340B UNIVERSITY LOGISTICS
340B University Logistics

- Overview of Session
- What’s in your Participant Packet
  - Agenda
  - CE Credit (p. 5)
  - 340B Glossary (p. 7)
  - 340B Acronym Guide (p. 19)
  - HRSA Audit Handout (p. 23)
  - Material Breach Documentation Tool (p. 27)
  - 340B Price Not Available Tool (p. 29)
  - Session Slides (p. 31)
Ask Your 340B Questions Today

• You can use the Apexus mobile app to ask questions by using the “Questions” module.

• Don’t have the Apexus app? See the blue handout on the table for more information.

• Questions will be sent to speakers to address during the session
Networking Do’s & Don’ts

- Introduce yourself to your seatmates
- Share your stories
- Ask your questions
- Turn your cell phones to silent
- Be ready to start the program when you hear the “340B News”
Tools and Resources

Why join the Prime Vendor Program? Learn more now.

Who we are:
Apexus works with more than 27,000 health care providers across the United States to lower their costs for purchasing specialty pharmaceuticals.

How Apexus can help you:
340B Tools

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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 and sub-WAC 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’ needs 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
• 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.
Mega-guidance Overview

- Mega-guidance published 8-28-15
- 60 day comment period (through 10-27-15)
- Timeline could be 1-2 years before finalization
- Focused on improving program integrity
- Increased requirements for both entities and manufacturers
Apexus Answers call center
Peer-to-Peer program & webinars
340B tools located on the Apexus web site
Participant dashboard
Many others
A NEW ERA FOR THE 340B PROGRAM
Transition to an Era of Integrity

- Responsibility
- Compliance
- Accountability
BACK TO 340B BASICS
340B BASICS
Objectives

1. Discuss 340B basic concepts at a high level.
2. Describe 340B compliance.
WHAT IS THE 340B PROGRAM?
• Resulted from a 1992 federal statute
• 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
340B Price

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

  **340B ceiling price**

- Manufacturer submits data to CMS
Pricing Comparison

PRIVATE SECTOR PRICING
“BEST PRICE” 63%

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<tr>
<td>AMP</td>
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<td>340B</td>
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<tr>
<td>Veterans Administration</td>
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340B Covered Outpatient Drugs

- Outpatient drugs
- Over-the-counter drugs (with a prescription)
- Clinic administered drugs
- Biologics
- Insulin
WHY IS THERE A 340B PROGRAM?
340B Intent

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

Consider this…

Think of the last time you looked at the 340B savings you receive.

Have you ever written a statement in your policies and procedures describing how your use of 340B aligns with the program intent?

ask your questions by using the Apexus Mobile App
Tool: 340B Benefit and Use of 340B Savings Tool

340B University
340B Benefits and the Use of 340B Savings Documentation Tool

Purpose: This tool is designed to allow entity leaders to have a framework to help guide the written documentation of 340B savings.

Instructions:
1. Answer the question in the left column with a written response in the right column.
2. Read the sample use of savings statements.
3. Circle aspects of the sample savings statements that align with your entity’s mission.
4. Draft your own statement documenting the use of 340B savings.
WHO IS INVOLVED IN THE 340B PROGRAM?
340B Program Stakeholders

- Federal Agencies & Congressional Offices
- Contract Pharmacies
- Businesses & Consulting Organizations
- Hospital and other Trade Associations
- Manufacturers & Wholesalers (Suppliers)
- Covered Entities (hospitals and HRSA grantees)
## 340B Eligible Entities

<table>
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<tr>
<th>Federal Grantees/Desigenees</th>
<th>Certain Hospitals</th>
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<td>• Disproportionate share hospitals</td>
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<td>• Federally qualified health center look-alikes</td>
<td>• Children’s hospitals</td>
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<tr>
<td>• Title X family planning grantees</td>
<td>• Critical access hospitals</td>
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<td>• State aids drugs assistance programs</td>
<td>• Free standing cancer hospitals</td>
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<td>• Ryan White care act grantees (A,B,C,D,F)</td>
<td>• Rural referral centers</td>
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<td>• Black lung clinics</td>
<td>• Sole community hospitals</td>
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<td>• Hemophilia treatment centers</td>
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<tr>
<td>• Native Hawaiian health centers</td>
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<tr>
<td>• Urban Indian organizations</td>
<td></td>
</tr>
<tr>
<td>• Sexually transmitted disease grantees</td>
<td></td>
</tr>
<tr>
<td>• Tuberculosis grantees</td>
<td></td>
</tr>
</tbody>
</table>
HRSA 340B Database: Statistics

- HRSA 340B Database
  - January 2016
    - 34,492 registered sites; 15,712 are non-hospital sites
    - 17,448 unique contract pharmacies
Consider this...

When was the last time you reviewed your 340B database entry?

ask your questions by using the Apexus Mobile App
Apexus Focus

CONTRACTING
340B Prime Vendor Program

EDUCATION
340B University
340B University OnDemand

ASSISTANCE
Apexus Answers Call Center

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Contracting: 340B Prime Vendor

**Sub-Ceiling**
Negotiate sub-ceiling 340B pricing on brand and generic pharmaceuticals

**Sub-WAC**
Negotiate sub-WAC pricing on brand and generic pharmaceuticals for entities subject to the GPO Prohibition

**Value Added**
Vaccines, blood glucose monitoring supplies, point-of-care test kits, pharmacy hardware and software automation

**Distribution**
Establish wholesale distribution networks that improve access to affordable medications: national, regional, specialty

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Apexus contract for cyclophosphamide injection
   - Multi-source (generic) injectable product
   - Contract commitment by Sandoz

DSH oncology infusion center failed to convert
   - Missed $ 9,797 savings in one month
   - Pricing may change but Apexus contract will stay lower priced vs competitors

DSH did not monitor contract notices; opportunity was identified and converted immediately but after several months of lost savings

What contract opportunities are you missing?
Examples of Contract Opportunities

- Flu vaccines: use Apexus for outpatients
- IUDs and steep sub-340B oral contraceptive pricing
- Biosimilars: filgrastim-sndz coming soon
- Plasma products: IVIG, blood factors
- Contrast media: radiology and MRI
- Generic multi-sourced products:
  - Cyclophosphamide, Oxaliplatin
  - Bivalirudin, Azacitidine
  - Leucovorin, Levoleucovorin
- Hundreds of brand name drugs at sub-340B pricing
HOW DOES AN ENTITY PARTICIPATE IN THE 340B PROGRAM?
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
• Change requests: changes to existing information, rolling basis

<table>
<thead>
<tr>
<th>Update Official</th>
<th>October 1</th>
<th>January 1</th>
<th>April 1</th>
<th>July 1</th>
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<tr>
<td>Registration Period</td>
<td>July 1 – 15</td>
<td>October 1 - 15</td>
<td>January 1 – 15</td>
<td>April 1 - 15</td>
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</tbody>
</table>
• HRSA uses:
  – Cost reports for hospitals
  – Electronic Handbook (EHB) and other documentation for grantees
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
Electronic Handbook

- 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
Recertification

• Entities are required to recertify information in the HRSA 340B Database annually

• HRSA sends a notification email to authorizing official and primary contact

• HRSA sends username/password only to the authorizing official

• 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
Consider this…

Think of the individual at your institution who is the Authorizing Official (AO).

How informed is the AO about 340B? Would the AO delete an email about recertification?

ask your questions by using the Apexus Mobile App
WHAT ARE THE RULES AND HOW ARE THEY ENFORCED?
Why 340B is like an onion...
340B Audits

- HRSA audits of entities
  - Operational Site Visits for HRSA grantees
- HRSA audits of manufacturers
- Manufacturer audits of entities
- Self-audits
1. Duplicate discount prohibition
2. No diversion (patient definition)
3. Certain hospitals only
   - Group Purchasing Organization (GPO) Prohibition
   - Orphan drug exclusion
What do you see?
Duplicate Discount Prohibition

340B price

Medicaid rebate

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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
- Orphan drug list: click here
HOW DOES AN ENTITY ESTABLISH INFRASTRUCTURE TO SUPPORT COMPLIANCE?
Consider this…

Think about your 340B-dedicated staff. Do they have the support, resources, and training they need?

ask your questions by using the Apexus Mobile App
340B Resources

- Dedicated FTEs
- Standard operating procedures
- Self-auditing
- Program oversight committee
- Relationship and oversight of third parties
  - Contract pharmacies
  - Split-billing software
- Ongoing staff education
- Tools, call center
Apexus Answers is verified and endorsed by HRSA.

Staff in constant communication with HRSA to ensure messaging is consistent.

FAQs available on [apexus.com](http://apexus.com)

Average monthly interactions ~1,500-2,000

Tiered levels of response: can handle from basic to complex.
Questions

ask your questions by using the Apexus Mobile App
340B & MEDICAID
Objectives

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

340B price

Medicaid rebate

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Medicaid Exclusion Terminology

- Carving-In
- Carving-Out

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• At registration, covered entities inform HRSA whether the covered entity will purchase and dispense 340B drugs to their Medicaid patients (“carve-in”) or whether they will purchase drugs for their Medicaid patients through other mechanisms (“carve-out”)

• HRSA provides the 340B Medicaid Exclusion File as the official data source to determine whether 340B drugs are billed to Medicaid in order to prevent duplicate discounts.

• December 12, 2014 Release No. 2014-1
340B Drug Pricing Program

340B University OnDemand, created by Apexus, is an online educational program designed to support compliance and integrity for all 340B program stakeholders. Topics covered: eligibility, registration, recertification, pricing, contract pharmacy, implementation and audit preparedness.

HRSA, Office of Pharmacy Affairs issued proposed 340B Drug Pricing Program Omnibus Guidance for notice and comment on Friday, August 28, 2015 in the Federal Register. The proposed guidance addresses key policy issues including eligibility and registration of hospitals and outpatient facilities, individuals eligible to receive 340B drugs (patient definition), drugs eligible for purchase under the Program, prohibition of duplicate discounts, and manufacturer compliance, and others. The proposed guidance will be open for public comment through October 27, 2015. HRSA encourages interested parties and stakeholders to provide comments. Please refer to the Federal Register for instructions on how to submit comments. (PDF - 289 KB)

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How does the Medicaid Exclusion File work?

- Manufacturer
- Entity
- Medicaid Exclusion File
- Medicaid Rebate
- State
- 340B Discount
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?
Our entity carves-in (uses 340B for drugs billed to Medicaid), and we have listed our entity’s NPI in the exclusion file. Can duplicate discounts still occur?
Can we use 340B for Medicaid patients at our contract pharmacy?
Targeting Program Integrity

Office of Pharmacy Affairs
340B Database

REPORTS/FILES

Medicaid Exclusion File

Archived Medicaid Exclusion File

Orphan Drug File

Contract Pharmacy Carve-Ins

Daily Reports

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Is there a risk of creating a duplicate discount if we use 340B drugs for Medicaid MCO claims?
Our entity wants to use 340B drugs for Medicaid at some clinics, but not at other clinics. Is there a way to support doing this in the HRSA Medicaid Exclusion File?
We bill at an all-inclusive rate for Medicaid, no NDC is transmitted to Medicaid, and therefore no duplicate discount will occur. We do use 340B for these patients; does HRSA expect us to answer YES to its Medicaid question?
Use of 340B medications for medication which the Medicaid patient is not charged for, i.e. the provider treats a patient with Silvadene during an office visit. The clinic charges Medicaid for the office visit, but not for the Silvadene. The clinic writes off the Silvadene as an incidental expense. We currently are listed as Carve-out is that compliant?
Can an FQHC location **carve-in** for clinic administered drugs and decide to **carve-out** for their on-site retail pharmacy if they utilize a different NPI and Medicaid billing number?
Targeting Program Integrity

Our entity carves-in and is located in NY and currently has our Medicaid Provider number for NY listed in the MEF. We also bill Medicaid in 12 other states. Are we in compliance with preventing duplicate discounts since the state that we are located in is listed appropriately?
• If a HRSA audit reveals that a covered entity’s information on the 340B Medicaid Exclusion File does not reflect actual billing practices, the covered entity could be found in violation of the duplicate discount prohibition and may be required to repay manufacturers in an amount equal to the reduction in the price of the drug.

• Through the corrective action process, HRSA will direct covered entities to work with States and manufacturers to determine whether a duplicate discount occurred as a result of the incorrect 340B Medicaid Exclusion File listing.
Program Integrity

• All covered entities are expected to have **written policies and procedures** pertaining to the prevention of duplicate discounts, and **ensure their database listing is consistent with actual practice.**
Program Integrity

FY15 Audit Results

Updated 10/29/15. The results chart includes audits where the findings have been finalized. Remaining audits are still under review. Information on Corrective Action Plans and Sanctions will be updated once approved by HRSA. HRSA recommends manufacturers do not contact audited entities regarding sanctions until a corrective action plan has been approved by HRSA and posted on this website.

QA Findings:

1. Covered outpatient drugs obtained through a Group Purchasing Organization prior to October 2014.
2. Incorrect 340B database record. Offsite outpatient facilities were not listed on the 340B database, contract pharmacies not terminated from the 340B database whose contracts were terminated, incorrect entries for shipping address and Primary Contact.
3. Diversion – 340B drugs dispensed at contract pharmacy for prescription originating from ineligible site.
4. Duplicate Discounts – Medicaid billing numbers were incorrect on the Medicaid Exclusion File.

Sanctions: Repayment to manufacturers.

Corrective Action: Pending.
Do you see any problems here?

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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
What to Ask Your State

- What is the state’s general policy on Medicaid rebates on 340B drugs (for example, does the Medicaid Agency use the OPA Exclusion File or other methods of segregating claims?)

- If our entity uses 340B for Medicaid, what procedure should we use to notify the state Medicaid agency that a 340B drug was unavailable?

FROM RELEASE No. 2014-1

In the event that a covered entity that is listed on the 340B Medicaid Exclusion File as using 340B drugs for MFFS patients, but is unable to use a 340B drug in a particular instance, it must have a mechanism in place to notify the state Medicaid agency.

- Does the State Medicaid Agency exclude 340B claims when seeking a Medicaid Rebate on claims from patients:
  1. That are billed from Medicaid Managed Care
  2. That received physician administered Drugs
  3. That are “Dual Eligible” (Medicaid/Medicare)
  4. In any other circumstance?
Tips for Technicians and 340B Coordinators

- Check the HRSA 340B Database listing to ensure the Medicaid information reflects practice (remember MCO not addressed)

- 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
Questions

ask your questions by using the Apexus Mobile App
340B IMPLEMENTATION
CONTRACT PHARMACY

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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

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

Pharmacy Services
# Contract vs. In-House Pharmacy

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<thead>
<tr>
<th>Contract Pharmacy</th>
<th>In-House Pharmacy</th>
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<tbody>
<tr>
<td>• Contracts with covered entity 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>• Covered entity 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 HRSA 340B Database</td>
<td>• Not eligible to be listed as child site</td>
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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

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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
First, entity has a written contract pharmacy agreement in place with specified pharmacy, including full listing of all pharmacy locations that may be utilized under that agreement.

Entity has written 340B policies and procedures to ensure program compliance and oversight activities of the contract pharmacies. Entity is prepared to follow CP oversight plan and be in compliance with requirements.

Entity registers contract pharmacies on HRSA database for participation in 340B Program, with obligation of ensuring ongoing compliance.
Implementation Decision Points

- Entity-Contract Relationship
- Contract Negotiations
- Compliance Safeguards

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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 3\textsuperscript{rd} party administrator

#### Role of 340B 3\textsuperscript{rd} Party Administrator

- 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

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Implementation Decision Points

- Entity-Contract Relationship
- Contract Negotiations
- Compliance Safeguards
Entities can negotiate the terms of their contract pharmacy agreements.

Entities to ensure contract terms support program integrity and align 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
• 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
• Entity is not permitted to contract with other pharmacies as contract pharmacies
Fee Structure Example

Scenario:

Self-pay: Pharmacy shall collect and receive a $18 dispensing fee and a $1 administrative fee from patient

Insured: Pharmacy shall collect and retain 35% 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 3rd party administrator?
- Have you set up fee relationships with a contract pharmacy to provide discounts for your patients?
  - Cash pay/sliding fee
**Tool: Contract Pharmacy Vendor Assessment**

---

**340B Compliance Self-Assessment: Vendors**

**A Tool to Help 340B Entity Leaders Assess Contract Pharmacy Vendors**

**Purpose:** The purpose of this tool is to enable entity leaders to quickly assess the basic level of 340B program integrity resources provided by contract pharmacy vendors to help the entity achieve 340B compliance.

**Instructions:** Read the question under the column “Does the Entity…?”

1. Review the information in the chart. Consider including green light criteria as part of a vendor request for proposal (RFP).
2. After receiving vendor proposals, read the question under the column “Does the vendor offer...”
Implementation Decision Points

Entity-Contract Relationship  Contract Negotiations  Compliance Safeguards

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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

• Covered entity responsible for ensuring compliance with all 340B requirements

• Covered entity 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)
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.

<table>
<thead>
<tr>
<th>Tool</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Entity leadership will determine specific proposal component requirements. Entity may consider including a cover letter that outlines purpose of solicitation, expectations and general provisions for proposal submission, award criteria, and the scope of 340B operations that are included in the audit request.</td>
<td></td>
</tr>
</tbody>
</table>
## Compliance Elements

<table>
<thead>
<tr>
<th>Operations</th>
<th>Diversion</th>
<th>Duplicate Discount</th>
<th>Auditable Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Covered entity purchases and owns the inventory</td>
<td>• Contract pharmacy to establish and maintain a tracking system</td>
<td>• 340B drugs will not be subject to Medicaid rebates</td>
<td>• Contract pharmacy 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 covered entity</td>
</tr>
<tr>
<td>• Covered entity informs 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

• Contract pharmacy reports
  – Dispense to accumulation reports
  – Replenishment invoice

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# 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 Medicaid cost report 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>Medicaid</th>
<th>Pharmacy</th>
<th>Provider</th>
<th>Active</th>
<th>Eligible Location</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>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>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>Sornberger</td>
<td>yes</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>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>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>yes</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>yes</td>
<td>1206596</td>
<td>yes</td>
</tr>
</tbody>
</table>

What other aspects of the prescriptions would you audit?

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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>

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### 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 fee-for-services</td>
<td>• Contract pharmacy claim dispensing report</td>
</tr>
<tr>
<td>• Standard Operating Procedures (SOPs) 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:**

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?
Takeaways

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

• Entities can negotiate the terms of their contract pharmacy agreements
Questions

ask your questions by using the Apexus Mobile App
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
What are the 340B-related roles and responsibilities for you and your organization?

ask your questions by using the Apexus Mobile App
Manufacturer: Role/Responsibilities

• Uphold responsibilities in the pharmaceutical pricing agreement
  – Calculate and charge a correct public health service (PHS) price
  – Ensure that you charge the price to valid 340B entities
    • Validate customers on indirect sales (chargebacks) to the HRSA 340B 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></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></td>
</tr>
<tr>
<td>• Charge 340B entities a price that does not exceed the 340B ceiling price</td>
<td></td>
</tr>
<tr>
<td>• Retain necessary records for not less than 3 years from date of creation</td>
<td></td>
</tr>
<tr>
<td>• Afford secretary (or designee) reasonable access to records relevant to compliance</td>
<td></td>
</tr>
<tr>
<td>• Permit CMS to share AMP and URA with secretary in order to carry out agreement</td>
<td></td>
</tr>
<tr>
<td>• Participate with HRSA 340B Prime Vendor Program (voluntary)</td>
<td></td>
</tr>
</tbody>
</table>
Wholesaler: Role/Responsibilities

- Open accounts with only eligible entities
- Deliver correct price to 340B entities
- Process chargebacks with manufacturer correctly
• 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 \([(\text{AMP} \times 23.1\%) \text{ or } (\text{AMP} - \text{BP})]\) plus inflation penalty
• **Generic/OTC**: 13% of AMP

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• 340B ceiling price

\[
\text{WAC} - \text{AMP} - \text{URA} \quad \text{equals} \quad \text{340B Unit Price} \\
\quad \times \quad \text{Units per Package} \\
\quad \text{equals} \quad \text{340B Ceiling Price}
\]
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?

ask your questions by using the Apexus Mobile App
Question for the Panel

How do you implement a chargeback?

ask your questions by using the Apexus Mobile App
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 three and one regional wholesaler’s 340B pricing for comparison
3. Contract pharmacy and entity identification
   - Health industry number (HIN), DEA, 340B ID

4. Returns
   - The correct invoice must be chosen when returning a product
• Manufacturer **MUST** validate entity on the chargeback to confirm 340B eligibility

• Manufacturer will deny the chargeback if they cannot validate eligibility
  – “Bill to” address on the chargeback identifies eligibility
  – Manufacturer may use DEA#, 340B ID, and/or HIN to identify the covered entity and the specific account
  – Correct information is critical
What types of adjustments do manufacturers make to their Medicaid, AMP and BP?

ask your questions by using the Apexus Mobile App
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?

ask your questions by using the Apexus Mobile App
What is the procedure used by manufacturers that wish to refund payment to covered entities who are overcharged for 340B?
What are special situations or challenges for you specific to 340B?

ask your questions by using the Apexus Mobile App
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
Manufacturer: Special Situations

- 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 specialty pharmacy, how would a 340B patient access that drug?

ask your questions by using the Apexus Mobile App
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
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 for manufacturer updates
Tips for Pharmacy Technicians

• Log in to the Apexus website (www.apexus.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

• Actions entities take can impact a manufacturer’s calculations and ultimately impact the manufacturer’s compliance
ask your questions by using the Apexus Mobile App
340B AUDIT PANEL
Objectives

- Review the key points of the audit processes
- Outline key lessons learned from HRSA and manufacturer audits
HRSA AUDIT OVERVIEW
### 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</th>
<th>FY 2016* (As of 01/04/16)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of covered entities audited</strong></td>
<td>51</td>
<td>94</td>
<td>99</td>
<td>200</td>
<td>48</td>
</tr>
<tr>
<td>• Outpatient facilities/sub-grantees</td>
<td>410</td>
<td>718</td>
<td>1,476</td>
<td>2,720</td>
<td>874</td>
</tr>
<tr>
<td>• Contract pharmacies</td>
<td>860</td>
<td>1,937</td>
<td>4,028</td>
<td>4,443</td>
<td>1,083</td>
</tr>
<tr>
<td><strong>Number of finalized reports</strong></td>
<td>51</td>
<td>94</td>
<td>97</td>
<td>152</td>
<td>3</td>
</tr>
</tbody>
</table>

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ENTITY EXPERIENCES: LESSONS LEARNED
**Scenario:**

We had a contract pharmacy script that was filled on 340B. Patient had an eligible encounter at our hospital. The script, however, did not come from that encounter. The patient had called the physician at a non-340B clinic asking for a refill months after the eligible encounter itself. Could this result in a finding?

**HRSA FINDINGS:**

- 340B drug dispensed for prescription written at ineligible site, by ineligible provider, or not supported by medical record
- 340B drug dispensed to an inpatient
- 340B drugs not properly accumulated
- Entity did not have adequate controls in place for proper accumulation and prevention of diversion
Diversion occurs when a 340B drug is provided to an individual who is not an eligible outpatient of that entity (not meeting all or part of the patient definition), AND/OR dispensed in an ineligible area clinic.

Different approaches to eligibility verification (to include location):
- Barcodes, location codes, e-prescribing

No eligibility encounter window defined
- Eligible encounter but script coming from second ineligible encounter

Infrequent/inappropriate load of prescriber file
**Scenario:**

Bundled billing for everything within four walls of our hospital and hence state Medicaid unable to seek rebates for those claims. We do, however, use 340B for Medicaid patients. Same NPI for parent hospital and offsite locations/child sites. Might we receive a finding?

**HRSA FINDINGS:**

Entity was billing Medicaid contrary to information contained in Medicaid Exclusion File

340B drugs dispensed to Medicaid patients by contract pharmacy, absent arrangement to prevent duplicate discounts

Inaccurate or incomplete information in Medicaid Exclusion File
Duplicate Discounts: Lessons Learned

• All clinics under the same Medicaid provider number/NPI must handle Medicaid drugs in the same manner.

• In past audits, entities have received findings for Medicaid Exclusion File (MEF) inaccuracies, whether or not those inaccuracies have led to duplicate discounts.

• Medicaid Exclusion File requirements must be followed in all cases, even in carve-in arrangements for contract pharmacies.

• Contact State Medicaid director before audit on how handling entity’s claim in regards to rebates.
  – Try to get documentation of confirmation.
Auditing Contract Pharmacies: Considerations

**Scenario:**
Some contract pharmacies consider payer information to be proprietary and are not sharing this data with the entity. Not having payer information would make it challenging to ensure prevention of duplicate discounts. What do we do if our vendor won't share that information?

**HRSA FINDINGS:**
- 340B drug dispensed to non-patients at a contract pharmacy
- 340B drug dispensed for a prescription written at ineligible site, or written by ineligible provider, or not supported by medical record
- Registered a contract pharmacy without a contract in place
- Entity did not provide contract pharmacy oversight

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Auditing Contract Pharmacies: Lessons Learned

- Possible to query payer information on a global level (not claim level). This allows you to audit the absence of any BIN/PCN names for Medicaid, without knowing the payer for each claim.
- Ensure contract pharmacy uploading data feeds as frequently as decided upon in agreement
- Process for when contract pharmacy identifies violation
- Self-audit contract pharmacy transactions with hardcopies of scripts
- HRSA expects annual independent audits
Auditable Records: Considerations

HRSA FINDINGS:
Entity failed to maintain auditable medical records

- What constitutes as auditable records?
- How long do these records have to be kept?
- How far back does/can HRSA “audit” from the date you are notified?
- Data request: A copy of the last physical inventory report(s), including reconciliation(s). What does this mean?
• Auditable records include specific documentation that all 340B Program requirements are met for every 340B drug.

• Handling self-audit records; who reviews these and makes decisions about self-reporting? Are they shared with others, and if so, under what circumstances?
Scenario:
Our hospital was contacted by a consulting company on behalf of a manufacturer asking us to participate in a “Good Faith Evaluation” of our 340B purchases, but the data request included looks more like a formal audit. What do you recommend?
• Covered entity should seek legal counsel in reviewing data request prior to submission as a part of this “Good Faith Evaluation”

• HRSA guidance required approval before conducting an audit
  – Approved audit work plan; third party auditing firm

• Covered entities should work with manufacturers who are attempting to resolve matters directly through informal dispute resolution
  – An audit can be avoided
MANUFACTURER PERSPECTIVE
Self-Disclosure of Non-Compliance: Manufacturer’s Role

• Covered entity
  – Identifies issue(s)
  – Corrects issue(s)
  – Self discloses issue and proposed 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(s)
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
**Scenario:**

We identified diversion during self-auditing, which constituted a material breach and led us to self-disclose. We sent out letters to 50 manufacturers, and only heard back from 3, so will only process those repayments. This means the other 47 don’t want repayment, correct?

- What is the entity’s responsibility—where does it end?
- What does HRSA expect?
- Do all manufacturers expect the same thing?
Repayment Considerations

• What are some tips in reaching out to manufacturers for repayment?
  – Who to contact and how to get correct contact information
    • 340B HRSA Database technical contact for manufacturer
  – What to include in correspondence/request
    • Concise explanation of violation
    • Period of review and scope
    • Historic 340B and WAC prices from wholesaler
What are the “triggers” that manufacturers use to determine need for informal dispute resolutions and/or audits of entities?

What data is used by manufacturers to substantiate these engagements? Challenges in data transparency?

What can an entity expect when contacted by a manufacturer as an informal engagement/inquiry?
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
- There are lessons to be learned from prior audits
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: ensure procedures are being followed and report issues to leadership

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340B IMPLEMENTATION
MIXED-USE: GPO
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
GPO Prohibition

- Requirement: the hospital “does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement”
  - IDNs
  - Health system arrangements
  - Wholesaler contracts
    - Apexus Prime Vendor Program (PVP) contracts are not GPO
    - True individual contracts are not GPO
- Drugs that are not COD are not subject to the GPO prohibition
• 340B is limited to **outpatients**

• Patients must meet patient definition
  – Patient status = outpatient (at time of service)
  – Prescriber = eligible prescriber
  – Location of service = reimbursable on cost report, registered on HRSA 340B Database (if required)

• No GPO use for covered outpatient drugs for DSH/PED/CAN hospitals

• The GPO prohibition applies to **all** outpatients of the parent and registered child sites, not just 340B eligible outpatients
Mixed-use setting in a nutshell

- In a mixed-use area, the entity dispenses/distributes medications to both inpatients and outpatients from the same location (e.g., central pharmacy)

- Examples

  - Emergency department, cardiac cath lab, endoscopy, same-day surgery, radiology
• HRSA February 2013 Policy notice; enforced as of August 7, 2013: clarified HRSA expectations
• Must discontinue GPO purchases before 1st day
  – May use remaining inventory after 1st day
• GPO replenishment is not authorized
  – Must replenish by first purchasing from non-GPO/WAC account
  – Must maintain auditable records
• Violation: removal from 340B program and repayment to manufacturers
• Establishment of a neutral inventory for mixed use dispensing/distribution
Accommodates one physical drug inventory serving both inpatients and outpatients

- Mixed use, neutral inventory replenishment with purchases from GPO and 340B accounts

This software merges data from patient visits (date/time of service, patient status, prescriber, location/clinic, Medicaid status) to help split orders for replenishment via correct accounts

- Splits transactions into 340B or GPO “buckets” according to patient definition eligibility
Accumulators and Eligibility

Accumulator: 340B
- 340B eligible outpatients

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
Question

What data do you feed into your split-billing software?

What is the source of the data?

ask your questions by using the Apexus Mobile App
### Wholesaler Account Setup
**-DSH/PED/CAN with GPO Prohibition**

#### Inpatient

<table>
<thead>
<tr>
<th>GPO</th>
</tr>
</thead>
<tbody>
<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>
</tr>
</tbody>
</table>

**Account #1**

#### Outpatient

<table>
<thead>
<tr>
<th>Outpatient (not 340B eligible)</th>
<th>Outpatient (340B eligible)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-GPO/WAC</strong></td>
<td><strong>340B</strong></td>
</tr>
<tr>
<td>• WAC Pricing</td>
<td></td>
</tr>
<tr>
<td>• PVP Sub-WAC (if enrolled in PVP)</td>
<td></td>
</tr>
<tr>
<td>• Apexus Generic Portfolio (AGP) (if enrolled in PVP)</td>
<td></td>
</tr>
<tr>
<td>• Individual Hospital Agreement (single entity only)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• PHS/340B</td>
</tr>
<tr>
<td></td>
<td>• PVP Sub-340B (if enrolled in PVP)</td>
</tr>
<tr>
<td></td>
<td>• Apexus Generic Portfolio (AGP) (if enrolled in PVP)</td>
</tr>
<tr>
<td></td>
<td>• Individual Hospital Agreement (single entity only)</td>
</tr>
</tbody>
</table>

**Account #3**

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Update: Account Load Options

340B GPO Prohibition and Wholesaler WAC Account Load Options

A Feb. 7, 2013 HRSA Policy Release 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.

Key Messages

1. Establishing an outpatient non-GPO (i.e., PVP Non-340B) account provides a compliant
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
  - Should not be used (only exception is if it is the only product available to meet patient critical need)

- IVIG
  - Must be purchased via appropriate accounts, even if ordered direct from manufacturer

- Drug shortages
  - 11 digit NDC replenishment required in mixed-use areas with virtual inventory; will need to purchase first at WAC, start accumulation of new product, and replenish as appropriate

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Do you utilize vendor inventory consignment in your mixed-use inventory?
Maintaining Compliance

Verify that all covered outpatient drugs are purchased from the correct accounts

| 340B | Non-GPO/WAC |

Answer these questions

| How do you purchase outpatient blood products, contrast media and gas? | Are you purchasing GPO private label products? |
Two Key Questions HRSA Will Ask

1. What outpatient accounts do you have?
2. How do you purchase drugs for ineligible outpatients?

Be prepared to describe your purchasing and inventory system and explain how you assure compliance with the GPO prohibition.
What is your biggest challenge regarding record-keeping/inventory management?

ask your questions by using the Apexus Mobile App
Mixed-Use Inventory/Record Keeping Challenges

• Steps to take
• Pitfalls to avoid
• Example
**Tool: Minimize 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 to help minimize unnecessary WAC exposure in 340B hospitals subject to the [GPO Prohibition](#) (DSH, PEDs CAN). These hospitals must use a non-GPO/WAC account for purchases for outpatients who are ineligible for 340B.

<table>
<thead>
<tr>
<th>Strategy Areas Shared by Hospitals</th>
<th>Additional Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. WAC purchase report analysis</td>
<td>Hospitals run regular WAC purchasing reports, analyzed by an individual or committee, to identify why items are purchased via the WAC account and then to determine mechanisms to change purchasing patterns.</td>
</tr>
<tr>
<td></td>
<td>1. Hospitals devise a mechanism to manually adjust accumulators with adequate documentation for why the adjustment was made for products</td>
</tr>
</tbody>
</table>

---

Minimize WAC Exposure

340B Tools

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• 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.
Strategy #2: GPO “Only” Clinics

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 #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
WAC Purchase for New NDC

• Replenishment model
  – New products purchased as a new NDC will begin a new replenishment
  – New NDC must be purchased at WAC since no accumulation available
  – WAC should be used the first time an NDC is purchased by the entity, and anytime the quantity needed exceeds the 340B accruals available
  – You may purchase on your 340B account as soon as you have enough accumulations to make a purchase

• In 340B-only areas (not replenishment model), not necessary to purchase new NDCs under WAC
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 charge code to NDC crosswalk stays updated
Takeaways

1. Establish neutral inventory for mixed use areas
2. Carefully consider which options you elect if using split billing software
3. Take steps to minimize your WAC spend
4. Load correct contracts, including Apexus sub-WAC pricing
5. Define: inpatient, outpatient
6. Interpret: covered outpatient drug
7. Account: for waste and lost charges
Questions

ask your questions by using the Apexus Mobile App
340B IMPLEMENTATION IN-HOUSE PHARMACY
<table>
<thead>
<tr>
<th><strong>In-House, Owned Pharmacy</strong></th>
<th><strong>Contract Pharmacy</strong></th>
</tr>
</thead>
<tbody>
<tr>
<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>
</tr>
<tr>
<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>
</tr>
<tr>
<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>
</tr>
<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>

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# 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.
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**

**Wholesaler**

- **340B Inventory**
- **Retail Inventory**

**In-House Pharmacy**

- **340B Patient**
- **Retail Patient**

**Patient**

- **340B Provider**
- **Retail Provider**

**Provider**

- **340B Billing**
- **Retail Billing**

**Billing**

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Strategies for Growth:
12-month Start-Up Plan

- Detail strategies to achieve growth rate
- Tracking and reporting on progress
- Educating patients and prescribers to use pharmacy
- Added value services for clients
- Sales and Marketing

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In-House Pharmacy Keys to Success

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

Optimize Savings Control Costs

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Maximize Technology & Work Flow

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

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Control Costs

**Cost of Goods**

- Cost of goods reviewed at every order
- Quarterly price changes
- Apexus 340B Prime Vendor Program

**Perpetual Inventory System with Par Levels**

- Monthly unused drug report
- Quarterly drug level check
- Labor as a percent of sales

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Eligibility and Registration

- A grantee has a new clinic that opens March 15th.
- It must be added to the electronic handbook prior to registration in the HRSA 340B Database.

What steps have to be taken before the clinic can begin using 340B?
Accurate 340B Eligibility Determination

Covered entity carving out Medicaid must ensure that 340B drugs are not provided to Medicaid patients.
• Referral Prescriptions
  – If we refer a patient to an outside clinic, can we fill their prescriptions from our 340B clinic?
Compliance Considerations

- 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>Shared EMR access with outside provider</td>
</tr>
</tbody>
</table>
Compliance Considerations

- Eligible providers who are “floaters”

Covered entity 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

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

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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

ask your questions by using the Apexus Mobile App
340B IMPLEMENTATION FOR RURAL HOSPITALS
Objectives

- Discuss policy and history of orphan drug exclusion requirements
- Outline implementation background associated with complying with the exclusion
- Apply lessons learned to scenarios that outline operational considerations for rural hospitals
FDA designates a drug as an orphan drug if a manufacturer/sponsor requests such a designation and the FDA determines that the drug will treat a "rare disease or condition".

A "rare disease or condition" is one that affects fewer than 200,000 individuals, or when there is no reasonable expectation that costs incurred to develop and market the drug would ever be recovered from sales of the drug.

SEC. 525 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT [21 USC 360a]
Orphan Drug Exclusion Genesis: Policy

- Exclusion added to 340B Program as a result of 2010 amendment of Affordable Care Act
- Exclusion of orphan drugs for certain covered entities: Critical Access Hospitals (CAH), Rural Referral Centers (RRC), Sole Community Hospitals (SCH), Cancer Hospitals (CAN)
- Statute: the term “covered outpatient drug” shall not include a drug designated by the Federal Food, Drug, and Cosmetic Act for a rare disease or condition
  - Not covered outpatient drug → 340B pricing not obligated
Orphan Drug Exclusion: History

- **July 2013**: HRSA publishes 340B regulation
- **September 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
Orphan Drug Exclusion: History

July 2014
HRSA issues new interpretive guidance, PhRMA asks judge to invalidate interpretive guidance or determine if it should survive

October 2014
PhRMA files lawsuit challenging HRSA’s interpretive rule

October 2015
Judge vacates HRSA’s interpretive rule on the basis that it is inconsistent with the statute
• Failure to comply has been considered diversion
• Entities (parent and child sites) must attest upon registration and on an annual basis that they are able to comply with the orphan drug exclusion
• HRSA will audit compliance with the orphan drug exclusion including a review of the covered entity’s auditable records
• Manufacturers can audit a covered entity for compliance with the orphan drug exclusion
• Manufacturers cannot condition the offer of the 340B discount upon entity’s assurance of compliance
Reflection: Rural Hospital Participation

- Will the orphan drug ruling impact your decision to participate in 340B – why or why not?
- What are factors to consider when making this decision?
  - Integration of in-house/contract pharmacies to support 340B dispensing
  - Drug market basket
  - 340B capture rate based on patient eligibility
  - Reimbursement
  - Resources to oversee 340B Program
  - Trusted and compliant resources from vendors (split billing software, wholesaler) in determining orphan drugs
Orphan Drug List: Implementation

Background

• Knowing which drugs are subject to orphan drug exclusion is essential

• HRSA developed the “Orphan Drug List”
  – Based on FDA list of orphan drug designations
  – Updated quarterly
  – Should be used as source of truth for 340B purposes
  – Covered entities may need to conduct additional analysis

• Challenge with orphan drug list: no NDCs
There are various components of the orphan drug list that should be considered in order to comply with the orphan drug exclusion, less having NDC-level information.

<table>
<thead>
<tr>
<th>Row Num</th>
<th>Generic Name</th>
<th>Trade Name</th>
<th>Designation Date</th>
<th>Designation Contact</th>
<th>Contact Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ascorbic acid</td>
<td>n/a</td>
<td>5/11/2009</td>
<td>Treatment of Charcot-Marie-Tooth disease type 1A.</td>
<td>Murigenetics SAS</td>
</tr>
<tr>
<td>2</td>
<td>budesonide</td>
<td>n/a</td>
<td>12/20/2006</td>
<td>Treatment of patients with eosinophilic esophagitis</td>
<td>Shire ViroPharma Incorporated</td>
</tr>
</tbody>
</table>
Contact company or “sponsor”

- Sponsor assumes responsibility for a clinical or nonclinical investigation of a drug
- A sponsor may be an individual, partnership, corporation, or government agency and may be a manufacturer, scientific institution, or an investigator
- Matching the sponsor and the generic name fields allows entities to identify that the product is considered an orphan drug when it is associated with that particular sponsor
- Challenging to identify exact product when sponsor listed is not a manufacturer
HRSA only includes orphan drugs with a status of “Designated” & “Designated/Approved” (identified in FDA list)

- “Designated/approved” refer to an orphan-designated product that has received FDA marketing approval for an indication that falls within the designated disease or condition

- “Designated”: There are some products considered orphan drugs which are only categorized as “designated,” as these products do not have marketing approval for the specific indication within the designated disease
  - Such drugs might be marketed for other common conditions, and therefore sold in the United States

- Orphan drugs with either status are included in the orphan drug list and subject to orphan drug exclusion
• If the sponsor of the orphan drug creates a new dosage form of the same generic product for which orphan designation was granted, i.e., capsule instead of an injectable, is the new version also subject to that designation?
In the orphan drug list, is the following product limited to the 10% strength, or does the designation include the 5% as well?

| Intravenous immune globulin (human) 10% | Octagam(R) | 7/31/2008 | Treatment of stiff-person syndrome | Octapharma USA, Inc. |

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Questions

ask your questions by using the Apexus Mobile App
SOLUTION OPPORTUNITIES:
MIXED-USE GPO
Objectives

1. Improve understanding of specific GPO prohibition requirements through individual case studies.
2. Apply knowledge of the GPO prohibition to improve CE policies and procedures.
3. Improve ability to evaluate existing CE procedures to determine GPO prohibition compliance.
4. Understand GPO prohibition to achieve compliance while minimizing WAC spend.
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
GPO Prohibition Basics

• Requirement: “does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement”
  – All acquisition of COD within the 4 walls and registered clinics must not be via GPO (some exceptions for non-registered clinics outside the 4 walls)
  – Must purchase initially via non-GPO to establish neutral inventory for mixed inventory area (central pharmacy); replenish via 340B, GPO and WAC accounts
  – May not use another entity to obtain GPO meds to circumvent the GPO prohibition requirement
  – Apexus Prime Vendor Program contracts are not GPO contracts (sub-340B and sub-WAC)
  – True individual contracts are not GPO arrangements
• Drugs that are not COD are not subject to the GPO prohibition
A DSH hospital is approved as a 340B covered entity as of January 1\textsuperscript{st}. The acute care community hospital serves inpatients and outpatients from the central pharmacy. To set up a neutral, mixed-use inventory, how does the hospital set up accounts with the drug wholesaler and how does the split-billing software integrate with the purchasing system?
Questions:

• Where do we start? Help!
• What wholesaler accounts need to be established?
• When do we have to stop purchasing everything under GPO? What do we do with the existing inventory?
• How do we set up a neutral inventory?
• Does the split-billing vendor handle everything?
• What do we have to buy at WAC?
Give wholesaler advance notice: one month minimum
Evaluate, contract, and implement split-billing software system (minimum of 6 months)
Establish separate GPO, 340B and non-GPO/WAC accounts
Discontinue purchases of GPO drugs for outpatients upon date of 340B eligibility (HRSA database)
Carefully setup and thoroughly understand the split-billing software system and transaction processing
Carefully review processes to minimize unnecessary WAC spend
Monitor purchases and accumulators to assure compliance and understand WAC spend
The DSH hospital eligible for 340B on January 1st is part of a multi-hospital health system. Drug contracts are negotiated by a system purchasing agent for all hospitals. Purchasing is done by the pharmacy buyer in each hospital using GPO and system negotiated contracts. Does anything have to change?

What are individual contracts?
• Are individual **system** contracts acceptable?
• Can the hospital use system contracts for purchase of CODs for 340B non-eligible patients? Within the 4 walls? Outside the 4 walls in non-registered clinics?
• Can an individual contract for just the hospital be negotiated by the system purchasing agent using total system purchase volume?
• Are wholesaler contracts considered GPO purchases?
• Where can “true” individual contracts be loaded…which accounts?
Individual Contracts

- Individual drug contracts must be specific to the single CE, not negotiated by a group or system, and not by a group purchasing agent using total system purchase volume in the negotiations.
- Wholesaler contracts (e.g. generic source) are considered GPO contracts.
- Individual contracts may be loaded into any account; however, the 340B account should be lower priced and loading only into the GPO and non-GPO/WAC may be applicable.
- GPO prohibition requirements apply to the hospital, not a clinic owned by another institution.
Case III: Mixed-Use Inventory

The 340B DSH hospital serves patients and clinics from a common inventory in central pharmacy. The central pharmacy dispenses/distributes to the ED, surgery, endoscopy, cardiology, radiology, a primary care clinic, and all inpatient areas within the 4 walls. How can the hospital be compliant with the GPO prohibition and dispense to inpatients and outpatients from the same inventory?
Mixed-Use Inventory

- How can a neutral inventory be established and maintained?
- Do we have to purchase at WAC first or can we purchase first under GPO and then replenish via 340B or GPO purchases?
- If MgSO₄ injection is shorted, can we use its accumulation to purchase MgSO₄ from another manufacturer?
- What do we do if the ONLY product available is a GPO private label product, e.g., propofol?
- Can we borrow and loan products from the mixed-use inventory?
- What do we do about IVPBs that expire and are wasted? Do we have to replace at WAC since no charge transaction hits the accumulator?
- If we only dispense TPNs to inpatients, can we set-up a dedicated inventory purchased at GPO for TPN compounding?
Neutral inventory is established by first purchasing via a non-GPO/WAC account, then replenished via the correct 340B or GPO account.

Products must be replenished at the 11-digit NDC level:
- Accumulation for one generic cannot be used for purchase of another generic, even if it’s the same drug.

If only one product is available, purchase, keep records, and inform HRSA.

Borrow/loan or buy/sell has risks.

Dedicated inventories may be established but must be compliant with auditable records.
The 340B hospital has an entity owned outpatient oncology infusion center located across the street from the hospital (different address) that only accepts patients of the CE (all patients are 340B eligible). The entity owned pharmacy located in the oncology center prepares chemo and has a retail pharmacy license to dispense outpatient meds to oncology center patients. Does the oncology pharmacy have to obtain meds from the mixed-use inventory of the hospital or can a dedicated 340B inventory be established within the oncology center pharmacy?
Dedicated vs. Mixed-Use Inventories

- Can the entity owned oncology pharmacy establish a dedicated 340B inventory?
- Do the drug charges have to go through the main pharmacy split-billing software?
- Can the pharmacy loan a drug to another hospital or private physician office from the 340B inventory?
- Can the pharmacy purchase meds under GPO contracts if the prices are better than 340B?
- Can the clinic carve out Medicaid and purchase those drugs for Medicaid patients under GPO?
- If the infusion center starts treating non-340B eligible patients, can the pharmacy have a hybrid model with a 340B inventory and a WAC inventory?
• A child site may establish a dedicated 340B inventory
  – If non-eligible patients are served, a WAC account must also be established
• If the clinic carves out Medicaid, a WAC account will be required
• Medications may not be loaned from one 340B inventory to another 340B entity
• A 340B account and a WAC account may be established but mechanisms must be in place to assure non-eligible patients do not receive 340B drugs; a split-billing system may be required
The 340B hospital implements a split-billing system to facilitate establishment and maintenance of the neutral, mixed-use inventory. The split-billing vendor allows the CE to choose the system set-up options. After first purchasing through the non-GPO/WAC account, accumulation occurs and replenishment is made through purchases via the GPO and 340B accounts. The accumulators are monitored, and unusually large accumulation is occurring for some items and large WAC purchases for other items. What’s going on?
Who is responsible for proper set-up of the split-billing system, the vendor or the CE? Who is liable if improper set-up results in violation of the GPO prohibition?

Is the pharmacy responsible for establishment of the crosswalk from the charge master to the purchasing system?

Who is supposed to determine and specify the building units to match the package purchase size?

How do you correct errors in the accumulators?

How do we adjust the accumulator for direct purchases?

Do we have to order Controlled Substances through the GPO, 340B, and non-GPO/WAC accounts? Can we still use CSOS for purchases of CIIIs?

Are all the split-billing software systems compliant with HRSA expectations for GPO prohibition?
The CE is responsible and liable for any errors in the split-billing software set-up or operation that result in violation of the GPO prohibition.

The pharmacy computer system and the financial system charge-master must be kept up-to-date with correct NDC numbers.

- Transactions going to the split-billing system must reflect the NDC of the product administered to enable accumulation of the correct NDC product.

The accumulators and the WAC purchases should be monitored daily to detect incorrect transactions or product build and to minimize unnecessary WAC spend.

Controlled substance are not exempt from the GPO prohibition.

Split-billing systems must be set-up and maintained by the CE to assure compliance; a good split-billing system may not be compliant if it is not set-up or maintained properly.
Takeaways

1. GPO, 340B and non-GPO/WAC accounts must be established to create a neutral inventory for mixed-use areas

2. A mixed-use inventory can be established by first purchasing via a non-GPO/WAC account and replenishing via the GPO and 340B accounts

3. Processes should be established to minimize unnecessary WAC spend

4. Individual contracts must be specific to the individual hospital, no other entity

5. Carefully consider which options you select when setting up split-billing software; monitor daily
Questions

ask your questions by using the Apexus Mobile App
SOLUTION OPPORTUNITIES: IN-HOUSE PHARMACY
Objectives

1. Referrals
2. Medicaid and Duplicate Discount Compliance
3. Sliding Fee Scales-setting payment structures
4. Contract pharmacy
Q. If we refer a patient to an outside clinic, can we fill their prescriptions from our 340B clinic?

A. A covered entity may refer an individual for consultation to an outside clinic not registered for the 340B Program and consider that patient 340B eligible only if the individual receives health care from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity (61 Fed. Reg. 55156 (October 24, 1996). If the covered entity can document that it retained responsibility for the health care services provided to the referred individual, then that individual may be eligible to receive 340B drugs from the covered entity. How a covered entity counts referrals under the 340B Program should be addressed in their written policies and procedures.
Referral Documentation Background

1. Patient sees 340B eligible primary HCP*

2. Referral request noted in patient’s medical record

3. Patient has referral visit and receives prescription

4. Referral visit summary sent to 340B eligible primary HCP

5. Referral visit summary placed in patient’s medical record
A patient presents to your pharmacy with a prescription written by an non-eligible provider (not employed). Upon review of the patient’s EMR you find an outbound referral documented by their PCP and no additional information.

• Let’s discuss the steps you could take prior to filling this patient’s prescription with 340B purchased medication.
Did the patient bring a copy of his visit summary notes from the provider? **YES**

- How would you include a copy in the patient’s EMR? Would you also staple the copy to the prescription order?
- Does your SOP require the patient’s primary care provider to review and sign/stamp for inclusion and prior to filling prescription(s)?
- What happens if the prescription is not covered by the patient’s insurance and you contact the provider and they change the medication? Documentation and Prescription no longer match?
Did the patient bring a copy of his visit summary notes from their provider? **NO**

- To Fill or Not to Fill?
- Contact referral provider and request documentation
How does the Medicaid Exclusion File work?

Manufacturer

Entity

340B Discount

Medicaid Exclusion File

State

Medicaid Rebate

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A covered entity is carve-in and has listed their MPN on the MEF and has participated in the 340B program since 2009. During their most recent HRSA audit the following has been identified:

1. The state utilized the MEF but requires the CE’s NPI to be listed in order for the CE’s dispensations to be excluded from the rebate file.

2. The state also requires National Council of Prescription Drug Programs (NCPDP) claim modifiers to be included for outpatient prescription claims. Entity has been in compliance with processing requirements.

3. The state has submitted and received rebates on physician administered drugs since January 2011.
OPA has issued findings:

• Duplicate Discounts: Medicaid billing numbers were incorrect on the MEF
• Sanctions: repayment to manufacturers

What things should you consider to address these findings in your Corrective Action Plan (CAP) and strategy for addressing repayment?
Corrective Action Plan

- Internal
  - Are you submitting MPN or NPI to Medicaid? Billing office inclusion for resolution

- External CAP
  - Update to MEF and inclusion of NPI(s)

Manufacturer Repayment

- How to identify the physician-administered drugs (PAD) utilized during the time period?
  - Who/How to contact manufacturer?
Health center has a system in place to determine eligibility for patient discounts adjusted on the basis of the patient’s ability to pay.

- This system must provide a full discount to individuals and families with annual incomes at or below 100% of the Federal poverty guidelines (only nominal fees may be charged) and for those with incomes between 100% and 200% of poverty, fees must be charged in accordance with a sliding discount policy based on family size and income.

- No discounts may be provided to patients with incomes over 200% of the Federal poverty guidelines.

- No patient will be denied health care services due to an individual’s inability to pay for such services by the health center, assuring that any fees or payments required by the center for such services will be reduced or waived.

(Section 330(k)(3)(G) of the PHS Act, 42 CFR 51c.303(f), and 42 CFR 51c.303(u))

http://www.bphc.hrsa.gov/programrequirements/index.html
### Sliding Fee Scale - Examples

<table>
<thead>
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<th>110%</th>
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| **Example 2**  |       |       |       |       |       |       |       |       |       |       |       |       |
| DISCOUNT off of Usual and Customary Charge | 100%  | 100%  | 90%   | 80%   | 70%   | 60%   | 50%   | 40%   | 30%   | 20%   | 10%   | 0%    |

| **Example 3**  |       |       |       |       |       |       |       |       |       |       |       |       |
| Charge to patient | $5.00 | $5.00 | 20% of U&C | 20% of U&C | 20% of U&C | 40% of U&C | 40% of U&C | 60% of U&C | 60% of U&C | 80% of U&C | 80% of U&C | 100% of U&C |

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John, an insured patient, receives a service for which the site has established a fee of $80, per its fee schedule. Based on John’s insurance plan, the co-pay would be $60 for this service. John is at 150 percent of the federal poverty guidelines and thus qualifies for the site’s SFS (a 50 percent discount of the $80 fee, resulting in a charge of $40 for this service). Rather than the $60 co-pay, the site would charge John no more than $40 out-of-pocket, consistent with its SFS, as long as this is not precluded by the insurance contract terms.
• Your in-house pharmacy may give careful consideration to SFS pricing structure, as it could impact third party reimbursement
  – Consider a separate self-pay or cash customer fee schedule

• When should you use SFS vs. Self-pay?
  – Non-formulary items not on your indigent care program/SFS formulary?
  – Non-covered item on patient’s insurance? (Viagra)
If you have chosen to work with insurance companies, consider whether you are charging your cash-paying clients a different rate than those who are filing on their insurance. Regardless of your intent, **charging different clients different fees for the same service (based only on whether or not your client pays cash / uses insurance) may be problematic.**
Q. If our contract pharmacy has been purchased by another pharmacy, do we need to update our records with OPA?

A. If a contract pharmacy has changed ownership, HRSA considers this to be a new contract pharmacy arrangement. The covered entity must have a written contract in place with the new contract pharmacy and register the contract pharmacy arrangement on the 340B database prior to use. Covered entities must complete the online portion of the contract pharmacy registration process during an open registration period. For information on how to register a contract pharmacy, see http://www.hrsa.gov/opa/implementation/contract/index.html. The covered entity must also terminate the contract pharmacy relationship established under the previous owners. To effectuate the termination, complete an online termination request: (http://opanet.hrsa.gov/OPA_Mod/CPRegCeSearch.aspx). Failure to report a change in ownership may result in a lapse in 340B access through the specific contract pharmacy.

FAQ 1555
How will this impact your contract pharmacy registration(s) on the OPA database? Recent acquisitions: Walgreens- Rite Aid, Albertsons- Safeway, CVS – Omnicare, CVS – Target Pharmacy

Is the existing contract between the CE and the purchased pharmacy null and void after the date of acquisition?

If a physically separated inventory is maintained at the contract pharmacy what steps will need to be taken to address that 340B inventory? Does your contract address change in ownership and 340B on-hand inventory?
• What can you do to audit a contract pharmacy and identify if sharing between stock has occurred for a physically separate stock at contract pharmacy?
  – Review dispense history for a transaction that occurred on a medication prior to purchase
  – On-site visit and ask staff “How do you handle a situation when you are out of stock of a medication for a 340B ineligible patient, but it is in-stock in one of your other inventory areas (e.g. 340B)?”
Q. If a DSH and a CHC both claim 340B eligibility for a patient (for example, in the case of a referral), which entity can claim 340B eligibility?

A. Only one covered entity may claim 340B eligibility on a specific drug for a particular patient. The individual facts and circumstances of any situation will determine the application of patient definition. HRSA encourages the covered entities to work together, in good faith, to resolve any issues specific to claiming 340B eligibility for a patient. Covered entities that utilize replenishment must have systems in place that ensure that the drug dispensed was not already purchased under 340B and auditable records that demonstrate compliance.
• DSH and CHC are setup with the same contract pharmacy. Who claims 340B savings on the prescription?

• Consider language in contract to define how these prescriptions will be handled?

• How can you monitor?

• Do you exclude referrals completely from your contract pharmacy eligible claims?

• Does the contract pharmacy utilize the same software vendor for all contract pharmacy claims?
ask your questions by using the Apexus Mobile App
SOLUTION OPPORTUNITIES: RURAL HOSPITALS
Inventory Management

• How do you handle expired medications and returns?

• Does your organization link multiple NDCs 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?
• Do you maintain a list of NDC numbers for orphan drugs?
• What are potential pitfalls with the various sources?
  – Split-billing software vendor
  – Wholesaler
Orphan Drug Account Setup

- What process does your wholesaler use to “block” orphan drugs in the 340B account?
- What information and discussions have you had about orphan drugs and 340B pricing with suppliers and wholesalers?
- How will the split-billing software work with the wholesaler account loads to ensure compliance?
After October 14, 2015, a manufacturer of an orphan drug has chosen to continue to offer 340B prices to 340B covered entities?

- Would you as a rural hospital be considered non-compliant for accepting that pricing on orphan drugs?
- Which suppliers are currently supplying you with orphan drugs at 340B pricing?
- What is a conservative approach in operationalizing this in your wholesaler accounts?
Medicaid

- How do you handle managed care organization (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?
Our rural hospital participates in the 340B program and carves-in Medicaid. How should we handle not being able to purchase orphan drugs at a 340B price, when we have stated we bill Medicaid for 340B drugs?

What if our state requires us to carve-in?
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?
- Any comments on pharmacy benefits manager (PBM) contracting/challenges?
• 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?
Orphan Drug Exclusion Repayment

• Have you been approached by a manufacturer for a rebate or repayment on purchases of Orphan Drugs prior to October 14, 2015?

• If you do get approached by a manufacturer, what would your response be?

• What could the process look like for repayment from entities to manufacturers (for 340B purchased orphan drugs)?

• Should you attempt to credit rebill all items to the wholesaler from 340B to GPO?

• What if it is outside of the credit rebill window?
Questions

ask your questions by using the Apexus Mobile App
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
• SOPs to address:
  – Oversight of contract pharmacies (internal and external audits, documentation, plan for when discrepancies occur)
  – When and how self-disclosure would occur, material breach definition
  – Handling controlled substances
How do you define material breach?

ask your questions by using the Apexus Mobile App
Material Breach

- X% of total 340B purchases or impact to any one manufacturer
- $X (fixed amount), based upon total outpatient or 340B spend, or impact to any one manufacturer
- X% of total 340B inventory (units)
- X% of audit sample
- X% of prescription volume/prescription sample
Contract Pharmacy Auditing Question

Do I have to audit my contract pharmacy?

Should I?

What does HRSA expect?

ask your questions by using the Apexus Mobile App
I discovered my vendor/contract pharmacy had been “correcting” non-compliance on its own, without telling us; is this OK?
• Contract pharmacy solution
  – Didn’t load/update the prescriber file at the agreed to interval: diversion
  – Made automatic corrections to non-compliance without notifying the entity: non-transparent to manufacturers
  – Loaded incorrect BIN/PCNs for Medicaid: duplicate discounts

• Split-billing software
  – Updated its software and made a configuration change without notifying the entity: diversion
  – Loaded incorrect orphan drug list: orphan drug exclusion violation

• Apexus split-billing tool: standards checklist
Termination from 340B

- What sorts of things will cause an entity to be terminated from the 340B program?

### 340B DATABASE TERMINATION CODES

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<th>Code</th>
<th>Reason for Termination</th>
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<td>Failure to recertify</td>
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<td>DSH percentage below statutory minimum</td>
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<td>31</td>
<td>Loss of qualifying grant</td>
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<td>32</td>
<td>For-profit conversion</td>
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<td>38</td>
<td>Change of covered entity type</td>
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<td>50</td>
<td>Termination for cause</td>
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<tr>
<td>51</td>
<td>GPO violation</td>
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<tr>
<td>52</td>
<td>Failure to maintain auditable records</td>
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<tr>
<td>99</td>
<td>Other</td>
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1. Sample 340B job descriptions (new)
2. CSOS and 340B (new)
3. 340B Independent Audit RFP Checklist
4. Split-Billing Software Considerations Checklist
5. Self-disclosure tool
6. Sample self-audit guides and SOPs

Tools here:
Five Questions for Entity Leadership

1. How does the entity’s use of 340B align with the intent of the program, and how is that communicated?

2. Does your entity have adequate internal resources devoted to 340B compliance oversight; if you got the audit letter tomorrow, what is the plan?

3. What level of confidence does your entity place in its vendor to assist with compliance?

4. Does your entity optimize the value of 340B and the PVP?

5. What is your entity’s plan for continuous staff education as 340B evolves in the future?
Q: In a contract pharmacy arrangement that incorporates a central fill pharmacy, under what circumstances should the central fill pharmacy be registered as a ship-to address of the entity vs. an additional contract pharmacy?

A: If the central fill pharmacy is a separate entity from the covered entity and is providing medications directly to patients (in person or via mail), then it should be registered as a contract pharmacy.

• If the central fill pharmacy is a separate entity from the covered entity and provides services such as repackaging, but does not take prescriptions directly from patients nor dispense medications directly to patients or their agents, then the central fill location may be a ship-to address of the covered entity.

  – HRSA has permitted on a limited basis and when requested in writing, that such a central fill location that does not take prescriptions from patients nor dispense medications directly to patients or their agents, functioning in conjunction with a contract pharmacy arrangement, be added as a ship-to address of the entity.
Mega-guidance Overview

- Mega-guidance published 8-28-15
- 60 day comment period (ended 10-27-15)
- Timeline could be 1-2 years before finalization
- Focused on improving program integrity
- Increased requirements for both entities and manufacturers
Mega-Guidance Key Areas

- **Entity restrictions/areas**
  - Hospital eligibility (government contracts)
  - Covered outpatient drug (limiting definition, Medicaid bundled claims)
  - Patient definition (discharge, referral, self-insured plans, infusion “only,” billed as outpatient)
  - Records (5 years for entities and manufacturers)
  - Correction through credit-rebill within 30 days
  - No GPO at entity owned pharmacies
  - Improper accumulation could be diversion
  - Contract pharmacy annual and quarterly audits (expectation)

- **Medicaid**
  - HRSA considering changes to Medicaid Exclusion File to handle separate carve-in decisions for MCO vs FFS

- **Manufacturer restrictions/areas**
  - 90 days for manufacturers to correct overcharges
  - Limited distribution plan submission to HRSA for specialty drugs with restricted availability
  - Manufacturer recertification
  - HRSA potentially audits wholesalers
  - Potential OIG involvement if manufacturer fails to provide auditable records or respond to HRSA audit/data requests
Question

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340B UNIVERSITY WRAP-UP
Take Action

Apexus Answers

340BPVP.com

• Register for access to secure section for contract maximization

ApexusAnswers@340BPVP.com
THANK YOU FOR ATTENDING 340B UNIVERSITY!