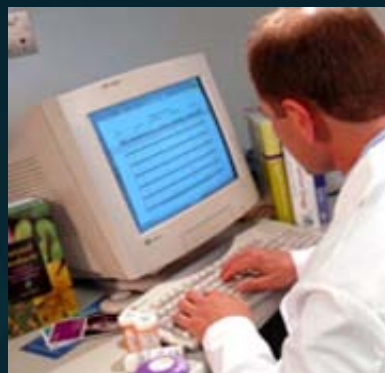


HRSA Pharmacy Services Support Center: The 340B Access Resource



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

An arrow points from the top of this circle to the word "clinically" in the mission statement above.



340B Drug
Discount
Program

An arrow points from the top of this circle to the words "cost effective" in the mission statement above.



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.”

H.R. Rep. No. 102-384(II), at 12 (1992)



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 patient



Eligible Entities

Federal Grantees

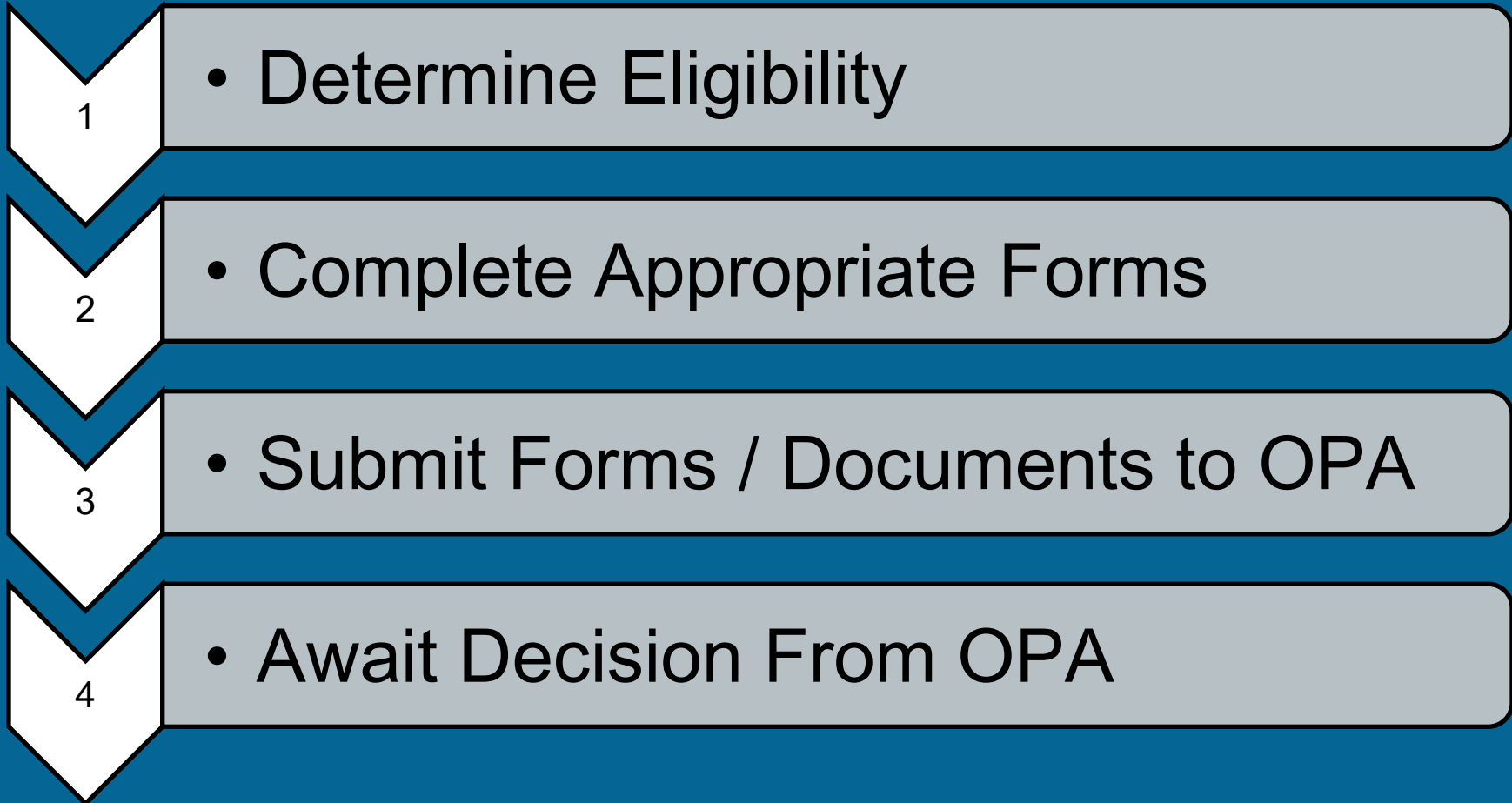
- Hemophilia Treatment Centers
- Federally Qualified Health Centers/ Look A-likes
- Ryan White Programs
- Sexually Transmitted Disease/Tuberculosis
- Title X Family Planning
- Urban/ 638 Health Center
- Native Hawaiian Health Centers

Non-grantees

- Disproportionate Share Hospitals
- **Critical Access Hospitals**
- **Rural Referral Centers**
- **Sole Community Hospitals**
- **Children's Hospitals**
- **Free Standing Cancer Hospitals**



340B Enrollment Steps



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

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 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

Managed by Apexus

***340B Prime Vendor
Program
Fundamentals***

Mary Ellen England

Apexus

Dir. Marketing and Education

340B Program Administration

340B
Prime Vendor
PROGRAM
Managed by Apexus

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

340B
Prime Vendor
PROGRAM
Managed by Apexus



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)**



- AGREEMENTS
- PARTICIPATION
- FAQ/RESOURCES
- BID CALENDAR
- 340B TUTORIAL
- TESTIMONIALS
- ABOUT US

340B Prime Vendor

To register to enroll into the Apexus/PVP

APPLY HERE TO PARTICIPATE

To register for username and password after enrolling into PVP

- SUPPLIER LOGIN
- PARTICIPANT LOGIN**

DON'T HAVE ACCESS TO OUR PARTICIPANTS ONLY WEB SITE?

SIGN UP!

[\(instructions\)](#)

- September 20, 2010**
HRSA publishes Two Advance Notices of Proposed Rulemaking for Manufacturer Civil Monetary Penalties and Administrative Dispute Resolution Process ([more](#))
- August 2, 2010**
Apexus Announces \$4.5 Million Shareback Program for Eligible Participants ([more](#))
- July 26, 2010**
HRSA Webinar: Enrollment of New Entities Webinar Available July 28, 2010 ([more](#))
- July 15, 2010**
Director of the Office of Pharmacy Affairs (OPA) Announcement ([more](#))

NAVIGATING



Requires Flash Player

UPCOMING 340B-RELATED EVENTS/PROGRAMS

[View/print entire year >](#)

<< September 2010 >>						
S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

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

PVP & 340B Selling Price Look Up

The PVP & 340B Selling Price Look Up will allow the PV Participants to look up specific pricing by searching any word or phrase of any available columns or selecting specific AHFS Therapeutic Description.

Disclaimer: The prices contained in this report are contract prices compiled from several pharmacy wholesalers and represent a combination of 340B PHS Selling Prices and 340B Sub-ceiling PVP Prices. Availability and quantity of NDC's on hand may vary with each pharmacy wholesaler. These reports are for use by PVP Participants as a reference tool only. Apexus is not responsible for any pricing errors that may be contained in the reports. These reports do NOT represent an official PHS price file. Some pharmacy manufacturers allow Apexus to post their official 340B Ceiling Price files each quarter by permission but they are located in a different section of [this secure website](#).

Quick Search: (Searches all fields using single criteria)

Search Results:

NDC: 58160081511
Label Name: TWINRIX VACCINE VIAL
Manufacturer Name: GLAXOSMITHKLINE
Dosage Form: VIAL
Drug Strength Description: 720-20/ML
Package Size: 1,000,000,000,000
Additional Description: 10'S,SDV
Generic Name: HEPATITIS A & B VACCINE/PF
AHFS Therapeutic Class Description: VACCINES

Period	Cardinal's PHS Selling Price	ABC's PHS Selling Price	M&D's PHS Selling Price	McKesson's PHS Selling Price
Q2 2010	\$0.00	\$0.00	\$0.00	\$0.00
Q1 2010				
Selling Q2 2009	\$415.00			

340B Prime Vendor PROGRAM (888) 340-BPVP (340-2787) HOME | MY PROFILE | LOGOUT

Reports Best Buys

Best Buys reports should be used when a facility is verifying a lowest priced item within a given category or searching for penny buys to make purchasing decisions. The pricing of products will change on a quarterly basis.

BY THERAPEUTIC CLASS

340B Prime Vendor PROGRAM (888) 340-BPVP (340-2787) HOME | MY PROFILE | LOGOUT

STD (Sexually Transmitted Disease)
Apexus STD Suggested Drug List

340B Prime Vendor PROGRAM (888) 340-BPVP (340-2787) HOME | MY PROFILE | LOGOUT

Title X (Women's Health)
Apexus Women's Health Suggested Drug List

The following reports contain two price columns:

1. The first column is the 340B Selling Price which is the actual discounted price a manufacturer sells its products via pharmacy wholesalers (distributors) to 340B participating covered entities. The Prime Vendor Program (PVP) obtains this price through a validation process from the prices reported by the pharmacy wholesalers and is subject to change on a quarterly basis.
2. The second price column is the 340B Prime Vendor Program (PVP) sub-ceiling (sub-340B) price. This price is not mandated by manufactures, and therefore, not all the products have a negotiated sub-ceiling PVP price.

All pricing contained in these reports are base prices and do not include the wholesalers distribution fee (which may be "cost plus" or "cost minus" depending on your agreement with your distributor). You must factor your distribution fee into the price of the product in order to obtain a final delivered cost. Further, all prices factored are PER CYCLE prices. Pharmacy Distributors sell in larger pack quantities so pricing must be multiplied by the QTY column to obtain the distributor's true selling price. [See example >](#)

There are two methods of ordering most contraceptives:

- ***Website upgrades***
 - New look
 - Higher usability
 - More information
- ***Social Networking***
 - Apexus 340b Prime Vendor ‘
- ***Newsletter updates.***

Contact Information

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

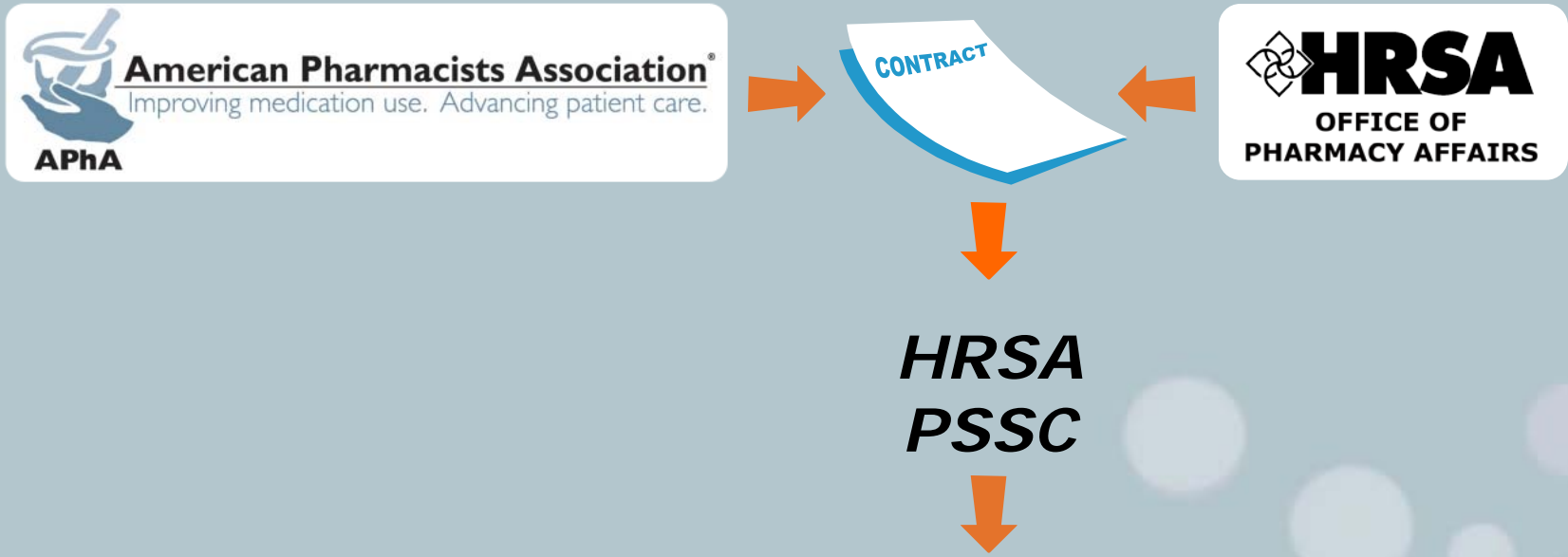
2

Describe the
valuable services
HRSA PSSC offers

3

List the
foundational
principles upon
which HRSA
PSSC operates

Purpose



Serves as the primary access resource for 340B

Information & Assistance



GOAL:

Optimize value



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



Value of HRSA PSSC



**HRSA
PSSC**



ACCESS



- **Timely**
- **Reflects Current Policy**
- **Meets High Quality Standards**

- **Understanding**
- **Implementing**
- **Optimizing**

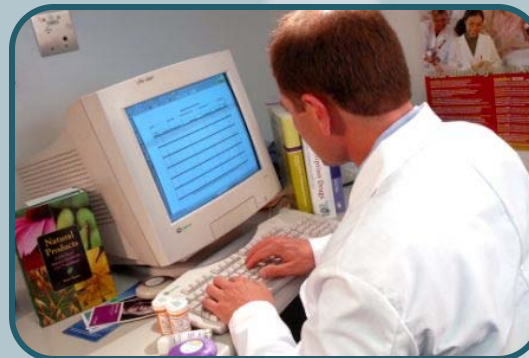
Services

**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



pssc.aphanet.org/resources.htm

Pharmacy Payer Type	Mix	SFS Structure		Pharmacy Services in MA "All Inclusive" Rates
3rd Party Insured (Non-Medicaid)		Level 1		HMO managed MA will be included in an "All Inclusive" Rate:
HMO Managed Medicaid		Dispensing Fee		If "No", FFS Dispensing Fee:
State Medicaid		% Mark-up on Meds	0.0%	If "Yes", PPS Increase for Pharmacy
Sliding Fee Scale - Level 1		Maximum Charge? (Y / N)	N	# of Clinic PPS Visits per year
Sliding Fee Scale - Level 2		Maximum Charge		
Sliding Fee Scale - Level 3		Level 2		State managed MA will be included in an "All Inclusive" Rate:
Sliding Fee Scale - Level 4		Dispensing Fee		If "No", FFS Dispensing Fee:
Sliding Fee Scale - Level 5		% Mark-up on Meds	0.0%	If "Yes", PPS Increase for Pharmacy
Manf. Assistance Programs		Maximum Charge? (Y / N)	N	# of Clinic PPS Visits per year
Samples		Maximum Charge		
Total (must be 100%)	0.0%	Level 3		Revenue from Clinical Services
		Dispensing Fee		Encounters/year
Clinic Prescription Volume		% Mark-up on Meds	0.0%	Avg. \$/Encounter
Utilization Rate (Rxs/visit/year)		Maximum Charge? (Y / N)	N	
Clinic Visits/year		Maximum Charge	\$0.00	
		Level 4		
Capture Rate (%)		Dispensing Fee		
3rd Party Insured		% Mark-up on Meds	0.0%	
HMO MA		Maximum Charge? (Y / N)	N	
State Medicaid		Maximum Charge	\$0.00	
SFS		Level 5 (Cash U&C)		
		Dispensing Fee		
Generic Medication Utiliation		% Mark-up on Meds	0.0%	
% Generic, SFS		Maximum Charge? (Y / N)	N	
% Generic, Non-SFS		Maximum Charge	\$0.00	
3rd Party Margin (%)		MAP Fee per Rx		
Brand				
Generic				
Avg. Drug Cost (\$)				
per Brand Rx				
per Generic Rx				

Profit/Loss Summary			
Projected Income	Revenue	P/L by Payer	
3rd Party Insured	\$0	#DIV/0!	
HMO Medicaid	\$0	#DIV/0!	
State Medicaid	\$0	#DIV/0!	
SFS Level 1	\$0	#DIV/0!	
SFS Level 2	\$0	#DIV/0!	
SFS Level 3	\$0	#DIV/0!	
SFS Level 4	\$0	#DIV/0!	
SFS Level 5	\$0	#DIV/0!	
MAP Administration	\$0	#DIV/0!	
Clinical Services	\$0	#DIV/0!	
Total Projected Income	\$0		
Projected Expenses			
Payroll	\$0		
Supplies	\$0		
Contract Services	\$0		
Miscellaneous	\$0		
Total Projected Expenses	\$0		
Projected Annual Profit/Loss	\$0		
Projected Start-up Expenses	\$0		
Projected Profit/Loss, Year 1:	\$0		

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Worksheet developed via support provided by the Pharmacy Services Support Center of the American Pharmacists Association (<http://pssc.aphanet.com>) and HRSA.

Author: Todd D. Sorensen, Pharm.D., University of Minnesota (June 2005)

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

The screenshot shows the homepage of the Pharmacy Services Support Center (PSSC). The header features the PSSC logo and the text 'PHARMACY SERVICES SUPPORT CENTER' on the left, and the phone number '800-628-6297' and 'Managed by APhA' on the right. A navigation menu includes 'HOME', 'ABOUT US', 'SERVICES', and 'CONTACT PSSC'. The main content area is divided into four columns: 1) A '340B Journey' graphic with the text 'Click on the luggage tag to access all of PSSC's 340B Program Resources'. 2) An 'About Us' section with a photo of a pharmacist and a patient, describing the center's mission and a 'Learn More' link. 3) A 'Services' section with links for '340B Policy Issues', '340B Resource Tools', 'Technical Assistance', and '340B Resource Network', including a quote from DSH - Rural, PA. 4) A 'Latest Announcements' section with several news items and a 'View All Announcements' link. A 'QUICK ACTIONS' sidebar is also present on the left.

Call PSSC 800-628-6297 or email us at 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



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:



www.hrsa.gov/opa

www.hrsa.gov/patientsafety

Pharmacy Services Support Center



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