PYA Healthcare Regulatory Roundup #95 – 340B & You: What to Know, What to Watch For, What to Do Today

Presented June 11, 2025 by PYA's Sarah Bowman | Part of the Healthcare Regulatory Roundup Webinar Series

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WEBINAR SUMMARY

This webinar provides a comprehensive review of the 340B Drug Pricing Program, designed to help covered entities stay compliant, manage risk, and prepare for regulatory changes. PYA's Sarah Bowman covers eligibility requirements, split billing systems, contract pharmacy arrangements, Medicaid carve-in decisions, the group purchasing organization (GPO) prohibition, and upcoming federal changes—highlighting practical action steps and common pitfalls. With looming shifts such as the Centers for Medicare and Medicaid (CMS) taking over the Health Resources and Services Administration (HRSA) oversight and drug manufacturers pushing for rebate models, this session equips healthcare leaders with critical updates and compliance strategies.

WEBINAR HIGHLIGHTS AND FREQUENTLY ASKED QUESTIONS

What is the 340B Drug Pricing Program and who qualifies?

- Enacted in 1992, the 340B Program requires drug manufacturers to offer outpatient drugs at reduced prices to eligible healthcare organizations.
- Hospitals such as disproportionate share hospitals (DSH), critical access hospitals (CAH), sole community hospitals (SCH), and certain federal grantees qualify if they meet specific cost report thresholds.

What are the most common compliance pitfalls with 340B?

- Incorrect eligibility classifications (e.g., inpatient drugs or non-eligible prescribers)
- Missing or outdated contract pharmacy agreements
- Failing to align OPA database with operational practices
- Duplicate discounts due to incorrect Medicaid carve-in/carve-out declarations
- Improper GPO use by DSH hospitals
- Poorly maintained provider eligibility lists

What changes to 340B are pharmaceutical manufacturers pushing for?

- Manufacturers like Eli Lilly and Sanofi are pushing for rebate models, requiring providers to pay full drug prices upfront and seek reimbursement later.
- This shift is widely opposed by covered entities due to financial and administrative burdens.

What new regulatory changes to 340B are expected?

- CMS to take over 340B oversight from HRSA (per FY 2026 HHS budget request)
- Potential cuts to Medicare reimbursement for 340B drugs
- State legislation increasing protection for 340B participants

- Tariffs and drug pricing pressure that could affect future 340B savings

340B Compliance Checklist: What to do today

- Review your OPA database for accuracy (addresses, pharmacy relationships, Medicaid carve-in status)
- Audit your contract pharmacy agreements—ensure they include HRSA's 12 compliance elements
- Validate your split billing software logic with recent dispensation reports
- Check for orphan drug exclusions and GPO compliance (as applicable)
- Update provider eligibility lists and policy documents
- Monitor state and federal legislative developments
- Engage in advocacy and develop public-facing impact statements on how 340B benefits your community

FINAL THOUGHTS

"Now is not the time to be quiet about 340B." — Sarah Bowman

Covered entities should reinforce their compliance infrastructure and increase advocacy efforts as the regulatory landscape rapidly evolves.

ACTION ITEMS

- Review and update 340B program policies and procedures to reflect current operations.
- Locate and review all contract pharmacy agreements to ensure they meet HRSA's 12 essential compliance elements.
- Verify that the locations listed in contract pharmacy agreements match what is registered on the HRSA OPA database.
- Develop an organizational impact statement highlighting the benefits of the 340B program to the community.
- Pursue local and state advocacy efforts to educate lawmakers on the importance of the 340B program.

WEBINAR OUTLINE

Introduction and Overview of the Webinar

- Presenter, Sarah Bowman introduces herself and outlines the agenda, focusing on 340B program basics and recent events.
- The webinar aims to provide a refresher for seasoned professionals and introduce newcomers to the 340B program.

Historical Context and Program Basics

- Sarah Bowman explains the enactment of the 340B program in 1992 by President Bush.
- The program requires drug manufacturers to provide covered outpatient drugs at significantly reduced prices.
- Covered entities use savings to provide additional community benefit programs.
- The program has grown significantly, with over $66 billion in total 340B program purchases in 2023.

Eligibility Criteria and Compliance Requirements

- Sarah Bowman discusses the eligibility criteria for hospitals and federal designees, emphasizing disproportionate share hospitals (DSH).
- Reminder that for-profit healthcare providers and private practice groups are not eligible for the 340B program.
- Hospitals must meet specific DSH percentages based on their most recently filed Medicare cost report.
- The importance of registering child sites and meeting additional compliance criteria is highlighted.

Registration Process and OPA Database

- Sarah Bowman explains the registration window for new covered entities and changes to existing registrations.
- The next registration window is from July 1 to July 15, with changes effective October 1.
- The OPA database contains detailed information about covered entities, including parent and child site information, Medicaid billing status, and contract pharmacy relationships.
- The importance of maintaining accurate and current information on the OPA database is emphasized.

Policies and Procedures for 340B Compliance

- Sarah Bowman stresses the importance of having well-documented policies and procedures that reflect current operations.
- Policies should include detailed eligibility criteria for patients and prescribers, and procedures for retaining records.
- Regular auditing and monitoring of 340B inventory models are crucial for compliance.
- The vast majority of covered entities use a replenishment model for inventory management.

Contract Pharmacy Relationships and Compliance Risks

- Sarah Bowman discusses the benefits and risks of establishing contract pharmacy relationships.
- Covered entities can expand their program scope and increase savings through contract pharmacies.
- The importance of ensuring contract pharmacies correctly identify eligible patients and prescribers is emphasized.
- HRSA expects covered entities to have contract pharmacy agreements that meet 12 essential compliance elements.

Common Compliance Pitfalls and Testing

- Sarah Bowman highlights common compliance pitfalls, such as duplicate discounts and ineligible patients.
- Regular testing of prescription eligibility and dispensation data is recommended.
- Large swings in volume should be investigated to determine the root cause.
- The importance of maintaining accurate and current Medicaid exclusion files is reiterated.

Impact of Pharmaceutical Manufacturer Restrictions

- Sarah Bowman discusses the impact of pharmaceutical manufacturer restrictions on 340B pricing for contract pharmacies.
- Some manufacturers have implemented rebate models, requiring covered entities to pay full price upfront and later receive rebates.
- Covered entities are generally not thrilled with this model, and legal challenges are ongoing.
- State and federal legislation aims to protect covered entities' right to receive 340B discounted drugs.

Future of 340B Program and Advocacy

- Sarah Bowman discusses the potential impact of tariffs on drug prices and 340B savings.
- The recent announcement of HHS plans to eliminate HRSA and transfer its responsibilities to CMS is highlighted.
- Now is a great time for covered entities to strengthen their compliance efforts and pursue advocacy.
- Attendees are encouraged to develop impact statements and engage in local and state advocacy efforts.

Conclusion and Additional Resources

- Sarah Bowman concludes the webinar by encouraging attendees to stay engaged and informed about 340B updates.
- The importance of maintaining accurate and current information on the OPA database is reiterated.