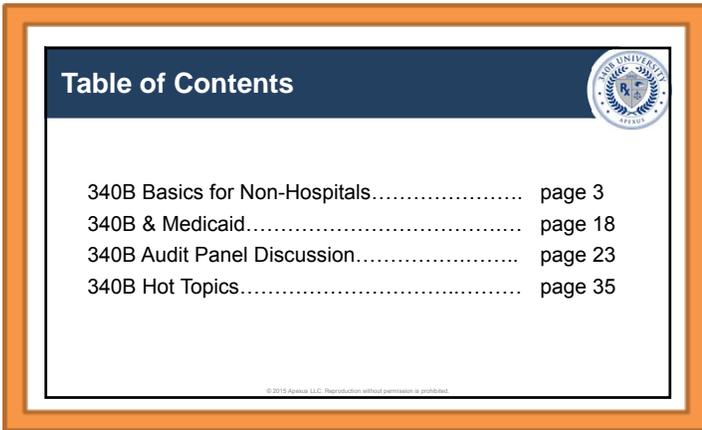
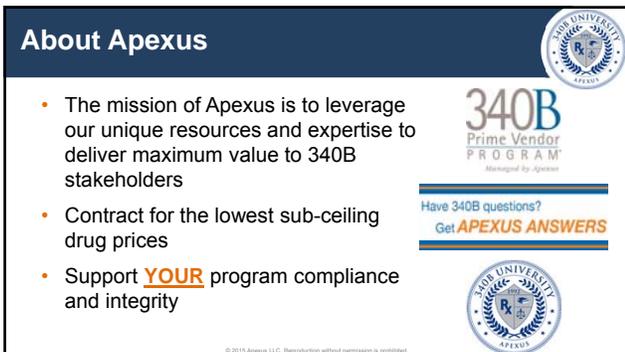


TABLE OF CONTENTS





Goals of 340B University 

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

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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

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Program Scrutiny & Era of Compliance 

- 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.

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HRSA-Supported Tools & Resources

- Apexus Answers call center
- Peer-to-Peer program & webinars
- Many others



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340B BASICS FOR NON-HOSPITALS




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Objectives

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



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1. 340B PROGRAM

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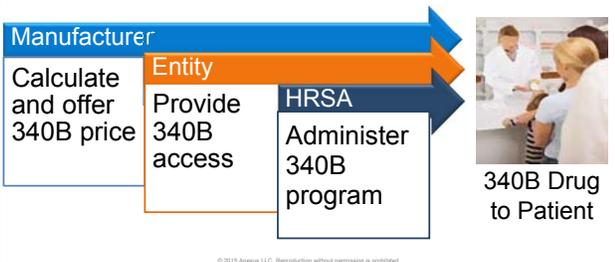
340B Statute



- Resulted from a [1992 federal statute](#), administered by the Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs (OPA)
- Manufacturers participating in Medicaid drug rebate program must sign a [pharmaceutical pricing agreement \(PPA\)](#) with the secretary of Health and Human Services
 - The manufacturer agrees to charge a price for covered outpatient drugs that does not exceed the 340B price

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Major 340B Stakeholders



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340B Eligible Entities

Federal Grantees/Designees	Certain Hospitals
<ul style="list-style-type: none"> Federally qualified health center Federally qualified health center look-alikes Title X family planning grantees State aids drugs assistance programs Ryan white care act grantees (A,B,C,D,F) Black lung clinics Hemophilia treatment centers Native Hawaiian health centers Urban Indian organizations Sexually transmitted disease grantees Tuberculosis grantees 	<ul style="list-style-type: none"> Disproportionate share hospitals Children's hospitals Critical access hospitals Free standing cancer hospitals Rural referral centers Sole community hospitals

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340B Price

- Calculated quarterly
 - Average manufacturer price (AMP)
 - Medicaid unit rebate amount (URA)
 - 340B ceiling price**
- Manufacturer submits data to CMS

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340B Price, with PVP Savings = Lowest in the Marketplace

Pricing Model	Percentage
AMP	100%
AMP	79%
GPO	66%
Medicaid	64%
Coalition	58%
FFS	53%
340B	51%
PVP	49%
BIP prior	42%
VA Average	42%

Adapted from a slide by Safety Net Hospitals for Pharmaceutical Access. Source: Data derived from [Pricing for Brand-Name Drugs Under Selected Federal Programs](#), Congressional Budget Office (June 2005). © 2015 Apexus LLC. Reproduction without permission is prohibited.

340B Covered Outpatient Drugs

Excluded (Red Circle with slash):

- Vaccines
- Inpatient drugs
- Drug not directly reimbursed
- FDA doesn't require NDC

Covered (Green Circle):

- Outpatient drugs
- Over-the-counter drugs (with a prescription)
- Clinic administered drugs
- Biologics
- Insulin

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HRSA 340B Database: Statistics

- HRSA 340B Database: <http://opanel.hrsa.gov/opa/default.aspx>
 - March 2015
 - 29,706 registered sites; 14,526 are non-hospital sites
 - 16,007 unique contract pharmacies

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340B Contract Pharmacy – Overview

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

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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

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Title X and Contract Pharmacies

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2. 340B PROGRAM INTENT

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340B Intent

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



H.R. Rep. No. 102-384(II), at 12 (1992)

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Question

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?

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Apply: 340B Benefit and Use of 340B Savings Tool



340B Benefits and the Use of 340B Savings Documentation Tool Page 1

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

See Handout Page 19

https://docs.340bwp.com/documents/publicresourcecenter/340B_Benefit_and_Use_of_340B_Savings.pdf



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Pearls

- How would you collect this financial data?
- What sorts of things do entities consider “benefit”?
- When and how have entities used this information?




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3. PARTICIPATION IN 340B

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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



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Registration Process

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

Update Official	October 1	January 1	April 1	July 1
Registration Period	July 1 – 15	October 1 -15	January 1 – 15	April 1 - 15

- Change requests: changes to existing information, rolling basis

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Registration, Accountability, and Inventory

- Parent-child vs. different 340B IDs
- HRSA expectations: inventory sharing/transfer

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340B Purchasing, Inventory Transfer

```

graph TD
  G[Grantee] --- SB[Subgrantee B]
  G --- SC[Subgrantee C]
  G --- SD[Subgrantee D]
  SB --- B1[B1]
  SB --- B2[B2]
  SC --- C1[C1]
  SD --- D1[D1]
  SD --- D2[D2]
  
```

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Pearls

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




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Recertification

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



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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



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2015 Title X Recertification

- Wednesday May 13th – June 10th
- Advanced notifications will go out to all covered entities on May 11th with dissemination of usernames and passwords to all Authorizing Officials on May 13th



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Pearls

- Make sure your authorizing official knows the email is coming, knows what to do with it, and does NOT delete it
- If you have a material breach of non-compliance, you may still recertify
- Recertify early in the window so that time to correct issues if they arise

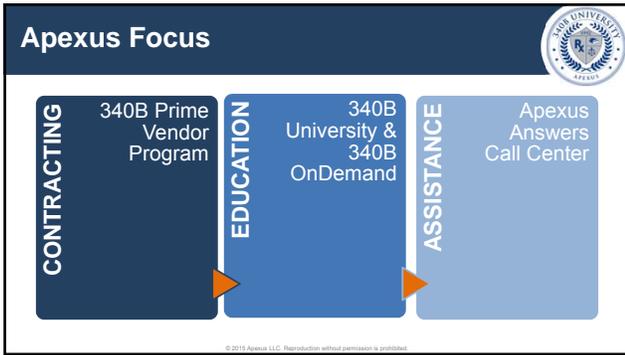


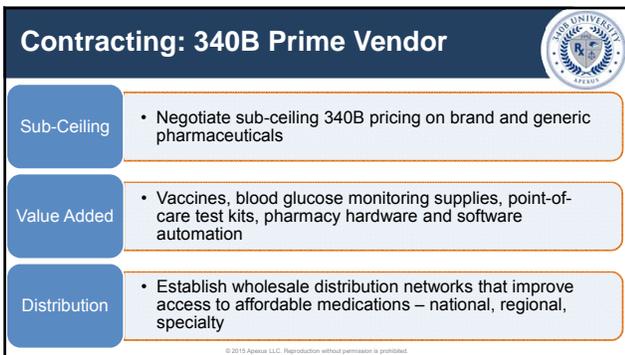

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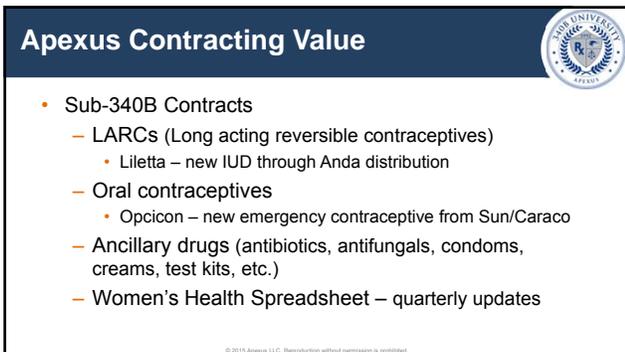


4. THE PRIME VENDOR PROGRAM

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- ### Assistance: Apexus Answers
- National 340B source of truth, communicates HRSA policy
 - Staff in constant communication with HRSA to ensure messaging is consistent
 - FAQs available here: <https://www.340bpvp.com/resource-center/faqs/>
 - Average monthly interactions ~1,500-2,000
 - Tiered levels of response: can handle from basic to complex



5. 340B PROGRAM OVERSIGHT/COMPLIANCE





- ### Major 340B Compliance Areas
1. Duplicate discount prohibition
 2. No diversion (patient definition)
 3. Certain hospitals only
 - Group Purchasing Organization (GPO) Prohibition
 - Orphan drug exclusion
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Takeaways



4. The 340B Prime Vendor Program provides:
 - Contracting (contracting with distributors and suppliers)
 - Education (340B University)
 - Assistance (Apexus Answers Call Center)
5. Covered entities must maintain auditable records:
 - Only patients of the covered entity receive 340B drugs
 - A Medicaid rebate is not paid on a 340B drug
 - All eligibility criteria are met

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Questions




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340B & MEDICAID




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Objectives

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

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Duplicate Discount Prohibition

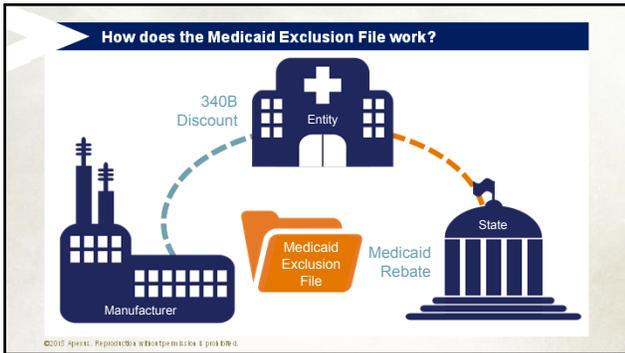
The diagram features a central white pill bottle with an orange label. To its left is a blue arrow pointing right with the text "340B price". To its right is a blue arrow pointing left with the text "Medicaid rebate".

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Medicaid Exclusion Terminology

Carving-In	Carving-Out
	

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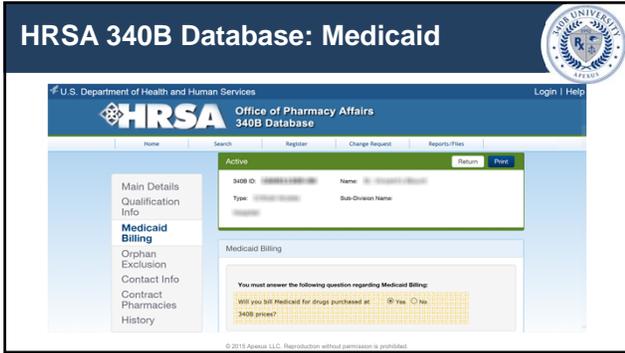


HRSA, CMS & State 340B Policy

This slide details the policies of HRSA, CMS, and the State regarding 340B drugs. It includes logos for HRSA, CMS, and the State of Virginia. The HRSA Policy section lists: Prevent duplicate discounts; Use the Medicaid Exclusion File; and Bill according to the state policy (no HRSA AAC requirement). The CMS Policy section lists: Collect rebates on claims (including MCO and clinic administered); and 340B drugs are not subject to these rebate collection requirements. The State Policy section lists: How will duplicate discounts be prevented in the state? and How will 340B entities bill Medicaid and how will Medicaid reimburse these entities when using 340B drugs?

Who uses the Medicaid Exclusion File?

This slide identifies the three main users of the Medicaid Exclusion File: Covered Entities, State Medicaid Agencies, and Manufacturers. Covered Entities designate if they will be billing the state for 340B drugs. State Medicaid Agencies use the file to exclude 340B claims from their rebate requests to manufacturers. Manufacturers use the file to verify denial of payment of Medicaid rebates for 340B claims.



Actions to Review Duplicate Discount Prohibition Compliance

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

Medicaid Reimbursement Leading Practices

What states are doing:

- Surrogate pricing model
 - WAC-X% is maximum state pays, regardless of what is submitted
- Rebate bill back
 - State pays typical reimbursement, invoices entity for the rebate usually paid by manufacturer
- MAC pricing of limited-use medications
 - State sets MAC for a group of 340B drugs (ex. HTC)

Medicaid Scenarios



- Medicaid in one state required 340B entities to share with the state any 340B overcharge repayments from manufacturers to entities.
- Medicaid in another state announced mandatory “self-auditing” for 340B entities to determine/repay the state if the entity had ever billed Medicaid for a “non-covered outpatient drug” in the last six years. There was not a list of non-covered outpatient drugs provided to the entity.
- Medicaid in a different state announced it will not use the HRSA Medicaid Exclusion File, and instead uses NCPDP. Manufacturers are directed to work with entities regarding disputes.

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Tips for Pharmacy Technicians



- Check the HRSA 340B Database listing to ensure the Medicaid information reflects practice
- Ensure Medicaid patients with retroactive eligibility are accounted for in 340B software/operations and treated consistently with standard operating procedures

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Takeaways



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

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Questions



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340B AUDIT PANEL



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Objectives

- Explain the key points of the audit processes
- Describe current events in HRSA and manufacturer audits
- Discuss tools available to self-assess in preparation for an audit



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HRSA AUDITS

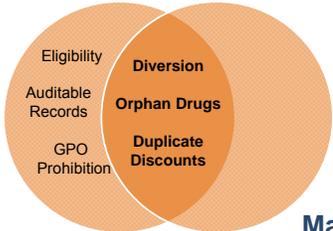
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HRSA vs. Manufacturer Audit of Entity



HRSA

- Eligibility
- Auditable Records
- GPO Prohibition



Manufacturer

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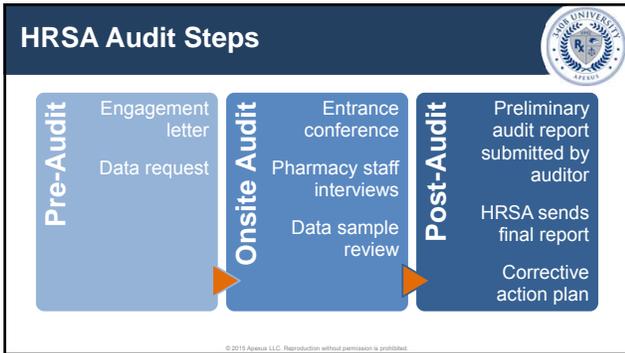
Types of HRSA Audits of Entities

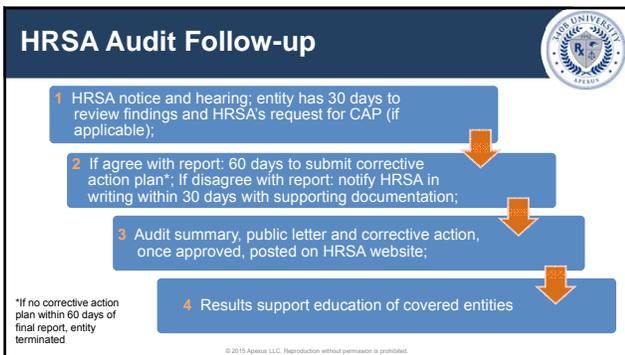




- 1. Randomized/risk-based**
 - Complex program administration
 - Number of child sites
 - Volume of purchases
 - Contract pharmacy arrangements
- 2. Targeted**
 - Allegations of violations

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HRSA Audits by the Numbers

	FY 2012	FY 2013	FY 2014	FY 2015* (As of Mar 6)
Number of covered entities audited	51	94	99	61
• Outpatient facilities/sub-grantees	410	718	1,476	764
• Contract pharmacies	860	1,937	4,028	1,786
Number of finalized reports	51	83	42	4

An orange arrow points upwards from the bottom right of the table.

Example HRSA Audit Findings



Diversion

340B drugs dispensed at ineligible sites	Not spot checking inventory to check for diversions and correcting them (variance)	340B drugs dispensed at ineligible site and by an ineligible provider	340B drugs dispensed to non-patient at contract pharmacy
--	--	---	--

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Example HRSA Audit Findings



Duplicate Discount

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

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Example HRSA Audit Findings



Eligibility, Auditable Records

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

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Audits – Manufacturer Conducted



- Authority
 - 340B statute, guidelines
- Requirements
 1. Reasonable cause
 2. Workplan to HRSA
 3. Independent auditor
 4. Limited to diversion/duplicate discounts
- HRSA has received 10 work plans
- HRSA works with them throughout the process

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**ENTITY EXPERIENCE:
PREPAREDNESS
& LESSONS LEARNED**

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Objectives



- Family Health Council of Central Pennsylvania, Inc. (FHCCP) at-a-glance
- HRSA audit steps
- Highlight sub-grantee audit experience
- FHCCP compliance plan
- Tools
- Best practices

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Family Health Council of Central Pennsylvania, Inc.



- 501(c)(3) non-profit
- Incorporated in 1973
- Mission
 - To build and support community based networks through:
 - Partnerships
 - Education
 - Advocacy
 - Effective resource allocation

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Family Health Council of Central Pennsylvania, Inc.



- Prime Contractor
 - Women, Infants and Children's Program
 - HIV- Ryan White, housing
 - Family planning
- 16 Sub-Grantees/24 sites
 - 5 federally qualified health centers (FQHC's)
 - 5 hospital-based clinics (non-DSH)
 - 4 stand alone clinics
 - 1 Planned Parenthood
 - 1 college-based clinic
- 340B program covered entity since 1998

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FHCCP 340B Timeline



1998-2012	<ul style="list-style-type: none"> • Ordered in bulk • Stored inventory • Filled orders for network
2012-2013	<ul style="list-style-type: none"> • Stopped keeping inventory onsite • Ordered on behalf of sub-grantees • Manufacturer shipped directly to clinic site
2014-Present	<ul style="list-style-type: none"> • Integrated 340B compliance into family planning program compliance • Education component to family planning orientation • Shifted responsibility of ordering and storing inventory to sub-grantees

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340B Compliance Concerns

- Definition of a patient
- Medicaid Exclusion File (MEF)
- Policies & Procedures
- Compliance
- Self Audit



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FHCCP Sub-Grantee Audit Experience

FY 2012 • First HRSA audit

FY 2014 • Second HRSA audit

FY 2012-Present • No sub-grantees in the FHCCP network have experienced a manufacturers audit



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HRSA Audit Steps

Pre-Audit	HRSA Letter Data request	Onsite Audit	Entrance conference Staff interviews Data sample review Exit Interview	Post-Audit	Preliminary audit report HRSA sends final report Corrective action plan
------------------	-----------------------------	---------------------	---	-------------------	---



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Pre-Audit Process

- Authorizing official is notified of pending HRSA audit
- Audit period and data request clearly outlined
- Begin pulling data
- Identify key stakeholders that will be involved in process
 - Authorizing official
 - Billing
 - Fiscal

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HRSA Audit Steps

```

    graph LR
      A[Pre-Audit  
HRSA letter  
Data request] --> B[Onsite Audit  
Entrance conference  
Staff interviews  
Data sample review  
Exit Interview]
      B --> C[Post-Audit  
Preliminary audit report  
HRSA sends final report  
Corrective action plan]
  
```

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On-Site Audit Tips

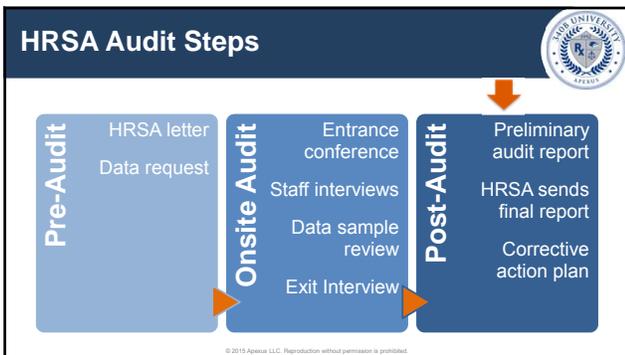
- Ensure familiarity with policies and procedures
 - Make certain your processes validate policies and procedures
 - Staff education
- Involve staff who understand data sets and can maneuver through medical record efficiently
- Keep all documents/contracts/audits in one easily accessible location
 - Organize in same format as HRSA data request

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On-Site Audit Tips

- When possible use flow charts or diagrams to facilitate discussions with auditor
- Consider external and internal audit results that can be shared with auditor
- Have staff available who can respond to questions
 - 340B policies & procedures
 - Credentialing of professional staff
 - Billing office (Medicaid billing)
- Consider interaction with auditor as collaborative

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Post-Audit Steps

- No formal conclusions made on-site
- Types of outcomes
 - Areas for improvement
 - Adverse findings
 - Corrective action plans (CAP)
 - Repayment to manufacturers
 - Removal from program
 - Lack of auditable records
 - Lack of submission of CAP if required

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Corrective Action Plan (CAP)



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

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FHCCP Sub-Grantee Audit Experience



<ul style="list-style-type: none"> • FY 2012 – 1st Sub-grantee audit <ul style="list-style-type: none"> – Duplicate discounts – Inaccurate Medicaid provider number in the HRSA Medicaid Exclusion File (MEF) – HRSA encouraged the organization as a sub-grantee to work with FHCCP to ensure 340B Program compliance – Corrective action plan <ul style="list-style-type: none"> • Public letter to manufacturers • Repayment to manufacturer 	<ul style="list-style-type: none"> • FY 2014 – 2nd Sub-grantee audit <ul style="list-style-type: none"> – Duplicate discounts – Inaccurate Medicaid provider number in the HRSA MEF – NPI number not listed on MEF – Corrective action plan <ul style="list-style-type: none"> • Repayment to manufacturer
---	---

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Components of FHCCP's 340B Compliance Plan



- Core team of individuals (Compliance Manager, Family Planning Director, Provider Relations Director, Fiscal Officer) responsible for family planning program integrity
 - Attend 340B meetings
 - Meet regularly regarding 340B issues
 - Title X Advisory Council – Apexus
- 340B policies and procedures
 - Procurement & inventory management
 - Dispensing/ distribution
 - Handling of Medicaid
 - Responsibility of MEF
 - Recertification process
 - Self-audits

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Tools: Apexus 340B University




Sample 340B Policy & Procedures Manual
A Guide for Family Planning Entities Page 1

Family Planning 340B Compliance Self Assessment: Policy
https://docs.340bvp.com/documents/public/resourcecenter/FP_340B_Compliance_SelfAssessment_Policy.pdf

340B Compliance Self-Assessment: Self-Audit Process for CHCs
https://docs.340bvp.com/documents/public/resourcecenter/CHC_340B_Compliance_SelfAssessment_DataTransactions.pdf

Self Reporting 340B Non-Compliance Template
https://docs.340bvp.com/documents/public/resourcecenter/All_Entities_Self_Reporting_340B_NonCompliance.pdf



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Must Haves...For Best Practice and 340B Compliance



- Internal 340B team that is engaged
 - Roles
 - Responsibilities
- Ongoing collection of data that will be requested by HRSA
- Self-audits – use Apexus audit tool
- Review Medicaid exclusion file

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Key Takeaways



- Grantees can help sub-grantees prepare for HRSA and manufacturer 340B audits with available tools and resources
 - Apexus tools: self-audit, sample policy and procedure manual, self-reporting
- Prepare for a HRSA audit now
 - assemble an internal team and self-audit
- The goal is perpetual compliance readiness

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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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Takeaways

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

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Questions



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340B HOT TOPICS



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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

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Authorizing Officials

- Is your authorizing official at the state level or at the local level?
- How did you arrive at that decision?
- How does that decision impact your organization?

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Transfer of 340B Drug



- If you needed to transfer a 340B drug from a FP entity to a private physician (for example, an IUD for insertion), what 340B-related concerns would you have?

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Best Practices in Auditable Records



- Think about the records you keep for 340B patients/drugs. What 340B record-keeping best practices can you share with your peers?

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Material Breach



- Consider the last time you suspected or observed 340B non-compliance. How did you decide whether or not to disclose this to HRSA?
- How have you defined material breach? When would that be helpful?

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Apply: Defining Material Breach




340B University
Defining Material Breach Documentation Tool

Page 1

Purpose: This tool is designed to provide entity leaders with a framework to guide the written documentation of the entity's definition of a material breach of compliance and the development of a process to determine materiality that requires self-disclosure, based on leading practices. Note: Materiality is commonly required as

See Handout Page 21

https://docs.340bvp.com/documents/public/resourcecenter/Establishing_Material_Breach_Threshold.pdf



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Termination from 340B



- What sorts of issues have you heard about that have caused an entity to be terminated from the 340B program?

340B DATABASE TERMINATION CODES

Code	Reason for Termination
12	Site closure
13	Failure to recertify
30	DSH percentage below statutory minimum
31	Loss of qualifying grant
32	For-profit conversion
38	Change of covered entity type
50	Termination for cause
51	GPO violation
52	Failure to maintain auditable records
99	Other

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340B University: Top Compliance-Focused Tools



- 340B Independent Audit RFP Checklist (new)
- Defining material breach (new)
- Self-disclosure tools
- Sample self-audit guides
- Sample SOPs

<https://www.340bvp.com/340b-university/tools-and-resources/>



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Apexus Certificate Program



- Overview
 - Three-tiered certificate program for individuals
 - Role-specialized 340B training
 - Assessment-based
 - Mode of delivery—OnDemand
- Purpose
 - To certify that individuals who have completed the required training program and assessment, have demonstrated accomplishment of the intended learning outcomes, and have the proficiency to support their particular role in 340B.

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Apexus Certificate Program: Curriculum Structure & Audience



Level 1	Open Course	Level 2	Application Certificate	Level 3	Master Certificate
	<u>Overview</u> of foundational 340B knowledge		<u>Application</u> in 340B operational integrity		<u>Policy</u> to practice compliance interpretation

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Apexus Education and Compliance Support



- Field-based pharmacists
 - Focus on providing participants 340B compliance support and PVP contracting optimization
- Site visits
 - Exchange ideas with leading practices and inform the stakeholder community via 340B University, tools, and Apexus Answers

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Questions




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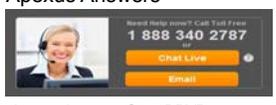
340B UNIVERSITY WRAP-UP




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Take Action

Apexus Answers



ApexusAnswers@340BPVP.com

340BPVP.com

- Register for access to secure section for contract maximization



Apexus | 340B Prime Vendor Program | 290 E John Carpenter Frwy | Irving, TX 75062

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**THANK YOU FOR ATTENDING
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