



The 3 Ps of the 340B Drug Pricing Program: Participation, Pricing and Program Integrity

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Learning Objectives



- Identify the requirements to participate in the 340B Drug Pricing Program
- Understand the requirements of the recertification process
- Become familiar with the new site visit and audit requirements
- Identify available tools and resources including the Peer to Peer Program



Office of Pharmacy Affairs Mission



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



340B Program: Overview and Benefits



- Provides discounts on outpatient drugs to certain safety-net covered entities
- Average savings of 25-50%
- **Savings may be used to:**
 - Reduce price of pharmaceuticals for patients
 - Expand services offered to patients
 - Provide services to more patients
- Estimated \$6 billion dollars in 340B drug purchases last year
- Manufacturers that participate in Medicaid must also participate in the 340B Program



Intent of the 340B Program



Permits eligible safety net providers “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)



Participation



Eligible Entities



Federal Grantees

- Comprehensive Hemophilia Treatment Centers
- Federally Qualified Health Centers
- Urban/638 Health Center
- Ryan White Programs
- Sexually Transmitted Disease/Tuberculosis
- Title X Family Planning

Hospital Types

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



Community Health Center Eligibility



Section 340B (a)(4)(A)

“A Federally-qualified health center (as defined in section 1905(1)(2)(B) of the Social Security Act).”



340B Enrollment Steps



1. Determine Eligibility
2. Complete Appropriate Forms
3. OPA verifies scope of grant
Registration information **MUST** match the EHBs
4. Await Decision From OPA



340B Enrollment



The following dates represent ***new*** enrollment deadlines that will begin on October 1, 2012.

Registration Period	January 1- January 15	April 1- April 15	July 1- July 15	October 1- October 15
Start Date	April 1	July 1	October 1	January 1

The enrollment deadline for this current quarter is September 1st in order to be eligible for October 1st.



340B Enrollment



- Once enrolled, the newly participating entity must:
- Set up an account with wholesaler using 340B ID
 - Determine if contract pharmacy services are appropriate
 - Contact HRSA's Pharmacy Services Support Center (PSSC) for assistance with any/all technical issues
 - Contact the 340B Prime Vendor Program (PVP) to discuss participation in their added services.



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 - bill 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.



340B Database



- Entities are not eligible for the program 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
- Includes the Medicaid Exclusion File
- Online registration available for all applicants
- <http://opanet.hrsa.gov/opa/default.aspx>



Recertification



- Required by Statute
- Ensure program integrity, compliance, transparency and accountability
- Ensure accuracy of covered entity information in the 340B database
- **It is the covered entity's responsibility to ensure the accuracy of the information in the 340B database**



- Current
 - FQHC grant eligibility
 - DSH percentage quarterly
 - Ownership status quarterly
- Began phased implementation of annual recertification
 - Ryan White Programs, STD/TB – completed
 - Family Planning - completed
 - Hospitals – completed
 - FQHC – anticipated January 2013



340B Recertification Steps



1. Ensure all information in 340B Database is accurate and prepared for recertification via change request form
2. Only Entities that have been in the system at least 12 months will be required to recertify
3. Email with user name and Password will be mailed to the Authorizing Official and primary contact listed for the parent covered entity
4. Authorizing Official for Parent will be required to recertify for Parent and all Outpatient Facilities/satellite sites/sub-grantees/sub-contractors and contract pharmacies associated with the covered entity



Recertification steps cont.



5. Authorizing Official will be required to certify and update any information that is not complete. As the database has progressed throughout time, more requirements have been added and additional information may be required to be entered by Authorizing Official
6. Once Authorizing Official has completed any additional program updates they will “Certify” that their information is true, accurate, and that the covered entity will be in compliance with all program requirements.
7. HRSA/OPA will review certifications and verify-**ALL INFORMATION MUST MATCH THE EHBs**
8. HRSA/OPA will Recertify or Decertify the Covered Entity



340B Recertification Steps



- Keys to successful recertification?
 - Verify contact information is up to date in the 340B Program database
 - Update all information in EHBs
 - Submit 340B Program change form to update entity information
 - Monitor 340B Program webpage and your email prior to recertification
 - Do not mistake change form for recertification



Covered Entity Responsibilities



During recertification, the covered entity will attest to the following:

1. All information listed on the 340B Program database for that covered entity is complete, accurate, and correct;
2. the covered entity meets all 340B Program eligibility requirements;
3. the covered entity is complying with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity;
4. the covered entity maintains auditable records demonstrating compliance with the requirements described in paragraph (3) above;



Covered Entity Responsibilities cont.



5. the covered entity has systems/mechanisms in place ensure ongoing compliance with the requirements described in (3) above;
6. if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement is being performed in accordance with OPA requirements and guidelines including, but not limited to, that the covered entity obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the covered entity has utilized an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism);
7. the covered entity acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any material change in 340B eligibility and/or material breach by the covered entity of any of the foregoing; and
8. if the entity does not notify OPA in a timely fashion, the entity acknowledges that it may be required to remit payment back to manufacturers which would represent the difference between the 340B discounted price and the drug's non-340B purchase price.



Program Integrity & Recertification



Program Prohibition: Diversion



- Diversion means:
 - a drug is provided to an individual who is not a patient of that entity
 - a drug is dispensed in an area of a larger facility that is not eligible (e.g. an inpatient service, a non-covered clinic)
 - Entities must enroll all eligible outpatient or satellite sites
- Required to follow patient definition guidelines - 61 Fed. Reg. 55156 (October 24, 1996)



Program Prohibition: Duplicate Discounts



- Duplicate Discount = Accessing the 340B Discount and Medicaid Rebate on same drug
- Safety-net providers required to inform HRSA (by providing their Medicaid billing number) at the time they enroll whether they plan to purchase and dispense 340B drugs for their Medicaid patients and bill Medicaid.
- HRSA maintains this list known as the Medicaid Exclusion File on HRSA's public website
- Final Notice, Duplicate Discounts and Rebates on Drug Purchases published at 58 Fed. Reg. 34058 (June 23, 1993)



Program Integrity Current Activities



- Determination of eligibility
- Annual Recertification
- Quarterly calculations of 340B prices
- Maintenance of Medicaid Exclusion File
- Investigations/resolutions of alleged drug diversion and incorrect pricing/inappropriate limits on drug access
- Technical Assistance, webinars, FAQs, guidances



Policy Releases



- Penny Pricing – Nov. 2011
- Non-discrimination – Nov. 2011, May 2012
- Manufacturer audits – Nov. 2011
- Covered entity audits – March 2012
- ACOs – May 2012
- Medicaid exclusion file
- Hospital eligibility requirements



- All covered entity types will be considered for random audit selection, including non-HRSA grantees and the hospitals
- Audit Proposed Focus Areas:
 - Eligibility status
 - Policies and procedures – procurement, inventory, distribution, dispensing, billing
 - Internal controls
 - Policies, procedures, & records – Diversion
 - Procurement & distribution – duplicate discount
- One pager on audit process available at <http://www.hrsa.gov/opa> - Program Integrity page



- Authority
 - Reasonable cause
 - Independent auditor
- Submit audit workplan to OPA prior to conducting - December 12, 1996 (61 Fed. Reg. 65406)
- OPA encourages manufacturers to submit plans and we will work closely with them throughout the process



A-133 audits and Site visits



- A-133 compliance supplement now includes 340B Program compliance questions
- Grantee site visits will include 340B Program compliance questions beginning FY 2013



340B Peer to Peer Program



Bob Brown

Pharmacy Manager

Travis County Health Care District

Central Texas Community Health
Centers



What is the 340B Peer to Peer Program?

- Technical assistance in an all teach all learn environment
- Upcoming Webinar
 - 340B and the 'C-suite': What Leadership should know about 340B August 22, 2012 2:00pm ET
- Past Webinars
 - Audit
 - Contract Pharmacy
- Healthcare Communities tools
- How to sign up? <http://pssc.aphanet.org/p2network/>



Patient Safety and Clinical Pharmacy Services Collaborative (PSPC)



- Ties together 340B medication access with safe medication use systems
- Quality improvement effort aimed at improving health outcomes and patient safety
- Driven by community based organizations and interprofessional teams who are supported by local, regional, state partnerships
- Starting 5th year (in partnership with CMS)
 - Had over 200+ teams participate in our 4th year
- How to sign up?
<http://www.hrsa.gov/publichealth/clinical/patientsafety/index.html>



340B Resources



Pharmacy Services Support Center (PSSC)

- <http://pssc.aphanet.org>
- Contract with the American Pharmacists Association
- Services to 340B covered entities
 - Free Technical Assistance
 - Program development
 - Information and analysis
 - Relationships and networking
 - Peer to Peer Learning and Support



340B Resources



Prime Vendor Program (PVP)

- <http://www.340bpvp.com>
- No cost to participate
- Drug price negotiation services
 - Discounts on over 3500 covered drugs
 - Discounts average 15% below 340B ceiling prices
- Multiple wholesale distributor agreements
- Favorable discounts on other pharmacy related products/service



340B Resources



Office of Pharmacy Affairs (OPA)

Phone: 301-594-4353 or 1-800-628-6297

Web: <http://www.hrsa.gov/opa>

<http://www.hrsa.gov/patientsafety>

Pharmacy Services Support Center (PSSC)

Phone: 1-800-628-6297

Web: pssc.aphanet.org

Prime Vendor Program (PVP)

Phone: 1-888-340-2787

Web: <http://www.340bpvp.com>



Questions?