CHAPTER 15 Preparing for and Surviving a HRSA Audit

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BACKGROUND

340B of the Veteran's Healthcare Act of 1992 requires that pharmaceutical manufacturers provide discounts on covered outpatient medications to participating covered entities. The Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) is responsible for the oversight and integrity of the 340B program. HRSA ensures the integrity of the program—by both the eligible entities and manufacturers—through promulgation of guidance and other support, including audits. Specifically, Section 42 of the United States Code (USC) 256b(a)(5)(C) states that HRSA has the authority to audit both the covered entity and manufacturer.[1]

HRSA has been empowered to audit participating covered entities and manufacturers from the inception of the 340B program and historically has conducted audits and other investigations for cause. With the increased scrutiny and public discussion of the 340B program, HRSA has increased the oversight of program implementation through random audits and targeted audits based on criteria that HRSA believes represent higher compliance risk scenarios (e.g., multiple child sites, large contract pharmacy networks, dramatic shifts in purchasing patterns). In addition to audits, HRSA has demonstrated a commitment to regular review of program participation through annual recertification and attestation. Covered entities share in the responsibility of upholding program integrity with required self-disclosures of material breaches. The intent of this chapter is providing guidance to covered entities to facilitate adherence to 340B program integrity and to meet the challenges of internal program oversight and external audits. Annual recertification and self-disclosures are highlighted, but the primary focus of this chapter is covered entity audits. A general overview and outline is provided, along with applicable strategies and infrastructure development, that covered entities can utilize in preparation for an audit.

HRSA posts audit results from previous fiscal years on their web site as they are finalized, permitting covered entities an opportunity to identify trends, areas of program integrity, and interest to HRSA as well as common challenges, failures, and the ensuing corrective actions and penalties.[1] All covered entities are well-advised to undertake preparation for a HRSA audit, as OPA audits approximately 200 covered entities annually, with a focus on hospitals. Over the first 5 years of HRSA audits, nearly three-quarters of audited hospitals report an audit finding and more than half have a manufacturer repayment associated with the finding. Review of the web site shows an outline of the audit process and may identify the auditors' focal points that may need to be addressed as well as provide a description of the audit process. Diversion of 340B drugs to ineligible patients is the most common finding followed by an inaccurate listing on the HRSA database and duplicate discount violations.

KEY POINT

HRSA's audit focus changes over time. Reviewing posted audit results and networking with recently audited peers is a "best practice" to stay aligned with HRSA's current audit focus and methods.

Covered entities should anticipate a HRSA audit to focus on Medicaid duplicate discounts, elements of program implementation and operations related to the group purchasing organization (GPO) prohibition, determination of provider eligibility, a full review of parent/child locations on the Medicare cost report, and a review of policies and procedures.[1] Based on the visibility of the 340B program and close Congressional oversight, hospital covered entities should anticipate a HRSA audit every 3–5 years with a focus on:

- Medicaid duplicate discounts
- Key elements of 340B program implementation and operations, including virtual inventory management and contract pharmacy
- A review of data and practices related to the GPO prohibition
- An assessment of methods used to determine and manage provider eligibility
- A review of parent/child locations on the Medicare cost report
- A review of policies and procedures

During the audit, the covered entity should not expect to review charity care programs, use or application of 340B savings, nor any specifics regarding justification of any vendor or technology that supports 340B compliance.

Contract pharmacies will not be reviewed in detail in this chapter. Covered entities that utilize contract pharmacies introduce additional complexity to their 340B program. Guidance for navigating the business and compliance considerations of contract pharmacy are found in Chapter 9. Audits of covered entities that do not utilize contract pharmacies should expect to skip that portion of the audit. Note, however, that contract pharmacy oversight remains among the most cited audit findings.[2,3]

Best practices, ideas, and recommendations in this chapter cannot guarantee a successful audit result. However, the effectiveness of the policies, practices, and advice in this chapter has been demonstrated by covered entities in successful audits. Preparation, sound covered entity infrastructure, and undertaking a constant state of readiness for an audit with an eye to upholding the integrity of the 340B program are all keys to a successful audit.

HRSA INTEGRITY MEASURES

Annual Recertification

The annual recertification process requires the covered entity to attest to meeting qualification to participate in the 340B program and to the covered entity's compliance with 340B program requirements.[1] HRSA, the 340B prime vendor, and others offer detailed guidance for recertification through webinars and materials published on their respective web sites.[1,4,5] Covered entities need to be aware of the recertification timelines, as failure to follow them will present eligibility challenges and may cause a covered entity to be removed from the program if fully missed. All covered entities must recertify, including federally qualified health centers, Ryan White HIV/AIDS program grantees, specific hospitals (e.g., disproportionate share, critical access, children's), and specialized clinics.