

Hospital and Health System Pharmacy

DIR Fees

Frier Levitt has been at the forefront of fighting against PBM-imposed DIR Fees. Certain types of pharmacies, including health system pharmacies, are disproportionately impacted by DIR fees, given the high-cost, low-margin medications they dispense frequently. Our attorneys have been successful in developing strategies to assist health system pharmacy clients suffering DIR fees by leveraging their positions as part of a hospital health system and utilizing many protections available under State and Federal law.

PBM Network Access

If you are being denied entry into a PBM network and need assistance obtaining network access, Frier Levitt can help. PBMs are notorious for their onerous credentialing requirements and our attorneys are knowledgeable about the specific roadblocks PBMs place on health system pharmacies when contracting and have assisted multiple pharmacies in overcoming such contracting hurdles often by leveraging many State and Federal “any willing provider” requirements to gain access to restricted networks.



340B Compliance/Contract Pharmacy Negotiation

Frier Levitt has extensive knowledge on issues surrounding 340B compliance and assists many pharmacies including health system pharmacies with a variety of 340B matters, including:

- Becoming a 340B In-House or Contract Pharmacy, including eligibility and compliance with on-going requirements
- Service Agreements between Contract Pharmacy and Covered Entities with an emphasis on regulatory compliance with Federal and State Laws and tailored to evolving PBM reimbursements
- Vendor agreements related to 340B operations of In-House and Contract Pharmacies
- Implementation of 340B Operations Compliance Programs
- Response and defense of HRSA Section 340B audits and PBM/third-payor audits

Site of Care Optimization Challenges for Health System Pharmacies

Site of care optimization strategies have shifted the infusion therapy market where payers are leveraging tactics that are driving patients to receive high-cost specialty infusion drugs in lower-cost settings. As such, alternate site of care strategies are being implemented, redirecting patients away from hospitals to lower-cost settings such as physician’s in-office infusion suites, stand-alone infusion centers, and even patients’ homes. Another strategy is white bagging, where payers require hospitals to administer medications shipped from an outside designated pharmacy to the health system for it to be administered to the patient. While these practices may potentially reduce costs for payers, they do not always lower costs for patients or maximize patient care,

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safety, and convenience. Frier Levitt can help health system pharmacies facing these issues to get involved in legislative efforts to address white bagging concerns. Additionally, we can negotiate with payers for the health system pharmacy to become in-network or initiate home infusion therapy services through the stand-alone infusion suites within the health system's pharmacy.

Plan Sponsor Services

Frier Levitt boasts a Plan Sponsor team dedicated to serving a diverse range of clients, including Self-Funded Plans (employers, labor funds, public sector, federal), Health Plans (commercial, Medicare, Medicaid, and Exchange Plans), as well as Regulated Markets (Medicare, Medicaid, Public Health Exchanges). Our firm offers unique services tailored to Plan Sponsors, such as:

- Representing Plan Sponsors in contractual negotiations with PBMs
- Auditing of PBM performance and compliance with contractual and fiduciary obligations
- Ensuring that Plan Sponsors understand their contractual and legal rights and relationships with PBMs, including pass-through pricing and manufacturer rebates
- Pursuing legal action against PBMs to enforce Plan Sponsor Agreement terms and conditions
- Conducting and guiding Requests for Proposals
- Reviewing and analyzing existing PBM Agreements
- Assisting Plan Sponsors with CMS Reporting and CMS Audits
- Providing regulatory compliance with respect to various Federal and State laws (i.e. Consolidated Appropriations Act)

Frier Levitt assists Pharmacy Providers in a variety of matters, including:

- 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
- 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