

# HRSA 340B Audit Overview

## HRSA AUDITS: SUPPORTING PROGRAM INTEGRITY

Entities can be chosen for either risk-based or targeted audits. All covered entity (CE) types are considered for risk-based audit selection.

Risk factors for a risk-based audit include characteristics that make your 340B program more complex; these include the number of outpatient facilities, number of contract pharmacies, and volume of purchases.

Targeted audits are triggered by allegations of violations of 340B requirements at a specific covered entity; these are not limited to allegations that may have been made by whistleblowers or manufacturers. OPA may also perform a target audit to follow up on a covered entity's corrective action plan.

## HRSA AUDIT STEPS

### 1 Pre-Audit

- Engagement letter
- Data Request

### 2 Onsite Audit

- Opening Meeting
- Pharmacy staff interviews
- Data sample review

### 3 Post-Audit

- Preliminary audit report submitted internally by auditor
- HRSA sends final report
- Corrective action plan

## PRE-AUDIT

- The covered entity's authorizing official will receive the engagement letter from HRSA four to eight weeks prior to the audit.
  - The letter will specify which 340B ID number has been selected for audit and that the scope of the audit will include any offsite outpatient facilities, contract pharmacies, and associated 340B ID numbers.
- The CE should identify a point person to communicate with the HRSA auditor who would be responsible for scheduling both the pre-audit preparation call with the auditor and the coordination of data requested by HRSA.
- The CE primary contact should coordinate a conference call with the institution's audit team and the auditor to discuss the data request as well as any other questions the team may have for the auditor regarding the audit.
- The data request information is usually due to the auditor two weeks prior to the onsite audit.
- This is a good opportunity to ensure that you have provided 340B education to your audit team and applicable organization staff.

# ONSITE AUDIT

Have your entire audit team available on call as resources. Length of the onsite visit varies case by case based on the entity's details.

## OPENING MEETING

### PHARMACY TOUR AND STAFF INTERVIEWS

- Ensure that your audit team is familiar with the organization's 340B policies and procedures, because this is an integral part of your audit.
- Clearly articulate your 340B processes and procedures to the auditor.

### DATA SAMPLE REVIEW

- In preparation for the data transaction tracers that occur during the onsite audit, it is recommended to determine audit tracer personnel based on 340B, pharmacy operations, and/or IT system knowledge prior to the audit.
  - Conduct tracer practice sessions to determine the most efficient and rapid methods for retrieving information, including different outpatient locations, anesthesia records, and areas that may still use paper records.
- Perform transaction eligibility testing for mixed-use and contract pharmacy settings.
- Checklist:
  - ✓ Documentation of a prescription or medication order in the medical record with associated date of service
  - ✓ Documentation that it was written by a qualified provider
  - ✓ Documentation that transaction derived from an eligible location
  - ✓ Documentation that patient is in outpatient status

## HAVE AN AUDIT TEAM

The 340B program is an entire organization's responsibility and is not limited to one department. It is best practice that an interdisciplinary team have oversight of an organization's 340B program established prior to an audit engagement.

Each of the following groups plays an integral role in the various steps of a HRSA audit.

## ROLES IN AUDIT PREPAREDNESS: INTERNAL

### Pharmacy leadership:

---

- Provides the policies and procedures related to the 340B program, including procurement, inventory, dispensing, replenishment, contract pharmacy (CP) oversight, and prevention of duplicate discounts.
- Provides components surrounding inventory reconciliation and purchases under each of the purchasing accounts.
- Provides information related to the CPs (including the list of all arrangements and documentation surrounding CP monitoring).

### Authorizing officials:

---

- Identifies audit engagement letter from HRSA and contacts the primary contact for next steps.

### IT department:

---

- Prepares a data set that lists all 340B prescriptions or medication orders in the six-month period designated by the auditor. This data set has a level of detail that includes NDCs, prescribers, NPI, date, and patient status, among others.
- It is recommended to share this responsibility with the organization's IT department contacts even prior to an audit, so that they are familiar with the type of requirements for this data set and are able to aggregate it from various IT platforms and data sources in the event of an audit.

### Government:

---

- Provides the most recently filed Medicare cost report (for hospital CEs only).
- Provides a copy of the covered entity's Medicaid provider enrollment verification letter.
- Provides contract with state or local government, if applicable.

### Office of provider credentialing:

---

- Provides a list of all providers who are either employed by the covered entity or provide health care under contractual or other arrangements.
- It is recommended that the organization is able to locate the contracts for all of these eligible providers if requested during an audit.
- The organization should be familiar with how often the provider list is updated, how the list is utilized for eligibility verification, and includes that procedure in its 340B standard operating procedures.

# HRSA AUDIT FOLLOW-UP STEPS

- 1 HRSA notice and hearing; entity has 30 days to review findings and HRSA's request for Corrective Action Plan (CAP) (if applicable).
- 2 If agree with report: 60 days to submit corrective action plan\*; If disagree with report: notify HRSA in writing within 30 days with supporting documentation.  
  
\* If no corrective action plan within 60 days of that report, entity terminated
- 3 Audit summary and corrective action, once approved, posted on HRSA website.
- 4 Results support education of covered entities.

## CORRECTIVE ACTION PLAN (CAP)

- Provide immediate remedy
- Propose plan for periodic assessment, continuous monitoring, and method to determine when CAP is completed
- Identify implementation date
- Devise internal 340B communication/education strategy
- Provide entity contact person
- HRSA to provide a general outline dependent on type of finding

## TYPES OF SELF-AUDIT

It is essential to have continuous self-auditing processes and have your internal audit team to evaluate the results of the self-audits to identify any systematic issues in your 340B program.

### Annual mock HRSA/ manufacturer audit

- Policies and procedures
- New/updated regulations
- Organized communication
- Billing Medicaid
- GPO exclusion
- HRSA website information

### Ongoing system audits

- Policies and procedures
- New/updated regulations
- Organized communication
- Billing Medicaid
- GPO exclusion
- HRSA website information

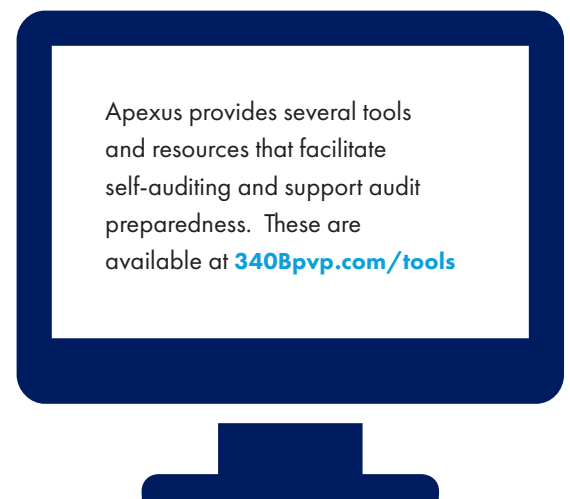
### Monthly mini-audits

- Drug specific
- Patient specific
- Location specific



### Workflow audits

- Interview staff
- Identify knowledge gaps
- Capture opportunities for systems failure (e.g., borrowing)



Apex provides several tools and resources that facilitate self-auditing and support audit preparedness. These are available at [340Bvp.com/tools](https://www.340bvp.com/tools)

## POST-AUDIT

- The auditor will not provide any determination on compliance or gaps in compliance at the end of the audit.
- Onsite findings will be considered preliminary, and a basis for review by HRSA's Office of Pharmacy Affairs.
- Formal notification of the audit findings will be sent typically within 30 to 90 days.
- Potential outcomes:
  - No adverse findings
  - Identified areas for improvement
  - Adverse findings and a request for a corrective action plan (CAP)
- Failure to provide a requested CAP in a timely fashion can result in removal from the 340B program



For more information contact Apexus Answers.

Apexus | 340B Prime Vendor Program  
888.340.BPVP (2787) | [apexusanswers@340Bvp.com](mailto:apexusanswers@340Bvp.com)  
[www.340Bvp.com](http://www.340Bvp.com)