



340B program solutions

Achieving 340B program integrity



Smart decisions. Lasting value.™

For many healthcare organizations, the 340B Drug Pricing Program offers significant cost savings that enables them to continue serving at-risk populations. However, the lack of clarity within the program's complex regulations and increased scrutiny over covered entity operations has made it challenging for many healthcare entities to remain compliant while also meeting the U.S. Health Resources & Services Administration's (HRSA's) expectations.

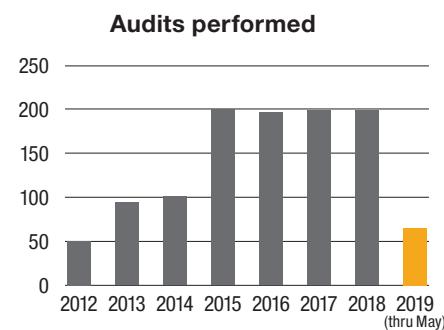
HRSA's increased scrutiny has come in the number of 340B program audits completed and enhancements to the overall audit process. In addition, more severe penalties are being considered when entities show insufficient monitoring processes and a lack of program oversight, even including disqualification from the contract pharmacy setting or removal from the program entirely.

Crowe has worked with hundreds of healthcare organizations to assist them in maintaining 340B program compliance and identifying areas for increased future savings. Our comprehensive approach to 340B auditing and consulting includes the use of robust data analytics across all 340B services.

HRSA audit process

HRSA began performing audits in 2012 and continues to enhance their audit procedures. It is important for entities to stay informed of these and future changes and consider enhancing monitoring practices to stay ahead of the curve.

| HRSA enhancement | Entity takeaway |
|---|---|
| Outsourced audit fieldwork to The Bizzell Group | Increased auditor sophistication – many are pharmacists with 340B experience |
| Accelerated audit timeline | Preparation is key – mock HRSA audits recommended |
| Risk-based sample, not purely random | Monitoring activities should follow suit |
| Focus on split-billing accuracy, including requests to view system transactions | Split-billing maintenance (crosswalks, multipliers, negative balances, etc.) should be part of internal monitoring procedures |
| Expanded data request elements | Auditable trail and ability to supply information in a short time frame |
| Corrective action plan (CAP) time requirements | Processes in place to fulfill CAP, including settlements with manufacturers |





340B program solutions

- Independent audits – mixed-use and contract pharmacy
- Post-audit support
- Mock HRSA audits
- HRSA audit support and preparation assistance
- Program improvement/optimization
- Policy and procedure enhancement
- Savings analyses
 - Preregistration
 - Program definitions
 - Regulatory changes
 - Program design and implementation assistance

Regardless of the services provided, our collaborative approach typically results in:

- More thorough understanding of 340B throughout the organization
- Enhanced operations, including monitoring procedures
- Greater degree of compliance with regulations

340B independent audits

What do they include?

- Eligibility and registration review
- Office of Pharmacy Affairs (OPA) database reconciliation
- Policy and procedure review
- Detailed testing options
 - Industry-standard sampling methodology
 - **Data analytics enables us to test 100% of an entity's dispensations, if desired**
- Compliance focus on:
 - Diversion
 - Duplicate discounts
 - Group purchasing organization (GPO) prohibition (if applicable)
 - Orphan drugs (if applicable)
- Purchasing appropriateness
- National drug code (NDC) matching
- Monitoring and oversight procedure assessment

Our comprehensive audit approach provides covered entities a true picture of program performance.

340B Program Monitor solution

Automated solution for monitoring 100% of dispensation

While nearly all covered entities perform periodic program monitoring, we find most still rely on a sampling approach when assessing compliance. Leveraging our data analytics capabilities and 340B experience, we have developed an automated solution that enables continuous monitoring without relying on only a small number of transactions. Our 340B Program Monitor tool offers:

- Customizable tests
- Interactive reporting capabilities for detailed investigation
- Exception tracking and resolution
- Scenario analysis
- Lost opportunity analyses designed to increase future savings



Learn more

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Be prepared for HRSA's audit areas of focus

HRSA continues to focus on the following areas of compliance during their program integrity audits of 340B-covered entities:

- Hospital eligibility documentation, including private nonprofit hospital status and local or state government contract
- Diversion prevention by compliance with patient definition requirements, including establishing a patient relationship, maintaining healthcare records, providing care from an eligible provider, and maintaining responsibility for the care provided
- Location site eligibility, including Medicare cost report review and referral relationship documentation
- Infusion eligibility requirements, including providing health services in connection with an infusion
- Accumulation errors, including improper accumulation based on charge master description instead of the 11-digit NDC
- 340B OPAIS record accuracy, with focus on child site and contract pharmacy locations
- Duplicate discount prevention, including compliance with state Medicaid regulations and out-of-state Medicaid agencies

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HC2004-004A