

Health Resources and Services Administration

Office of Pharmacy Affairs
340B Drug Pricing Program:
340B 101

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Health Resources and Services Administration

Healthcare Systems Bureau

Office of Pharmacy Affairs

Office of Pharmacy Affairs Mission

To promote access to clinically and cost effective pharmacy services

- Maximize the value of participation in 340B
- Develop innovative pharmacy services
- Serve as a Federal resource for pharmacy practice

Program Administration

Three Legs of the 340B

- Federal Team (OPA)
- Pharmacy Services Support Center (PSSC)
- 340B Prime Vendor Program (PVP)



340B Drug Pricing Program: Overview

- **Section 340B of the Public Health Service Act**
- **Provides discounts on outpatient drugs to certain safety-net covered entities**
- **Manufacturers that participate in Medicaid must also participate in the 340B Program**

Program Benefits

Average savings of 25-50% on outpatient drug purchases for 340B covered entities

Savings may be used to:

- **Reduce price of pharmaceuticals for patients**
- **Expand services offered to patients**
- **Provide services to more patients**

Note: OPA does not regulate how savings attained through participation in this program are to be used.

Program Requirements

Auditable Records

- Covered entities must maintain auditable records that demonstrate compliance with all Program requirements
- Subject to audit by the government or manufacturers

Ongoing Eligibility and Recertification

- Covered entities must immediately notify OPA in the event of any change in eligibility, location, operating status, and authorizing official/contacts.

Program Prohibitions

Diversion

- Drug provided to individuals who are not patients
- Drug dispensed in an area of a larger facility that an integral part of the eligible and participating entity

Duplicate Discounts

- Accessing the 340B Discount + Medicaid Rebate on same drug
- Covered Entities must report Medicaid billing status
- For more information:
<http://www.hrsa.gov/opa/medicaidexclusion.htm>

340B Program Enrollment

Eligible entities must complete the following steps to enter the 340B program:

- Determine eligibility
- Complete appropriate forms (in entirety)
- Submit forms to OPA (via fax or mail)
- Await decision from OPA

Note: Participation usually begins on the first day of the quarter

340B Program Enrollment

Deadline	December 1	March 1	June 1	September 1
Start Date	January 1	April 1	July 1	October 1

DEADLINES- 1 month before the start of the quarter

340B Program Enrollment

Once enrolled in the newly participating entity must:

- **Set up an account with wholesaler using 340B ID**
- **Determine if contract pharmacy services are appropriate**
- **Contact PSSC for assistance with any/ all technical issues**
- **Contact the PVP to discuss participation in their added services.**

Contract Pharmacy Services

- **The Covered Entity purchases the drug, but “ship to bill to” procedure may be used.**
- **The Covered Entity retains legal title to all drugs purchased under 340B. The Covered Entity MUST pay for all 340B drugs.**
- **The contract pharmacy is subject to audits to identify and prevent diversion and/or duplicate discount**

PSPC Performance Story: Building high-performing delivery systems for high risk patients

PSPC is an action learning collaborative that produces three strategic results at the community level:

- *Population Health Status Breakthroughs*
- *Medication Safety Breakthroughs*
- *Community capability to build population focused, integrated delivery systems.*

Key Attributes of this Collaborative

- Patient-Centered
- Interdisciplinary Care Team
- Cross-Organizational with Health Homes at the Center
- Systematically Addresses Medication Management, Safety and Risk -- Huge Issues for Ambulatory Care Patients
- All Teach, All Learn

*It Is Truly the Next
Generation of Collaboratives!*

CPS is a Cost-Effective Solution

- **Each year, medication errors:**
 - **Injure 1.5 million Americans**
 - **Kill 7,000 Americans**
 - **Cost America \$177 billion**
- **CPS Costs \$240 / patient / year**
- **Medication therapy management (MTM) return on investment**
 - **\$4:\$1 on average**
 - **\$12:\$1 using a targeted approach for high-risk patients**

Pharmacy Services Support Center (PSSC)

- **American Pharmacists Association (APhA)**
- **Services to OPA and 340B covered entities**
 - **Free Technical Assistance**
 - **Program development**
 - **Information and analysis**
 - **Relationships and networking**

Prime Vendor Program (PVP)

- **No cost participate**
- **Drug price negotiation services**
 - **Discounts on over 3500 covered drugs**
 - **Discounts average 15% below 340B ceiling prices**
 - **Representing over \$5 billion in purchase volume for over 10,000 participants**
- **Multiple wholesale distributor agreements**
- **Favorable discounts on other pharmacy related products/services**

Contact Information

Office of Pharmacy Affairs (OPA)

Phone: 301-594-4353 or 1-800-628-6297

Web: <http://www.hrsa.gov/opa>

Pharmacy Services Support Center (PSSC)

Phone: 1-800-628-6297

M– F from 9:00 a.m. to 4:30 p.m. (EST)

Web: <http://pssc.ahpanet.org>

Prime Vendor Program (PVP)

Phone: 1-888-340-2787

Web: <http://www.340bpvp.com>