

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 also has several clinician attorneys who are able to understand firsthand some of the clinical issues that surround home infusion and related legal issues. 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 allows for patients to receive medical services in the comfort of their own home rather than in a hospital or skilled nursing facility, which are costlier and less convenient alternatives. Further, 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 has and 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.
- Frier Levitt works with clients to create intercorporate documents for entity owners, shareholders, and employees including sales contracts.

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 regularly 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 up through arbitration proceedings.
- Frier Levitt assists providers with obtaining various accreditations as well as successful completion of PBM credentialing processes.
- With respect to reimbursement issues, 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.

Continued

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:

- Combatting prescription leakage and PBM prescription “trolling” – a practice wherein a PBM receives a drug claim for adjudication by the home infusion pharmacy, but instead reroutes the prescription to the PBM’s wholly owned specialty pharmacy without the patient or prescriber’s consent
- Developing compliant copayment collection policies and copayment assistance programs
- Change of ownership
- Prior Authorization PBM and regulatory compliance
- Structuring arrangements and relationships between Wholesalers/Manufacturers and pharmacies to maximize profitability
- Participation in HUB arrangements
- Relationships with pharmacy services administrative organizations (PSAO)
- Compliance with State Boards of Pharmacy rules and regulations
- State pharmacy licensing issues
- Prescriber relations and physician marketing
- Evaluating telemedicine and telehealth compliance
- Off-label dispensing and REMS compliance
- Drug sourcing and inventory maintenance practices
- Structuring central fill and shared-services arrangements
- Direct-to-physician marketing of physician infused medications
- Pharmacy transactions and related real estate
- OIG and governmental self-disclosure protocols
- Mail order practices
- Access restricted PBM and payor networks

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 today to speak with an attorney.