

# Specialty Pharmacy Checklist

For over 20 years, Frier Levitt has represented thousands of pharmacies across the country in fighting PBM abuses, negotiating payor and manufacturer contracts, defending governmental investigations, advising on regulatory compliance and ensuring large transactions close without issue.

## Has Your Pharmacy Addressed Each of These Recent Marketplace Issues and Trends?

### PBM Issues

- **DIR Fees:** Has your pharmacy evaluated whether it is being compensated below acquisition cost in violation of Medicare regulations?
- **Hub Participation Risk:** Does your participation in a Hub referral program increase your recoupment risk?
- **Copayment:** Are you properly collecting copayments from commercial patients and governmental beneficiaries, and properly applying coupons and patient assistance programs?
- **340B:** Has your PBM contract lowered reimbursement for 340B claims?
- **MAC Appeal:** Are you using MAC appeals to your full benefit?
- **NADAC:** Does NADAC or AAC pricing render your reimbursement below acquisition cost?
- **Patient Steering:** Have your patients or prescribers been called by PBM/PBM-owned pharmacies to switch pharmacy providers?
- **Payor Contracts:** Does your pharmacy have proper specialty pharmacy contracts in place to satisfy private equity investors?
- **Formulary Compliance:** Does your pharmacy's drug mix comport with payor contractual limitations or requirements to use best efforts to achieve formulary compliance?
- **Mailing:** Does your pharmacy's mailing and/or delivery practices violate payor contractual limitations?

### Regulatory Compliance

- **Referral Arrangements:** Has a healthcare attorney reviewed your third-party contracts for potential anti-kickback violations?
- **Physician Ownership:** Has your pharmacy ownership and referral relationship been evaluated for Stark Law violations?
- **Hub Arrangements:** Does your participation in a HUB referral program expose your pharmacy to regulatory scrutiny?
- **Prior Authorization Support:** Have your pharmacy's prior authorization activities been reviewed for compliance with federal law and payor contracts?

- **Manufacturer Relationships:** Does your relationship with a manufacturer cause health care fraud exposure?

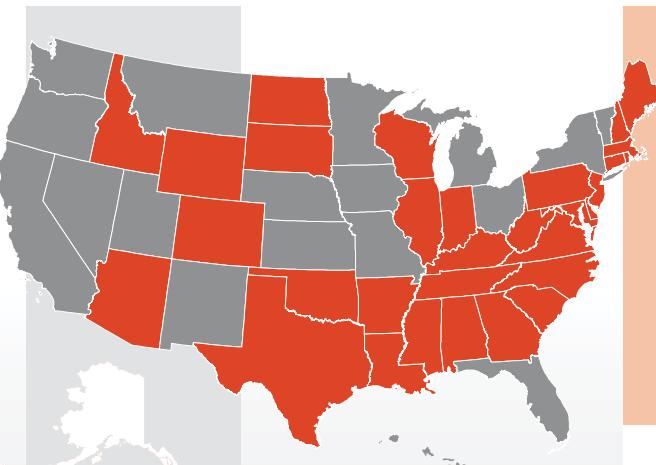
- **Pharmacy Practice Act:** Do your arrangements with Management Services Organization (MSO), partners or vendors constitute the unlicensed practice of pharmacy?

### Payor and Manufacturer Contracting

- **Class of Trade:** Does your Class of Trade match your business type (i.e., specialty, long term care, mail order)?
- **Credentialing:** Have you been unfairly denied specialty credentialing by a PBM or third-party accreditation entity?
- **Reimbursement:** Has your designation as a specialty pharmacy directly lead to decreased reimbursements?
- **Mail Order Limitation:** Are you being prevented from mailing into states in which you hold a valid license?
- **Manufacturer Service Payments:** Do your data and other service arrangements with manufactures expose you to PBM and regulatory risk?

### Governmental Investigations

- **Marketing:** Are you or your marketing companies paying representatives as an employee or 1099 contractor?
- **Shared Services Agreement:** Do your shared services or central fill agreements comply with federal/state laws?
- **Therapeutic Interchange:** Is your pharmacy properly dispensing exactly what was directed by the prescriber?
- **Automatic Refill:** Does your pharmacy utilize automatic refills programs where they are impermissible or exposing the pharmacy to investigation based on unwanted medications?
- **Self Disclosure:** Has your pharmacy explored utilizing the Self Disclosure Protocol to prevent criminal exposure and treble damage risk?
- **PBM Referral:** PBMs are increasing referrals to authorities, has your pharmacy made admissions in the audit appeal process, increasing the risk of a governmental investigation?



**32  
STATES**

have an  
Any Willing  
Provider Law



Forced PBMs  
to pay back  
**\$40+ MILLION**  
in DIR Fees to  
FL clients



**NUMEROUS**  
CLINICIAN ATTORNEYS

**\$1B+** IN TOTAL  
HEALTHCARE  
& LIFE SCIENCES  
TRANSACTIONS

ranging from \$100K-\$400MM



**3 CLASS  
ACTION  
SUITS**

+DOZENS OF MULTI-PARTY  
ACTIONS AGAINST PBMS

