STAY ENGAGED. STAY INFORMED.

TUESDAY, MARCH 21:
340B COMPLIANCE & AUDIT PREP
WELCOME

Anthony Pudlo, PharmD, MBA, BCACP
Vice President of Professional Affairs
Iowa Pharmacy Association
Kelly Kolker, RPh
Senior Manager of Pharmacy Services
Health Enterprises
HRSA 340B AUDITS

Understanding the Audit Process to Maintain a Compliant 340B Program
AGENDA

- Review of key compliance areas
- HRSA audits background
- Preparing for an audit
- Audit Updates from the field
KEY COMPLIANCE AREAS

- Diversion
- Eligibility
- Duplicate Discounts
HRSA AUDITS BY THE NUMBERS

• Since 2012 – 600+ HRSA audits completed
• Number of audits conducted annually increasing
• % of audits with at least one finding – 65%
• % of audits requiring repayment to manufactures – 65%
• entities have been removed entirely from 340B Program
HRSA AUDIT TRIGGERS

- Risk-based
- Targeted
- Allegations of non-compliance by manufacturer or public
COMMON AUDIT FINDINGS

HRSA AUDIT FINDINGS

- DSH %: 1%
- AUDITABLE RECORDS: 1%
- ORPHAN DRUG: 2%
- CP OVERSIGHT: 4%
- GPO EXCLUSION: 11%
- DUPLICATE DISCOUNTS: 25%
- INCORRECT DATABASE: 42%
- DIVERSION: 51%

Source: 340B Health, 2017
HRSA AUDITS UNDER THE BIZZELL GROUP

• HRSA contracted with the Bizzell Group to audit 340B covered entities effective October 1, 2016.
• Bizzell auditors are primarily pharmacists or pharmacy technicians.
• Process is generally the same
• Transaction level testing (approximately)
  – 35 Contract pharmacy
  – 35 In-house pharmacy
  – 25 entity administered/dispensed samples
HRSA AUDITS UNDER BIZZELL GROUP

- Pre-audit Data Request
- Audit 30 samples per setting
- Target several high cost items

- Eligible provider
- Eligible location
- Entity retains responsibility for care

- Contract Pharmacy Oversight
- Duplicate Discounts
- Accumulations and ordering process
BIZZELL GROUP AUDITORS ALSO FOCUS ON:

1. **Replenishment Process**
   - Review accumulators
   - Corresponding 340B Purchase

2. **Credentialing**
   - Match credentialing dates to sample scripts/orders

3. **Invoices and Purchase Orders**
   - Demo creating and sending order
   - Speak with purchaser

4. **Prescriptions**
   - E-script
   - Hard copy from contract pharmacy
HRSA AUDIT TIMELINE

• Day 1-3
  – HRSA Audit letter
  – Bizzell email from Auditor(s)
  – Schedule Welcome/Pre-Site Visit Call
• Day 3-7
  – Welcome/Pre-Site Visit call
  – Turn in Information request form prior to call
• Day 10
  – Turn in data request
• Day 30-60
  – Onsite portion of audit
Notice of 340B Drug Pricing Program Audit From HRSA:

- Attached to email from 340baudit@hrsa.gov
- Purpose of HRSA 340B audits
- Scope of the audit
- No conclusions or recommendations given by auditor
- Covers self-disclosures made between receipt of notice and the on site audit
- Items required by auditor during the on-site audit
Notice of 340B Drug Pricing Program Audit from Bizzell Group

- Bizzell Group email from @thebizzellgroup.com
- Introduction to auditor
- Pre-site visit call instructions
- Information Request Form
- Data Request Form
- On-site audit dates
Pre-Site Visit Call

- Call will last approximately 30 minutes
- The audit coordinator and your specific auditor will be on the call
- Confirm participation in 340B Program and review the purpose of the audit
- Confirm dates of the audit again
- Auditor will review specific items listed on the Data Request Form, how to submit (NIH Portal, file format)
- Confirm what EMR in use, # of contract pharmacies, # of child sites
- Auditor will review who needs to be available for the on site portion of audit
- Entity will have the opportunity to ask any questions
## Data Request – Covered Entity (CE)

1. **Policies and procedures**
   - A. CE registration/recertification and ensuring that the 340B database is up-to-date
   - B. Description of procurement process (including contract pharmacy, if applicable)
   - C. Prevention of GPO violations (applies only to DSH, PED & CAN)
   - D. Definition of covered outpatient drugs, including any exclusions
   - E. CE’s process for conducting oversight of its contract pharmacy(ies)
   - F. How the CE accounts for 340B inventory or replenishment/accumulation (including NDC matching), if applicable
   - G. Prevention of diversion at CE and contract pharmacy – Process for confirming the following: site eligibility location, referral/responsibility of care remained with CE, medical/patient health record, patient eligibility (including status change), provider eligibility (relationship), consistent with the scope of grant (if applicable / non-hospital)
   - H. Mechanism to prevent duplicate discounts at CE, off-site outpatient facilities, and contract pharmacies with details explaining carve-in or carve-out status
   - I. When and how CE would self-disclose and CE’s definition of non-compliance material breach

2. Most recently filed (and applicable) Medicare cost report and trial balance documentation.
Data Request Form

3. 340B Universe: 340B Drug Orders or Prescriptions (include in-house and contract pharmacies)
   A listing of all 340B drug orders or prescriptions issued during the 6-month sampling period April 1, 2017 through September 30, 2017 – preferably in Excel format or another electronic format. The following data elements should be included:
   A. Unique identifying number – this is likely the RX number, but can be any number you assign that will allow tracking through your system to retrieve all information associated with the order
   B. The drug/product name/NDC
   C. The acquisition price
   D. The type of account the drug was purchased through and the associated 340B ID number
   E. The quantity issued
   F. The patient id number
   G. The payer (All payers including Medicaid)
   H. The date of the order and date it was dispensed or administered
   I. The ordering provider
   J. The location/site 340B drug was administered/ordered/prescribed
   K. Whether the drug was dispensed/or used, reversed, or returned to stock

Description of the 340B Universe:
The CE should include a narrative describing the methodology, by which the data was gathered, and any limitations or exclusions (e.g. whether reversed transactions, or any other elements, were excluded or other 340B orders or dispenses, were direct purchases included or other purchasing mechanisms).

A sample of prescriptions will be selected for testing while the audit team is on site. For the selected items, individual records will need to be available in either electronic or paper format. If electronic health records are utilized, please provide an individual with system knowledge to navigate the EHR. Scans of hardcopies of selected documents may be requested to be uploaded to the NIH Secure Site
4. CEs should be prepared to show the auditor proof of employment, contract, or credentialing for providers during the audit.

5. A listing of CE’s wholesalers and 340B drug purchase orders made between dates of selected time frame, including price paid.

6. A listing of contract pharmacies utilized, and the current contracts individually identifying each contract pharmacy.

7. A copy of any self-disclosures made to the Office of Pharmacy Affairs since the beginning of the audit timeframe.

8. A listing of all accounts used to purchase drugs for the parent and off-site outpatient facilities, which includes locations dispensing or distributing 340B drugs and a description of the applicable pricing (340B, GPO, WAC, CSOS, Other).

9. A listing of all clinics and locations where health care services are provided to individuals for which the CE deems itself responsible for the health care services provided for purposes of meeting 340B eligibility.

10. A listing of all Medicaid billing numbers and NPI numbers utilized to bill Medicaid for 340B drugs (include out-of-state Medicaid billing numbers and the state associated with that number, if applicable).

11. If the hospital has a contract with a State or local government to provide health care services to low income individuals, provide a copy of that contract.
# On-Site Audit Agenda

**THE BIZZELL GROUP**

**Agenda**

**HRSA 340B Program Audit**

<table>
<thead>
<tr>
<th>Date: March 22, 2017</th>
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</thead>
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<table>
<thead>
<tr>
<th>Time</th>
<th>HRSA:</th>
<th>Entity:</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00 am - 9:30 am</td>
<td>Introduction and purpose of site visit. Provide sample(s) to entity.</td>
<td>Introduction of participants.</td>
<td></td>
</tr>
<tr>
<td>9:30 am - 10:30 am</td>
<td>Review CHCCC sites eligibility, overall utilization of 340B drug Program, and 340B drug operations and environment.</td>
<td>Provide overview of entity, pharmacy operation and 340B Drug Pricing Program.</td>
<td>Entity staff with knowledge of 340B Program administration</td>
</tr>
<tr>
<td>10:30 am - 12:00 pm</td>
<td>Provide tour of clinic and pharmacy setting. Provide demonstrations of processes for inventory, dispensing, and procurement of drugs. Provide information regarding pharmacy systems used (e.g., software, equipment).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12:00 pm - 12:30 pm</td>
<td>Lunch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12:30 pm - 5:00 pm</td>
<td>Review and analysis of samples.</td>
<td>Provide answers and/or documentation to questions during sample review.</td>
<td>Entity staff with knowledge of EHR, pharmacy, split billing, vendor and billing software. Credentialing staff.</td>
</tr>
<tr>
<td>5:00 pm - 5:30 pm</td>
<td>Day 1 exit conference</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## On Site Audit Agenda

<table>
<thead>
<tr>
<th>Date: March 23, 2017</th>
<th>Time</th>
<th>Activity</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8:30 am - 9:00 am</td>
<td>HRSA: Provide outline of audit activities for the day. Ask the entity clarifying questions identified during the audit process. Entity: Provide answers and/or documentation to questions during sample review.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9:00 am – 10:00 am</td>
<td>HRSA: Review and analysis of samples. Entity: Provide answers and/or documentation to questions during sample review.</td>
<td>Entity staff with knowledge of EHR, pharmacy, split billing, vendor and billing software. Credentialing staff.</td>
</tr>
<tr>
<td></td>
<td>10:00 am – 1:00 pm</td>
<td>HRSA: Walkthrough of the covered entity’s child site and contract pharmacy. Observe and ask questions regarding processes and systems. Entity: Provide tour of clinic and pharmacy setting. Provide demonstrations of processes for inventory, dispensing, and procurement of drugs.</td>
<td>Child site TBD on day 1</td>
</tr>
<tr>
<td></td>
<td>1:00 pm – 1:30 pm</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1:30 pm - 3:30 pm</td>
<td>HRSA: Review and analysis of samples. Entity: Provide answers and/or documentation to questions during sample review.</td>
<td>Credentialing staff.</td>
</tr>
<tr>
<td></td>
<td>3:30 pm - 4:00 pm</td>
<td>Break</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4:00 pm - 5:00 pm</td>
<td>HRSA: Ask follow up questions raised during audit. Entity: Provide answers and/or documentation to questions raised during audit.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5:00 pm - 5:30 pm</td>
<td>Exit Conference No results will be provided by the auditor. Results of the audit report will be provided in a Final Report issues by the Office of Pharmacy Affairs (OPA).</td>
<td>The covered entity should keep any sampling information from the audit in case it is needed as a reference to respond to OPA’s Final Report.</td>
</tr>
</tbody>
</table>

* All times are subject to change

**Auditor is unable to provide comment or suggestion regarding entity's 340B Program practices**
AUDIT PROCESS

• Entrance meeting
• Introductions
• Highest priority is to ensure compliance requirement through verification of:
  – Eligibility
  – Prevention of diversion through adequate processes
  – Prevention duplicate discount
  – Verify eligibility of samples (Auditor provides samples)
ON-SITE AUDIT PROCESS

• Tour of onsite pharmacy and clinic
• Clinic visit
• Pharmacy visit
  – Ask to see non 340B and 340B inventory and checks in place to keep them separated
  – Speak with pharmacists about their program
  – Spot checking of specific drugs
PRESCRIPTION/ORDER REVIEW

✓ Outpatient Status
✓ Rx written in eligible location
✓ Hospital responsible for patient’s care
✓ Provider is employed, credentialed, contracted by hospital
✓ Medicaid billing
TIPS FOR A SMOOTH ONSITE VISIT

• Contact 340b Administrator and independent auditor upon notification from HRSA
• Have a team work ahead
• Notify contract pharmacy and clinics that HRSA will be visiting
• Know who your referral docs are
  – Referral documentation is critical
TIPS FOR A SMOOTH ONSITE VISIT

• Have credentialing in the entrance meeting and begin to pull providers on transaction samples
• Member of IT present or extremely close to conference room
• Answer auditor questions without elaborating
AUDIT REPORT & BEYOND

• OPA reviews the auditor’s findings & writes final audit report
• Report sent to entity via email from HRSA
• CE has 30 days from receipt of report to submit any disagreements and supporting documentation
• CE has 60 days from receipt of report to submit a corrective action plan (CAP)
• If CAP is not submitted, CE risks removal from 340B Program
CORRECTIVE ACTION PLAN

• Provide immediate remedy
• Propose plan for periodic assessment, continuous monitoring, and method to determine when CAP is completed
• Identify implementation date
• Devise internal 340B communication/education strategy
• Provide entity contact person
• HRSA to provide a general outline dependent on type of finding
REPAYMENT TO MANUFACTURER

- Entity is responsible for identifying and contacting each manufacturer to discuss methods of repayment
- HRSA will post a public notice on the 340B Program website to inform manufacturers of violations that have occurred. Notice will include a summary of findings and CE contact information
CLOSING THE AUDIT

- Letter of attestation submitted to OPA
  - CAP fully implemented
  - Settlements with manufacturers finalized
  - Any necessary repayments made
AUDIT ACTION PLAN

- Identifies who within and outside of the organization needs to be contacted upon receipt of a HRSA audit notification
- Key resources: Authorizing Official, Primary Contact, 340B Coordinator, Director of Pharmacy, Contract Pharmacy representatives, consultants, IT support
- Identify location of or how to access pre-audit data request information
- Identify roles for pre-audit through closing of audit
AUDIT ACTION PLAN

• Understand replenishment process and 340B Software
• Notify Contract Pharmacies
• Notify Purchasing agent
• Notify Credentialing office
QUESTIONS

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THANKS FOR ATTENDING!

JOIN US TUESDAY, APRIL 10:
MODERNIZING THE PMP - PREVIEW
AWARxE PLATFORM

Questions? Contact David Schaaf at dschaaf@iarx.org or 515-270-0713