The 340B Drug Pricing Program: State Optimization of 340B

Promoting Integrity, Access, & Value

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Learning Objectives

1. Intent of the program
2. 340B Pricing
3. Entity location, eligibility and enrollment
4. Program requirements and prohibitions
5. Program regulation, guidance and policy
6. Implementation Options
7. Patient Safety and Clinical Pharmacy Collaborative
8. State Optimization
9. Available resources
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

The 340B price is actually a “ceiling” price

25-50% of the average wholesale price

Drug Manufacturers

Centers for Medicare and Medicaid Services

340B DRUG PRICING PROGRAM
The 340B Price

Pharmacy services in HRSA programs & safety-net partners are growing rapidly

$5,000,000,000
The 340B Price
Financial Savings

**Heinz Foundation Report** (Rhode Island)
- Comprehensive statewide evaluation
- Net savings estimated at $2M first year

[www.hfp.heinz.org/pdfs/ri340b.pdf](http://www.hfp.heinz.org/pdfs/ri340b.pdf)

**Wellpartner™ Analysis** – California Medicaid
- Adjusted dispensing fee
- 12.2% savings below net Medicaid price

340B Entity Locations by State

Total Entities
13,139

American Samoa 1
FS of Micronesia 2
Guam 6
Marshall Islands 4
Palau 1
Growth of 340B Program by Agency
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 Statute Requirements & Prohibitions

- Prime Vendor
- Audit
- Resell/Transfer Prohibition
- Duplicate Discount Prohibition
- Disproportionate Share Hospital GPO Exclusion
340B Regulation and Policy

Interpreting the legislation and implementing the 340B Program may at times be a challenge

Federal Register Notice publication

www.hrsa.gov/opa
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](http://www.hrsa.gov/opa/federalregister.htm)
Proposed Guidance:
3 Federal Register Notices

**Definition of Patient** – 72 FR 1543
- Clarifies previous FR Notice of October 1996
- Provides specific guidance and examples
- A clear and enforceable definition to help ensure against diversion and support 340B program integrity

**Contract Pharmacy** – 72 FR 1540
- Updates previous FR Notice of August, 1996
- Builds upon experience with Demonstration Projects
- Incorporates Multiple Pharmacies as standard option

**Status**
- Comment Period 1/12/07 – 03/13/07
- Comments being reviewed and final publication being developed
Proposed Guidance: 3 Federal Register Notices, continued

Children’s Hospitals
- Clarifies that children’s hospitals are subject to the same 340B responsibilities as other covered entities
- Describes application procedures for children’s hospitals
- Reaffirms drug manufacturers’ responsibility to furnish discounts under Pharmaceutical Pricing Agreement (PPA).

Status
- Published in Federal Register July 9, 2007 with 60 day comment period
- Comments being reviewed and final publication being developed
340B Implementation Options

Entities expressed interest in new ways to increase access to 340B drugs

www.hrsa.gov/opa/alternativemethods.htm
Call To Action: Institute of Medicine on Patient Safety

Medication Errors are Most Common
Injure 1.5 Million People Annually
Cost Billions Annually
“...for every dollar spent on ambulatory medications, another dollar is spent to treat new health problems caused by the medication.”
HRSA Patient Safety & Clinical Pharmacy Services Collaborative: Goals

- Improve Health Outcomes
- Increase Cost-Effective Clinical Pharmacy Services
- Enhance Patient Safety
HRSA Patient Safety & Clinical Pharmacy Collaborative: Update

- 34 High Performer Site Visits: Dec 07 to April 08
- Change Package: April 2008
- State Leadership Meeting: May 1, 2008
- Teams Identified – July 1st
- Team pre-work: July 16th
- Learning Session 1: August 14-15th
HRSA Patient Safety & Clinical Pharmacy Services Collaborative: Teams

Total Team Submissions: 91
## Patient Safety & Clinical Pharmacy Collaborative: Our Partners

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...and Many Others
Patient Safety & Clinical Pharmacy Collaborative: Pharmacist Role

- Drug formulary management
- Patient-specific counseling, education and monitoring
- Medication Therapy Management
- Medication education for providers
- Health promotion seminars
- Collaborative disease management
- Provide immunizations
- Perform drug utilization review
- Safe Medication Use
State Optimization of 340B: Reasons to Consider

• Increased prescription drug utilization
• Increased numbers of uninsured and underinsured
• Skyrocketing health care costs
• Dual eligible transition to Medicare
• Growth in 340B program utilization, value and support
State Optimization of 340B: Challenges to Address

- Underutilization by covered-entities
- Procurement policy restrictions
- Need for program adherence
- Provider relationships/collaboration
- Continuity of Care
- Funding
- Evaluation methods
- On-going administration
State Optimization of 340B: 
**Key Implementation Steps**

**Step 1** – Evaluate opportunity and potential impact from both a financial and system service delivery perspective.

**Step 2** – Identify and resolve regulatory barriers to implementation.

**Step 3** – Implement measures to facilitate program participation and utilization of 340B resources.
340B Program Resources:

**Integrity**

**Access**

**Value**
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
340B PSSC Inquiries by State:

Total Entities*
1767

*October 2007 to present

American Samoa 0 FS of Micronesia 0 Guam 0 Marshall Islands 0 Palau 0
Value Resource:

Prime Vendor Program (PVP)

- Negotiates sub-ceiling prices
- Helps with access to drug distribution solutions

- Offers value added products and services
- Offered at no cost to entity

Value
How to Access Resources:

- www.hrsa.gov/opa
- 1-800-628-6297
- pssc@aphanet.org
- pssc.aphanet.org
- 1-888-340-2787
- 340B_primevendor@340bpvp.com
- www.340bpvp.com
Thank You!

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Office of Pharmacy Affairs

340B Prime Vendor Program
Managed by Apexus