340B HRSA Audit Session
(The Good, The Bad, The Reality)

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Madeline Carpinelli Wallack, PhD, MS

CEO/Founder

Rx|X Advisory Services, LLC

Jason Prokopik, Pharm.D., 340B ACE

Senior Manager - Pharmacy

Blue & Co. LLC

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August 25 & 26, 2025

DISCLOSURE STATEMENT

- Madeline Wallack and Jason Prokopik:
  - have no relevant financial relationship(s) with ineligible companies to disclose.

    and
  - None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

LEARNING OBJECTIVES

At the completion of this activity, the participant will be able to:

- Review standard HRSA auditing practices and outline the covered entities responsibilities in this process.
- Discuss real word experience from multiple HRSA audits.
- Identify best practices and areas of opportunities for covered entities undergoing HRSA audits.

Presentation Agenda

- 340B Audit Basics
- Past Results
- Overview of Audit Life Cycle
- Audit Preparation & Best Practices
- Overview of Non-Compliance
- Correction Action Plan Overview
- Real World Examples
- Questions

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340B Audit 101

- Initiated by the Health Service and Resource Administration (HRSA) and the Agency's contracted vendor, the Bizzell Group
- Approximately 200 conducted per year
- Covered entities selection both random and purposive
- The audit cycle aligns with the fiscal year in September;
  - New Data Request List published in September
  - Notices distributed typically every 2 months; September, December, & March for audits through June.

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HRSA Audits

- Conducted in most cases by auditors from the Bizzell Group who came from PSSC or Covered Entities, but some recent audits conducted by HRSA employees
- Typically, one to two days either onsite or virtually one-day

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HRSA Audit Findings

2024 Results

- DSH – 52 (findings – 29) with 16 resulting in repayment or terminations
- CAH – 44 (findings – 26) with 10 resulting in repayment or terminations
- FQHC – 21 (findings – 11) with 7 resulting in repayment or terminations
- SCH/RRC – 15 (findings – 10) with 1 resulting in repayment or terminations
- Ryan White / STD – 8 (findings – 2) with 1 resulting in repayment or terminations
- Pediatrics – 3 (findings – 1) with 0 repayments or terminations

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Ohio HRSA Audit Results

- **2022** – 7 results posted
  - 2 DSH, 1 CAH, 1 SCH, 1 RRC, 1 PED, 1 CHC
  - 5 results had finding but 0 had repayment requirements
- **2023** – 10 results posted
  - 3 RRC, 2 DSH, 1 DSH, 1 PED, 3 CHC
  - 7 results had finding with 4 resulting in repayment or terminations
- **2024** – 7 results posted
  - 3 DSH, 2 CAH, 1 RRC, 1 CHC
  - 4 results had finding with 1 resulting in repayment
- Findings did not all result in payback (incorrect OPAIS record or suspected Medicaid duplicate discounts)

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340B Audit Life Cycle

1. Audit Notification and Pre Audit data Preparation and timelines
2. Interim preparation process (time after data submission but before onsite review)
3. Pre-audit sample review (3 days prior to Day 1)
4. Onsite review onsite / virtual visit
5. Post audit (3 days for follow-up production) and awaiting report

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Example Notification Letter

HRSA
Health Resources & Services Administration
Office of Special Health Initiatives
5600 Fishers Lane
Rockville, MD 20857

[redacted]

[redacted]

[redacted]

The Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA) is undertaking program integrity measures related to participation in the 340B Drug Pricing Program (340B Program) to ensure compliance with program requirements. Per 42 USC 256b(a)(5)(C), HRSA has the authority to perform audits of a covered entity's records that directly pertain to the entity's compliance with 340B Program requirements. [redacted], 340B ID [redacted], has been selected for audit. HRSA has contracted with Bizzell US, to perform this audit. The scope of the audit may also include 340B Program compliance for offsite outpatient facilities, contract pharmacies, and associated 340B ID Numbers. Please be aware that sometimes associated sites are not determined until the first conference call with the entity selected for audit.

In general, the 340B Program audit is designed to (1) Obtain an understanding of the entity's policies, procedures, and drug operation environments; (2) Review the entity's eligibility status, including compliance with the Group Purchasing Organization (GPO) prohibition for certain entity types; (3) Review the entity's 340B Office of Pharmacy Affairs Information System (OPAIS) record for accuracy; (4) Review drug procurement and distribution to determine whether the entity provided 340B drugs to appropriate patients as defined by Section 340B(a)(5)(B) of the Public Health Service Act (PHSA); and (5) Determine whether the entity properly prevented duplicate discounts, as required by Section 340B(a)(5)(A) of the PHSA.

Prior to the onsite portion of the audit, Bizzell US will work with the personnel that you select to arrange a welcome conference with you, key management/administrative staff, and those who are closely involved with the activities of the 340B Program and to collect relevant documents at the entity site. HRSA 340B Program audit procedures will, at a minimum, include review of the facility's

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Sample HRSA 340B Audit Data Request List (DRL) for Covered Entities

Purpose: This tool provides an example data request list (DRL) for a HRSA 340B audit. This is only a sample and may differ from an actual HRSA data request.

Covered Entity Data Request

1. Provide Policies and Procedures on the Following Topics

A. Description of covered entity's registration and recertification process

B. Process for ensuring that the 340B OPAIS record is up to date and accurate for the parent, applicable off-site outpatient facilities/grant-associated sites, and contract pharmacies (including regular review and timely update of 340B OPAIS records)

C. Process for determining which sites are eligible; address whether each service area in which 340B drugs are purchased, ordered, or provided is included on the grant or reimbursable on the covered entity's most recently filed Medicare cost report (MCR)

D. Description of purchasing process (including all pharmacies, if applicable)

E. Prevention of GPO Prohibition violations (applies only to DSH, PED, and CAN)

F. Definition for any exclusions to the definition of covered outpatient drugs (e.g., bundled drugs, orphan drugs, or inpatient drugs)

G. Covered entity's process for conducting oversight of its contract pharmacy(ies):
- Internal audits
- Independent audits

H. How the covered entity accounts for 340B inventory or accumulation, if applicable (physical inventory vs. virtual inventory replenishment)

I. Prevention of diversion at **covered entity**—process for confirming the following:
- Site eligibility location
- Referral/responsibility of care remained with covered entity
- Medical/patient health record
- Patient eligibility (including status change)
- Provider eligibility (relationship)
- Service in the scope of grant (if applicable/non-hospital)
- Documenting and accounting for wastage of a drug not administered

J. Prevention of diversion at **all pharmacies**—process for confirming the following:
- Site eligibility location
- Referral/responsibility of care remained with covered entity
- Medical/patient health record
- Patient eligibility
- Provider eligibility (relationship)
- Service in the scope of grant (if applicable/non-hospital)

Sample HRSA 340B Audit Data Request List (DRL) for Covered Entities

9. Provide Medicaid Billing Documentation (cont.)

C. For any pharmacy that is registered as a contract pharmacy, provide a list of the state(s) billed and the corresponding billing number(s) listed on the claims billed to Medicaid fee-for-service for each state. Billing number(s) are listed on paper or electronic claims to Medicaid fee-for-service and may include the billing provider's NPI and/or state-assigned Medicaid number.

- For each pharmacy, provide one Medicaid fee-for-service claim during the sample period (INSERT 6-MONTH PERIOD) for each state billed. If a Medicaid bill for a site is not available during the sample period, provide a recent bill.

Example Table C:

Contract Pharmacy Name	Contract Pharmacy Address	State Medicaid	State Medicaid BIN	State Medicaid PCN	Billing NPI(s)	Billing State Medicaid Number(s)	Medicaid Fee-for-Service Claim Form
		MA			1234567890	101112	[Embedded document]
		CT			1234567890		[Embedded document]
		MA			1234567890	131415	[Embedded document]

D. Describe each state's requirement for billing 340B drugs when dispensed at pharmacy(ies) and when administered at a facility (e.g., claims modifiers). Be prepared to present additional copies of claims during the on-site/remote audit (all payers including primary, secondary, and tertiary).

10. Provide Combined Purchasing and Distribution Model (CPDM) Documentation

(Skip this section if there is no approved CPDM)

A. Provide a description and supporting documentation of the covered entity's most updated CPDM proposal approved by OPA, including the list of the purchaser and all receivers by 340B ID.

Note: The covered entity should be prepared to provide the auditor with additional documentation related to all sites participating in the CPDM.

11. Re-Audit

A. Provide a description and supporting documentation of how the covered entity determined the full scope of noncompliance (e.g., identified affected manufacturers, amount of repayment, communication with state Medicaid agency).

B. Provide a list of all affected manufacturers, letters sent to manufacturers offering repayment, and list of settlements.

C. Provide description(s) and supporting documentation of continuous monitoring with periodic assessment related to the previous audit finding(s).

***This is a sample of the first and last page, of a HRSA Audit DRL for Covered Entities.**

340B Audit Preparation

- Preparation is the key!
  - Review Onsite logistics and schedule with team and departments
  - Walk through buying process and interview clinic staff
  - Validate claims and accumulations ahead of time!
    - Prescription origination or else? How do you explain your interpretations?
    - Are there any issues with units?
  - Provider credentialling

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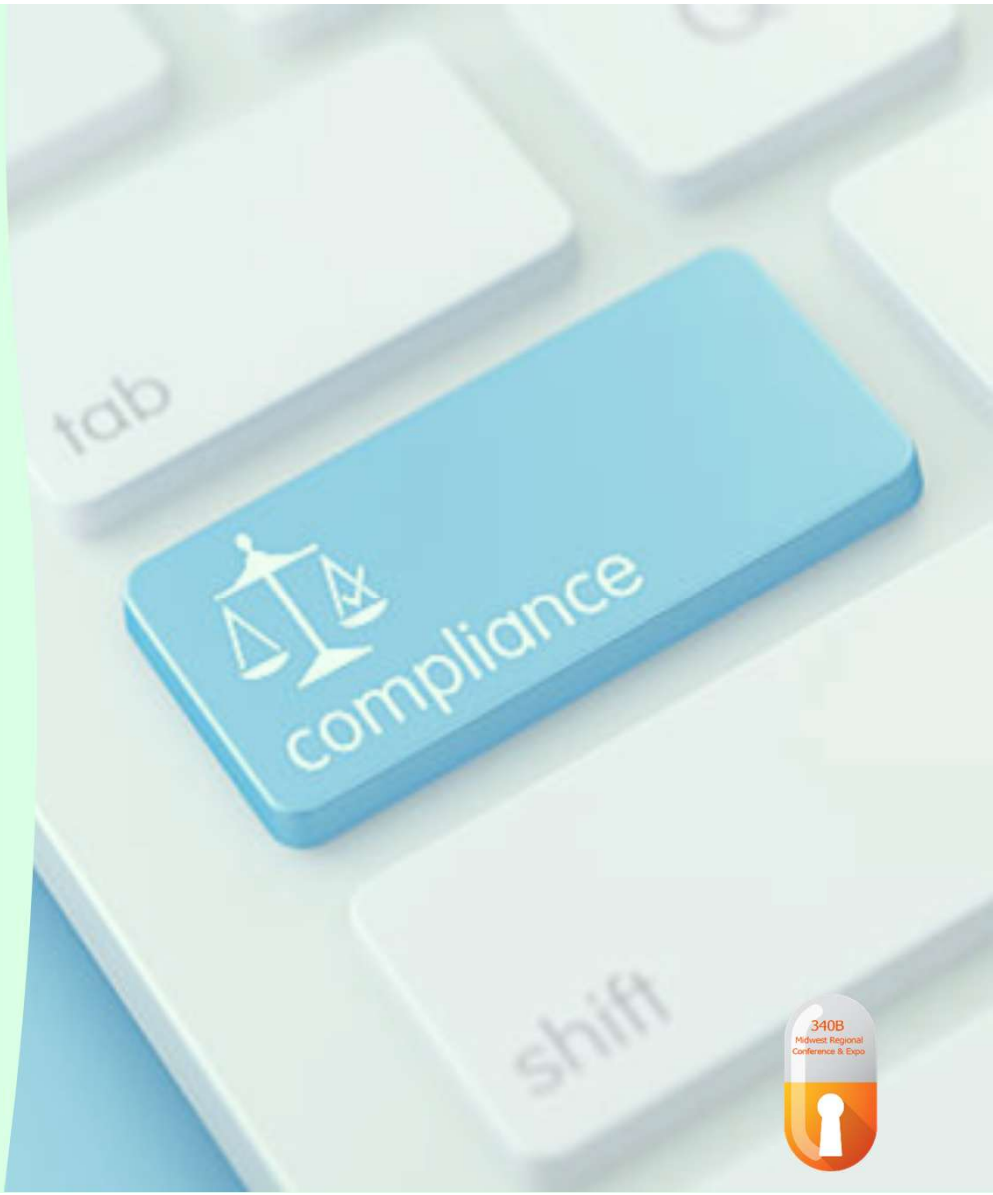
Audits-Compliance

Areas of Focus

- Eligibility
- Registration and Database Issues
- Drug Diversion
- Duplicate Discount (out of state Medicaid
- GPO Violations (DSH, PEDS, CAN)
- Other



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Drug Diversion

Examples:

- Prescription written at ineligible Location
- Prescription written by ineligible Provider
- Drug dispensed to In-patients
- Prescription not supported in the medical record
- Drugs not accumulating properly
- Patient not 340B eligible
  - Not a patient of the CE
  - Referrals – gray area of 340B compliance

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Duplicate Discounts

- Manufacturers that participate in Medicaid are required to issue a rebate to the State's each quarter
- Manufacturers are not required to provide a rebate on the same drug it sold at 340B pricing
- Covered entities must have mechanisms in place to prevent duplicate discounts from happening

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Duplicate Discounts

HRSA Medicaid Exclusion File

- MEF applies to FFS Medicaid only
- States with Managed Medicaid – questions are asked by HRSA auditors
- Will you bill Medicaid for drugs purchased at 340B prices
  - ANSWER YES- Must list your Medicaid Provider #s and NPI #s on the MEF
  - Out of State Medicaid-Must list ALL NPI #s
- MEF must be accurate and complete for every registered site

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HRSA Audit Findings

Remedies

- Corrective Action Plans – some CAPs satisfied findings
  - Responsibility of covered entity to determine full scope of finding(s)
- Possible repayment to manufacturers
  - Responsibility of covered entity to determine amounts
- Some resulted in termination of child site clinics and/or contract pharmacies
- Removal from program – does not appear to have happened in 2023

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Correction Action Plan Timing

- OPAIS delivers final report (Bizzell collects data)
  - Findings and / or Areas for Improvement
  - 3 months to 12 months to distribute
  - 30 days to dispute findings
  - 60 days to provide correction action plan (CAP)
  - 6 months to finish restitution with manufacturers

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CAP Best Practices

- Should you dispute it or not?
- Provide a thorough response
- Be specific in your answers
- Establish a detailed plan
- Seek legal and consulting advice

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Audit Experiences

- Data request
- Onsite / virtual visits
- Questions asked
- Findings
- Provider eligibility
- Referrals
- Changes over time

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NEED MORE INFORMATION?

Madeline C. Wallack, PhD, MS, 340B ACE

Rx|X Advisory Services

mwallack@rxxconsulting.com

612.801.0976

Jason Prokopik, PharmD, 340B ACE

Blue & Co., LLC

jprokopik@blueandco.com

317-713-7916