

340B Audit Findings and Corrective Action Plans

The Health Resources and Services Administration (HRSA), Healthcare Systems Bureau (HSB), Office of Pharmacy Affairs (OPA) regularly conducts audits of covered entities to ensure compliance with 340B Drug Pricing Program (340B Program) requirements. When a covered entity undergoes an audit by HRSA and has findings or evidence of non-compliance with a 340B Program requirement, the covered entity must provide a corrective action plan (CAP) to HRSA describing the planned and implemented actions to ensure program compliance. The CAP may also include the covered entity's plans and actions addressing any potential repayment to manufacturers as a result of the non-compliance. HRSA continuously reviews and updates processes to improve program integrity, and has identified a number of areas to strengthen in the audit process. Based on our review, HRSA is updating our audit expectations regarding the implementation of a covered entity's CAP, including any settlements with manufacturers, as outlined below. Many covered entities have already been able to meet these expectations through the course of their audits. In addition, HRSA is implementing these changes in order to ensure the CAP and repayment process are completed in a timely manner.

Corrective Action Plan Implementation and Repayment

- Unless otherwise approved by HRSA, full CAP implementation, including any settlement with manufacturers, is expected to be complete within six months of the CAP approval date. Covered entities unable to meet this expectation may be subject to termination from the 340B Program.
- HRSA will post a notice on its website to alert manufacturers to the extent that violations have occurred at the following link: <https://www.hrsa.gov/opa/program-integrity/index.html>. This notice will include findings of the 340B Program audit requiring repayment and entity contact information for manufacturers to utilize. In addition, a covered entity is responsible for identifying and contacting all affected manufacturers to notify them of 340B Program violations and to discuss a method for possible repayment. HRSA will close out an audit once the covered entity attests that all applicable repayments have been resolved, and that the CAP has been fully implemented.
- The covered entity may be required to submit additional documentation, as determined by HRSA, to demonstrate its CAP has been implemented, including any applicable repayment to manufacturers.
- HRSA may conduct a re-audit to assess a covered entity's compliance with 340B Program requirements.
- Covered entities with a re-audit that identifies the same exact finding of non-compliance, may be subject to additional audits. A finding of non-compliance in two or more audits, depending on the type of violation, may be considered systematic and egregious, as well as knowing and intentional, which may result in the covered entity being removed from the 340B Program in accordance with section 340B(d)(2)(B)(v) of the Public Health Service Act. Such a finding may also disqualify the covered entity from re-entry into the 340B Program for a reasonable period of time.

To learn more about 340B Program integrity and the 340B Audit Process, see <https://www.hrsa.gov/opa/program-integrity/index.html>

If you have any questions, or need further information, the 340B contracted Prime Vendor Program is available at ApexusAnswers@340bpvp.com or by phone at 888-340-2787.