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 is actually a “ceiling” price.

25-50% of the average wholesale price

Drug Manufacturers

Can offer sub-ceiling prices
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

<table>
<thead>
<tr>
<th>Covered Entity Type</th>
<th>Statutory Definition</th>
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<tr>
<td>Critical Access Hospitals</td>
<td>1820 (c)(2) of SSA</td>
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<tr>
<td>Rural Referral Centers</td>
<td>1886(d)(5)(C)(i) of SSA</td>
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<tr>
<td>Sole Community Hospitals DSH&gt;8%</td>
<td>1886(d)(5)(C)(iii) of SSA</td>
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<tr>
<td>Free Standing Cancer Hospitals</td>
<td>1886 (d)(1)(B)(v) of SSA</td>
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<tr>
<td>Children's Hospitals</td>
<td>1886 (d)(1)(B)(iii) of SSA</td>
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**OPA website:** [http://www.HRSA.gov/OPA](http://www.HRSA.gov/OPA)
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
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)

- Administers 340B program
- 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
- Application of “best practices”
- Efficient pharmacy management
- 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
- Web Site
- Outreach Program
- Pharmacy Technical Assistance Program
Contacts:

OFFICE OF PHARMACY AFFAIRS

HRSA

www.hrsa.gov/opa

Pharmacy Services Support Center

1-800-628-6297
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pssc.aphanet.org

Prime Vendor Program

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