

340B Drug Pricing Program

Polsinelli's premier provider-focused 340B team helps clients proactively address financial, transactional, compliance and regulatory 340B matters with an eye toward long-term program sustainability. As health care institutions increasingly face financial pressures, Polsinelli helps clients maintain compliant programs and negotiate with stakeholders to maximize savings. We partner with health care entities to create programs that allow them to take full advantage of the benefits offered without sacrificing confidence in knowing their practices are fully compliant and defensible.

Polsinelli's Health Care practice includes several industry-leading 340B attorneys that provide strategic, compliance, and regulatory solutions to Covered Entities located throughout the country. The 340B practice spans multiple disciplines within Polsinelli's national platform providing Covered Entities with an unparalleled level of resources. Our 340B practice frequently interfaces with the firm's health care privacy, antitrust, health care mergers and acquisitions, government investigations, employee benefits and technology practices to provide high-value, efficient solutions to the unique and complex issues Covered Entities face under the 340B program.

Polsinelli's 340B client base includes hospitals and health systems, federally qualified health centers, grantees, pharmacies, accountable care organizations and related vendors. Our team applies its significant audit and compliance experience when providing the below services to Covered Entities:

Strategy

- 340B eligibility/feasibility assessments, including disproportionate share hospital percentage validations and assessments of alternative 340B program participation methods
- 340B program development, including preparation of local government contracts, comprehensive 340B policies and procedures, and staff training programs
- Enhance patient access to 340B drugs by converting/adding eligible provider-based sites
- Negotiate and structure 340B contract pharmacy arrangements with local pharmacies that range from national retailers to single community pharmacies
- Assess and restructure employee benefit plans to provide Covered Entity employee access to 340B drugs
- Develop other unique partnerships with community providers to enhance patient access to 340B drugs
- Pharmacy benefit manager ("PBM") credentialing and contract negotiations, including significant experience negotiating 340B drug pricing program, mail order, central fill and chain pharmacy terms

340B Audit Readiness

- Perform 340B audit readiness assessments and provide operationally feasible recommendations on how to improve compliance
- Provide onsite Office of Pharmacy Affairs audit assistance, including development of audit data request responses and preparation of audit team members
- Assist with follow-up audit responses, including development of Corrective Action Plans

- Aid Covered Entities with manufacturer audits and inquiries

Compliance/Regulatory

- Negotiate vendor agreements for necessary 340B compliance tools, including virtual inventory and contract pharmacy management products
- Provide day-to-day regulatory analysis and support, including the application of the patient definition, GPO prohibition, Medicaid duplicate discounts prohibition, and orphan drug rule
- Secure technical assistance from the Office of Pharmacy Affairs and its contractors
- Prepare timely regulatory and industry updates that impact Covered Entities
- Assist health system entity-owned, chain and independent pharmacies with various payor and PBM audit and compliance matters, including responding to audits and appealing adverse determinations

340B Registration Database Support

- Assist with Office of Pharmacy Affairs 340B database registrations, including recertification and changes to scope/locations
- Counsel Covered Entities on applicable registration deadlines that may have a significant impact on 340B program eligibility and the underlying transaction
- Update clients on changes to database processes and key deadlines

340B Pricing Access

- Navigate evolving manufacturer contract pharmacy restriction policies impacting access to 340B pricing
- Negotiate manufacturer agreements to obtain 340B pricing for Covered Entities
- Advise on complex data-sharing arrangements to ensure compliance with applicable privacy laws
- Assess risks and benefits of different strategies to obtain 340B pricing with Covered Entities

Public Policy

- Monitor and update participating providers on new guidance and regulations affecting the Program
- Develop and file comments on new regulations
- Assist clients in executing an effective legislative plan to ensure that their concerns are heard

Publications

April 13, 2026

2026 340B Program Update – 340B Rebate Model RFI Comments Due and Manufacturers Continue Restricting 340B Pricing

February 4, 2026

Mandatory Provider-Based Attestations Make a Comeback

November 26, 2025

What 340B Hospitals Need to Know About CMS's CY 2026 OPPS Final Rule

October 31, 2025

Ready or Not: HRSA's 340B Rebate Pilot Model Takes Off Despite Questions on Readiness and Authority

August 7, 2025

The 340B Rebate Pilot: Voluntary for Manufacturers, Costly for 340B Covered Entities

April 19, 2024

HRSA Aims for Swift Dispute Resolution with new 340B ADR Final Rule

July 11, 2023

CMS Proposes \$9B in Relief for 340B Hospitals

December 19, 2022

340B Hospital Reimbursement Update – Underpayments and the Need to Act Now

July 19, 2022

SCOTUS 340B Decision Drives CMS to Restore Part B 340B Payments and Seek Comments on Remedies in the CY 2023 OPPS Proposed Rule

June 16, 2022

SCOTUS Sides with 340B Hospitals and Denies CMS's Attempt to Cut Reimbursement for 340B Drugs