

PHARMACY OPERATIONS & 340B

Health care is increasingly being delivered in the non-acute setting, and pharmacy operations are at the forefront of that modality shift. That shift needs to be coordinated with complex laws governing 340B pricing, drug pricing and pharmacy delivery systems optimization. Hall Render's holistic and integrated approach to health law makes us uniquely qualified to address the complexities faced by health care providers and suppliers of all types involved directly or indirectly in the provision of prescription drugs.

SCOPE OF SERVICES

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.

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.

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