NPS PHARMACY

Staying Audit-Ready: Compliance Without the Panic

SPEAKERS

Danielle Mathers, 340B ACE
Senior Vice President, 340B
NPS Pharmacy
Dmathers@npspharmacy.com
410-562-3806

Amber Roelofs, JD, 340B ACE
Chief Operating Officer
Ponaman Healthcare Consulting
Amberr@ponamanhc.com

Michael Gonzalez, 340B ACE
Chief Financial Officer and Founder
FQHC 340B Compliance
mgonzalez@fqhc340b.com

Why Does HRSA Conduct 340B Audits?

To ensure covered entities are compliant with 340B statute and guidelines

To ensure duplicate discounts are not occurring

To prevent diversion and duplicate discounts

Who Conducts the Audits?

HRSA audits are performed by the Bizzell Group on behalf of the Office of Pharmacy Affairs (OPA)

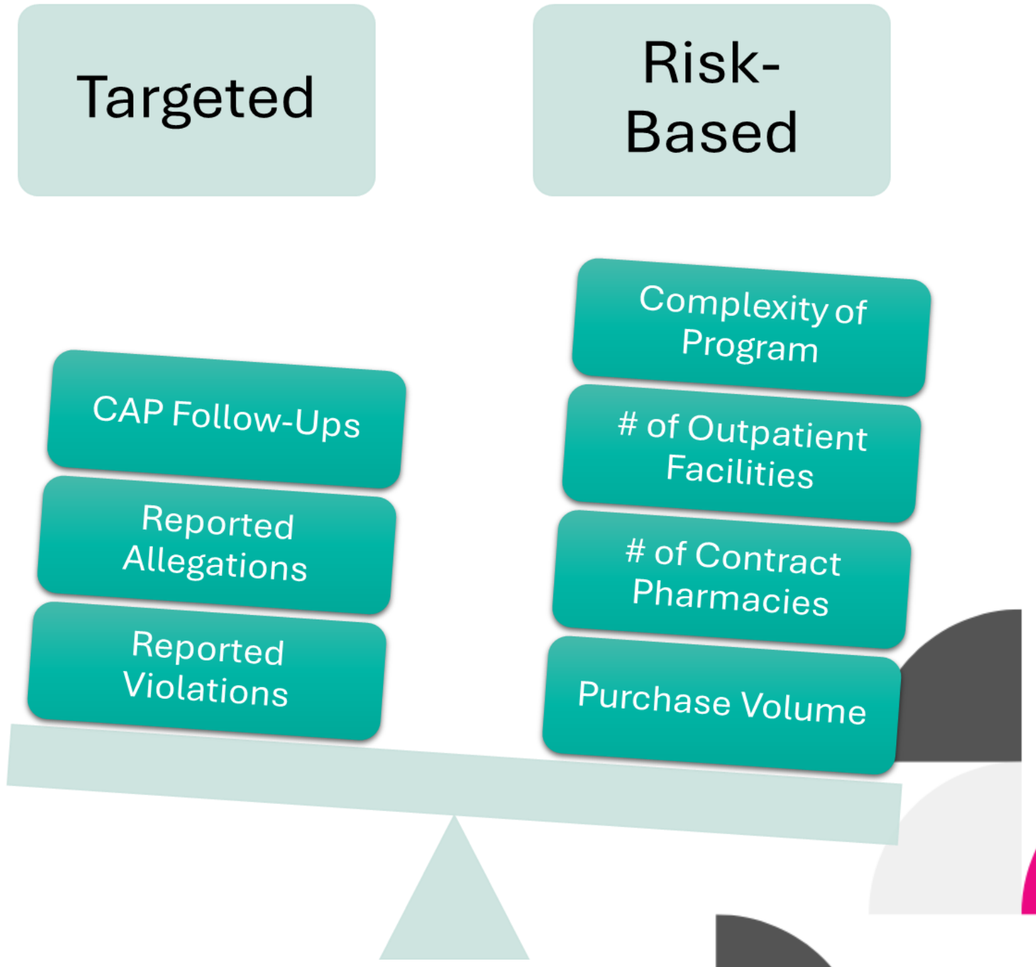
Audits can be on-site or virtual

HRSA is averaging 55-day notice period

HRSA Audit Basics

- About 200 Audits each year
  - ~80% Hospital,15% FQHC, 3% STD, & 2% RW
- Risk-based audits begin after **15** months in the Program
- Adverse findings may result in MFR repayments or termination from Program
  - Audit results published on OPA website:

    https://www.hrsa.gov/opa/program-integrity



HRSA Audit Results 2020-2025

CE Type	2020	2021	2022	2023	2024	2025	Total
FQHC	30	33	34	22	18	1	138 (15%)
Hospital	160	158	160	139	128	5	750 (80%)
Other Grantee	3		1		2		6 (1%)
Ryan White	1	6	2	6	2		17 (2%)
STD	6	3	3	7	5		24 (3%)
Grand Total	**200**	**200**	**200**	**174**	**155**	**6**	**935**

The Audit Notification Process

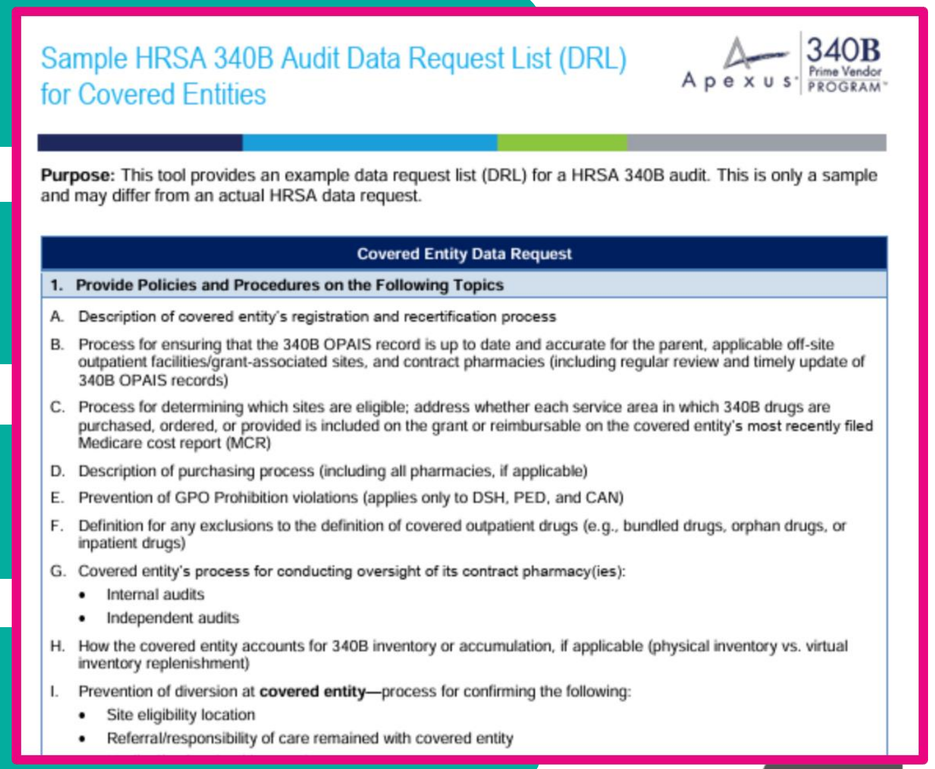
Audit notification letter sent to the Authorizing Official (AO) and Primary Contact

Includes Data Request List (DRL) and pre-audit questionnaire

Entity must confirm audit date and begin collecting documents

Data Request List (DRL) Overview

- 1. Patient eligibility documentation
- 2. Provider list and credentialing info
- 3. Pharmacy services contracts
- 4. Policies and procedures
- 5. Inventory and replenishment documentation



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

Apexus 340B Prime Vendor PROGRAM

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

Preparing for an Audit

Review and organize DRL materials early

Ensure P&Ps are up to date and reflect current practice

Verify pharmacy and provider contracts

Maintain clear records of 340B eligibility and purchases

Conduct a mock audit if possible

What Happens During the Audit?

- Opening conference
- 340B related staff interviews
- Site visits
- Data sampling
- Credentialling testing
- Dispense to replenishment testing
- Closing conference

HRSA FINAL REPORT EMAIL

- Sent to AO and PC
- May go to Spam or Junk folder
- Audit results are in the attached document

From: HRSA 340B Audit <340baudit@hrsa.gov>
Sent: Wednesday, [redacted] Date [redacted] 10:52 AM
To: [redacted] Authorizing Official
Cc: [redacted] Primary Contact
Subject: [redacted] Covered Entity Name [redacted] - [redacted] 340B ID [redacted] - 1st Final Report Documentation-[redacted]

***** WARNING: This email is from outside of our organization. Do not click on links or open attachments unless you know they are safe. *****

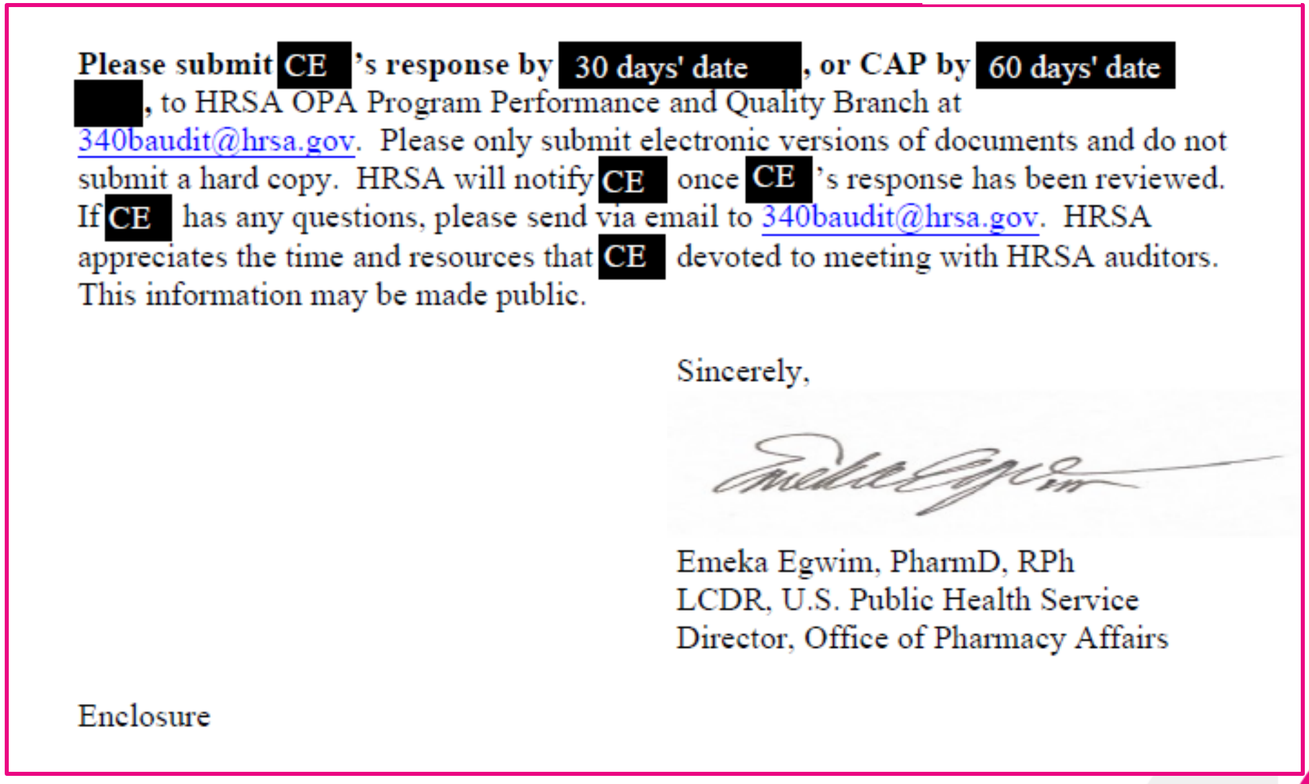
Dear [redacted] AO [redacted]:

The Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA) has completed its review of the 340B Drug Pricing Program (340B Program) audit for [redacted] ([redacted]: 340B ID: [redacted]). Please find the attached PDF of your Final Report Letter, Final Audit Report and Corrective Action Plan (CAP) template that includes all of the required CAP elements based on your Final Audit Report that need to be addressed.

Also attached is a fillable Microsoft Word version of the CAP template. This is a document that HRSA is including to provide assistance for the CAP process and will allow covered entities to easily fill in the required CAP information. OPA encourages the use of this template when completing the CAP, however if a different format for the CAP document is chosen, [redacted] is still responsible for ensuring all applicable elements noted in the CAP template are addressed. Please include additional information as applicable.

340B Audit Completion Letter

- **Response Options**
  - Disagree?
    - 30 days to respond
- Corrective Action Plan?
  - 60 days to respond
    - 6 months to implement
    - Can use template provided, but not required
    - Can request assistance from Apexus Answers to develop CAP
    - HRSA must approve the CAP before closing the audit



Please submit [CE] 's response by [30 days' date], or CAP by [60 days' date], to HRSA OPA Program Performance and Quality Branch at 340baudit@hrsa.gov. Please only submit electronic versions of documents and do not submit a hard copy. HRSA will notify [CE] once [CE] 's response has been reviewed. If [CE] has any questions, please send via email to 340baudit@hrsa.gov. HRSA appreciates the time and resources that [CE] devoted to meeting with HRSA auditors. This information may be made public.

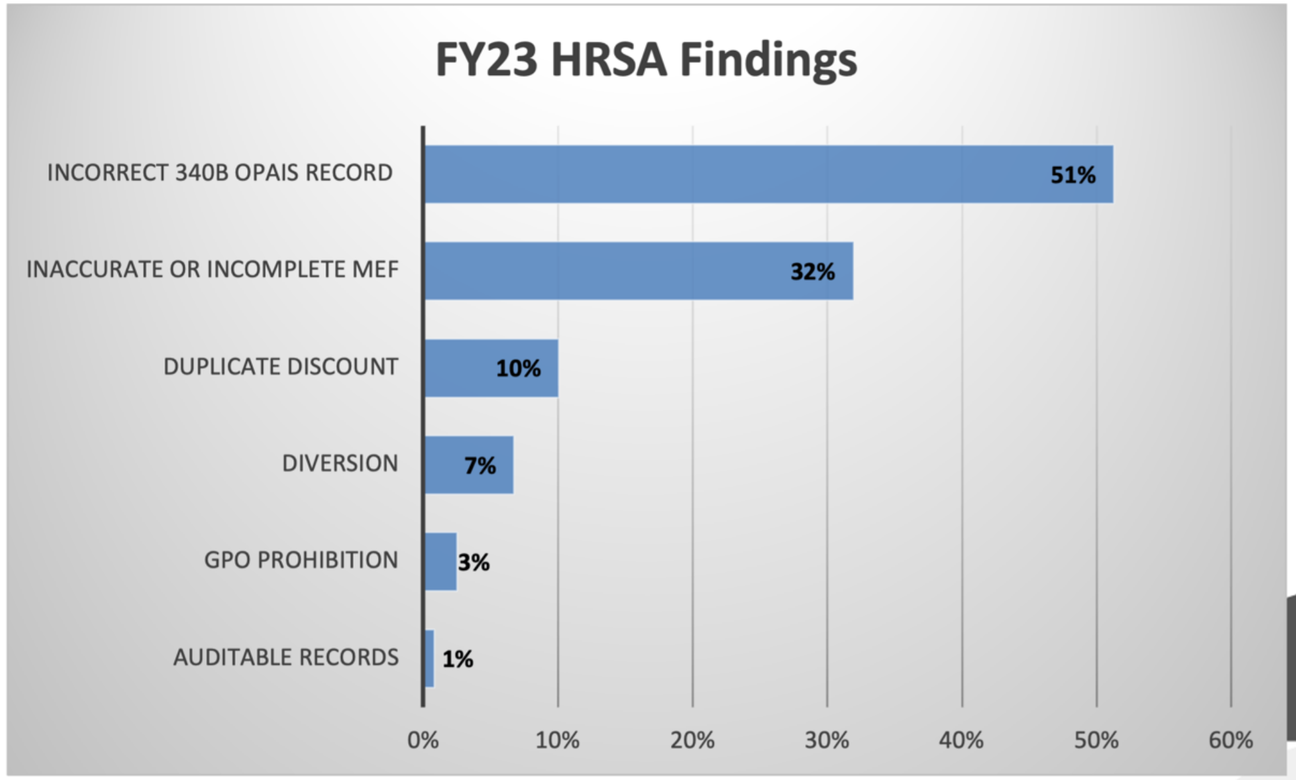
Sincerely,

Emeka Egwim, PharmD, RPh
LCDR, U.S. Public Health Service
Director, Office of Pharmacy Affairs

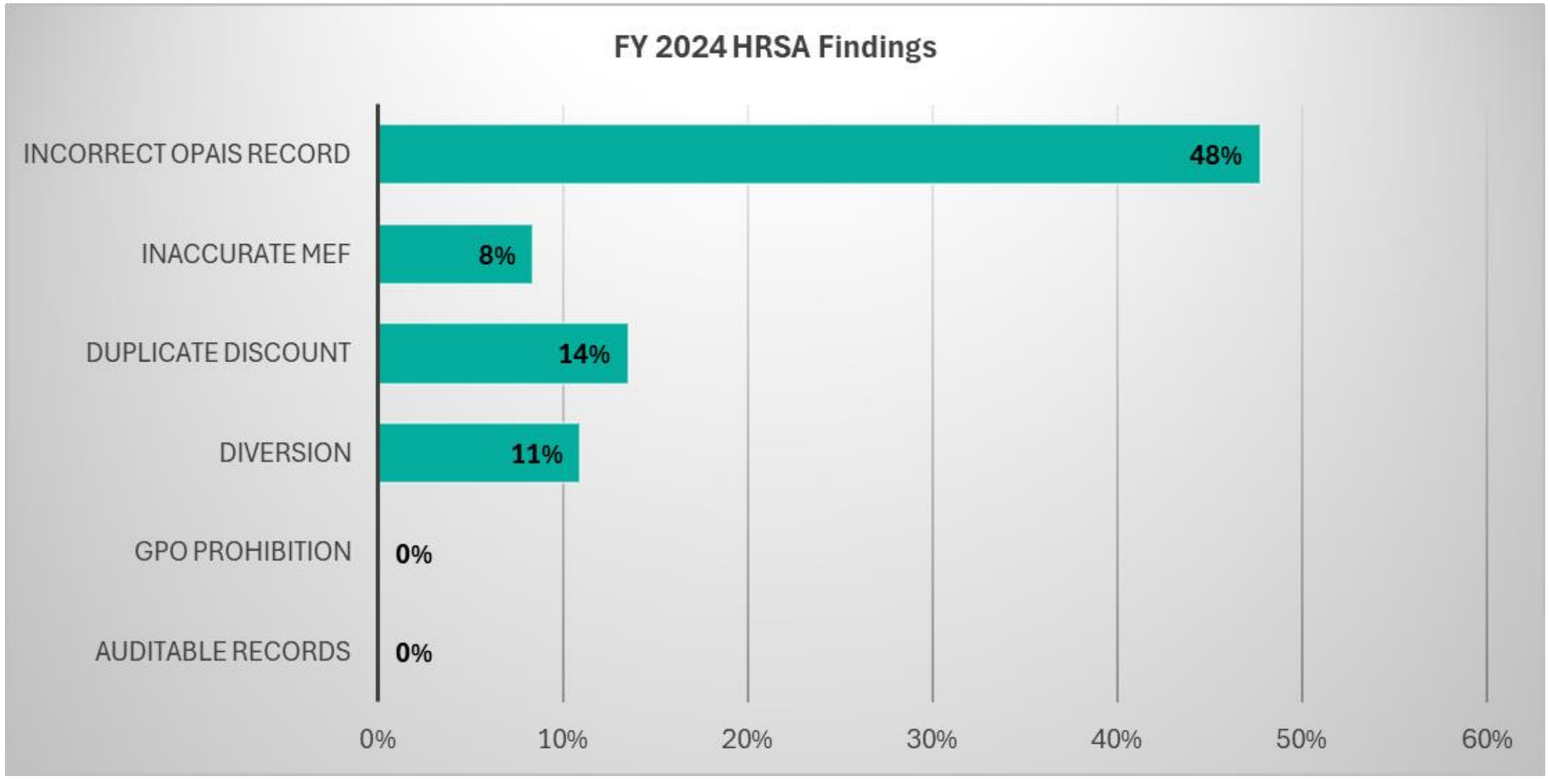
Enclosure

Common Audit Findings

- **Diversion: dispensing 340B drugs to ineligible patients**
- **Missing/incomplete policies and procedures**
- **Duplicate discounts: Medicaid billing errors**
- **Non-compliance with contract pharmacy oversight requirements**



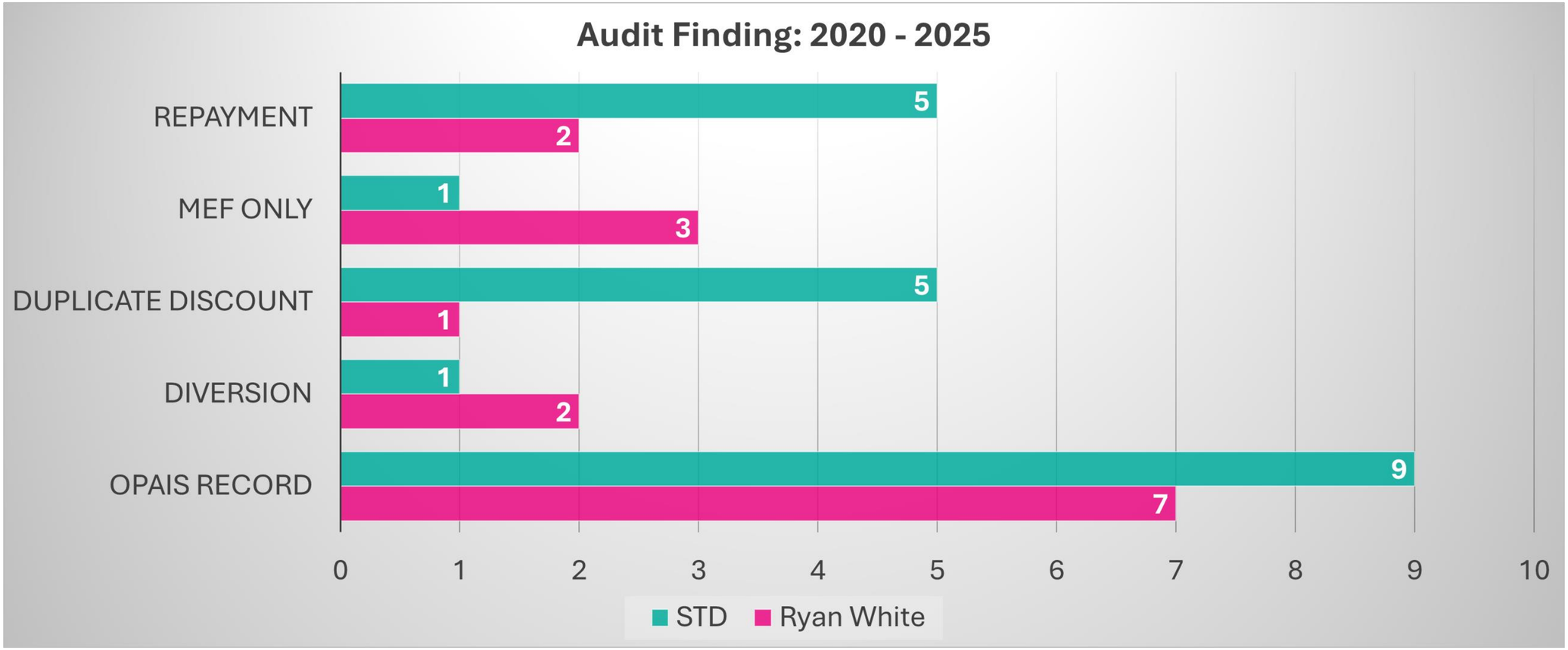
FY 2024 HRSA Audit Trends



155 Audits Completed, 45 Reports Pending

- **62 CEs with No Findings**
- **32 CEs had Repayments**

STD & RW HRSA Audit Findings: 2020-2025



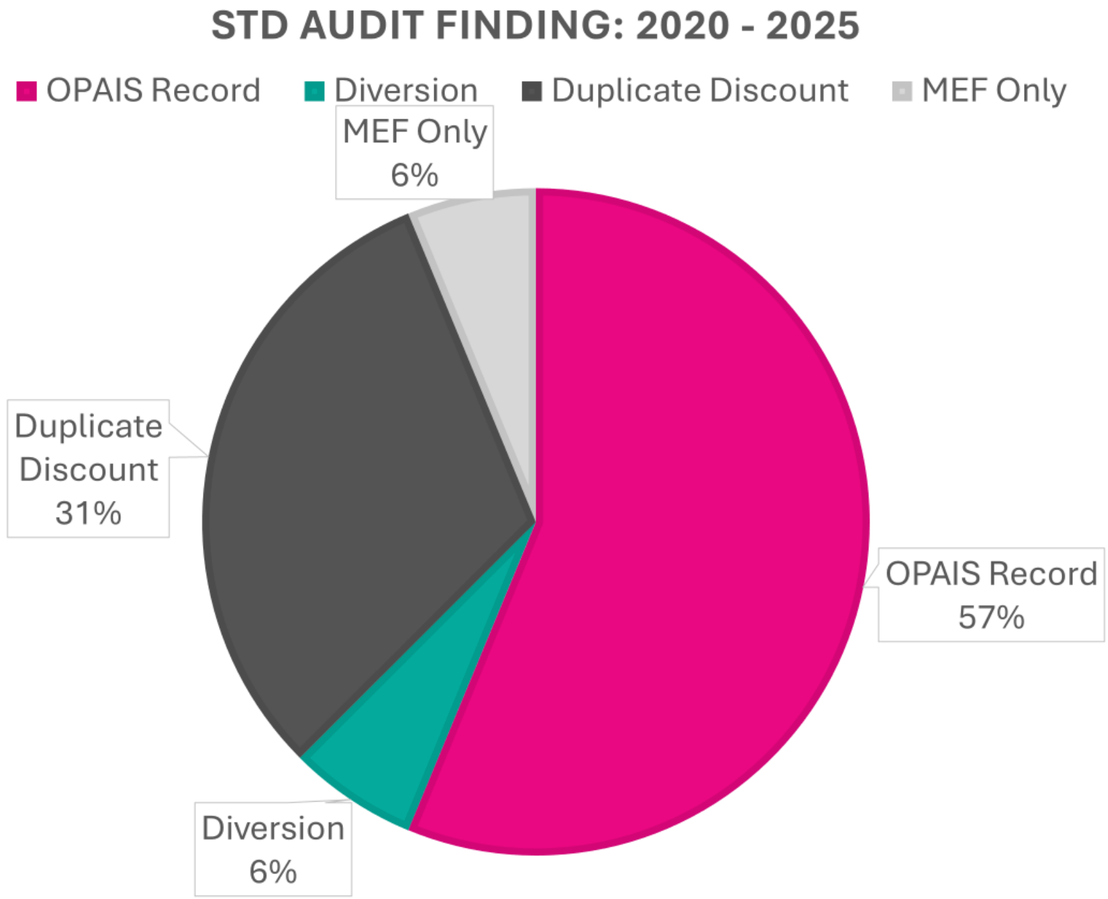
Published From 2021-2024

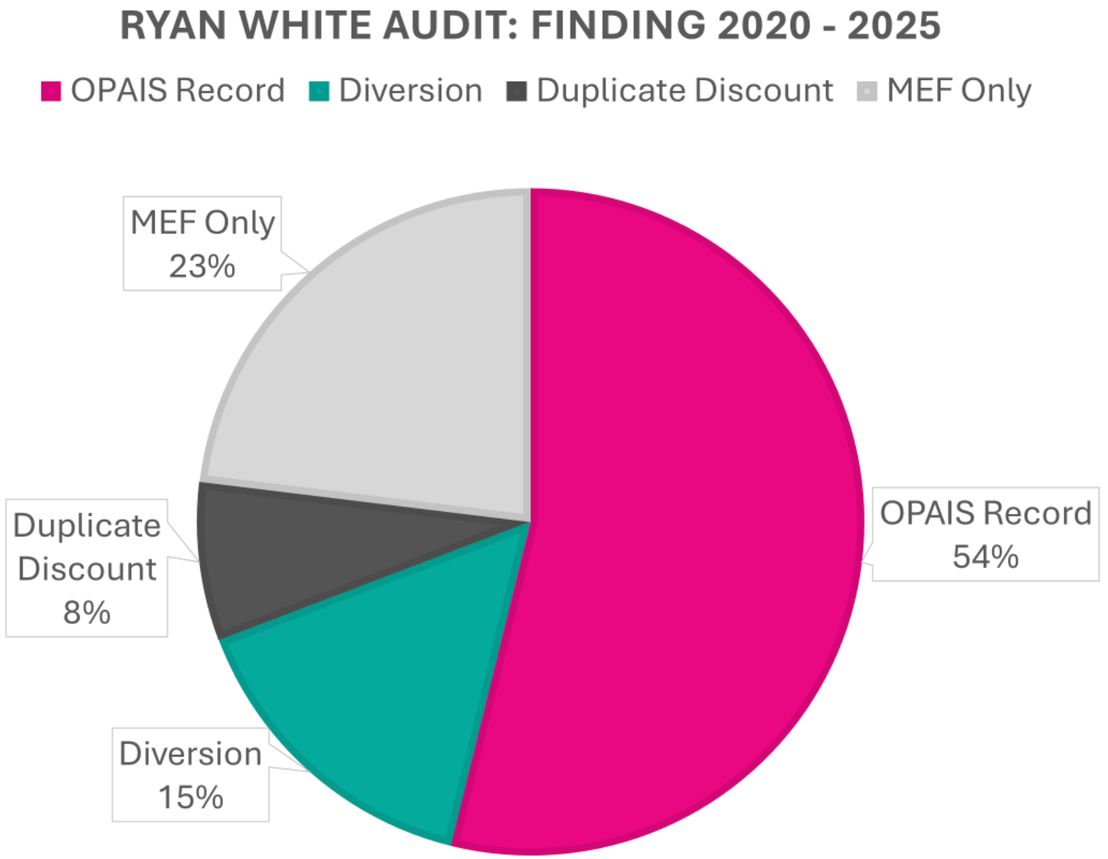
41 Ryan White & STD CE Audits Completed

21 (51%) had No Audit Findings and 7 (17%) Resulted in Repayments*

^As of OPA 5/8/2025 Update

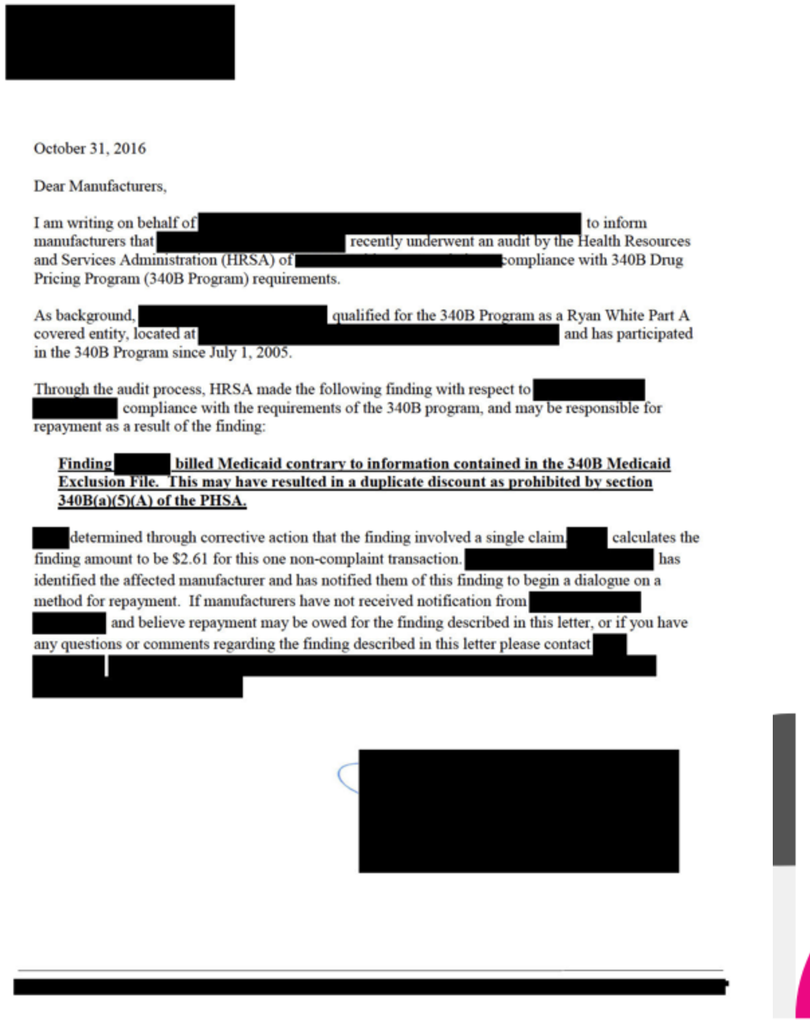
STD & RW HRSA Audit Findings: 2020-2025





Responding to Audit Findings

- HRSA issues a final audit report
- Entity has 60 days to submit a Corrective Action Plan (CAP)
- CAP must address each finding with timelines and process changes
- HRSA monitors and must approve the CAP before closing the audit



[redacted]

October 31, 2016

Dear Manufacturers,

I am writing on behalf of [redacted] to inform manufacturers that [redacted] recently underwent an audit by the Health Resources and Services Administration (HRSA) of [redacted] compliance with 340B Drug Pricing Program (340B Program) requirements.

As background, [redacted] qualified for the 340B Program as a Ryan White Part A covered entity, located at [redacted] and has participated in the 340B Program since July 1, 2005.

Through the audit process, HRSA made the following finding with respect to [redacted] compliance with the requirements of the 340B program, and may be responsible for repayment as a result of the finding:

Finding [redacted] billed Medicaid contrary to information contained in the 340B Medicaid Exclusion File. This may have resulted in a duplicate discount as prohibited by section 340B(a)(5)(A) of the PHSA.

[redacted] determined through corrective action that the finding involved a single claim [redacted] calculates the finding amount to be $2.61 for this one non-complaint transaction. [redacted] has identified the affected manufacturer and has notified them of this finding to begin a dialogue on a method for repayment. If manufacturers have not received notification from [redacted] and believe repayment may be owed for the finding described in this letter, or if you have any questions or comments regarding the finding described in this letter please contact [redacted]

[redacted]

[redacted]

Best Practices to Avoid Findings

Use a robust split-billing software system

Conduct regular internal reviews

Use external consultants for mock audits

Train staff on 340B compliance roles

Keep documentation organized and readily accessible

Key Documentation to Maintain

- Eligibility documentation (patients, providers)
- Purchase and inventory record
- Contracts with pharmacies and TPAs
- Medicaid exclusion files
- Policies and procedures (reviewed at least annually)

Helpful Resources

- HRSA 340B Program Integrity Page
- Mock audit checklist
- Sample DRL
- Apexus Answers
- Contact info for assistance

Apexus Answers
CALL CENTER

Questions?

Danielle Mathers, 340B ACE
Senior Vice President, 340B
NPS Pharmacy
Dmathers@npspharmacy.com
410-562-3806

Amber Roelofs, JD, 340B ACE
Chief Operating Officer
Ponaman Healthcare Consulting
Amberr@ponamanhc.com

Michael Gonzalez, 340B ACE
Chief Financial Officer and Founder
FQHC 340B Compliance
mgonzalez@fqhc340b.com