

## PHARMACY & PHARMACY BENEFIT MANAGEMENT

Hall Render attorneys have diverse and extensive experience addressing issues unique to pharmacies, pharmacy benefit managers and providers involved in drug dispensing and distribution. Among others, we counsel retail pharmacies, mail-order pharmacies, pharmacy benefit managers, hospitals and long-term care providers regarding the full spectrum of pharmacy and drug-related matters. We provide a broad range of pharmacy-related services to address provider and professional issues, including regulatory compliance and enforcement support, development and maintenance of compliance programs, Medicare and Medicaid reimbursement matters, private payor reimbursement matters, and fraud and abuse advice and litigation defense.

In carrying out these services, our attorneys provide advice to pharmacy and pharmacy benefit manager 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; auto-dispensing; drug recalls; institutional and individual licensure/enrollment; payor certifications (Medicare, Medicaid, private payors); Medicare Part D compliance; 340B Program implementation and oversight; pharmaceutical pricing issues; infusion service; pharmaceutical environmental issues; supply chain (product and related services agreements); HIPAA/HITECH; immunizations; and patient safety and quality improvement.

### AREAS OF FOCUS

- 340B
- Assessment
- Audit Advice
- Auto-Dispensing
- Centers for Medicare & Medicaid Services
- Civil Monetary Penalties Law - Relationships with Beneficiaries
- Compliance Programs
- Controlled Substances Act (individual and institutional registrations, ordering, dispensing)
- Drug Enforcement Administration
- Drug-Seeking Patients
- E-Prescribing and Telemedicine
- Education and Communication
- Electronic Medical Records
- False Claims Act Defense
- Food, Drug and Cosmetic Act
- Fraud and Abuse - Federal and State Anti-Kickback Statutes
- HIPAA/HITECH
- Immunization Matters
- Infusion Pharmacies and Services
- Labor and Employment
- Medicare Part D
- Office of Inspector General
- Patient Safety/Quality Improvement
- Pedigree Requirements/Counterfeit Drugs
- Pharmaceutical Environmental Issues
- Pharmaceutical Pricing and Rebates
- Pharmacy Benefit Management Contracting and Regulatory Compliance
- Prescription Drug Marketing Act
- 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
- Traditional Medicare and Medicaid