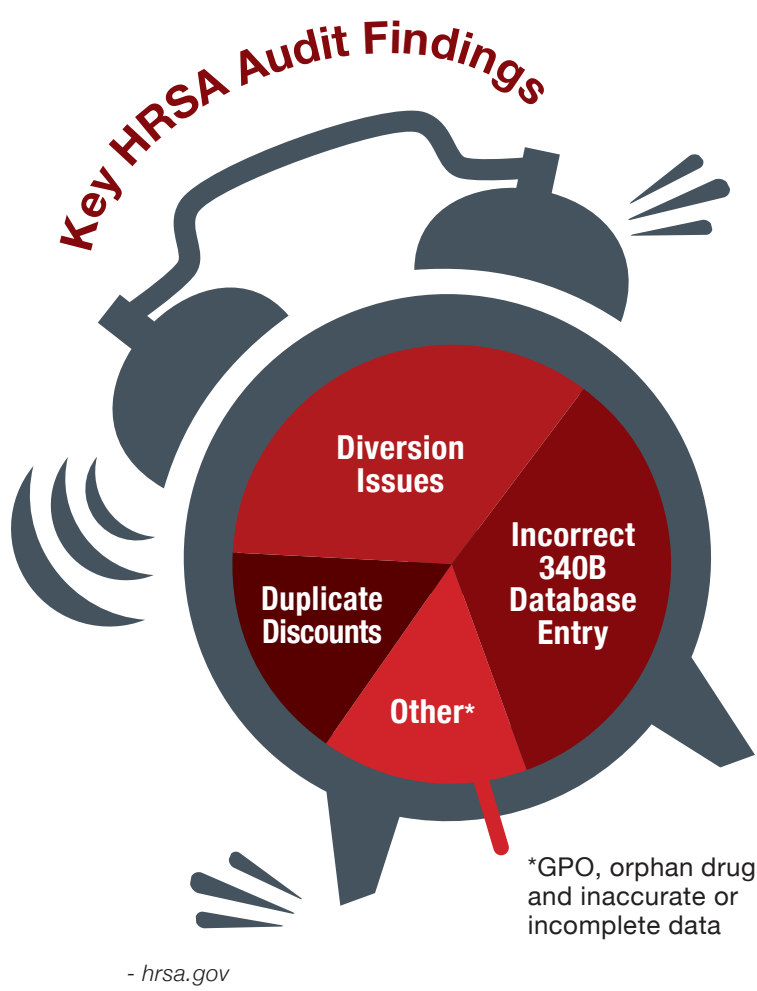


What Keeps a 340B Administrator Up at Night?



340B Compliance Alarm

HRSA Audits are Ramping Up...

As the HRSA 340B audit goals for covered entities (CEs) are nearly doubling in 2016, there is an increased risk of fees, repayment, and worst case scenario – program termination – potentially resulting in a crucial loss of program savings.

2012	2013	2014	2015	2016
51	94	99	199	300+

- hrsa.gov

Who is Chosen for Audit?

You are either **TARGETED** for an audit or you may be **AT RISK**.

TARGETED AUDITS

- Alleged violations reported to HRSA
- Specific compliance violation occurrence

RISK-BASED FACTORS

- Number of registered child sites
- Number of contract pharmacies
- Complexity of the 340B program
- Volume of 340B purchases

HRSA's 2016 budget includes a \$7 million increase from FY 2015 for 340B Drug Pricing Program and a new user fee of \$7.5 million to help continue supporting the program's activity in the long term.

- hss.gov 2016

Are You Ready for the Proposed Mega-Guidance?

New proposed guidance clarifies and limits eligibility criteria, which may result in a smaller "pool" of eligible patients for 340B pricing, and thus less savings available. Further, the cost of maintaining compliance is likely to increase with stricter requirements.

Be Ready.

- 340B prescriptions must originate from a healthcare service provided at a registered facility. **Prescriptions to patients seen in a physician's private practice are not eligible.**
- Prescribing provider either must be employed by the CE or an independent contractor such that the entity may bill for services on behalf of the provider. **Medical staff privileges alone are not sufficient to determine prescriber eligibility.**
- Patient status should be determined based on how the patient's service is billed to insurance. **Thus, prescriptions issued at the time of a patient's hospital discharge from an inpatient surgical stay may no longer be eligible.**
- CEs must now make a determination regarding carve-in or carve-out status for **Medicaid Managed Care.**
- Patients must receive a healthcare service other than the dispensing or infusion of a drug. **Thus, infusion must now be prescribed in the CE to be eligible,** which may result in a significant increase in the cost of infusion drugs.
- Contract pharmacy arrangements **subject to annual independent audits.**

Don't Lose Sleep

With the growing number of requirements and criteria for eligibility, CEs must safeguard the valuable savings received from this program. The question is, how can CEs keep up with all of this and still sleep at night?

If You Suspect an Issue, You're Probably Right

Some signs are clear, others you may suspect. Implement auditing and monitoring processes to identify issues before they escalate.

Split-Billing Software Is Not A Foolproof Option

CEs are ultimately responsible for 340B program compliance.

Risk of HRSA Audit

Proactive compliance will save money in penalties and future audit costs if found to be non-compliant.

External, independent 340B audits are an important component of ongoing compliance.

PYA Can Help

PYA is comprised of experienced (field-tested) professionals who assist healthcare organizations in designing and maintaining sound internal controls, processes, and procedures. We identify risk and recommend controls for remedy.

Areas of 340B concentration include:

- Policy & Procedure Development
- Review 340B Infrastructure
- Purchasing & Inventory Walk-Through
- Testing of Prescription Eligibility
- Assess Contract Pharmacy Agreements
- Assist with Parent & Child Site Eligibility
- Review Controls to Prevent Duplicate Discounts and Diversion
- Cost Report Reviews
- Onsite Education "Bootcamp"

PYA's independent assessments are focused on key risk areas and are customized according to the unique needs of each CE.



Visit our site for helpful checklists and tools



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