



The Complex Balance of 340B Compliance

340B covered entities must maintain compliance with all of the program eligibility requirements in order to avoid repayment penalties and the publicity of adverse HRSA audit findings while participating in the program. With a deep understanding of the issues underlying the hundreds of HRSA audits that have taken place over the past few years and broad experience with covered entities, we regularly counsel and assist clients regarding proper administration of their 340B programs so they can stay compliant and realize the program's significant cost-savings.

We proactively advise clients on how to strengthen existing programs, identify areas for improvement and address any potential issues. We are known for our ability to assist covered entities in maintaining the compliance of their 340B programs to reduce the risk of a government audit and its associated publicity.

► Eligibility and Compliance

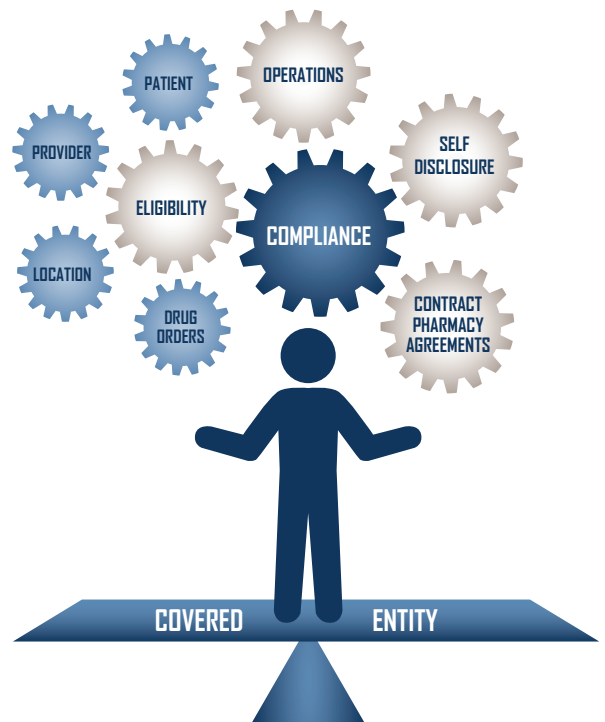
Covered entities of all types rely on us to help them monitor compliance practices in regards to patient, prescriber, location and drug order eligibility, which are critical to maintaining compliance with program rules.

We also help covered entities evaluate and maintain their enrollment registrations with HRSA for all eligible locations.

► Operations

We will assist you in maintaining the correct policies and procedures to ensure that all departments in your organization are engaged in compliant activities. We advise clients regarding:

- Maintaining auditable records that demonstrate compliance with all program requirements
- Program oversight
- Avoidance of diversion and duplicate discounts
- CHOW implications on enrollment and compliance
- Policy and claim negotiations with the Ohio Department of Medicaid regarding Medicaid rebate and drug exclusion issues



▶ Self-disclosures

We've handled self-disclosures to HRSA and drug manufacturers involving a variety of compliance issues and their resolution, including:

- Drug diversion involving ineligible patients, locations, prescribers and drugs
- Duplicate discount issues, group purchasing organization misuse and 340B enrollment issues
- Drug diversion and purchasing errors
- Negotiation with HRSA on plans of correction, refund methodology and completion of refund process
- Repayment of discounts back to manufacturers

▶ Audit assistance

HRSA audits focus on all areas of 340B enrollment including potential diversion, duplicate discounts and 340B database records. The risk of a poor audit outcome includes loss of program eligibility and repayment of 340B discounts to manufacturers. We can assist you in preparing for a HRSA or manufacturer audit and guide you through the actual audit process with the goal of continued participation in the 340B program, reduced repayment obligations and elimination of the adverse publicity of negative audit results.

▶ Negotiating agreements and resolving disputes

Negotiating contracts and effectively handling disputes are critical components of 340B compliance. We have extensive experience with:

- Contract pharmacy agreements with local and national drug chains
- Third-party pharmacy management agreements
- Contract disputes involving 340B disclosures and liability

Maintaining enrollment in the 340B Drug Pricing Program is dependent on an organization's demonstrated compliance with all program requirements. Contact us if you need help keeping the requirements in balance.



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At the center of health care law
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