

Pharmacy

Polsinelli's pharmacy law practice is recognized as one of the nation's premier pharmacy law practices. Our attorneys advise pharmacy clients and pharmacy professionals on regulations associated with drug distribution from manufacturers, wholesalers and pharmacies to hospitals, physicians, clinics, other facilities and ultimately to patients. We represent national and regional pharmacy chains, home and alternate site infusion pharmacies, specialty pharmacies, mail-order pharmacies, independent retail pharmacies, long-term care pharmacies, hospitals and retailers with pharmacy operations, group purchasing organizations, pharmacy services administrative organizations, pharmacy benefit managers, and technology vendors supporting pharmacy operations. Our clients include 340B pharmacies and related contract pharmacies.

Polsinelli's attorneys advise its pharmacy clients in matters relating to business organization, commercial contracting, mergers, acquisitions and divestitures, reimbursement, third-party payor audits (including state audits), allegations of diversion, pharmacy compounding matters, federal and state anti-kickback issues, and privacy and security issues.

Polsinelli's regulatory attorneys routinely represent its pharmacy clients before state and federal agencies including state boards of pharmacy, Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), Center for Medicare and Medicaid Services (CMS), Health Resource and Services Administration (HRSA), Office of the Inspector General (OIG) and Department of Justice (DOJ).

Matters

Federal & State Regulatory Compliance

- Represent pharmacies and pharmacy professionals in complying with State Boards of Pharmacy laws and regulations.
- Counsel on federal and state anti-kickback and anti-inducement laws, federal False Claims Act, Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health (HITECH) Act requirements.
- Advise on matters involving controlled substances, including DEA registration requirements, state Prescription Drug Monitoring Program requirements, electronic-prescribing, telemedicine and auto-dispensing.

Audits, Investigations & Litigation

- Represent pharmacies and pharmacy professionals across the country in administrative actions brought by State Boards of Pharmacy.
- Represent pharmacy clients in inspections, investigations, and litigation initiated by governmental agencies, such as the FDA, DEA, OIG, DOJ and state regulatory and professional licensing agencies.
- Represent clients with matters relating to the alleged diversion of drug products, including prohibited diversion under the Controlled Substance Act and 340B drug discount program.
- Represent pharmacies in government and commercial payor reimbursement audits, proceedings and appeals.

Mergers, Acquisitions, Joint Ventures

- Represent pharmacies and private equity sponsors in acquisitions, divestitures, mergers and joint ventures, including structuring, negotiating and documenting the transaction, performing due diligence.
- Advise clients on network pharmacy agreements, pharmacy services agreements with hospitals and accountable care organizations, and 340B contract pharmacy services agreements.

Licensure & Registration

- Counsel resident and non-resident pharmacies on change of ownership, transfer matters and other federal and state approvals.
- Advise national and regional mail service and specialty pharmacy operations regarding the applicability of in-state and out-of-state licensing requirements.
- Assist private equity groups in conducting health regulatory due diligence of retail, mail order and specialty pharmacy companies, including advising on federal and state “change of ownership” requirements.

Publications

April 2, 2026

NYBOP May 2026 Deadline Is Fast Approaching: Do Your Pharmacy and Pharmacists Have the Right Licenses?

March 9, 2026

Missouri Attorney General Files Suit Against Pharmacy Benefit Managers and Drug Manufacturers for Alleged Insulin Pricing Scheme

January 24, 2025

Swing and a Miss: the Government Strikes Out in Pharmacy Executive Kickback Trial

December 12, 2024

Massachusetts Issues Additional Update to Non-Resident Pharmacy Rules

November 21, 2024

Santa is Bringing Long-Awaited Regulatory Changes to Massachusetts Pharmacy Licensure

July 17, 2023

Are You Ready? Starting August 1st, New York Imposes New Review Process for Material Transactions Involving Health Care Entities