

Pharmacies

Hooper, Lundy & Bookman works closely with clients throughout the pharmacy sector to address regulatory and compliance concerns, develop and manage business arrangements, relationships, and transactions, and provide counsel on their payment, reimbursement, contracting, and litigation matters.

We represent retail, specialty, mail-order, institutional, hospital, and compounding pharmacies, as well as pharmacy benefit managers (PBMs) and wholesale distributors, to protect their legal interests, advance their business objectives, and help them navigate the regulatory complexities involved in the handling of prescription medications and controlled substances.

Our nationwide pharmacy practice includes litigators and business lawyers, payment and reimbursement experts, and an industry-leading compliance and regulatory team that provides counsel on various issues, including:

- Medicare Part D compliance
- Fraud and abuse investigations, compliance counseling, and defense, including Stark Law and federal and state anti-kickback statutes
- Mergers, acquisitions, and strategic collaborations for pharmacies and PBMs
- Structuring and negotiating supply chain, drug purchasing, and rebate arrangements
- Defense of Recovery Audit Contractor (RAC), Medicare, Medicaid, and third-party payor audits and claim denials
- PBM audits
- Issues with third-party administrators (TPAs) and other prescription drug programs
- Pharmacy licensing, including initial licensure and changes to licensure due to change of ownership (CHOW), change of location, or other operational or organizational changes
- 340B drug program registration and compliance
- Antitrust analysis
- Contractual and transactional matters
- Vendor and service agreements
- Arrangements with managed care organizations
- Operations and corporate governance
- Internal investigations
- Office of the Inspector General (OIG) self-disclosures
- Network provider contracting and policy drafting
- Payor contracting
- Compliance counseling for 503B compounding pharmacies
- FDA regulatory compliance
- DEA and state controlled substances requirements
- Drug Supply Chain Security Act compliance
- HIPAA and patient privacy compliance