

PHARMACY & 340B

Hall Render attorneys have diverse and extensive experience addressing issues unique to pharmacies of all types. These include retail chain pharmacies, specialty pharmacies, mail-order pharmacies, institutional pharmacies, home infusion pharmacies, long-term care pharmacies, compounding pharmacies, outsourcing facilities, central fill pharmacies and in-office physician pharmacies.

We have extensive experience representing providers and suppliers on matters common in the pharmacy space including pharmacy benefit management, government reimbursement, drug supply chain optimization, distribution, repackaging, long-term care/hospice, group purchasing organization matters and manufacturing along with the full spectrum of ancillary pharmacy and drug-related matters.

We also have extensive experience assisting pharmacy providers across the country subject to government investigation or self-reporting to the applicable government authorities on issues such as individual practitioner prescription practices, billing protocols, coverage authorization, disqualified personnel and 340B program eligibility. We work with pharmacies through their own corporate integrity structure to proactively identify potential compliance concerns, provide input as to effective plans of correction and self-report to the appropriate government/payor authorities as necessary before the issue escalates further. In those instances in which a governmental investigation is pending, we regularly work with the Department of Justice, Office of Inspector General, State Attorneys General, Medicaid Fraud Control Units and other federal and state investigators in defense of our clients.

Our practice encompasses a broad range of pharmacy-related services to address provider and professional issues, including regulatory compliance and enforcement support, licensure and certification (federal and state), development and maintenance of compliance programs, Medicare and Medicaid reimbursement matters, private payor reimbursement matters, fraud and abuse advice, and litigation defense.

Hall Render also has one of the nation's largest team of attorneys focusing on 340B Program matters for 340B Covered Entities. Our 340B Program practice advises Covered Entities on matters including 340B Program compliance, Program optimization (provider-based, telehealth), drug sourcing (class of trade, GPO, WAC and Prime Vendor account planning), contract pharmacy negotiations, manufacturer disputes, data aggregator disputes and virtually any other legal issue facing 340B Program Covered Entities and contract pharmacies.

AREAS OF FOCUS

- 340B
- 403(b) Tax-Sheltered Annuity Plans
- 503A Compounding Pharmacies
- 503B Compounding Pharmacies
- Assessment
- Audit Advice
- Automated Dispensing
- Boards of Pharmacy Enrollment/Certification
- Centers for Medicare & Medicaid Services
- Central Fill Pharmacy
- Civil Monetary Penalties Law - Relationships with Beneficiaries
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- Compliance Programs
- Controlled Substances Act
- Controlled Substances Act (individual and institutional registrations, ordering, dispensing)
- Counterfeit Drugs
- Current Good Manufacturing Practice Compliance
- Drug Enforcement Administration
- Drug Quality and Security Act
- Drug Quality and Security Act
- Drug-Seeking Patients
- E-Prescribing and Telemedicine
- Education and Communication
- Electronic Medical Records

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In carrying out these services, our attorneys provide advice to institutional and retail pharmacy clients related to the following matters: controlled substances (DEA and state); wholesale distribution, mail-order drugs, pharmacy and PBM contracting issues, pharmacy technology, security and EMR; e-prescribing and telemedicine; automated dispensing; drug recalls; 503 A and 503 B compounding; sterile procedures; institutional and individual licensure/enrollment; payor certifications (Medicare, Medicaid, private payors); Medicare Part D compliance; 340B Program implementation, oversight and optimization; pharmaceutical pricing issues; infusion services; home health pharmacy service; pharmaceutical environmental issues; supply chain (product and related services agreements); HIPAA/HITECH; immunizations; and patient safety and quality improvement.

- False Claims Act Defense
- Food, Drug and Cosmetic Act
- Fraud and Abuse - Federal and State Anti-Kickback Statutes
- HIPAA/HITECH
- Immunization Matters
- Importation
- Infusion Pharmacies and Services
- Labor and Employment
- Mail Order Pharmacies
- Medicare Part D
- Office of Inspector General
- Patient Safety/Quality Improvement
- Pharmaceutical Environmental Issues
- Pharmaceutical Manufacturing
- Pharmaceutical Pricing and Rebates
- Pharmacy Benefit Management Contracting and Regulatory Compliance
- Prescription Drug Marketing Act
- Private Label Manufacturing
- Regulatory Compliance
- Regulatory Enforcement Support and Litigation
- Security
- Stark Law - Relationships with Physicians
- State Enforcement Agencies
- State Licensing and Practice Hearings/Litigation
- State Pharmacy and Pharmacist Enrollment/Certifications
- Structure and Reporting
- Supply Chain (product and related services agreements)
- Technology

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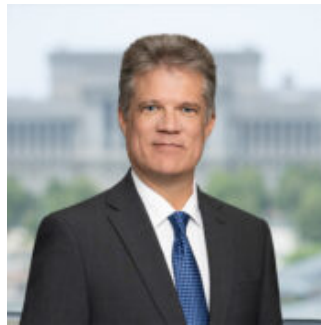
- Traditional Medicare and Medicaid
- Wholesale Distribution

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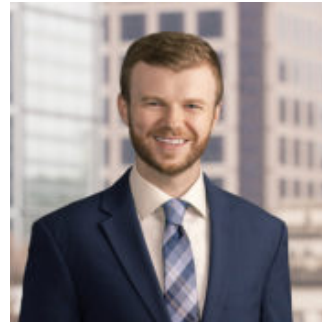
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