National Coalition of STD Directors

340B HRSA Audit Overview and Checklist

Updated October 12, 2021

Note: This information is provided by NCSD for general information purposes and does not constitute legal advice. This resource is designed to support 318 grantees and grantees, including, but not limited to, those receiving a grant or contract funded under the PCHD NOFO (19-1901) and the Ending the HIV Epidemic (EHE) NOFO (20-2010), in the event of a HRSA audit of 340B operations and compliance.

Background

The Office of Pharmacy Affairs (OPA), located in the Health Resources and Services Administration (HRSA), is the federal agency charged with administering and overseeing the 340B Drug Pricing Program (340B Program). Since 2012, HRSA has been conducting routine audits of 340B covered entities. These audits are part of the agency's attempts to improve its oversight of the 340B Drug Pricing Program (340B Program) as required under the Affordable Care Act. Each year, HRSA has increased the number of audits for all covered entity types. Audit findings can be found here. The focus of the audits are primarily on covered entity eligibility and the prevention of duplicate discounts and drug diversion.

HRSA recommends that covered entities have stand-alone policies and procedures that address 340B compliance and HRSA auditors will ask to see them during an audit. Although Apexus has created template policies and procedures for safety net hospitals, community health centers, and other grantees, it has not done so for 318 grantees. Accordingly, NCSD has developed template 340B policies and procedures for 318 grantees and subgrantees that can be used as a starting point; however, NCSD recommends that you work with your operations staff and legal counsel to ensure all 340B requirements are appropriately addressed.

HRSA has contracted with Apexus (also referred to as the 340B Prime Vendor) to serve as its educational and technical assistance advisor to covered entities and other 340B stakeholders. Apexus has created a number of resources to help covered entities understand and prepare for the audit process. These resources are summarized and available below. In addition, NCSD has created a checklist specifically for 318 grantees and subgrantees that can be used to support audit preparedness and respond to certain types of audit findings.

Apexus Audit Resources

1. HRSA 340B Audit Overview

This Overview document is a very good resource that lays out what a covered entity can expect during each step of a HRSA audit. Specifically, the resource addresses the following in detail:

Pre-Audit: During this stage the covered entity receives a letter from HRSA indicating which 340B IDs and associated contract pharmacies, if applicable, are subject to the audit. HRSA will send a data request form, which the covered entity will be expected to complete and send back to HRSA usually two weeks before the onsite visit. A conference call is set up with the auditor and covered entity's primary contact and 340B compliance team to prepare for the visit.

Onsite Audit: The onsite visit usually consists of an opening meeting, site tour and covered entity staff interviews. The auditor(s) will work with the covered entity's operations and IT staff to conduct a data sample review. Typically, an onsite visit can last 1-3 days.

Post-Audit: In some cases, findings may be discussed and resolved during the onsite visit. After the audit, a preliminary audit report is submitted internally by the auditor and then a final report is issued within 30-90 days. The covered entity submits a corrective action plan, which once approved by HRSA, is posted on a public website.

2. Sample HRSA Audit Data Request for Covered Entities

This resource provides a sample audit data request list from HRSA. It is a comprehensive list of what an auditor may ask to see before or during an audit. It includes detailed information on the following items:

- **340B Policies and Procedures**: This is a list of what items should be addressed in the covered entity's policies and procedures. (See also Apexus's Self Audit Tool for 340B Policies and Procedures below)
- **Documentation of a Covered Entity's Eligibility**: The covered entity may be asked to show the auditor the notice of grant award or contract that references the federal 318 grant number and Notice of Funding Opportunity (NOFO) number.
- **Data Request for Sample Period**: The auditor will request medication dispensing information for certain drugs during a sample period (usually six-months).
- **List of Eligible Providers**: The covered entity may be asked to provide a list of all of its eligible providers, including their name, National Provider Identifier (NPI) numbers, and evidence demonstrating whether the individual is employed by or under contract with the covered entity.

- **Purchasing Documentation**: The auditor may ask for a list of wholesalers and 340B drug purchase orders during the selected timeframe.
- **Contract Pharmacy Documentation**: If applicable, the covered entity may be asked to produce copies of the contract pharmacy agreements, a list of participating pharmacies, and policies and procedures governing the contract pharmacy relationship. (See also, Apexus's Self Audit Tool for Contract Pharmacies below)
- **Documentation of Self-Disclosures**: The covered entity may be asked for copies of any self-disclosures of noncompliance submitted to the Office of Pharmacy Affairs.
- **Medicaid Billing Documentation**: The covered entity should provide Medicaid fee-for-service billing documentation for each site subject to the audit.

3. Self-Audit: Policy and Procedure

This tool will help a covered entity evaluate its 340B policy and procedure documents, which are designed to standardize an entity's 340B operations and ensure compliance with 340B requirements. In the course of an audit, it is expected that a HRSA auditor will ask to see the covered entity's 340B policies and procedures. In addition to addressing all elements of program requirements, Apexus advises covered entities to include methods for routine self-audits and internal corrective action in their policies and procedures.

4. Self-Audit: Contract Pharmacy

Apexus has developed a self-audit tool for covered entities that have contract pharmacy arrangements. In a contract pharmacy arrangement, the covered entity retains the responsibility to prevent drug diversion and duplicate discounts, maintain auditable records, and ensure compliance with all other 340B requirements. Apexus suggests that covered entities use this self-audit tool on a quarterly basis. In addition, HRSA recommends that covered entities conduct annual independent audits of their contract pharmacies.

NCSD Resource

Audit Preparation and Compliance Checklist for 318 Grantees and Subgrantees

This resource can be used in conjunction with the Apexus Audit Resources above to assist 318 grantees and subgrantees with ongoing compliance and preparation for a HRSA Audit. It is not intended to be comprehensive. A covered entity should work with its operations staff and legal counsel to ensure compliance with all 340B requirements.

Compliance Element	Assessment Criteria/Questions
Entity Eligibility	● Is the federal grant authorized under Section 318 of the Public Health Service Act? ● Are the 318 federal grant and NOFO numbers readily available and listed in OPAIS as a part of each covered entity's registration record? ● Is each 318 recipient registered in OPAIS? ● Is the grant agreement or contract still effective? ● Do you have a plan in place for the required annual recertification of compliance?
OPAIS Accuracy	● Is the site's information complete and accurate in OPAIS for each participating site? ● Are the names of the Authorizing Official and Primary Contact accurate in OPAIS?

Patient Eligibility and Prevention of Drug Diversion	● Are 340B drugs only dispensed at 340B eligible sites that are registered in OPAIS?
	● Do each of your patients meet the 340B definition of a patient?
	  o For 318 grantees and subgrantees, (to meet the third prong of the 340B patient definition) does each patient receive a service consistent with the scope of the grant? Does the medical record reflect this service?
	● Do you have a system for reviewing claims periodically and/or randomly to ensure no drug diversion is happening?
	● Are you aware that once an individual meets the 340B definition of a patient, there are no restrictions on which drugs can be dispensed, provided that the drugs are medically indicated and dispensed in accordance with state pharmacy laws?
	  o Be prepared to respond to an auditor that (incorrectly) states that only drugs to treat STDs are 340B eligible. You can refer the auditor to Apexus FAQ #s 1565 and 1568 for an accurate interpretation of 340B policy.
	  o If an auditor questions the use of 340B drugs for expedited partner therapy, you can refer the auditor to Apexus FAQ # 1375, which clearly states that 340B drugs for EPT therapy is appropriate as the medication is being dispensed to prevent reinfection of the 340B eligible patient.

Medicaid and the Prevention of Duplicate Discounts	● Are your participating sites dispensing 340B drugs to Medicaid fee-for-service (FFS) eligible patients?
	  o If yes, did each of your eligible sites answer "Yes" to the question about Medicaid "carving-in" during its registration period (or have you updated the record in OPAIS to reflect this election)?
	  o If you are billing 340B drugs to FFS Medicaid, have you entered all of your dispensing providers' Medicaid and National Provider Identifier (NPI) numbers in the Medicaid Exclusion File (MEF) in OPAIS?
	● Are your participating sites dispensing 340B drugs to eligible patients with Medicaid managed care insurance?
	  o If so, are you billing 340B drugs in accordance with your state, MCO and/or PBM's policy so that the state can meet its obligation to prevent duplicate discounts?
	● Are you reviewing claims reports to ensure compliance with duplicate discount prohibitions?

Policies and Procedures	● Do you have comprehensive 340B policies and procedures? (See Apexus's Self-Audit: Policy and Procedure Tool above) ● Do you have a system for periodically updating your 340B policies and procedures?
Contract Pharmacy Arrangements	● Do you have an agreement in place with all participating pharmacies? ● Is each contract pharmacy arrangement registered and reflected in OPAIS? ● Are you conducting independent audits of each contract pharmacy arrangement at a minimum on an annual basis? ● If you are dispensing drugs to Medicaid fee-for-service patients through the contracted pharmacy, do you have a HRSA-approved arrangement between the covered entity, contract pharmacy and state Medicaid program? ● If you are dispensing drugs to Medicaid managed care patients through the contracted pharmacy, are you following the guidance of your state, MCO and pharmacy benefit manager (if applicable) to protect against duplicate discounts?
Inventory Management	● Is 340B inventory purchased under a 340B ID only dispensed to patients of that entity and not to patients of another unique 340B ID? ● Do you have a system in place to keep 340B and non-340B inventory separate? ● Do you have a system in place to keep inventory purchased under unique 340B IDs separate physically or through a replenishment/virtual inventory model?

Maintenance of Auditable Records	• Are you maintaining and regularly updating auditable 340B records?
Self-Audits	• Are you conducting internal self-audits to ensure 340B requirements are met? • How often are you performing self-audits? • Do you have a procedure in place defining a material breach and when self-disclosure to HRSA is required?
Covered Entity Audit Team	• Do you have an interdisciplinary team identified that is responsible for the oversight of the 340B Program? • Do you have an audit response team responsible for engaging with HRSA auditors?

About NCSD

National Coalition of STD Directors is a national organization representing health department STD directors, their support staff, and community-based organizations across 50 states, seven large cities, and eight US territories. NCSD advances effective STD prevention programs and services in every community across the country.

Contact

For more information or questions, please contact Stephanie Arnold Pang at sarnold@ncsddc.org.