligible to be a Covered Entity include:

- Ryan White-funded Programs
- Comprehensive Hemophilia Treatment Centers
- Federally Qualified Health Centers
- Urban 638 Health Centers
- STD/TB grantees
- Title X Family Planning
- Hospitals, including Disproportionate Share (DSH), critical access, rural referral centers, sole community, children's and free standing cancer hospitals

An organization that is eligible to be a Covered Entity must register with the federal government through OPA.

Covered Outpatient Drugs

In general, Covered Outpatient Drugs are defined as outpatient medications and biologics, excluding vaccines. Inpatient medications are excluded from the definition of Covered Outpatient Drugs. There are a few other limitations that typically do not affect Ryan White Program grantees. Learn more about these limitations on the OPA website. Collectively, in 2014, the 340B Program generated $3.8 billion in savings on Covered Outpatient Drugs. While a significant amount of these savings accrue to eligible hospitals and health systems, Ryan White funded Programs report savings ranging from hundreds of thousands to millions of dollars.
Eligible Patient

OPA has developed the following definition for an Eligible Patient to receive Covered Outpatient Drugs acquired through the 340B Program:

1. The individual must have an established relationship with the Covered Entity such that the entity maintains a record of the individual’s care, and;

2. The individual must receive care from a professional employed by the Covered Entity or under contract or other arrangement with the Covered Entity, and;

3. The individual must receive care that is consistent with the grant funding that is provided to the Covered Entity.

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. Providing Covered Outpatient Drugs to an individual who is not an Eligible Patient is strictly prohibited.

Contract Pharmacy

A Covered Entity may dispense Covered Outpatient Drugs through a pharmacy that it owns and/or through one or more Contract Pharmacy(ies). In a Contract Pharmacy arrangement, the Covered Entity must purchase the Covered Outpatient Drugs and remains responsible for all areas of compliance. OPA has specific requirements for Contract Pharmacy(ies) that can be found on its website.
Prime Vendor Program

The Prime Vendor Program serves a Covered Entity in three primary ways:

1. Negotiates sub-ceiling 340B pricing, which are prices below the 340B price 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.

Participation in the Prime Vendor Program is voluntary and open to any Covered Entity. For more information about the Prime Vendor Program visit the website below.

Additional Resources

- Office of Pharmacy Affairs: [www.hrsa.gov/opa](http://www.hrsa.gov/opa)
- National Center for Innovation in HIV Care: [www.nationalhivcenter.org](http://www.nationalhivcenter.org)
- Prime Vendor Program: [www.340bpvp.com](http://www.340bpvp.com)