

# Specialty Pharmacy

## DIR Fees

Frier Levitt has been at the forefront of fighting against PBM-imposed DIR Fees. Specialty pharmacies and dispensing physicians are often disproportionately impacted by DIR fees, given the high-cost, low-margin medications they dispense more frequently. Frier Levitt has been successful in utilizing various legal strategies, including lawsuits and arbitrations against PBMs and plan sponsors, to challenge the propriety and legality of DIR fees on behalf of specialty pharmacies nationwide.

## PBM Network Access

Frier Levitt regularly negotiates contracts with PBM networks for pharmacies and assists with issues of network access. In many instances, pharmacies have been repeatedly denied for various reasons, despite having satisfied applicable credentialing terms. Frier Levitt has an in-depth knowledge of the PBM application process and has assisted many pharmacies with securing access to PBM networks, leveraging applicable Federal and State laws. If you are being denied entry into a PBM network and need assistance obtaining network access, Frier Levitt can help.

## Regulatory Compliance

Specialty pharmacies that enter into manufacturer sponsored arrangements and receive dispensing fees or other payment require a regulatory evaluation. Manufacturer sponsored arrangements, as well as pharmacy hub models, must comply with applicable laws, including the federal Anti-Kickback Statute, federal Health Care Fraud Statute, as well as state kickback and fee-splitting prohibitions. Frier Levitt can assist and provide a regulatory evaluation of these models to ensure compliance.



## Government Litigation

Specialty pharmacy has long been a focus of government enforcement due to typically higher reimbursement amounts involving Medicare and Medicaid claims. There is an increasing number of government investigations being opened based on referrals by private payors and PBMs. Likewise, the specialty pharmacy industry is a perennial target of opportunistic whistleblower lawsuits. Accordingly, business stakeholders, including private equity investors, should be prepared to respond effectively if and when scrutiny arises. If your business is the subject of Federal or State investigations or lawsuits, Frier Levitt will leverage its deep multidisciplinary knowledge to develop the best possible strategy for your defense. Frier Levitt has attorneys with decades of criminal defense experience who have handled countless Federal and State healthcare fraud investigations.

## Frier Levitt assists in variety of matters 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

