

HRSA 340B Program Audits

This document provides additional information to covered entities and manufacturers regarding 340B Drug Pricing Program (340B Program) audits to increase the understanding of audit objectives and process. For basic information on HRSA 340B Program integrity efforts, including audit selection criteria, see Policy Release No. 2012-1, "[CLARIFICATION OF HRSA AUDITS OF 340B COVERED ENTITIES](#)."

Audit Scope

HRSA's 340B Program audits review covered entity compliance with respect to eligibility status, including compliance with the Group Purchasing Organization (GPO) prohibition, as applicable, under 42 USC 256b(a)(4)(L)(iii), diversion, and duplicate discounts as defined by 42 USC 256b(a)(5)(A) and (B).

Audit Process

HRSA regional auditors conduct audit field work for the HRSA Office of Pharmacy Affairs (OPA).

Pre-Audit

- Covered entities selected for audit receive an engagement letter explaining what to expect and how to appropriately prepare.
- HRSA regional auditors conduct an introductory teleconference with the entity to request and obtain specified documents, including policies, procedures, and internal controls.
- HRSA regional auditors work with the entity to schedule an entrance conference with key entity management to discuss expectations for the onsite audit.

Onsite Audit

- HRSA regional auditors obtain and review select program data and internal controls.
- Audit procedures include, at a minimum:
 - review of relevant policies and procedures and how they are operationalized;
 - verification of eligibility, including GPO and outpatient clinic eligibility;
 - verification of internal controls to prevent diversion and duplicate discounts, including appropriateness of inpatient/outpatient designations and Medicaid exclusion file designations;
 - review of contract pharmacy compliance; and
 - test 340B drug transaction records on a sample basis.
- HRSA regional auditors conduct an exit interview, sharing areas of concern and preliminary findings.

Post Audit

- HRSA regional auditors forward preliminary findings to OPA for review.
- OPA reviews the preliminary findings and works directly with the covered entity to obtain any necessary additional information, address any concerns and discuss the appropriate remedy and required corrective action(s), including potential removal from the 340B Program and/or repayment to manufacturers.
- Once an audit report is finalized by OPA, the findings and the entity's response will be summarized on the OPA public website at <http://www.hrsa.gov/opa>.
- OPA will pursue further follow up with the entity as needed.