HRSA Pharmacy Services Support Center: The 340B Access Resource

Lisa Scholz PharmD, MBA
Vice President, APhA
HRSA Pharmacy Services Support Center
Office of Population Affairs Webinar 9/16
Health Resources and Services Administration
Information Session

Office of Pharmacy Affairs
340B Drug Pricing Program

Krista Pedley, PharmD, MS
Director

U.S. Department of Health and Human Services
Health Resources and Services Administration
Healthcare Systems Bureau
Office of Pharmacy Affairs
Office of Pharmacy Affairs Mission:

• Promote access to **clinically** and **cost effective** pharmacy services

Patient Safety and Clinical Pharmacy Services Collaborative

340B Drug Discount Program
Program Administration

- Three Legs of the 340B Program
  - Federal Team/OPA
  - Pharmacy Services Support Center (PSSC/PharmTA)
  - 340B Prime Vendor Program (PVP)
Intent of 340B

Permit covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

340B Program: Overview

- Provides discounts on outpatient drugs to certain safety-net covered entities
- Program’s intent is to allow safety net entities to increase patient services with savings
- Estimated $6 billion dollars in 340B drug purchases last year
- Manufacturers that participate in Medicaid must also participate in the 340B Program
340B 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
Eligible Entities

Federal Grantees

• Hemophilia Treatment Centers
• Federally Qualified Health Centers/ Look A-likes
• Ryan White Programs
• Sexually Transmitted Disease/Tuberculosis
• Title X Family Planning
• Urban/ 638 Health Center
• Native Hawaiian Health Centers

Non-grantees

• Disproportionate Share Hospitals
• Critical Access Hospitals
• Rural Referral Centers
• Sole Community Hospitals
• Children’s Hospitals
• Free Standing Cancer Hospitals
340B Enrollment Steps

1. Determine Eligibility
2. Complete Appropriate Forms
3. Submit Forms / Documents to OPA
4. Await Decision From OPA

Enrollment is now ONLINE!!
340B 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.
## 340B Enrollment

<table>
<thead>
<tr>
<th>Deadline</th>
<th>January 1</th>
<th>April 1</th>
<th>July 1</th>
<th>October 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 1</td>
<td>March 1</td>
<td>June 1</td>
<td>September 1</td>
<td></td>
</tr>
</tbody>
</table>

**DEADLINES**- 1 month before the start of the quarter
340B Database

- Entities cannot participate unless listed in the 340B database
- Wholesalers will not ship discounted drugs unless it is an exact match to the 340B database
- Information is updated daily
- Links to the Medicaid Exclusion File
Program Prohibitions

Diversion

• Drug provided to individuals who are not patients

• Drug dispensed in an area of a larger facility that is an integral part of the eligible and participating entity (e.g. an inpatient service, a non-covered clinic)

• Entities are encouraged to enroll all eligible outpatient or children sites
Program Prohibitions

Duplicate Discounts

• Accessing the 340B Discount + Medicaid Rebate on same drug
• Covered Entities must report Medicaid billing status
• HRSA recommends that covered entities refer to their respective Medicaid State agency drug reimbursement guidelines for applicable billing limits
Program Integrity Current Activities

- Determination of eligibility and maintenance of system
- Recertification
- Quarterly calculations of 340B prices
- Posting Medicaid Exclusion File
- Investigations/resolutions of alleged drug diversion and incorrect pricing/inappropriate limits on drug access AND DUPLICATE DISCOUNT
- Audits by HRSA
- Technical Assistance, webinars, FAQs, guidances
Program Integrity - Recertification

• Current:
  • FQHC grant eligibility quarterly
  • DSH percentage quarterly
  • Ownership status quarterly

• Began phased implementation of annual recertification
  • Ryan White Grantees currently in process
  • STD/TB – October
  • Continue with other entities as online systems are developed
Contract Pharmacies

- 340B program allows entities to have multiple contract pharmacies for increased patient access to cost effective pharmaceuticals

- The Covered Entity purchases the drug, but “ship 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.
Contract Pharmacies Cont.

• The contract pharmacy is subject to audits diversion and duplicate discount provisions

• A single covered entity (parent organization) is permitted to enter into contracts with one or more pharmacies to provide services to all sites of the covered entity.

• 15% of entities have a contract pharmacy arrangement
Patient Safety and Clinical Pharmacy Services Collaborative: Overview

• Action learning collaborative that produces three strategic results in communities nationwide:
  • Population Health Status Breakthroughs
  • Medication Safety Breakthroughs
  • Community capability to build patient-centered, integrated delivery systems

• PSPC fosters high-performing delivery systems for the patients at highest risk

Now Enrolling new teams!

www.hrsa.gov/patientsafety
Contact Information

Office of Pharmacy Affairs (OPA)
Phone:  301-594-4353 or 1-800-628-6297
Web:  http://www.hrsa.gov/opa and www.hrsa.gov/patientsafety

Pharmacy Services Support Center (PSSC)
Phone:  1-800-628-6297
Web:  http://pssc.ahpanet.org

Prime Vendor Program (PVP)
Phone:  1-888-340-2787
Web:  http://www.340bpvp.com
340B Prime Vendor Program Fundamentals

Mary Ellen England
Apexus
Dir. Marketing and Education
The 340B Program Team:

- HRSA’s Office of Pharmacy Affairs
- 340B PVP Prime Vendor Program (Apexus Inc.)
- Pharmacy Services Support Center (PSSC/PharmTA)
Apexus – Mission

Apexus leverages its unique purchasing power and expertise to deliver value which helps eligible health care and public service organizations to access unmatched savings and optimize performance.
Apexus, the 340B PVP provides…

The Prime Vendor serves participants in three distinct areas:

• Negotiating sub-340B pricing on pharmaceuticals

• Establishing distribution solutions and networks that improve access to affordable medications

• Providing other value-added products and services.
Strategic Initiatives 2011:

- Increase Value to PVP Participants
- Increase Participant Satisfaction
- Improve Critical Elements of the 340B PVP
- Meet the Evolving Needs of HRSA
Benefits of PVP to Covered Entities

- No risk or cost to participate
- No change of distributor required
- Maximize value delivered through a single national program
- Access to 340B sub-ceiling prices for drugs and discounts on other products/services
- Longer term contracts to base formulary decisions
- Pricing transparency via secure website
PVP Portfolio/Contracting

- Over 3500 covered drugs at sub-ceiling pricing
- One or two products within therapeutic drug class
- Best market pricing for non-covered drugs, vaccines, supplies and services
- Two to three year agreements
- No rebates; but performance based contracting is permitted
- Participant advisory councils:
  - Hospitals
  - Title X (FP Clinics)
  - Community Health Centers
  - Hemophilia Treatment Centers
What Drugs Are Covered within the 340B program

Covered drugs:

• Outpatient Prescription drugs
• Over-the-counter drugs (accompanied by prescription)
• Clinic administered drugs within eligible facilities

Non-covered drugs:

* Vaccines
In-patient drugs
Other Outpatient Rx Products and Services

- Vaccines – all
- Patient assistance program Software
- Auditing and overcharge recovery services
- Prescription vials/labels/printer cartridges
- Diabetic supplies – meters, strips and syringes
- Outpatient Rx technology and automation – ScriptPro, Automed, Innovation, VoiceTech, others
- Apothecary supplies
- Reverse distribution (pharmacy returns)
To register to enroll into the Apexus/PVP

To register for username and password after enrolling into PVP

September 20, 2010
HRSA publishes Two Advance Notices of Proposed Rulemaking for Manufacturer Civil Monetary Penalties and Administrative Dispute Resolution Process

August 2, 2010
Apexus Announces $4.5 Million Shareback Program for Eligible Participants

July 20, 2010
HRSA Webinar: Enrollment of New Entities Webinar Available July 28, 2010

July 15, 2010
Director of the Office of Pharmacy Affairs (OPA) Announcement
Informational Tools & Resources

- Drug price forecasts and other budgeting tools
  - Best Buy by Therapeutic Class Report
  - PHS Selling Price Comparison (Quarterly)
  - 340B Selling Price Look-Up & Download
On the Horizon

- **Website upgrades**
  - New look
  - Higher usability
  - More information

- **Social Networking**
  - Apexus 340b Prime Vendor

- **Newsletter updates**
The 340B Prime Vendor Program

Mary Ellen England, MS, MBA - Marketing and Education
Phone: 972-910-6638
Email: mengland@340bpvp.com

Beverly Daniel - membership
Phone: 972-910-6616
Email: bdaniel@340bpvp.com

Customer Service Hotline
1888-340-2787
LEARNING OBJECTIVES

1. Describe the purpose and function of HRSA PSSC

2. Describe the valuable services HRSA PSSC offers

3. List the foundational principles upon which HRSA PSSC operates
Purpose

Information & Assistance

GOAL:
Optimize value

Serves as the primary access resource for 340B
Vision and Mission

VISION
access to affordable, clinically, and cost effective pharmacy services

MISSION

• provide information, education, and policy analysis

• optimize the value

• improve medication use and advance patient care
Clinically and Cost Effective Pharmacy Services

INTEGRITY • ACCESS • VALUE
Value of HRSA PSSC

• Timely
  • Reflects Current Policy
  • Meets High Quality Standards

• Understanding
  • Implementing
  • Optimizing
Services

Information Analysis and Management

Relationships and Networking

Program Development
Information Analysis and Management

Call Center 1-800-628-6297 or PSSC@aphanet.org
Information Analysis and Management

PharmTA

Free technical assistance to eligible entities

To request, call 1-800-628-6297
# Interactive Financial Analysis

[Image of a table with various financial metrics and calculations]

## Pharmacy Services in MA "All Inclusive" Rates

<table>
<thead>
<tr>
<th>Pharmacy Services</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>HMO managed MA will be included in an &quot;All Inclusive&quot; Rate.</td>
<td></td>
</tr>
<tr>
<td>If &quot;No&quot;, FFS Dispensing Fee.</td>
<td></td>
</tr>
<tr>
<td>If &quot;Yes&quot;, FFS Increase for Pharmacy.</td>
<td></td>
</tr>
<tr>
<td># of Clinic FFS Visits per year.</td>
<td></td>
</tr>
<tr>
<td>State managed MA will be included in an &quot;All Inclusive&quot; Rate.</td>
<td></td>
</tr>
<tr>
<td>If &quot;No&quot;, FFS Dispensing Fee.</td>
<td></td>
</tr>
<tr>
<td>If &quot;Yes&quot;, FFS Increase for Pharmacy.</td>
<td></td>
</tr>
<tr>
<td># of Clinic FFS Visits per year.</td>
<td></td>
</tr>
</tbody>
</table>

## Revenue from Clinical Services

- **Encounters/Year**:
- **Avg. $/Encounter**:

## Profit/Loss Summary

<table>
<thead>
<tr>
<th>Category</th>
<th>Revenue</th>
<th>Profit/Loss by Payor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Projected Income</td>
<td>3rd Party Insured</td>
<td>$0</td>
</tr>
<tr>
<td>HMO Insured</td>
<td>$0</td>
<td></td>
</tr>
<tr>
<td>State Medicaid</td>
<td>$0</td>
<td></td>
</tr>
<tr>
<td>SFS Level 1</td>
<td>$0</td>
<td></td>
</tr>
<tr>
<td>SFS Level 2</td>
<td>$0</td>
<td></td>
</tr>
<tr>
<td>SFS Level 3</td>
<td>$0</td>
<td></td>
</tr>
<tr>
<td>SFS Level 4</td>
<td>$0</td>
<td></td>
</tr>
<tr>
<td>SFS Level 5</td>
<td>$0</td>
<td></td>
</tr>
<tr>
<td>MAP Administration</td>
<td>$0</td>
<td></td>
</tr>
<tr>
<td>Clinical Services</td>
<td>$0</td>
<td></td>
</tr>
<tr>
<td><strong>Total Projected Income</strong></td>
<td>$0</td>
<td></td>
</tr>
</tbody>
</table>

## Projected Expenses

<table>
<thead>
<tr>
<th>Category</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payroll</td>
<td>$0</td>
</tr>
<tr>
<td>Supplies</td>
<td>$0</td>
</tr>
<tr>
<td>Contract Services</td>
<td>$0</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>$0</td>
</tr>
</tbody>
</table>

## Total Projected Expenses

<table>
<thead>
<tr>
<th>Amount</th>
</tr>
</thead>
</table>

## Projected Annual Profit/Loss

<table>
<thead>
<tr>
<th>Amount</th>
</tr>
</thead>
</table>

## Projected Start-up Expenses

<table>
<thead>
<tr>
<th>Amount</th>
</tr>
</thead>
</table>

## Projected Profit/Loss, Year 1

<table>
<thead>
<tr>
<th>Amount</th>
</tr>
</thead>
</table>

---

**Copyright ©2004 Medpin - A Program of the Public Health Institute**

Worksheet developed via support provided by the Pharmacy Services Support Center of the American Pharmacists Association (http://www.pharmacy.org) and HRSA.

Author: Todd D. Scopson, PharmD, University of Minnesota (June 2006).
Information Analysis and Management (cont.)

Policy Analysis

Monitors, analyzes, and communicates policy developments within the scope of the 340B Program
Information Analysis and Management (cont.)

Website

pssc.aphanet.org
Relationships and Networking

- Live Presentations
- Articles in journals and *Pharmacy Today*
- Interactive web-based learning opportunities

Dialogue and collaboration with other safety net stakeholder organizations
The Newest Technical Assistance Model: The 340B Peer-to-Peer Network!

Purpose and Goals

– Increase understanding of the issues covered entities face in implementing and optimizing the 340B program;
– Connect 340B stakeholders to share operational examples of best practices in 340B community;
– Strengthen pre- and post-graduate training of the next generation of pharmacists in 340B;
– Promote the expansion of clinical pharmacy services in underserved communities;
– Allow covered entities to share experiences with the 340B program with HRSA PSSC and OPA;
– Organizations self identify as leading practices.
340B Peer-to-Peer: Resources

- Electronic Peer-to-Peer Community: http://www.healthcarecommunities.org/default.aspx
- Interactive Peer-to-Peer Network Webinars- sign up on healthcare communities!
  - August 24th- Purchasing Optimization for Maximizing Medication Access
  - September 28th- Medicaid Billing Practices to Ensure Compliance and Increase Revenue
  - October 12th- Contract Pharmacy Implementation and Integrity
  - October 26th- Preventing Diversion Systems for Verifying Patient Eligibility
The 340B Peer-to-Peer Network

• The Network is growing: Applications for 2011 are now available!

• Benefits:
  – Organizations selected will receive a recognition plaque;
  – Acknowledgment in publications and HRSA PSSC website;
  – Complementary membership in APhA for three leadership team members in each organization;
  – Stipends up to $25,000 for their ambulatory care or community pharmacy residency programs;
  – Financial support for conference attendance to represent 340B stakeholders

http://pssc.aphanet.org/p2network/
Education Programs

Inter-Agency Agreements

Continuing Education

Educational Tools and Resources

Supported by the Pharmacy Services Support Center in cooperation with the APhA Academy of Student Pharmacists

Student Programs
Education Programs

• Education and Tools for covered entities
  – Drug Product Selection Guide, pssc.aphanet.org/resources
  – Multiple Contract Pharmacy Decision Analysis
Educational Partnerships: Project CHANCE

- Awards through the HRSA Pharmacy Services Support Center and Academy of Student Pharmacists at APhA
  - $10,000.00 (formerly $2,000)
  - Encourages pharmacy students along with other interdisciplinary students to work with 340B entities to develop innovative programs in the safety net community
  - Deadline: February 2012
  - Requirement: Poster presentation and Annual Project Report
Contacts:

Pharmacy Services Support Center

- www.hrsa.gov/opa
- www.hrsa.gov/patientsafety
- 1-800-628-6297
- pssc@aphanet.org
- pssc.aphanet.org
- Healthcarecommunities.org

Prime Vendor Program

- 1-888-340-2787
- 340B_primevendor@340bpvp.com
- www.340bpvp.com