



To Audit or Not to Audit? (We have the Answer)

As most of us know, the Health Resources and Services Administration (HRSA) is an agency of the U.S. Department of Health and Human Services and is the organization that oversees the Office of Pharmacy Affairs (OPA). The OPA oversees the 340B Program. HRSA states that internal audits are required as part of overseeing your contract pharmacy program. HRSA also recommends that covered entities also conduct independent audits as part of ongoing compliance. We strongly feel that performing audits, whether self-auditing or hiring an outside consulting company to perform a mock HRSA audit, is good judgment and best practice.

Questions to ask yourself:

- Covered Entities are responsible for all actions of contract pharmacies related to the 340B program; when performing self-audits, are you simply reviewing your TPA records or are you executing complete audits on all the fundamentals?
- If you were notified today by HRSA that your entity would be subject to an audit based on the federally mandated guidelines in just 2 weeks, would you be confident of passing their compliance standards?
- Have you taken the time to thoroughly review and/or update your Policy and Procedures, record keeping practices, OPAIS entries and possess meticulous data reporting?

With responding to these three simple questions you can assess your readiness for a 340B HRSA audit. Your answers could determine if there are findings during a HRSA audit that may result in repayment obligations and a corrective action plan. It is your responsibility to ensure the integrity of the program and maintain compliance.

Things to take into consideration when reviewing and conducting an internal audit:

- We suggest conducting monthly audits on your contract and in-house pharmacies.
- Ensure that your claims are for eligible patients, by eligible providers and at eligible locations.
- Conduct sampling audits – at a minimum 5 claims per contract pharmacy/per month.
- Ensure that you fully understand your States procedures for Medicaid Carve-In/Carve-Out to prevent Duplicate Discounts.
- Institute a 340B Oversight or Compliance Committee with written procedures on responsible personnel.
- All information on the OPAIS is accurate and up-to-date.
- Save all your self-audit reports, findings, and communication of findings to your Oversight/Compliance Committee, HRSA will ask to see this.
- In conjunction with conducting your internal self-audits, it is recommended to employ a reputable consultant or firm to hold an annual independent mock HRSA Audit.

What to expect during an HRSA Mock Audit:

The objective of a mock audit is to assess the organizations preparedness for a HRSA audit. This is achieved by conducting an in-depth evaluation of all crucial 340B Program compliance and management elements, once the mock audit is complete, you should then be provided with strategies for remediation if necessary.

The Mock Audit will mirror that of a real HRSA audit, the following will be thoroughly evaluated:

- Policies and procedures meet HRSA/OPA Guidelines
- Eligibility
 - Provider eligibility
 - Patient eligibility
 - Referrals
 - Location eligibility
- Diversion
 - Drug Diversion
 - Group Purchasing Organization (GPO) exclusion
 - Orphan drug exclusion (if applicable)
- Duplicate Discounts
- Purchasing practices
 - 340B account
 - Group Purchasing Organization (GPO) account
 - Wholesaler Acquisition Cost (WAC) account
- Inventory replenishment model
- OPA database information accuracy
- Confirm Covered Entity details as well as any child sites
- Annual recertification process
- Contract pharmacy details including ship to, discharge prescriptions and mail-order pharmacy
- Medicaid Procedures
- “Carve-in” or “Carve-out”

Having a true Mock HRSA Audit will help take the guessing game out of passing a HRSA Audit. It will also give you a clear view into the areas that your organization needs to focus on to become and remain compliant. It is imperative to institute audits into your 340B monthly and quarterly activities.

If you have any questions, please reach out to us. We are experts in 340B and can answer all your questions.