Home Infusion Providers



For over 20 years, Frier Levitt has represented home infusion providers in a variety of matters ranging from corporate transactions and regulatory compliance reviews to pharmacy benefit manager ("PBM") audits and investigations. Frier Levitt is equipped with comprehensive knowledge of the home infusion therapy space and understands the complexities associated with the home infusion process, which typically requires coordination among multiple entities, including patients, physicians, hospital discharge planners, health plans, home infusion pharmacies, and, if applicable, home health agencies. Home infusion therapy, if the service is structured correctly, improves compliance, lowers costs to payors and patients alike, and also improves patient safety and adherence. Frier Levitt continues to provide several legal services to home infusion providers as detailed below.

Corporate Transactions

- As payers continue to transition from fee-for-service plans,
 Frier Levitt negotiates optimal value-based reimbursement
 with payers by leveraging the numerous benefits of home
 infusion providers. By way of example and not limitation,
 home infusion providers contribute to cost savings and
 increased compliance, while decreasing mortality and
 morbidities and increasing patient safety and medication
 adherence.
- Frier Levitt assists home infusion providers seeking to improve cost savings and collect data related to home infusion provider benefits by formation of Clinically Integrated Networks in which providers with like-minded objectives and service models utilize standard operating procedures and GPOs to ensure compliant home therapy services.
- Frier Levitt has a transactional group of attorneys dedicated to mergers and acquisitions, joint ventures with hospitals and physicians, and private equity transactions, in addition to contracts with payers.
- Frier Levitt also structures contracts with drug manufacturers which fall within the relevant rebate and discount safe harbors.

Regulatory Compliance

- Frier Levitt analyzes existing relationships with physician referral sources while also developing relationships with physicians and other industry stakeholders in compliance with State and Federal law.
- Frier Levitt counsels its clients to develop and implement comprehensive HIPAA compliance plans, data breach analysis, and reporting, as well as physician and staff required annual training.
- Frier Levitt counsels clients on State Board of Pharmacy and Department of Health rules and regulations.





PBM/Payor Relations

- Frier Levitt fights the abusive tactics of PBMs and has achieved success in all stages of audits and network termination disputes, from the initial appeal through arbitration proceedings.
- Frier Levitt assists providers with obtaining accreditations, as well as admission into PBM pharmacy networks.
- Frier Levitt can help home infusion pharmacies and providers receive proper reimbursement rates for drugs, supplies, and services rendered for commercial, Medicare and Medicaid payers.
- Frier Levitt has extensive experience handling Medicare Audit appeals for claims which have been denied or reopened for providers as well as beneficiaries seeking an exception to access a drug not on formulary.

Frier Levitt takes pride in being able to customize solutions to meet the varying legal needs of our clients. Our firm has over 20 years of experience in the healthcare and life science industries. For more information, contact Frier Levitt to speak with an attorney.

In addition to the services above, Frier Levitt assists in a variety of other matters related to Home Infusion Providers including, but not limited to:

- PBM and government audit defense
- · PBM network access and termination
- Preparation of policies and procedures (i.e. copayment collection, inventory management, etc.)
- Change of ownership credentialing
- Regulatory compliance of Prior Authorization practices
- Structuring arrangements between wholesalers, manufacturers, and pharmacies
- Regulatory and PBM review of Hub arrangements
- Transactional assistance and MSA
- PBM formulary and reimbursement issues
- State Boards of Pharmacy disciplinary and licensing issues
- Prescriber relations and physician marketing
- Evaluation of telemedicine and telehealth compliance
- Off-label dispensing and REMS compliance
- Central Fill and Shared Services arrangements
- Direct-to-physician marketing of infused medications
- Pharmacy and related real estate transactions
- OIG and governmental self-disclosure protocols
- Specialty and Mail Order Credentialing
- Market access and patient support programs
- FDA Regulatory Compliance
- DEA and controlled substance compliance
- Off-label dispensing and REMS compliance
- Structuring central fill and shared-services arrangements
- Direct-to-physician marketing of physician infused medications