WELCOME TO 340B UNIVERSITY!
The mission of Apexus is to leverage our unique resources and expertise to deliver maximum value to 340B stakeholders

• Contract for the lowest sub-ceiling drug prices

• Support **YOUR** program compliance and integrity
Goals of 340B University

- Support HRSA’s integrity initiatives with the 340B program
- Support the 340B PVP and other stakeholders’ need in providing a comprehensive program that assists in implementing compliant 340B pharmacy operations, consistent with HRSA’s interpretation
- Train new employees within the 340B covered entities
- Clarify misinformation received from unreliable sources
Goals of 340B University

- Continuously refreshed to reflect the latest HRSA policy and guidance
  - Contract pharmacy arrangements
  - Orphan drugs
  - Medicaid
- **ONLY** training program endorsed by HRSA
  - Ensures consistency with HRSA’s interpretation of 340B policy
- Program integrity and compliance for all stakeholders
Faculty Yearbook

Todd Karpinski  Rusol Karralli  Rob Nahoopii  George Oestreich
Faculty Yearbook

Fern Paul-Aviles
Katheryne Richardson
Donavan Smith
Larry Stepp
Staff Yearbook

Sara Cooper  
Lisa Sokol  
Meagan Thompson
HRSA’s intent remains consistent: To permit covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

It is more critical than ever to ensure that all 340B providers are carefully documenting their savings with this program, and how it aligns with the program’s intent.
HRSA-Supported Tools & Resources

- Apexus Answers call center
- Peer-to-Peer program & webinars
- Many others
340B BASICS FOR HOSPITALS
Objectives

1. Learn 340B basics
2. Apply basic 340B concepts to practice
3. Share pearls from faculty and attendees
1. 340B PROGRAM
340B Statute

• Resulted from a **1992 federal statute**, administered by the Health Resources and Services Administration’s (HRSA) Office of Pharmacy Affairs (OPA)

• Manufacturers participating in Medicaid Drug Rebate Program must sign a **Pharmaceutical Pricing Agreement (PPA)** with the Secretary of Health and Human Services
  
  – The manufacturer agrees to charge a price for covered outpatient drugs that does not exceed the 340B price
Major 340B Stakeholders

Manufacturer
- Calculate and offer 340B price

Entity
- Provide 340B access

HRSA
- Administer 340B program

340B Drug to Patient
### 340B Eligible Entities

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- Calculated quarterly
  - Average manufacturer price (AMP)
    - Medicaid unit rebate amount (URA)

340B ceiling price

- Manufacturer submits data to CMS
340B Price, with PVP Savings = Lowest in the Marketplace

Adapted from a slide by Safety Net Hospitals for Pharmaceutical Access
Source: Data derived from Prices for Brand-Name Drugs Under Selected Federal Programs, Congressional Budget Office (June 2005)
340B Covered Outpatient Drugs

Vaccines

Inpatient drugs

Drug not directly reimbursed

FDA doesn’t require NDC

Outpatient drugs

Over-the-counter drugs (with a prescription)

Clinic administered drugs

Biologics

Insulin

HRSA 340B Database: Statistics

  - January 2015
  - 29,752 registered sites: 14,533 are non-hospital sites
  - 16,257 unique contract pharmacies

- >$7.5B/year in 340B drug purchases
2. 340B PROGRAM INTENT
340B Intent

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

Question

Do you have a statement in your policies and procedures describing how your use of 340B aligns with the program intent?
Purpose: This tool is designed to allow entity leaders to have a framework to help guide the written documentation of 340B savings.

See Handout Page 13

Pearls

- How would you collect this financial data?
- What sorts of things do entities consider “benefit”?
- When and how have entities used this information?
3. PARTICIPATION IN 340B
To Participate in 340B, an Entity must...

1. Ensure it has the capability to follow (and maintain auditable records documenting compliance with) program rules

2. Register on the HRSA 340B Database

3. Recertify with HRSA annually
Registration Process

• New entities, entity sites, contract pharmacies, Medicaid information
  – 2 week registration periods, quarterly updates made to HRSA 340B Database

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• Change requests: changes to existing information, rolling basis
340B Eligible clinics should be reimbursable

340B Eligibility if line 33 shows DSH% >11.75 or ≥8%, depending upon hospital type

Hospital ownership/control on line 21

Date and time of eligibility-signature block

Shows outpatient charges
Pearls

- Entities **DO NOT** need to log into the HRSA 340B Database
- All links referenced on the homepage are accessible without a username & password
- The 340B ID is the most reliable search criteria
Recertification

- Entities are required to recertify information in the HRSA 340B Database annually
- HRSA sends a notification email to authorizing official and primary contact
- The authorizing official performs the recertification online
Recertification Statements

• Database entry is complete, accurate, correct
• Entity meets 340B eligibility requirements
• Compliance with 340B requirements/restrictions
• Maintenance of auditable records
• Systems in place to ensure compliance
• Contract pharmacy compliance, entity obtains sufficient information
• Entity contacts HRSA for any breach of the above
• Entity acknowledges possibility of payment to manufacturers for failure to notify HRSA in timely fashion
Pearls

- Make sure your authorizing official knows the email is coming, knows what to do with it, and does NOT delete it.
- If you have a material breach of non-compliance, you may still recertify.
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4. THE PRIME VENDOR PROGRAM
Apexus Focus

CONTRACTING
340B Prime Vendor Program

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Assistance: Apexus Answers

- National 340B source of truth, communicates HRSA policy
- Staff in constant communication with HRSA to ensure messaging is consistent
- Average monthly interactions ~1,500-2,000
- Tiered levels of response: can handle from basic to complex
5. 340B PROGRAM OVERSIGHT/COMPLIANCE
Why 340B is like an onion…
340B Policy Options
1. Duplicate Discount Prohibition
2. No diversion (patient definition)
3. Certain hospitals only
   - Group Purchasing Organization (GPO) Prohibition
   - Orphan Drug Exclusion
Do you see a musician or a woman’s face?
Duplicate Discount Prohibition

340B price

Medicaid rebate
Preventing Duplicate Discounts
Patient Definition

• Records of individual’s care
• Health care services, health care professional
  – Employed by, under contractual or other arrangements (referral)
• Entity has responsibility for care
• Service received is consistent with funding or designation status (hospitals exempt)
• Services must be more than dispensing
• AIDS Drug Assistance Program (ADAP) exception
GPO Prohibition

• Applies to:
  – Disproportionate Share Hospitals
  – Children’s Hospitals
  – Free-Standing Cancer Hospitals

• Such hospitals:

  “...will not participate in a group purchasing organization or group purchasing arrangement for covered outpatient drugs as of the date of this listing on the HRSA website.”

  HRSA GPO Certification
Orphan Drug Exclusion

- Final rule published July 23, 2013, effective October 1, 2013
- Free-Standing Cancer Hospitals, Rural Referral Centers, Sole Community Hospitals, and Critical Access Hospitals
- Excluded from 340B: drugs used for the indication for which they received an orphan designation but not when the drug is used for indications independent of that designation
- OCT 2014: PhRMA files lawsuit challenging HRSA’s interpretive rule
- OCT 2014: HRSA sends letters to manufacturers instructing them to offer 340B prices, repay entities; HRSA interpretation has always been in effect
Apply It: Take Action

1. Apply the brief tool 340B Compliance Self-Assessment Policy to your entity type

2. Review FAQs on specific policy topics for more information

3. Contact Apexus Answers to help you resolve any questions or concerns
“Our hospital saves $60 Million a year on drug purchases because of 340B. We spend about $200,000 a year on resources to ensure 340B compliance. That includes auditors, 340B program manager, etc.”

- A DSH Hospital in the southern US
Tips for Pharmacy Technicians

- Check your 340B standard operating procedures to make sure they reflect your entity’s operations.
- If a new location/contract pharmacy are added to the HRSA Database, remember the quarterly deadlines.
- Remind leadership they are not required to log in to the HRSA 340B Database for change forms or to view profiles.
Takeaways

1. The intent of 340B: “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services”

2. Major 340B stakeholders: federal government, certain drug manufacturers, certain covered entities, 340B Prime Vendor Program (managed by Apexus)

3. Covered entities must register on the HRSA 340B Database; once a year they must recertify accuracy of HRSA 340B Database information
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- Change requests: changes to existing information, rolling basis
HRSA uses it for validation of site information

Electronic Handbook (EHB) data incorporated as part of recertification in February 2014

Importance of EHB changes and timing, especially changes of scope

Possibility of chargeback denial and/or wholesaler delivery issues if EHB doesn’t match HRSA and entity’s wholesaler information
Beginning October 2014 grantees with OSV
Will be asked to demonstrate compliance with the 340B program
Standard set of questions about 340B
  - Results reports directly to HRSA
  - Potential trigger for further investigation by HRSA

For more details on requirements: http://www.hrsa.gov/opa/updates/october2014.html
A CHC uses employed healthcare professionals to provide elderly care services at a non-entity owned clinic. The CHC owns the records of care. Should the CHC register this location on the 340B Database? Is 340B use permissible?
Pearls

- Entities **DO NOT** need to log into the 340B database
- The 340B ID is the most reliable search criteria
- Plan ahead for timing of EHB updates and impact of 340B registration
- Review 340B policies for upcoming OSV site visit
- Watch the 340B OnDemand registration module
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Why 340B is like an onion...
340B Policy Options
Major 340B Compliance Areas

1. Duplicate Discount Prohibition
2. No diversion (patient definition)
3. Certain hospitals only
   - Group Purchasing Organization (GPO) Prohibition
   - Orphan Drug Exclusion
Please step up to a microphone so everyone can hear your question.

Do you see a musician or a woman’s face?
Duplicate Discount Prohibition

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“Our CHC saves $2 Million a year on drug purchases because of 340B.

We spend about $75,000 a year on resources to ensure 340B compliance. That includes auditors, 340B program manager, referrals, specialist, etc.”

- A CHC in northern US
Tips for Pharmacy Technicians

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Questions
340B IMPLEMENTATION
MIXED-USE: GPO
Overview: Mixed-Use

• Mixed-use setting in a nutshell
  – In a mixed-use area, the entity dispenses/administers medications to both inpatients and outpatients from the same location (pharmacy)
  – Examples
    • Cardiac cath lab, one-day surgery, emergency department, endoscopy
GPO Prohibition

• Applies to:
  – Disproportionate Share Hospitals
  – Children’s Hospitals
  – Free-Standing Cancer Hospitals

• Such hospitals:
  “...will not participate in a group purchasing organization or group purchasing arrangement for covered outpatient drugs as of the date of this listing on the HRSA website.”

HRSA GPO Certification
Entities Must Ensure

- 340B is limited to **outpatients**
- Patients meet patient definition
  - Patient status = outpatient (at time of service)
  - Prescriber = eligible prescriber
  - Location of service = reimbursable on cost report, registered on 340B Database (if required)
- No GPO use for covered outpatient drugs for DSH/PEDs/CAN
- No duplicate discounts on Medicaid transactions
Split-Billing Software to the Rescue

- There is one physical drug inventory serving both inpatients and outpatients

- This software merges data from patient visits (date/time of service, patient status, prescriber, location/clinic, Medicaid status) to help split orders into the right buckets
Accumulators and Eligibility

Accumulator: GPO

- Inpatients

Accumulator/Default: Non-GPO/WAC

- 340B ineligible outpatients
  - Medicaid carve-out
  - Lost charges
  - Clinics within 4 walls but not 340B eligible
  - In-house pharmacy open to public

Accumulator: 340B

- 340B eligible outpatients
Consider This

What data do you feed into your split-billing software, and what is the source of the data?
## Wholesaler Account Setup

- **DSH/PED/CAN with GPO Prohibition**

### Inpatient

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<tr>
<td>- GPO Contract</td>
</tr>
<tr>
<td>- DSH Inpatient GPO Contracts (DSH only)</td>
</tr>
<tr>
<td>- GPO or Wholesaler Generic Source Program</td>
</tr>
<tr>
<td>- Individual Hospital Agreement</td>
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### Outpatient (not 340B eligible)

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<td><strong>Non-GPO/WAC</strong></td>
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<td>- WAC Pricing</td>
</tr>
<tr>
<td>- PVP Sub-WAC (if enrolled in PVP)</td>
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<td>- Individual Hospital Agreement (single entity only)</td>
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### Outpatient (340B eligible)

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Update: Account Load Options

GPO Prohibition and Wholesaler Non-GPO/WAC Account Load Options

A Feb. 7, 2013 HRSA Policy Release1 provided clarification for hospitals subject to the Group Purchasing Organization (GPO) Prohibition. Apexus is providing this document to facilitate 340B compliance in the marketplace; the information contained in this document is not legal advice.

Contracting: Avoid These Pitfalls

- The following situations are not GPO-compliant contracting practices:
  - An individual DSH accessing contracts executed by a network (i.e. IDN, ACO, etc.) in which it is a member
  - A wholesaler’s generic source program (unless offered as a subcontracted solution to the Apexus Generics Source portfolio)
  - A manufacturer extending a discounted price to a group of covered entities (subject to the GPO prohibition) through a wholesaler, other third party or group purchasing arrangement, that is not supported by an individual contract between the 340B covered entity and the manufacturer. Such agreements should be reproducible for review during an audit of compliant 340B.
GPO: Special Situations

- GPO private label products
- IVIG
- Drug shortages
Two Key Questions HRSA Will Ask

- What outpatient accounts do you have?
- How do you purchase drugs for ineligible outpatients?
Consider This

What is your biggest challenge regarding record-keeping/inventory management?
Mixed-Use Inventory/Record Keeping Challenges

- Steps to take
- Pitfalls to avoid
- Example
Tool: Minimizing WAC Exposure

Strategies to Minimize Unnecessary WAC Exposure
A Checklist for hospitals subject to the GPO Prohibition

PURPOSE: The purpose of this tool is to share strategies that hospital leaders have used to help minimize unnecessary WAC exposure. 340B hospitals subject to the GPO Prohibition (DSH, PEDs, CAN) are not able to use a GPO for covered outpatient drugs. These hospitals must use a non-GPO/WAC account for purchases for 340B ineligible outpatients.

• A few strategies to minimize WAC exposure
Q: Can a hospital subject to the GPO Prohibition use a GPO for drugs that are part of/incident to another service and payment is not made as direct reimbursement of the drug (“bundled drugs”)?

A: If the entity interprets the definition of covered outpatient drug referenced in the 340B Statute and decides that drugs do not meet this definition, a GPO may be used for drugs that are not covered outpatient drugs. The decision the entity makes should be defensible, consistently applied in all areas of the entity, documented in policy/procedures, and auditable.
In certain off-site outpatient hospital facilities that meet all of the following criteria:

1. Are located at a different physical address than the parent;
2. Are not registered on the HRSA 340B Database as participating in the 340B Program;
3. Purchase drugs through a separate pharmacy wholesaler account than the 340B participating parent; and
4. 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 HRSA 340B Database.

Strategy #2: GPO “Only” Clinics
Strategy #3: Waste/Lost Charges

• Expired/returns-return company policy, entity policy
• Waste/lost charges
  – Multi-dose vials, insulin
  – Mixed product, but patient doesn’t get dose
Strategy #4: Charge Code to NDC

• Charge code to the correct NDC
• Charge quantity to the package size
  – Procrit, e.g.
    • Billing unit: 1000 units
    • Vial size: 20,000 units/1 mL vial
    • Package size: 4 vials per box
    • How many billing units per package?
      – 1000
      – 20
      – 80
Tips for Pharmacy Technicians

- Stay up to date with Apexus sub-WAC price changes; sign up for Contract News Brief
- Educate your colleagues and identify ways to capture lost charges and expired drugs, to avoid unnecessary WAC exposure
- Ensure the CDM to NDC crosswalk stays updated
1. Carefully consider which options you elect if using split billing software
2. Take steps to minimize your WAC spend
3. Load correct contracts, including Apexus sub-WAC pricing
4. Define: inpatient, outpatient
5. Interpret: covered outpatient drug
6. Account: for waste and lost charges
Questions
340B IMPLEMENTATION IN-HOUSE PHARMACY
**Pharmacy Model Benefits**

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<td>Generally lower average operating costs (average $10-15 per prescription) after start up costs are covered.</td>
<td>Less staffing resources needed; need pharmacy point person and for monthly reporting and compliance.</td>
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<td>Pharmacy staff can contribute as part of patient care team, improving patient outcomes and meeting organizational goals.</td>
<td>Less risk for low volume clinics or those with very high rate of uninsured patients.</td>
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<td>Achieve higher capture rates for pharmacy; patients can be very loyal.</td>
<td>Low start up costs: no need for infrastructure development or licensing.</td>
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<tr>
<td>Able to keep uninsured costs very low.</td>
<td>No building space requirements.</td>
</tr>
<tr>
<td>Pharmacy can be community resource; retail business can increase business of pharmacy <em>and clinic</em>.</td>
<td>Use negotiated contracts of pharmacy partner; do not need to negotiate your own.</td>
</tr>
</tbody>
</table>
Pharmacy Model Challenges

<table>
<thead>
<tr>
<th>In-House, Owned Pharmacy</th>
<th>Contract Pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Higher start up costs.</td>
<td>Higher ongoing operational costs and potential need for 3rd party administrator, too.</td>
</tr>
<tr>
<td>Requires space within or immediately proximate to entity site.</td>
<td>Added cost for quarterly drug reconciliation costs.</td>
</tr>
<tr>
<td>Greater administrative resources required; need to develop space, get licensed and hire staff.</td>
<td>Less opportunity for clinical integration of pharmacy services and improved patient outcomes.</td>
</tr>
</tbody>
</table>

Note: Pros and Cons are offered as generalizations and are not mutually exclusive. Entities can have *owned* and *contracted pharmacy* programs.
In-House Pharmacy Considerations

- What are the entity goals of creating a pharmacy program?
- Would your volume and payer mix support an in-house pharmacy?
- Consider types of clinical services offered or special populations served by entity
- Would your community benefit from a retail pharmacy?
In-House Pharmacy Operation

- **340B Account**
  - Retail Account

- **340B Inventory**
  - Retail Inventory

- **340B Patient**
  - Retail Patient

- **340B Provider**
  - Retail Provider

- **340B Billing**
  - Retail Billing

- **In House Pharmacy**

- **Wholesaler**

- **Patient**

- **Provider**

- **Billing**
Start-Up Steps

Planning, Design, Construction

Licensing and Accreditation

Inventory Model Choices

Carve-In vs. Carve-Out

Insurance Contracting

Wholesaler Negotiations

Pharmacy Operating System

Pharmacy Staffing Plan and Training

Policies and Procedures
Strategies for Growth: 12-month Start-Up Plan

1. Detail strategies to achieve growth rate
2. Educating patients and prescribers to use pharmacy
3. Added value services for clients
4. Tracking and reporting on progress
5. Sales and Marketing
In-House Pharmacy Keys to Success

- Staffing Considerations
- Manage Accounts Receivable
- Maximize Technology & Workflow
- Regulatory Compliance Plan

Optimize Savings Control Costs
Investments to increase pharmacy efficiency and improve 340B compliance

- Pharmacy operating system
- Robotic dispensing devices
- Barcode scanning through dispensing and check-out processes
- Interactive voice / text response
- Telepharmacy
## Control Costs

### Cost of Goods
- Cost of goods reviewed at every order
- Quarterly price changes
- Apexus Prime Vendor Program (PVP)

### Perpetual Inventory System with Par Levels
- Monthly unused drug report
- Quarterly drug level check
- Labor as a percent of sales
Eligibility and Registration

- A grantee has a new clinic that opens March 15th
- It must be added to the Electronic Handbook (EHB) prior to registration in the HRSA 340B Database.

What steps have to be taken before the clinic can begin using 340B?
Referral Prescriptions

- If we refer a patient to an outside clinic, can we fill their prescriptions from our 340B clinic?
Demonstrating “Responsibility for Care”

- Some examples of auditable records for a 340B prescription resulting from a referral prescription:

<table>
<thead>
<tr>
<th>Methods to help demonstrate responsibility for care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outgoing referral from covered entity</td>
</tr>
<tr>
<td>Incoming notes from outside provider</td>
</tr>
<tr>
<td>Shared EMR access with outside provider</td>
</tr>
<tr>
<td>Referring returning patient for follow up encounter to review outside care</td>
</tr>
</tbody>
</table>
CE maintains a list of providers who could prescribe at non-entity location.

Pharmacy should have means to verify entity address of floaters:
- Use provider address check
- Without means to verify floater’s address - NO 340B drugs should be used.
Compliance Considerations

- **Eligibility verification at filling**
  - Real-time access to patient and provider eligibility information

- **Retail inventory**
  - Right inventory to right person

- **Hospital prescriptions**
  - Do you have responsibility for care?

- **Specialist prescriptions**
  - Documentation of outgoing referral and incoming
Compliance and Business Reporting

End of Month Reporting:
- Weekly
- Monthly
- Quarterly

- Billing for all prescription
- Matching return-to-stock to correct account
- Patient and provider eligibility
- Inventory to match dispensations
- Duplicate discounts
Case Discussions

Thank You!
A patient came to our pharmacy with prescriptions from a local hospital discharge. Can we fill these prescriptions with 340B drugs?

1. Is the person an active patient of the health center?
2. Is your health center provider medically responsible for the care related to these prescriptions?
3. Does your health center have a contract with prescriber?
In-House Case #2: Provider

We have a cardiologist that sees health center patients once a month because we have no specialists in the area. Can the health center use 340B to fill these prescriptions?

1. Does the health center contract with the specialist to provide services to the patients?

2. Is the health center medically responsible for the care provided by the specialist to the patients?
The local mental health providers send uninsured patients to our pharmacy if they can’t afford prescriptions. Under what circumstances can we fill them?

1. Is the person a patient of the health center?

2. Can you verify documentation of a referral from the health center to the specialist and report back from the specialist?
May we use 340B for the Medicaid managed care patients and bill regular rates (U&C)?

1. What information do you need to know to make this decision?
Our health center provides dental and primary care. A patient presents to the pharmacy with two prescriptions, (Rx #1) is from a health center dentist for an antibiotic and (Rx #2) is for birth control from a non-health center OB/GYN provider.

1. Can 340B inventory be used for the antibiotic?
2. Is the health center medically responsible for the care provided by the OB/GYN to the patient?
Tips for Pharmacy Technicians

- Prior to dispensing prescriptions, verify prescriber and clinic/location for 340B eligibility
- Ensure your entity’s policy for referrals is reflected in the 340B standard operating procedure
- Ensure that your pharmacy operations are reflective of your state’s Medicaid 340B billing policy and HRSA 340B Database entry
1. The entity is responsible for compliance
2. Understand your state’s Medicaid billing policy (ambulatory, physician administered)
3. Identify the key policies and procedures that are needed to support your 340B program
4. Continually review 340B program and conduct self-audits to maintain program compliance
Questions
340B IMPLEMENTATION FOR RURAL HOSPITALS
Orphan Drug Update

- JUL 2013: HRSA publishes first final 340B regulation
- SEP 2013: PhRMA sues HRSA on basis regulation is outside of HRSA’s scope of authority
- MAY 2014: Judge vacates rule on the basis HRSA didn’t have authority to issue the regulation
- JUN 2014: HRSA stands by its position in the regulation as an “interpretive guidance”
- JUL 2014: HRSA issues new interpretive guidance, PhRMA asks judge to invalidate interpretive guidance or determine if it should survive
- AUG 2014: Judge does not invalidate interpretive guidance; PhRMA will have to file a new suit in order to challenge the interpretive guidance
- OCT 2014: PhRMA files lawsuit challenging HRSA’s interpretive rule
- OCT 2014: HRSA sends letters to manufacturers instructing them to offer 340B prices, repay entities; HRSA interpretation has always been in effect
Orphan Drugs/340B Eligibility

- What could the process look like for repayment from manufacturers to entities (for 340B prices not offered)?
- Which vendors are currently supplying you with orphan drugs at 340B pricing?
- What information and discussions have you had about orphan drugs and 340B pricing with suppliers and wholesalers?
- Will the orphan drug ruling impact your decision to participate in 340B – why or why not?
- What process does your wholesaler use to ‘block’ orphan drugs in the 340B account?
- Do you maintain a list of NDC numbers for orphan drugs?
Purpose: This sample document provides suggested fields to report to HRSA when a 340B price is unavailable for a product.

Instructions: Stakeholders may enter data in each field that describes their experience with the unavailable 340B price(s).
• Does your organization use an outside, third-party auditor, and how often?

• Within the organization, who has overall responsibility for the 340B program – pharmacy, finance, compliance?

• What procedures do you have in place for self-auditing?

• How often do you conduct self-audits and how often are policy and procedures reviewed?
Contract Pharmacy

- How do you handle identified non-eligible transactions with a contract pharmacy?
- What process does your contract pharmacy use to block orphan drugs?
- How do you determine contract pharmacy terms?
- Comment on pharmacy benefits manager (PBM) contracting/challenges
Medicaid

• How do you handle MCO patients?
• Do your sites carve-out or carve-in for Medicaid and why?
• How does your organization handle patients from different/surroundings states regarding Medicaid?
Replenishment/Inventory

• How do you handle expired medications and returns?
• Does your organization link multiple NDC to one charge code or does each NDC have its own charge code?
• How do you monitor your vendor in relation to crosswalk, accumulations/qualifications, and purchases? How are you made aware of changes in billing units/package sizes made by the vendor?
• How do you address borrow/loan issues for emergencies?
General

• How does your entity use 340B savings?
• How do you create your provider list?
• How do you handle referral prescriptions?
• How do you determine qualified orders in your entities Infusion center?
• How do you use pharmacy technicians to assist with 340B compliance, purchasing, or clinical programs?
• Review HRSA’s new registration changes.
Questions
340B PRICING
Objectives

• Identify the activities of the manufacturer and wholesaler in 340B pricing
• Explain 340B price calculation for covered outpatient drugs
• Discuss the manufacturer and wholesaler perspectives on policy issues
Panel Question

What are the 340B-related roles and responsibilities for you and your organization?
Manufacturer: Role/Responsibilities

- Uphold responsibilities in the pharmaceutical pricing agreement
  - Calculate and charge a correct PHS Price
  - Ensure that you charge the price to valid 340B entities
- Validate customers on indirect sales (chargebacks) to the HRSA Database (eligibility)
## Pharmaceutical Pricing Agreement

<table>
<thead>
<tr>
<th>HRSA Responsibilities</th>
<th>Manufacturer Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Public list of 340B entities, including Medicaid information</td>
<td>• Charge 340B entities a price that does not exceed the 340B ceiling price</td>
</tr>
<tr>
<td>• Require entities to maintain purchasing/dispensing records for covered outpatient drugs and Medicaid reimbursement for these drugs for not less than 3 years</td>
<td>• Retain necessary records for not less than 3 years from date of creation</td>
</tr>
<tr>
<td></td>
<td>• Afford Secretary (or designee) reasonable access to records relevant to compliance</td>
</tr>
<tr>
<td></td>
<td>• Permit CMS to share AMP and URA with Secretary in order to carry out agreement</td>
</tr>
<tr>
<td></td>
<td>• Participate with HRSA 340B Prime Vendor Program (voluntary)</td>
</tr>
</tbody>
</table>
Wholesaler: Role/Responsibilities

- Open accounts with only eligible entities
- Deliver correct price to 340B entities
- Process chargebacks with manufacturer correctly
Manufacturer Question

How is the 340B price calculated?
Manufacturer: 340B Calculation

- 340B price based on quarterly Medicaid metrics which are based on commercial contracting practices

**AMP: Average Manufacturer Price**
- For most drugs, it’s the weighted average price (net of discounts) to retail community pharmacies

**BP: Best Price**
- Lowest price to US customers, certain federal pricing, such as 340B, excluded

**URA: Unit Rebate Amount**
- **Brand:** Greater of [(AMP * 23.1%) or (AMP – BP)] plus inflation penalty
- **Generic/OTC:** 13% of AMP
Manufacturer: 340B Calculation

- 340B ceiling price

\[\text{WAC} - \text{AMP} \text{ minus } \text{URA} \text{ equals } \text{340B Unit Price} \times \text{Units per Package} \text{ equals } \text{340B Ceiling Price}\]
Manufacturer: 340B Implementation

- **Quarterly pricing**
  - 340B prices change quarterly
  - Manufacturers upload to authorized wholesalers 15-30 days prior to beginning of a quarter
  - 340B pricing lags behind Medicaid by two quarters

<table>
<thead>
<tr>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales transactions occur</td>
<td>Q1 AMP and BP calculated, submitted to CMS; 340B ceiling price calculated, submitted to wholesalers</td>
<td>340B ceiling price becomes effective (based on Q1 transactions)</td>
</tr>
</tbody>
</table>
Why is my 340B price different from another 340B entity’s price?
Panel Question

How do you implement a chargeback?
1. 340B price is established
2. Wholesaler purchases at WAC ($10)
3. Covered entity places 340B order with wholesaler
4. Wholesaler reviews HRSA 340B Database, then sells to covered entity at 340B price ($6)
5. Wholesaler sends manufacturer a 340B chargeback ($4)
6. Manufacturer verifies 340B eligibility of covered entity (reviews HRSA 340B Database)
7. Manufacturer pays wholesaler the chargeback

Potentially significant Medicaid implications if a manufacturer provides the 340B price to a non-participating entity
1. 340B Pricing changes quarterly: unique and challenging
   - 340B is the most challenging price file to administer in the pharmaceutical industry

2. No “verified” central file of all 340B pricing
   - Wholesale distributors receive more than 100 different notices from manufacturers, 4 times per year
   - PVP does provide a comparative price file to Participants which shows the Big 3 and one regional wholesaler’s 340B pricing for comparison
3. Contract pharmacy and entity identification:
   - HIN, DEA, 340B ID

4. Returns:
   - The correct invoice must be chosen when returning a product
Manufacturer: Chargeback Comments

- Manufacturer **MUST** validate entity on the chargeback to confirm 340B eligibility
- Manufacturer will deny the chargeback if they can not validate eligibility
  - “Bill to” address on the chargeback identifies eligibility
  - Correct information is critical
Manufacturer Question

What types of adjustments do manufacturers make to their Medicaid, AMP and BP?
Manufacturer: AMP/BP Pricing Adjustments

- Standard procedures
  - Routine Medicaid restatements
  - AMP and standard BP true-ups
- Medicaid restatements resulting from audits/investigations
- Reclassification/banking
What steps does an entity take to resolve what it believes to be an incorrect 340B price?
What is the procedure used by manufacturers that wish to refund payment to covered entities who are overcharged for 340B?
Panel Question

What are special situations or challenges for you specific to 340B?
Manufacturer: Special Situations

- Penny pricing
- Sub-ceiling prices (voluntary)
  - Through 340B Prime Vendor Program (non-FAMP exempt)
  - Not through 340B Prime Vendor Program (include in non-FAMP)
- Inpatient pricing
- Product allocation systems
  - 340B customers can be subject to product allocation systems just like commercial customers
- Non-discrimination guidance
  - Timing issues
  - Concern about hoarding
If a drug is only available through a specialty distributor or pharmacy, how would a 340B patient access that drug?
Wholesaler: Contract Pharmacy Challenges

- Complex 340B contract pharmacy relationships present additional challenges
- Manufacturer requirements are not consistent regarding 340B sales reporting for 340B contract pharmacy
- Process:
  1. Confirm accurate “bill to” 340B covered entity and “ship to” (contract pharmacy) information specific to the relationship on the HRSA website
  2. Request HIN (5-7 business days)
  3. Account Set Up (Multi-Ship To Form/Customer Application)
  4. Set ordering/delivery options
  5. Covered Entity Authorization
  6. Complete Credit Application if new customer
  7. Verify licenses, CSMP setup
  8. Set up EDI specific to 340B vendor
Apply It: Take Action

- Keep HRSA 340B Database information accurate/current to avoid chargeback issues
- Check the [HRSA website](http://www.hrsa.gov) for manufacturer updates
Tips for Pharmacy Technicians

• Log in to the Apexus website (www.340BPVP.com) to verify pricing, run customized reporting, and keep up-to-date with new contracts

• Communicate pricing changes to leadership; significant price changes may impact purchasing decisions
Takeaways

• Manufacturers and wholesalers have important roles in supporting program integrity
• Manufacturers have 340B compliance responsibilities
• The 340B price file is one of the most complex
• Actions entities take can impact a manufacturer’s calculations and ultimately impact the manufacturer’s compliance
Questions
340B IMPLEMENTATION
CONTRACT PHARMACY
Objectives

1. Learn about the following 340B delivery models:
   - Contract Pharmacy
   - In-House Pharmacy
   - Mixed-Use Areas (hospital only)

2. Apply decision points to your arrangements
   - Entity-Contract Relationship
   - Contract Negotiations
   - Compliance Safeguards

3. Share implementation strategies
Pharmacy Options

- Pharmacy Services
  - Mixed-Use
  - Contract Pharmacy
  - In-house Pharmacy
  - Other
    - Single Contract
    - Multiple Contract
    - Supplement with Contract
    - Clinic Administered Drugs
    - Central Fill, Telepharmacy or Specialty Pharmacy
## Contract Pharmacy vs. In-House Pharmacy

<table>
<thead>
<tr>
<th>Contract Pharmacy</th>
<th>In-House Pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Contracts with covered entity (CE) to provide services to its patients, including dispensing of entity-owned drugs</td>
<td>• Owned by, and a legal part of, the 340B entity</td>
</tr>
<tr>
<td>• CE must have a written contract aligning with compliance elements in guidance</td>
<td></td>
</tr>
<tr>
<td>• Bill-to/Ship-to arrangement</td>
<td>• Typically listed as shipping addresses</td>
</tr>
<tr>
<td>• Registered on 340B database</td>
<td>• Not eligible to be listed as child site</td>
</tr>
</tbody>
</table>
340B Contract Pharmacy – Overview

- HRSA guidance permits entities to partner with outside pharmacies to provide eligible patients with 340B medications
  - Identification via shared patient and provider data
  - Inventory via "Bill To - Ship To" wholesale arrangements
Contract Pharmacy Inventory Management

Separate Inventory
- Simpler maintenance
- Higher inventory costs

Replenishment Model
- Lower inventory costs
- Complex record-keeping
- Software needed

Simpler maintenance
Complex record-keeping
Lower inventory costs
Software needed
340B Contract Pharmacy Process

1. Contract Pharmacy dispenses drug (non-340B inventory) to 340B entity’s eligible patient

2. When a full package size of the Rx is reached, the pharmacy or vendor orders a 340B drug to replace it

3. Replacement 340B drugs are “billed to” the entity and “shipped to” the contract pharmacy

4. Entity pays contract pharmacy for its services
340B Contract Pharmacy Process

- Covered Entity
- Contract Pharmacy
- Switch
- PBM
- Patient
- Distributor
- Manufacturer
Implementation Decision Points

- Entity-Contract Relationship
- Contract Negotiations
- Compliance Safeguards
Considerations for selecting a contract pharmacy:

1. Sufficient volume of scripts to necessitate relationship
   - Trends in where organization’s scripts are being filled: location, chains, etc.

2. Existing arrangements with other entities

3. 340B vendor affiliations/exclusivity
Decision Point 1: Entity-Contract Relationship

1. Direct Contracting with a Pharmacy
2. Contracting through 340B Vendor

Role of 340B Vendor

- Minimizes impact on retail pharmacy workflow
- Provides the interface to identify eligible claims (matches entity data and pharmacy data)
- Reporting functions
- Manages inventory replenishment
- Retrospectively collects data from retail pharmacy at the switch
- Dependent on:
  - Contract terms
  - Quality and integrity of service delivery
  - Data submitted by covered entity
Roundtable Discussion

See Handout Page 7
Implementation Decision Points

- Entity-Contract Relationship
- Contract Negotiations
- Compliance Safeguards
Decision Point 2: Contract Negotiations

- Entities can negotiate the terms of their contract pharmacy agreements
- Entities to ensure contract terms support program integrity and aligns with program intent
Reasonable fee structure
- Pay flat fee per claim
- Stop-loss function
- Do not pay fees on claim reversals
- Pay lowest of U&C, MAC, and 340B

Transparent reporting
- Entity has access to ALL data

High complexity data management systems
- HL7 interface

Non-exclusivity
Contract Negotiations: The BAD

- Pay fees based on % of revenue or drug cost
- Entity does not keep 3rd party reimbursement
- Vendor recruits patients to its mail order pharmacy
- Early cancellation fees
- Not permitted to select wholesaler
- Purchase of partial bottles at high rates due to non-replenishment
- Not permitted to contract with other 340b vendors
Fee Structure Example

Scenario:

Self-Pay: Pharmacy shall collect and receive a $15 dispensing fee and a $1 administrative fee from patient

Insured: Pharmacy shall collect and retain 30% of the contracted rate + a $19 dispensing fee

Dispensing Fee: rates will increase according to the consumer price index yearly

• Is this a *reasonable* fee structure? Does this align with 340B program intent?
Share Pearls

• What do you wish you would have known prior to signing a contract with a pharmacy and/or vendor?

• Have you set up fee relationships with a contract pharmacy to provide discounts for your patients?
  – Cash Pay/Sliding Fee
PURPOSE: To enable participating 340B entity leaders to quickly assess the basic level of 340B program integrity contract pharmacy vendors will help the entity achieve, in selected areas.

INSTRUCTIONS: To use this tool:
Roundtable Discussion

See Handout Page 8
Implementation Decision Points

- Entity-Contract Relationship
- Contract Negotiations
- Compliance Safeguards
Reality of the Complexity

The flight of the bumblebee

Street science installation at the ScienceGallery in Dublin, Ireland that captures – literally – the flight of the bumblebee.
Decision Point 3: Compliance Safeguards

- CE responsible for ensuring compliance with all 340B requirements
- CE to determine the “HOW” in meeting compliance elements
  - Duplicate discounts
  - Diversion
Decision Point 3: Compliance Safeguards

- Independent Audits (External)
- Vendor Audits
- Internal Audits (By Covered Entity)
Tool: Independent Auditor RFP Checklist

340B Independent Audit
Request for Proposal (RFP) Checklist

Instructions: This tool is designed to provide entity leaders a checklist of action items to consider when developing a Request for Proposal (RFP) document to solicit proposals from external organizations to conduct 340B compliance audits on behalf of the covered entity, and in order to promote program integrity.

## Compliance Elements

<table>
<thead>
<tr>
<th>Operations</th>
<th>Diversion</th>
<th>Duplicate Discount</th>
<th>Auditable Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>• CE purchases and owns the inventory</td>
<td>• CP to establish and maintain a tracking system</td>
<td>• 340B drugs will not be subject to Medicaid rebates</td>
<td>• CP to provide reports consistent with customary business practices</td>
</tr>
<tr>
<td>• Comprehensive pharmacy services specified in agreement</td>
<td>• Establish system to verify patient eligibility</td>
<td></td>
<td>• Periodic independent audits performed by CE</td>
</tr>
<tr>
<td>• CE inform patient of freedom of choice of pharmacy provider</td>
<td></td>
<td></td>
<td>• Record of compliance with drug resale/transfer prohibition</td>
</tr>
<tr>
<td>• Federal, state, local law compliance</td>
<td></td>
<td></td>
<td>• Upon request, contract pharmacy service agreement to manufacturers</td>
</tr>
</tbody>
</table>

Compliance Monitoring Overview

1. Claim qualification
   - Patient definition
   - Charge capture

2. Inventory accumulation & replenishment

3. Billing

4. Policies and procedures
Compliance Monitoring: Data

- Data samples
  - First-time patients
  - Multiple providers
  - Ineligible prescriptions (i.e. Medicaid)

- Hardcopy prescriptions

- CP reports
  - Dispense to accumulation reports
  - Replenishment invoice
## Compliance Monitoring: Claim Qualification

<table>
<thead>
<tr>
<th>Monitoring Checklist</th>
<th>Data Reviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Patient definition</td>
<td>• Patient medical record</td>
</tr>
<tr>
<td>− Entity relationship with patient &amp; maintains records of his/her care</td>
<td></td>
</tr>
<tr>
<td>− Health care professional employed by entity or under contractual or other arrangements with entity</td>
<td></td>
</tr>
<tr>
<td>• Charge capture</td>
<td>• Entity provider list</td>
</tr>
<tr>
<td>− Does the patient have an encounter at clinic reimbursable on MCR within eligible window?</td>
<td></td>
</tr>
</tbody>
</table>
## Sample of Monthly Audit

<table>
<thead>
<tr>
<th>Date</th>
<th>Pt First</th>
<th>Pt Last</th>
<th>Billed MM</th>
<th>Pharmacy</th>
<th>Provider</th>
<th>Active</th>
<th>Rx #</th>
<th>Pass</th>
</tr>
</thead>
<tbody>
<tr>
<td>5/28/14</td>
<td>XXXX</td>
<td>XXXX</td>
<td>no</td>
<td>RA 10305</td>
<td>Buchsbaum</td>
<td>yes</td>
<td>1202869</td>
<td>yes</td>
</tr>
<tr>
<td>5/2/14</td>
<td>XXXX</td>
<td>XXXX</td>
<td>no</td>
<td>RA 10305</td>
<td>Bowen</td>
<td>yes</td>
<td>1176509</td>
<td>yes</td>
</tr>
<tr>
<td>5/18/14</td>
<td>XXXX</td>
<td>XXXX</td>
<td>no</td>
<td>RA 10305</td>
<td>Somberger</td>
<td>yes</td>
<td>1201566</td>
<td>yes</td>
</tr>
<tr>
<td>5/1/14</td>
<td>XXXX</td>
<td>XXXX</td>
<td>no</td>
<td>RA 10305</td>
<td>Lockhart</td>
<td>yes</td>
<td>1204278</td>
<td>yes</td>
</tr>
<tr>
<td>5/26/14</td>
<td>XXXX</td>
<td>XXXX</td>
<td>no</td>
<td>RA 10305</td>
<td>Elliott</td>
<td>yes</td>
<td>1182940</td>
<td>yes</td>
</tr>
<tr>
<td>5/24/14</td>
<td>XXXX</td>
<td>XXXX</td>
<td>N/A</td>
<td>RA 10305</td>
<td>Reversed</td>
<td>N/A</td>
<td>1201143</td>
<td>N/A</td>
</tr>
<tr>
<td>5/16/14</td>
<td>XXXX</td>
<td>XXXX</td>
<td>no</td>
<td>RA 10305</td>
<td>Patten</td>
<td>yes</td>
<td>1206596</td>
<td>yes</td>
</tr>
</tbody>
</table>

What other aspects of the prescriptions would you audit?
Scenario:

Pharmacy will update the patient and prescriber data once monthly, per data receipt from entity

- Is this frequency of updating appropriate?
- What kinds of data files could the entity use as sources for eligible prescribers/patients?
Scenario:

Prescriber eligibility is determined by a match to a prescriber “eligibility” list

• Is this enough? What additional information could be used?
## Compliance Monitoring: Inventory

<table>
<thead>
<tr>
<th>Monitoring Checklist</th>
<th>Data Reviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Matching prescription data in system with hard copy</td>
<td>• Hard copy prescriptions</td>
</tr>
<tr>
<td>• 11-digit NDC accumulated match 11-digit NDC dispensed?</td>
<td>• Dispense to accumulation data report</td>
</tr>
<tr>
<td>• Correct quantity accumulated</td>
<td>• Replenishment invoice</td>
</tr>
<tr>
<td>• Are accumulators manually adjusted for manual orders?</td>
<td></td>
</tr>
<tr>
<td>• Claim reversals in accumulators</td>
<td></td>
</tr>
</tbody>
</table>
## Compliance Monitoring: Billing/SOPs

<table>
<thead>
<tr>
<th>Monitoring Checklist</th>
<th>Data Reviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The claim should not be billed to Medicaid FFS</td>
<td>• CP claim dispensing report</td>
</tr>
<tr>
<td>• Standard Operating Procedures (SOP) consistent with practice?</td>
<td>• Policies and procedures</td>
</tr>
<tr>
<td></td>
<td>• Results from covered entity administered audits of contract pharmacies</td>
</tr>
</tbody>
</table>
**Scenario 4**

The contract will include patients with private insurance. Contract definitions of private insurance includes Managed Care Medicaid Plans.

1. How can you find out if your state collects Medicaid rebates on MCO drugs?
2. If your state collects rebates on MCO drugs, is this language appropriate to include in the contract?
Roundtable Discussion

See Handout Page 9
Takeaways

• Do not outsource your 340B compliance responsibilities to another party

• Entities can negotiate the terms of their contract pharmacy agreements

• The intent of 340B is to stretch scarce federal resources as far as possible to help entities and their patients
340B & MEDICAID
Objectives

- Review how a duplicate discount is created and how to prevent them
- List action steps to review compliance with the duplicate discount prohibition
- Share leading practices regarding compliance with the duplicate discount prohibition and Medicaid reimbursement
Duplicate Discount Prohibition

340B price

Medicaid rebate
### Medicaid Exclusion Terminology

<table>
<thead>
<tr>
<th>Carving In</th>
<th>Carving Out</th>
</tr>
</thead>
<tbody>
<tr>
<td>340B</td>
<td>340B</td>
</tr>
<tr>
<td>Medicaid</td>
<td>Patient</td>
</tr>
</tbody>
</table>

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How does the Medicaid Exclusion File work?

Manufacturer ➔ Entity ➔ Medicaid Exclusion File ➔ Medicaid Rebate ➔ State

340B Discount
**HRSA, CMS & State 340B Policy**

**HRSA Policy**
- Prevent duplicate discounts
- Use the Medicaid Exclusion File
- Bill according to the state policy (no HRSA AAC requirement)

**CMS Policy**
- Collect rebates on claims (including MCO and clinic administered)
- 340B drugs are not subject to these rebate collection requirements

**State Policy**
- How will duplicate discounts be prevented in the state?
- How will 340B entities bill Medicaid and how will Medicaid reimburse these entities when using 340B drugs?
Who uses the Medicaid Exclusion File?

Covered Entities:
Designating if they will be billing the state for 340B drugs

State Medicaid Agencies:
To exclude 340B claims from their rebate requests to manufacturers

Manufacturers:
To verify denial of payment of Medicaid rebates for 340B claims
HRSA 340B Database: Medicaid

You must answer the following question regarding Medicaid Billing:

Will you bill Medicaid for drugs purchased at 340B prices?  
- Yes  
- No
Actions to Review Duplicate Discount Prohibition Compliance

1. Verify the HRSA 340B Database is accurate
2. Contact your state Medicaid agency to ensure you understand state requirements
3. Determine way to account for retrospective Medicaid eligibility
4. Perform a self audit of Medicaid prescriptions
5. Ensure you do not use 340B for Medicaid patients at a contract pharmacy unless you’ve notified HRSA of an arrangement to prevent duplicate discounts
Medicaid Reimbursement Leading Practices

What states are doing:

- **Surrogate pricing model**
  - WAC-X% is maximum state pays, regardless of what is submitted

- **Rebate bill back**
  - State pays typical reimbursement, invoices entity for the rebate usually paid by manufacturer

- **MAC pricing of limited-use medications**
  - State sets MAC for a group of 340B drugs (ex. HTC)
Medicaid Scenarios

- Medicaid in one state required 340B entities to share with the state any 340B overcharge repayments from manufacturers to entities.

- Medicaid in another state announced mandatory “self-auditing” for 340B entities to determine/repay the state if the entity had ever billed Medicaid for a “non-covered outpatient drug” in the last six years. There was not a list of non-covered outpatient drugs provided to the entity.

- Medicaid in a different state announced it will not use the HRSA Medicaid Exclusion File, and instead uses NCPDP. Manufacturers are directed to work with entities regarding disputes.
Tips for Pharmacy Technicians

• Check the HRSA 340B Database listing to ensure the Medicaid information reflects practice

• Ensure Medicaid patients with retroactive eligibility are accounted for in 340B software/operations and treated consistently with standard operating procedures
Takeaways

1. Duplicate discounts are prohibited by 340B Statute
2. The entity can take action to check its compliance
3. There are leading practices emerging in the marketplace regarding Medicaid reimbursement
Questions
340B AUDIT PANEL
Objectives

• Explain the key points of the audit processes
• Describe current events in HRSA and manufacturer audits
• Discuss tools available to self-assess in preparation for an audit
HRSA AUDITS
HRSA vs. Manufacturer Audit of Entity

HRSA
- Eligibility
- Auditable Records
- GPO Prohibition

Diversion
Orphan Drugs
Duplicate Discounts

Manufacturer
Types of HRSA Audits of Entities

1. Randomized/Risk-based
   - Complex program administration
     • Number of child sites
     • Volume of purchases
     • Contract pharmacy arrangements

2. Targeted
   - Allegations of violations
HRSA Audit Steps

Pre-Audit
- Engagement letter
- Data request

Onsite Audit
- Entrance conference
- Pharmacy staff interviews
- Data sample review

Post-Audit
- Final Audit Report submitted by auditor
- HRSA finalizes report
- Corrective action plan
1. HRSA Notice and Hearing; entity has 30 days to review findings and HRSA’s request for CAP (if applicable);

2. If agree with report: 60 days to submit corrective action plan*; If disagree with report: notify HRSA in writing within 30 days with supporting documentation;

3. Audit Summary, public letter and corrective action, once approved, posted on HRSA website;

4. Results support education of covered entities

*If no corrective action plan within 60 days of final report, entity terminated
## HRSA Audits by the Numbers

<table>
<thead>
<tr>
<th></th>
<th>FY 2012</th>
<th>FY 2013</th>
<th>FY 2014</th>
<th>FY 2015* (As of Jan 15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of covered entities audited</td>
<td>51</td>
<td>94</td>
<td>99</td>
<td>33</td>
</tr>
<tr>
<td>• Outpatient facilities/sub-grantees</td>
<td>410</td>
<td>718</td>
<td>1,476</td>
<td>698</td>
</tr>
<tr>
<td>• Contract pharmacies</td>
<td>860</td>
<td>1,937</td>
<td>4,028</td>
<td>1,230</td>
</tr>
<tr>
<td>Number of finalized reports</td>
<td>51</td>
<td>75</td>
<td>18</td>
<td>0</td>
</tr>
</tbody>
</table>
### Example HRSA Audit Findings

<table>
<thead>
<tr>
<th><strong>Diversion</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>340B drugs dispensed at ineligible sites</td>
</tr>
<tr>
<td>Not spot checking inventory to check for diversions and correcting them (variance)</td>
</tr>
<tr>
<td>340B drugs dispensed at ineligible site and by an ineligible provider</td>
</tr>
<tr>
<td>340B drugs dispensed to non-patient at contract pharmacy</td>
</tr>
</tbody>
</table>
# Example HRSA Audit Findings

## Duplicate Discount

| Billing Medicaid contrary to HRSA Medicaid Exclusion File listing | 340B drugs used for Medicaid patients at contract pharmacy, with no arrangement to prevent duplicate discounts | Medicaid claims incorrectly coded when provided to the state | Incorrect Medicaid or NPI in HRSA Medicaid Exclusion File | Outpatient sites incorrectly listed on HRSA Medicaid Exclusion File |
### Example HRSA Audit Findings

#### Eligibility, Auditable Records

| Incorrect authorizing official | Primary location and contact information incorrect | Closed child sites remained registered; incorrect name listed for a child site | Incorrect address for facility, incorrect ship to address, pharmacy listed as entity with 340B ID | No written contract in place for contract pharmacies |
Audits – Manufacturer Conducted

- Authority
  - 340B statute, guidelines

- Requirements
  1. Reasonable cause
  2. Workplan to HRSA
  3. Independent auditor
  4. Limited to diversion/duplicate discounts

- HRSA has received 9 work plans
- HRSA works with them throughout the process

*Encourage manufacturers to share lessons learned*
ENTITY EXPERIENCE:
PREPAREDNESS & LESSONS LEARNED
HRSA Audit Steps

Pre-Audit
- Engagement letter
- Data request

Onsite Audit
- Entrance conference
- Pharmacy staff interviews
- Data sample review

Post-Audit
- Preliminary findings
- OPA finalizes report
- Corrective action plan
Have an Audit Team

340B Audit Team

- Pharmacy Leadership & Staff
- Information Systems & Technology Department
- Office of Credentials
- Compliance & Legal
- Executive Leadership “C-Suite”
- Internal Compliance Team
## Roles in Audit Preparedness - Internal

<table>
<thead>
<tr>
<th>Team Member</th>
<th>Pre-Audit/Data Request Role</th>
</tr>
</thead>
</table>
| Pharmacy Leadership & Staff       | • Policies and procedures; narratives of processes  
|                                   | • Copy of inventory report, total purchases under each contract  
|                                   | • Contracts with other pharmacies                                                           |
| Authorizing Official              | • Recipient of Engagement letter                                                             |
| Information System                | • Description of information systems  
|                                   | • Preparation of distinct data set                                                           |
| Government Reporting, Finance,    | • Most recently filed Medicare Cost Report  
| Legal                             | • Medicaid provider enrollment verification letter                                          |
| Internal Compliance/Audit         | • Internal audits                                                                            |
| Provider Credential Office        | • Eligible providers and provider contractual agreements                                     |
### Roles in Audit Preparedness - External

<table>
<thead>
<tr>
<th>Resource</th>
<th>Pre-Audit Role/Function</th>
</tr>
</thead>
</table>
| Third Party Administrator | • Provision of data extract  
|                   | • Sharing audit experience from other facilities  
|                   | • Available for questions relating to data analysis  
|                   | • Arrange availability for questions during audit                                      |
| Distributor      | • Provision of data extract                                                            |
| Apexus           | • Self-assessment tools  
|                  | • FAQs  
|                  | • Apexus Answers Call Center                                                           |
Pre-Audit Process

- Authorizing official notifies audit team of pending HRSA audit
- Identification of point person for HRSA communication
- Audit team meets and reviews audit period and data request
- Attend HRSA auditor conference call
- Contact State Medicaid office
340B Audit Survival Strategies

- Active engagement of leadership and accreditation and standards
- Ensure audit team understands all components of data request
- HRSA pre-audit conference call for questions/clarifications
- Discussion with similar facilities recently audited
- Use of Apexus’ 340B University tools/resources
HRSA Audit Steps

Pre-Audit
- Engagement letter
- Data request

Onsite Audit
- Entrance conference
- Pharmacy staff interviews
- Data sample review

Post-Audit
- Preliminary findings
- OPA finalizes report
- Corrective action plan
Setting the Tone

- Arrange room for audit
  - Laptops, projector, etc.
- Authorizing official and primary contact meet auditor to start audit
- C-suite attends entrance conference
  - Importance of program
  - Compliance is taken seriously
  - Resource commitment
- Confirm expectations and schedule with auditors
On-Site Audit Tips

• Ensure familiarity with policies and procedures
  – Make certain your processes validate P&P
  – Staff education

• Involve a very few experts who understand data sets and can maneuver through medical record efficiently
  – Some documentation in EMR may be mined from deep recesses

• Keep all documents/contracts/audits in one easily accessible location
  – Organize in same format as HRSA data request
On-Site Audit Tips

• Share processes through flow charts or diagrams to facilitate discussions with auditor
• Consider external and internal audit results that can be shared with auditor
• Have experts available who can respond to questions
  – Medicare Cost Report
  – Credentialing of professional staff
  – Billing office (Medicaid billing)
• Consider interaction with auditor as collaborative
Transaction Eligibility Testing

- ✔ Documentation of Rx/order in medical record with associated date of service
- ✔ Documentation that Rx/order was written by qualified provider
- ✔ Documentation that transaction came from eligible location
- ✔ Documentation of patient’s pattern of treatment at facilities
- ✔ Documentation of patient’s outpatient status at time of Rx/order transaction

All prescription/order samples reviewed meet all of the criteria above
GPO Prohibition

- GPO Exclusion
  - P&P defining process
  - Coordination / consult with distributor
  - Clearly defined purchase accounts for 340B, WAC & GPO
  - Appropriate use of account for type of setting
  - Audit of purchase levels
• Medicaid Exclusion File
  – Assist Medicaid agencies compliance with duplicate discount prohibition
  – Ensure MEF is populated correctly if carved in
    • State Medicaid number vs NPI
    • Institution NPI vs Pharmacy NPI
  – Communication with state Medicaid
HRSA Audit Steps

Pre-Audit
- Engagement letter
- Data request

Onsite Audit
- Entrance conference
- Pharmacy staff interviews
- Data sample review

Post-Audit
- Preliminary findings
- OPA finalizes report
- Corrective action plan
Post-Audit Steps

- No formal conclusions made on-site
- Types of outcomes
  - Areas for improvement
  - Adverse findings
    - Corrective action plans (CAP)
  - Removal from program
    - Lack of auditable records
    - GPO violations
    - No contract with a state or local government (if applicable)
    - Lack of submission of CAP if required
Corrective Action Plan (CAP)

- Provide immediate remedy
- Propose plan for periodic assessment, continuous monitoring, and method to determine CAP is completed
- Identify implementation date
- Provide entity contact person
- Devise internal 340B communication/education strategy
Types of Self Audit

• Annual mock HRSA/manufacturer audit
  – Policies and procedures
  – New/updated regulations
  – Organized communication
  – Billing Medicaid
  – GPO exclusion
  – HRSA website information

• Monthly mini-audits
  – Drug specific
  – Patient specific
  – Location specific

• Ongoing system audits
  – Pharmacy systems
  – Split billing systems
  – Billing systems

• Workflow audits
  – Interview staff
  – Identify knowledge gaps
  – Capture opportunities for systems failure (eg., borrowing)
Self-Disclosure

• Note: HRSA update on self disclosure 9/8/2014
• Entities to establish and document criteria of material breach of compliance
• Report violation issue to HRSA
  – “Self-Reporting 340B Non-Compliance”: suggested tool from Apexus website provides template
  – Include corrective action plan; strategy to inform manufacturers (if applicable)
• Work with manufacturer
  – Plan for financial remedy (if applicable)
• HRSA reviews self-disclosure and closes accordingly
Tool: Self-Audit

- Currently available for CHC, DSH, and Rural Hospitals

340B Compliance Self-Assessment: Self-Audit Process
A Sample Self-Audit Process for Community Health Centers

PURPOSE: To enable participating Community Health Center (CHC) leaders to determine a basic level of compliance for selected areas of the 340B pharmacy operations.

INSTRUCTIONS: Read the question under the column “Does Your Entity…?”

Roundtable Discussion

See Handout Page 11
Key Takeaways

• Entities can prepare for HRSA and manufacturer 340B audits with available tools and resources
  – Apexus tools: Self-audit, sample HRSA data request

• Prepare for a HRSA audit now: assemble a team of experts and self-audit

• Compliance is the entity’s responsibility; do not rely on a vendor’s records alone

• The goal is perpetual compliance readiness
MANUFACTURER AUDITS
What are potential compliance issues that a manufacturer might observe?
Manufacturer Audit Issues

- **Diversion**
  - Non-eligible entity or entity service (inpatient)
  - Non-eligible patient
  - Reselling of product
  - Non-compliance with Orphan Drug Final Rule
    (for RRC, SCH, CAH and Free-Standing Cancer Hospitals)

- **Medicaid duplicate discounts**
  - 340B discount and Medicaid rebate on same unit of utilization
  - Covered entity responsible for避免ing duplicate discounts
  - State Medicaid and rules for compliance
    - Example: UD Modifier for physician administered
  - Managed Medicaid
Other Issues

- GPO Prohibition
- Definition of patient
- Maintenance of auditable records
- Correct information on HRSA 340B Database
- Multiple “ship to” sites
- Split billing software and credit/re-bill activity
- Healthcare reform impact (ACOs, integration)
- Some other issues (ex. GPO Prohibition) are not auditable by manufacturers, but manufacturers can inform HRSA of these issues and HRSA will follow-up with covered entities
Manufacturer Audits of Entities: Overview

- If informal negotiations fail, a manufacturer may seek HRSA permission to conduct an audit
  - Demonstrate reasonable cause
    - Evidence of duplicate discount and/or diversion
    - Unsatisfactory attempt at informal dispute resolution
  - Submit proposed audit work plan

- HRSA response to request (within 15 days)
  - Approval
  - Denial
  - Request for revision/additional information

- Manufacturer provides covered entity with notice of audit
  - minimum 15-day period to prepare for audit
Manufacturer Audits of Entities: Overview

• Manufacturer notifies covered entity of audit
  – Identifies issue(s) & third party auditing firm

• Audit pre-work
  – Document requests (policies, SOPs, etc.)
  – Data request (inventory, billings, etc.)
  – Identification of key individuals to be interviewed

• On-site audit
  – Minimal time necessary to complete work (2-5 days)

• Conclusion of audit
  – Resolve any outstanding issues
  – Covered entity comment on findings
  – Final Audit report provided to HRSA and HHS OIG
  – Recoupment of 340B discount (discount = WAC – 340B or WAC-GPO depending on entity type)
Self-Disclosure of Non-Compliance: Manufacturer’s Role

• Covered entity
  – Identifies issue(s)
  – Corrects issue(s)
  – Self-discloses issue and proposed corrective action plan (CAP) to HRSA
  – Self Discloses to manufacturer – works in good faith to implement CAP

• Manufacturer
  – Identifies impact to manufacturer’s products
  – Works with covered entity to resolve issue
Corrective Action Plans: Manufacturer’s Role

• Covered entity must:
  – Prospectively correct issue
    • Conduct root cause analysis of underlying issue
    • Implement Plan to correct issue moving forward
  – Retrospectively correct issue
    • Identify products (and units) affected
    • Determine inappropriate discounts
  – Repayment challenges
    • Refund vs. offset
    • Work with manufacturers to determine best course
Tips for Pharmacy Technicians

- Report inventory discrepancies or software malfunctions to leadership; document the issue in writing and keep records of how the situation was corrected.
- Know your 340B policies and procedures for verifying patient, prescriber, and location eligibility.
- Self-audit: endure procedures are being followed and report issues to leadership.
Takeaways

- HRSA and manufacturers may both audit entities
- There are lessons to be learned from prior audits
- There are specific choices that place an entity at a higher risk of being audited
Questions
340B HOT TOPICS
Objectives

- Describe current events in the 340B environment
- Discuss 340B-compliant approaches used by leading practices to common hot topics
- Discuss tools available for entities
Current Events

- Mega “Guidance”
- Specialty distribution
- Corrective action plan (CAP)/repayment
- Emerging points of dispute
Does the entity:

- Have a relationship with the individual and maintain records of the individual’s health care?
- Provide health care services from a health care professional
  - Employed by entity
  - Under contractual or other arrangements (e.g. referral for consultation) with entity?
- Maintain responsibility for the patient’s health care services?
- Provide services consistent with funding or designation status (hospitals exempt)
Are employees of a covered entity eligible to receive 340B drugs?
If we refer a patient to an outside clinic, can we use 340B for their prescriptions?

What sort of recordkeeping are the auditors examining?
Inventory/Records

• Does the entity:
  – Maintain separate, auditable records for all 340B purchasing and dispensing?
  – Regularly evaluate 340B utilization reports to catch and correct problems?
If I dispense a manufacturer’s generic product to a 340B eligible patient, can I restock my inventory with a generic equivalent from another manufacturer?
Can we transfer 340B drugs to the HIV clinic that we own?
Can our organization transfer 340B drugs to another 340B entity?
What about in an emergency?
Does the prescription have to have a fill date that matches the date of service?
An entity lost its 340B eligibility in January, but feels it will hit the threshold again in April or July, regaining 340B eligibility.

Should they purge all previous accumulation and start again or do they only need to purge the period they were ineligible?
Will HRSA make an exception to their registration rules?

For example:

- My CEO deleted an email from HRSA that was critical, and HRSA removed our entity
- We made a mistake and forgot to register a site or pharmacy
How do I know when to self disclose to HRSA?

For example:

- Contract pharmacy data error for 6 months
- One incident of a physician writing a prescription at an ineligible location
- Defining “material breach” of non-compliance
Tips for Pharmacy Technicians

• Consider making a 340B eligibility checklist to keep at your workstation, if your software doesn’t help you manage this – don’t forget to address referral prescriptions

• Understand the policy for transferring 340B inventory from your entity to a child site, and ensure this is documented in your 340B standard operating procedures.

• If something doesn’t seem right, **LOOK INTO IT!** It will protect your covered entity.
• Stakeholders are not all going to interpret policy the same way
• Defend your decision and document it in your policies and procedures
• Use free tools and resources to support your decisions: FAQs, Apexus Answers
Questions
340B UNIVERSITY WRAP-UP
Take Action

Apexus Answers

ApexusAnswers@340BPVP.com

340BPVP.com
• Register for access to secure section for contract maximization

Apexus | 340B Prime Vendor Program | 290 E John Carpenter Frwy | Irving, TX 75062
THANK YOU FOR ATTENDING 340B UNIVERSITY!

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