

# Multistate Pharmacy Compliance 101: Navigating Pharmacy Transactions

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# Panelists



**Mateusz (Mat) Sakiewicz**  
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Mat is an experienced corporate practitioner, who devotes a significant amount of his practice to advising health care and life sciences clients on M&A, joint venture, capital markets, and other transactional matters.



**Erin S. Whaley**  
Partner  
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Erin represents health care providers on the full spectrum of legal issues they confront on a daily basis. Her regulatory experience includes advising clients on compliance with the plethora of federal laws that govern the health care industry, including Stark, the Anti-Kickback Statute (AKS), the False Claims Act and HIPAA, as well as state laws including state licensure, corporate practice of medicine and certificates of need.

# Firm Overview

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Our litigation, transactional and regulatory practices advise a diverse client base, from start-ups to multinational enterprises.

We provide sophisticated legal solutions to clients' most pressing business challenges, across several primary client industries, including:



Energy



Financial Services



Health Sciences



Insurance



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# Multistate Pharmacy Compliance 101 Series



## Navigating Pharmacy Disciplinary Procedures



## Navigating Pharmacy Transactions

Thursday, February 22, 12:00 p.m. – 1:00 p.m. ET



## Legal Landmines for Multistate Pharmacies

Tuesday, March 19, 2024 – 12:00 p.m. – 1:00 p.m. ET



## Topics for Discussion

**Pharmacy M&A Motivating Factors**

**Transaction Structure**

**Due Diligence Considerations**

**Regulatory Considerations**

**Reps and Warranties**

**Availability of R&W Insurance Coverage**

**Best Practices**

# Pharmacy M&A Motivating Factors



**Pharmacy M&A Motivating Factors**

**Expansion (or Exit) of Geographical Market**

**Divestiture of Non-Performing Assets**

**Expansion of Service Offering**

**Sale of Business (Final Exit)**

**Regulatory Changes**

# Transaction Structure



## Transaction Structure



**Purchase of Assets**  
**Purchase of Equity**



## Transaction Structure

### **Purchase of Assets**

**Ability to pick-and-choose certain portions of the business**

**May require a greater focus on post-closing integration**

**Liability for actions prior to closing typically retained by the seller**

- E.g., asset buyers can mitigate Medicare successor liability risks
- Asset deals are not a due diligence short cut!

**Regulatory filings often required**



## Transaction Structure

### Purchase of Equity

#### Buyer takes everything “under the hood”

- Often pursued to maintain business continuity
- Buyer generally bears successor liability risk
- Increased emphasis on due diligence

**All owners with a 5% or greater indirect ownership interest must be reported to Medicare and also to many state licensing/Medicaid agencies**

**May be regarded as a change of ownership requiring a full regulatory filing**

# CLE Code #1 Assets

# Due Diligence and Regulatory Considerations

# Licensure Diligence

## **Ensure the target has all relevant licenses to support its business**

- Retail pharmacy
- Facility (e.g. hospital, long term care)
- Compounding
- Controlled substances
- Wholesale
- Central Fill
- Automatic Dispenser
- Internet/Mail Order
- Resident vs Non-Resident

**Independent verification vs reliance on documentation**

**Verify the Pharmacist(s) In Charge (PIC) is properly licensed**

**Confirm appropriate accreditation for Internet or Digital Pharmacies**

**Review licensure applications to confirm they were properly completed or identify inaccuracies which could result in potential liabilities**

**Review any correspondence from state or federal regulatory agencies (e.g., inspection reports, deficiency notices, disciplinary actions, etc.)**

# Health Care Law Diligence

**Review all contracts or relationships with prescribers**

**Review all third-party payor agreements**

**Review contracts with health care facility customers (if applicable)**

**Consider a third-party claims review**

**Review any correspondence from third-party payors, including Medicare or Medicaid**

**Analyze any marketing or promotional programs**

**Analyze any refunds or recoupments outside the ordinary course**

**Analyze financial assistance policies and/or copay waiver practices**

**Breach of Contract**

**False Claims Act**

**Beneficiary Inducement**

**Anti-Kickback**

# Privacy and Security Diligence

**Determine whether HIPAA and/or state privacy laws apply**

**Identify which systems maintain or are used to transmit individually identifiable information (III)**

- Patient
- Employee

**Review Notice of Privacy Practices and website privacy policy**

**Review privacy and security policies and procedures**

**Confirm employee training has been conducted**

**Review security assessments completed in last 3-5 years**

**Review documentation associated with any security incidents or breaches**

**Review Business Associate Agreements or Data Protection Addenda with vendors or subcontractors**

**Analyze any secondary use of III or de-identified data**

# **Additional Due Diligence Considerations**

**Assess the pharmacy's operations**

**Conduct a thorough financial review**

**Review all contracts, including those with suppliers and employees**

**Verify the value of the pharmacy's inventory and physical assets**

**Investigate any pending or potential legal issues**

**Review the pharmacy's risk management practices**

# Change of Ownership

## State-by-state analysis

### Structure of transaction may impact the timing and type of filing

- Asset vs equity
- If equity, consider the level at which the equity ownership is changing

### Types of Pharmacy License

- Resident
- Non-resident

### Consider changes other than ownership

- Entity Name or dba
- Pharmacist in charge (PIC)
- Location

### Applications

- Each state is different
- Consider application answers if buyer is already a pharmacy
- Operational considerations (e.g., who will complete/submit the applications?)

Pre-Closing  
Approval

Pre-Closing  
Notice

Post-Closing  
Approval

Post-Closing  
Notice

# Reps and Warranties

# General Reps and Warranties

Organization, Power and Authority	Non-Contravention	Financial Information	Condition of Assets
Litigation	Compliance with Laws	Compliance with Health Care Laws	Compliance with Third-Party Payor Agreements
Real Property	Material Contracts	Intellectual Property	Taxes
Privacy and Security of Individually Identifiable Information	Labor and Employee Benefits Matters	Inventory	Insurance

# Health Care Reps & Warranties

## **Rely on general compliance with laws rep or include health care specific reps and warranties**

- Definition of “Health Care Laws”
- Licensure of the target and the applicable employees including a schedule of all licenses, permits and accreditation
- Compliance with Anti-Kickback, Stark, Beneficiary Inducement and similar state laws
- No investigations or violations or acts or omissions that could result in an investigation or violation
- No exclusion or debarment

# Compliance with Third-Party Payor Agreements

**No pending third-party payor audits, pre-payment reviews or payment suspensions**

**No self-identified, unresolved overpayment liability**

**Include schedule of historic overpayments**

- Exclude routine/ordinary course refunds
- Incorporate dollar (\$) threshold

**No proceeding to revoke, suspend or terminate provider's enrollment, participation or agreement**

# Privacy and Security Reps & Warranties

Compliance with HIPAA  
and all applicable state  
privacy laws

Written privacy and  
security policies

No Investigations/  
Breaches/ Security  
incidents

All Risk Assessments/  
System Vulnerability  
Assessments have been  
completed

Data Privacy and  
Security Training

Business Associate  
Agreements and DPAs



## **Reps and Warranties – Drug Inventory**



**Usable, merchantable, and saleable in the ordinary course of business**

**Shelf life**

**Manufacturer's original packaging**

**Non-excessive inventory**

**Inventory rep as a last line of defense for inventory adjustment discrepancies**

# CLE Code #2

## Equity



## **Reps and Warranties – Survival and Indemnification**

**6-year statute of limitations**

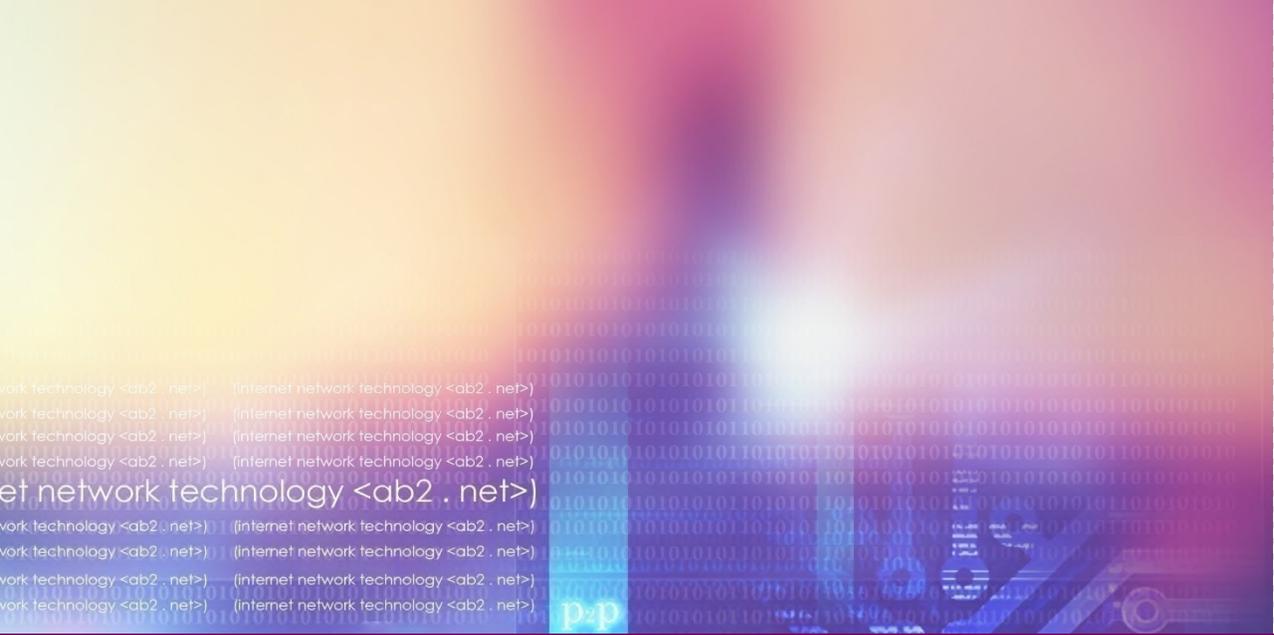
**Healthcare reps as fundamental**

**Bifurcation of survival as alternative**

**Exclusion from baskets/caps**

**RWI Coverage**

# Availability of R&W Insurance Coverage



# Availability of R&W Insurance



## Availability of Coverage

- High Breach Rates
- Compliance History

## Common Risks Covered by RWI

## Pricing

## Exclusions

\*Statistics courtesy of Aon | M&A and Transaction Solutions



# Best Practices

A photograph of a business meeting. In the foreground, a person's hands are visible, holding a silver pen and pointing at a tablet. On the table, there are several documents, including a large circular chart with concentric rings and a smaller pie chart. In the background, a woman with long dark hair, wearing a light-colored top and a peach-colored blazer, is looking at the tablet. To her left, a man in a dark suit is partially visible. The scene is brightly lit, suggesting an office environment.

## Best Practices

**Conduct thorough due diligence**

**Structure the transaction to minimizing risk**

**Develop a plan to obtain necessary regulatory approvals**

**Focus on post-closing integration**

# Questions & Answers

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