

The 340B Drug Pricing Program: The Basics



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Intent of the 340B Program



Safety net providers



340B Eligible Entities

SAVINGS

Improve financial stability
Stretch dollars to serve vulnerable patients



Patients

The 340B Price

340B

DRUG PRICING
PROGRAM

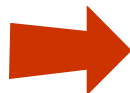
25-50%

of the average wholesale price

The 340B price is actually a "ceiling" price



**Drug
Manufacturers**



Can offer sub-ceiling prices

340B Entity Eligibility



The eligibility to purchase at the 340B price belongs only to the entities

Previous 340B Entity Eligibility

- **Consolidated Health Centers**
- **Federally Qualified Health Center, or FQHC look-alikes**
- **Family planning (Title X)**
- **Ryan White Care Act (Parts A, B, C, D) grantees**
- **Black lung clinics**

- **Comprehensive hemophilia diagnostic treatment centers**
- **Native Hawaiian health centers**
- **Urban Indian organizations**
- **Certified tuberculosis clinics**
- **Certain disproportionate share hospitals (>11.75%)**
- **Certified sexually transmitted disease clinics**

Newly Eligible Program Types

Covered Entity Type	Statutory Definition
Critical Access Hospitals	1820 (c)(2) of SSA
Rural Referral Centers	1886(d)(5)(C)(i) of SSA
Sole Community Hospitals DSH>8%	1886(d)(5)(C)(iii) of SSA
Free Standing Cancer Hospitals	1886 (d)(1)(B)(v) of SSA
Children's Hospitals	1886 (d)(1)(B)(iii) of SSA

OPA website: <http://www.HRSA.gov/OPA>

340B Enrollment Procedure



ELIGIBLE ENTITIES MUST ENROLL

FORMS AND ENROLLMENT INFORMATION

- ➔ <http://www.hrsa.gov/opa>
- ➔ Click on "Legal Resources"

ADMISSION PROCESS

- ➔ Submit completed form to OPA
- ➔ OPA verifies eligibility
- ➔ Participation begins next quarterly database update

340B Enrollment Procedure



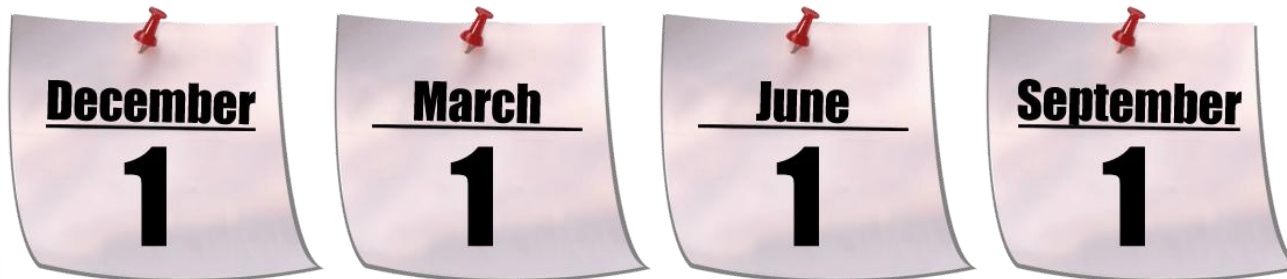
FIND THE FORM

➔ <http://www.hrsa.gov/opa/legalresources.htm>

COMPLETE THE FORM

➔ Click on "Introduction to 340B"

DEADLINES



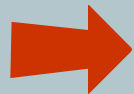
* participation begins 1 month after the enrollment deadline

340B Regulation and Policy



Definition
of a Patient

- 1** *entity has established relationship & maintains records of care*
- 2** *patient receives health care services from health care professional employed/contracted with entity*
- 3** *patient receives health care consistent with range of services from the covered entity*



Federal Register
Notice publication



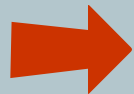
www.hrsa.gov/opa/federalregister.htm

340B Regulation and Policy



**Definition
of a Patient**

If three requirements are not met, the person is not eligible for 340B drugs



**Federal Register
Notice publication**



www.hrsa.gov/opa/federalregister.htm

What services are/are not 340b eligible?

The covered

Outpatient medications

- Used for facilities “patient”
- Written by facilities provider or referred provider

The uncovered

- Inpatient use
- Orphan drug list (for now???)
- Non-“patient”

New opportunity

Contract pharmacy

- 340b eligible entity can contract with one or many non-340b outpatient pharmacy(ies)
- Entity owns medications
- Contract pharmacy gets set dispensing fee
- Does require good record keeping

Integrity Resource:

Office of Pharmacy Affairs (OPA)



Develops
innovative
pharmacy
service models
and supports
technical
assistance

Serves as
Federal resource
for pharmacy
practice

Integrity

Importance of Comprehensive Pharmacy Services

- Access to affordable drugs
- Efficient pharmacy management
- Application of “best practices”
- Systems to improve patient outcome

Access Resource:

Pharmacy Services Support Center (PSSC)

Helps eligible entities, implement and optimize the 340B program



Provides information resources, policy analysis & education

Access

Operates

- Call Center
- Outreach Program
- Web Site
- Pharmacy Technical Assistance Program

Contacts:



www.hrsa.gov/opa

Pharmacy Services Support Center



1-800-628-6297



pssc@aphanet.org



pssc.aphanet.org

Prime Vendor Program



1-888-340-2787



340B_primevendor@340bpvp.com



www.340bpvp.com

