Disclosures

- Krista Pedley, Sherry Pontell, Allison Gross, Patrick Barnes, and Amanda Eamigh declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Learning Objectives

- Outline important HRSA updates regarding the 340B Drug Pricing Program
- Review entity’s eligibility documentation and reporting requirements of the 340B Drug Pricing Program
- Outline the components of an effective internal audit plan regarding 340B eligibility
- Discuss processes that Peer Mentors from the 340B Peer-to-Peer Program use to self-audit
- Describe a covered entity’s responsibility to provide contract pharmacy oversight

Which of the Following is a Fundamental Element of Being Able to Use the 340B Program?

- Be listed on the 340B Database
- Serve uninsured low income patients
- Be authorized through a qualifying grant or federal hospital designation and listed on the 340B Database
- Be a non-profit health organization
To Participate in the 340B Program, a DSH Hospital Must Monitor Which Eligibility Requirement(s)?

- DSH adjustment percentage (exceeds minimum threshold)
- GPO prohibition
- Departments/services listed as reimbursable cost centers on Medicare cost report
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Pertaining to Hospital Registration, Which Statement is True?

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Which Process Best Describes Effective GPO Compliance Review?

- The hospital determines which pharmacy purchasing accounts are established.
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- Ensure that the contract pharmacy has policy and procedures for 340B drug distribution
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- Verify purchase invoices periodically

340B Drug Pricing Program Update:

Captain Krista Pedley, Director of Office of Pharmacy Affairs, Health Resources and Services Administration

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340B Audit Update and Satisfying Eligibility Requirements

March 4, 2016
Sherry Pontell
Branch Chief, Program Performance & Quality
Office of Pharmacy Affairs
Healthcare Systems Bureau
Health Resources and Services Administration
U.S. Department of Health and Human Services

Improvements in Program Integrity

- Processes and Protocols
- Desk audits
- Training and Education
- Supplemental Site Visit Questionnaire
- Manufacturer audits

Things to Know About Audits

- Responsibility for 340B Program compliance
  - Plan for oversight
  - Policies and procedures compliant with 340B Program requirements
  - Contract Pharmacy contracts
- Have a plan to test
- National Drug Code (NDC) matching
- Disagreements
- Corrective Action Plan (CAP)
- Resources

HRSA Audits by the Numbers
as of February 2016

<table>
<thead>
<tr>
<th></th>
<th>FY 2012</th>
<th>FY 2013</th>
<th>FY 2014</th>
<th>FY 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of covered entities audited</td>
<td>51</td>
<td>94</td>
<td>99</td>
<td>200</td>
</tr>
<tr>
<td>Outpatient facilities/sub-grantees</td>
<td>410</td>
<td>718</td>
<td>1476</td>
<td>2720</td>
</tr>
<tr>
<td>Contract pharmacies</td>
<td>860</td>
<td>1937</td>
<td>4028</td>
<td>4443</td>
</tr>
<tr>
<td>Number of finalized reports</td>
<td>51</td>
<td>94</td>
<td>99</td>
<td>178</td>
</tr>
</tbody>
</table>

Types of HRSA 340B Audits

- 1. Randomized/Risk-based
  - Complex program administration
  - Number of child sites
  - Volume of purchases
  - Contract pharmacy arrangements
- 2. Targeted
  - Allegations of violations

Program Integrity

Areas of Focus

- Eligibility
  - Group Purchasing Organization (GPO)
  - Auditable records
- Duplicate Discount
- Diversion
HRSA Audit Steps

Pre-Audit
- Engagement letter
- Scheduling
- Data request

Onsite Audit
- Opening Meeting
- Staff interviews
- Data sample review

Post-Audit
- Preliminary findings
- Notice and Hearing
- Final Report
- CAP
- Attestation

Eligible Health Care Organizations: Covered Entities

- HRSA-supported health centers and look-alikes
- (RW) clinics and State AIDS Drug Assistance programs
- Medicare/Medicaid Disproportionate Share Hospitals
- Children’s Hospitals
- Other safety net providers

Requirements for eligibility are listed on the HRSA OPA website under the Eligibility and Registration section.

To Participate In the 340B Program

- Health organization must meet all 340B Program eligibility requirements, including the group purchasing organization (GPO) prohibition that applies to certain entity types.
- All sites/clinics/departments participating in the 340B Program must be eligible AND registered on OPA 340B Database with accurate information.
- Once listed on 340B Database, covered entity can purchase 340B drugs using their 340B ID.

Qualified Covered Entity Types

Covered Entities

- Grantees (non-hospitals)
- Hospitals
**Eligibility Supporting Documentation**

**Grantees:**
- Health Centers (RW)- HIV/ AIDS Specialized Clinics

**NOTICE OF GRANT AWARD**
- Active grant corresponding to registration
- Qualiﬁed period of the grant
- Scope of the grant
- List of approved program service sites/clinics
- 'Receipt for goods exchanged' document for TB/STD

HRSA, EHB, CDC

**Hospitals:**
- **MEDICARE COST REPORT:** DSH percentage, reimbursable cost centers
- Articles of incorporation for non-proﬁt status and governance
- One of the following requirements/documentation:
  - Contract with state or local government to provide care to low income patients
  - Hospital certiﬁcation of ownership/operation by state or local government
  - Document issued by the government that reflects formal granting of governmental powers
- If applicable, purchasing accounts documentation to validate compliance with GPO prohibition

**Eligibility Supporting Documentation**

**Compliance with the GPO Prohibition**

- Applies to DSH's, PED's, and CAN's
- A hospital subject to the GPO prohibition and registered on OPA 340B Database may not purchase covered outpatient drugs through a GPO for any of its clinics/departments within the four walls of the hospital (same physical address) under any circumstance.
- Off-site outpatient facilities registered on OPA 340B Database may not purchase covered outpatient drugs through a GPO either, except in certain circumstances.

**Exception to GPO Prohibition Rule**

Select off-site outpatient facilities may use a GPO if **all four criteria are met**:
- Located at different physical address than parent
- Not registered on OPA 340B Database
- Purchase drugs through a separate pharmacy wholesaler accounts than the 340B participating parent; and
- The hospital maintains records demonstrating that any covered outpatient drugs purchased through the GPO at these sites are not utilized or otherwise transferred to the parent hospital or any outpatient facilities registered on the OPA 340B Database.

**340B and Non-340B Purchasing Accounts**

<table>
<thead>
<tr>
<th>340B</th>
<th>GPO</th>
<th>WAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligible outpatient</td>
<td>Inpatient</td>
<td>ineligible outpatient</td>
</tr>
<tr>
<td>Covered outpatient drug</td>
<td>Bundled drug</td>
<td>Lost charges</td>
</tr>
<tr>
<td>Non-drug/Supply</td>
<td>Off-site location</td>
<td>Wasted drug</td>
</tr>
</tbody>
</table>

Because the GPO Prohibition is a 340B Program eligibility requirement, records of covered outpatient drugs purchased using a non-GPO account constitute auditable records for hospital subject to the GPO prohibition.

**340B Database Information**

**For each site registered:**
- Entity name and addresses
- Authorizing Ofﬁcial
- Primary Contact
- Medicaid Exclusion File
- Contract pharmacies (if applicable)
**Contract Pharmacy Participation Requirements**

- Current service agreements
  - Active and executed
  - List of all current participating pharmacy locations
- Registration
  - After date of contract execution
  - Accuracy of agreement contact details
  - Contract pharmacy locations serving specific registered care sites

**Maintenance of Auditable Records Requirement**

- Maintenance of auditable records is a 340B Program eligibility requirement
- Records:
  - Eligibility/registration
  - 340B drug distribution

**340B Eligibility and Auditable Records**

- Auditable records include any documentation related to the eligibility, registration and drug purchases of the covered entity, child sites, and contract pharmacies

<table>
<thead>
<tr>
<th>Document Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare Cost Report</td>
</tr>
<tr>
<td>Notice of Grant Award</td>
</tr>
<tr>
<td>Contract Pharmacies’ contract</td>
</tr>
<tr>
<td>Contract with government</td>
</tr>
<tr>
<td>340B &amp; non-340B drug purchase reports</td>
</tr>
<tr>
<td>Policy &amp; procedures regarding procurement and GPO prohibition</td>
</tr>
</tbody>
</table>

**OPA 340B Database Timeline**

<table>
<thead>
<tr>
<th>REGISTRATION Period:</th>
<th>340B Drug Use Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 1-15</td>
<td>January 1</td>
</tr>
<tr>
<td>January 1-15</td>
<td>April 1</td>
</tr>
<tr>
<td>April 1-15</td>
<td>July 1</td>
</tr>
<tr>
<td>July 1-15</td>
<td>October 1</td>
</tr>
</tbody>
</table>

**Annual 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

**Contact Information**

Office of Pharmacy Affairs (OPA)
Main Office Phone Line: 301-443-4353
Web: www.hrsa.gov/opa

Prime Vendor Program (PVP)
Phone: 1-888-340-2787
ApexusAnswers@340bpvp.com
Web: www.340bpvp.com
Effective Internal Audit Plan Regarding 340B Site Eligibility

Entity Self-Audit: Areas of Focus
- Sites Eligibility
- Group Purchasing Organization
- Diversion
- Duplicate Discount
- Contract Pharmacy

Elements of Eligibility Self-Audit
- Verify each site eligibility
- Validate accuracy of each site registration
- Check compliance with GPO Prohibition (if applicable)
- Confirm contract pharmacy registration and oversight

Verify Sites Eligibility
- Grantees
- Hospital

Testing Entities Eligibility and Registration
- Review eligibility requirements for specific entity types and locations where 340B drugs are used.
- Confirm the registration and accuracy of covered entity information in the OPA Database.
  - Identify all locations using 340B drugs (prescribed, administered, dispensed)
  - Clinic recently closed
  - Contract pharmacy terminated

340B Database Information To Be Reviewed
For each site registered:
- Entity name and addresses
- Authorizing Official
- Primary Contact
- Medicaid Exclusion File
- Contract pharmacies (if applicable)

Monitor OPA 340B Database entity information at least quarterly.

All information included in the OPA 340B Database must be accurate and up-to-date.
### Ensuring Accuracy of Registrations is Critical

- **Verify correct names, addresses of specific sites:** physical location versus billing and shipping addresses for 340B drugs, for corresponding 340B ID.
- **Ensure appropriate Authorizing Official (AO) listing:** the same individual should not be listed as both the hospital's AO and the Primary Contact.
- **Validate eligibility of off-site outpatient facilities registered or using the 340B Program:** most recent Medicare cost report to verify that the department/clinic/unit is listed as a reimbursable outpatient cost center.

### Ensuring Accuracy of Registrations

- **Verify separate registration for each service off-site the parent:** HRSA requires individual registrations of each service within hospital participating off-site outpatient facilities. Not applicable to grantees that have to register each clinic at a unique physical address.
- **Identify the worksheet A/C cost center line(s) associated with each off-site outpatient site/service registration**
- **Changes in hospital type should be treated as a new registration**

### Validating Hospital Sites Eligibility to Participate in 340B Program

<table>
<thead>
<tr>
<th>Identify</th>
<th>Verify</th>
<th>Participate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital's Clinics/ Departments/ Units Using 340B</td>
<td>Eligible if Reimbursable Outpatient Cost Center On Medicare Cost Report (Worksheets A/C)</td>
<td>Registered on OPA 340B Database Under Parent site (if within four walls of hospital) As separate child site (if located in off-site facility; separate registrations required)</td>
</tr>
</tbody>
</table>

### Verifying Contract Pharmacies Participation Requirements

- **Verify Contract Pharmacy contracts dates and locations registered**
- **Verify Contract Pharmacies registered are being utilized**
- **Review Contract Pharmacy policies and procedures exist at the covered entity**
- **Ensure compliance oversight activities are documented**

### Process Used by Peers to Self-Audit: Validate Site Eligibility

**Shands Jacksonville Medical Center at a Glance**

- 695 Bed academic medical center
- 19 Child sites
- 1 Ambulatory pharmacy
- Carve-in Medicaid
- Hospital mixed-use setting
How Do You Ensure that Your Organization is Ready to Demonstrate Site Eligibility?

- What is the process?
- Who participates?

System and Process to Validate Eligibility Requirements

- Multi-point review to ensure that eligibility requirements are met for each location area that utilizes 340B drugs
- Team involved: pharmacy, compliance, and finance departments
- Periodic review: three times per year
- Medicare Cost Report
- All child sites carefully reviewed
- Update as needed

Testing for Eligibility & Registration at a Disproportionate Share Hospital

- DSH site with outpatient facilities registered
- Eligible as a DSH:
  - Medicare Cost Report: DSH adjustment percentage >11.75%
  - Non-profit private hospital with a contract with the city of Jacksonville to provide care to low income individuals

Shands Jacksonville – OPA Database
Shands Jacksonville – OPA Database

Entity Eligibility Requirements Reviewed
Identify all locations using 340B drugs
- Parent entity
  - Outpatient service units within the four walls of the hospital
  - One ambulatory closed door pharmacy
  - One mixed use pharmacy
- Nineteen child sites
  - Off-site clinics
  - Reimbursable on the cost report

Self-Audit Process Key Points
- Team involved: Pharmacy, finance, and compliance department
- Several times per year
- Obtain a copy of Medicare Cost Report annually
- All child sites carefully reviewed
- All 340B Database profiles carefully verified
- Network within your facility: Keep connected with the decision makers of your entity
- Educate on the 340B Program

Contract Pharmacy Oversight

DuBois at a Glance

- Entity Type: Disproportionate Share Hospital (DSH): DuBois, Critical Access Hospital (CAH): Brookville
- GPO Prohibition: Yes, N/A
- Child sites: 27, 6
- CONTRACT PHARMACIES: Yes, Monthly, Yes
- Medicaid: Yes, Monthly
- Parent/Child Contract Pharmacy: Yes, Monthly
- Self-Audits: Yes, Monthly
- External Audits: Annual External Audit
- HRSA OPA 340B Audit: Yes, no findings

Dubois – Contract Pharmacy
- Dubois Regional Medical Center determined that utilizing the contract pharmacy program to increase access to affordable medications for patients would be a first step in promoting health with medication access and compliance.
Contract Pharmacy Oversight

- Covered entities are required to provide oversight of each contract pharmacy arrangement utilized to dispense 340B drugs (75 Fed. Reg. 10272 (Mar. 5, 2010))

Lack of oversight of each contract pharmacy can result in entity’s contract pharmacy removal from 340B database.

Oversight Areas of Focus

- Contract Pharmacies meet eligibility requirements (Covered Entity’s relationship with the Contract Pharmacy), and are properly registered.
- Covered Entity has policies & procedures for Contract Pharmacy oversight monitoring.
- Covered Entity is performing annual monitoring of each contract pharmacy: performing internal pharmacy oversight and/or independent audit at least annually.

Contract Pharmacy Eligibility Testing

- Written agreement(s) reflecting all contract pharmacy locations
- Contract pharmacy is actually being utilized (otherwise terminated)
- Documentation that covered entity has performed oversight of its contract pharmacy since registering the pharmacy(ies)
- Written policies and procedures for the contract pharmacy arrangements, including procedure(s) for oversight activities and actions the covered entity is taking to ensure 340B Program compliance

Review Covered Entity’s Contract Pharmacy Policies and Procedures

Review of Policies and procedures

- Process for review of contract pharmacy eligibility
- Processes for prevention of diversion: site eligibility location and “patient definition” met for all 340B dispensations
- Mechanism to prevent duplicate discounts at the contract pharmacies for outpatient prescriptions
- Processes of conducting oversight of contract pharmacies:
  - Internal audits
  - External/independent audits

DuBois Contract Pharmacy Registration in OPA 340B Database
### Contract Pharmacy Self-Audit Policies and Procedures Also Include

- **Frequency** of self-audit
- **Staff responsible** for self-audit
- **Compliance elements being monitored**
  - Database review: 340B Database accuracy pertaining to contract pharmacies registration – names, addresses, utilized if listed as active
  - How audit results will be documented and reported
  - How errors found will be communicated and corrected
  - How transactions will be selected and testing performed

### Additional Internal Contract Pharmacy Oversight Monitoring

- **Review of transactions** to ensure that the covered entity’s 340B purchased drugs are provided to eligible patients only; diversion has not occurred.
- Review of transactions for compliance with prevention of duplicate discounts; billing to Medicaid has not resulted in duplicate discounts.
- **Reconciliation of 340B drugs purchased against eligible prescriptions** sent to contract pharmacies.
  - If physical inventory at the contract pharmacy: Physical count of 340B drugs in stock to ensure that all 340B purchased drugs are accounted for.

### Contract Pharmacy 340B Compliance Oversight Required

- Oversight is the responsibility of the covered entity and cannot be substituted by a vendor or contract pharmacy’s own self-monitoring.
- Lack of contract pharmacy oversight could result in all covered entity’s contract pharmacies being removed from the entity’s 340B Database record.

### In Practice, Assess Eligibility & Accuracy of 340B Database

- **All contract agreements/amendments** (past and present) are accessible
- Contracts include: list of each contract pharmacy location, cross reference of specific entity location(s) to specific pharmacy location(s), service begin date(s), service termination date(s)
- All contracts executed (signed and dated)
- Entity’s policies and procedures describe how often the contracts are reviewed or updated

### DuBois Self Audits

- **Monthly**
  - Test transactions from each contract pharmacy to verify eligibility and replenishment of 340B drugs
  - Verify Medicaid billing for contract pharmacy program.
- **Semi-annually**
  - Review OPA Database
- **Quarterly**
  - Verify accumulation files for 340B and GPO
  - Communicate results to Compliance Oversight Committee

### Testing Contract Pharmacy Inventory Replenishment

1. **Eligible Prescription**
2. Drug Replenishment Level reached
3. **Drug replenished to Contract Pharmacy**
4. **Physical or Virtual replenishment**
5. **Inventory Validated by Covered Entity**
6. **Invoices paid by Covered Entity**
Entity Must Have Vigilant Oversight Of Its Contract Pharmacies

• Must confirm eligibility, prevent diversion and prevent duplicate discount.
• Must have written policies and procedures
• Must have tracking systems.
• Must have auditable records.
• Must perform periodic self-audit
  – An annual Independent Audit is “Expected”
• Violations must be disclosed to HRSA

Questions?

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