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Healthcare Transactions and Compliance With State and Federal Laws and Regulations

Structuring Transactions, Overcoming Regulatory Challenges, Determining FMV, and Performing Due Diligence

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Healthcare Transactions and Compliance with State and Federal Laws and Regulations

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Today's Discussion

1. Healthcare Trends Fueling Transactions
2. Structuring Transactions
3. Federal and State Regulatory Challenges
4. Effective Due Diligence
5. Valuation Review Checklist
6. Strategies to Minimize Regulatory Risks

Healthcare Trends Fueling Transactions

Healthcare Trends Fueling Transactions

- Patient Protection and Affordable Care Act
  - Triple Aim
    - Improve patient experience of care
    - Improve the health of populations
    - Reduce per capital cost of health care
  - Care Delivery Reform
    - Fragmented to Coordinated / Integrated Care Models
      - Accountable Care Organizations
      - Clinically Integrated Networks
      - Patient Centered Medical Home

Healthcare Trends Fueling Transactions

- Patient Protection and Affordable Care Act (Continued)
  - Payment Reform
    - Shift from volume based to value based reimbursement
      - Quality initiatives
      - Migration of value-based risk
    - Shift from payer-driven managed care to provider-driven accountable care
      - Say goodbye to HMOs
    - Accelerated movement to evidence-based medicine
    - Implementation and development of electronic medical records

Healthcare Trends Fueling Transactions

- Innovation in Healthcare Delivery Technology
  - Telehealth
    - Widespread acknowledgment of model's viability
    - Immense regulatory hurdles
- Technological and Clinical Innovation
  - Genetics
  - Proton Therapy
  - Clinical Pathways
- Patient Demand
  - Concierge Medicine
- Growing Information Technology Costs
- Dialysis, Ambulatory Surgery Center, and Imaging Center Joint Venture Development Remains Strong

Healthcare Trends Fueling Transactions

- Hospital / Health System Consolidation / Breakup
  - Unprecedented transaction volume
    - Private equity investment
    - System mergers
    - Spin-offs
    - System acquisitions
    - Strategic asset divestiture
- Physician Practice Acquisitions
- Health Insurance Companies Purchasing Hospitals and Other Providers
- Increased Enforcement

Healthcare Trends Fueling Transactions

- Other Factors Influencing M&A
  - New service lines
  - Response to mounting competition
  - Expand market penetration
  - Ensure long term financial viability
  - Improve access to capital for facilities and technology

Healthcare Trends Fueling Transactions

- Other Factors Influencing M&A (Continued)
  - Gain information technology expertise
  - Ensure easier referrals/consults
  - Achieve economies of scale -- Increase back office expertise and decrease costs
  - Non-financial factors
    - Governance
    - Cultural Issues -- Compatibility
    - Workforce
    - Continued Corporate/Charitable Mission

Structuring Health Care Transactions

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Health Care Transactions – Getting Started

- Socializing the Deal
  - Is the deal doable?
  - Cultural/Mission compatibility
  - Demystifying ethical and religious directives (ERDs)
  - Locality – Politics in the Local Market
  - Aligning strategic goals
  - Synergies and expansion of clinical services
  - Skilled leadership and management

Health Care Transactions -- Letter of Intent

- Generally
  - Sets out material Terms and schedule
- Structure
  - Asset Sale
  - Stock or Membership Interest sale
- Price
  - Fixed Price
  - Formula Price
- Payment Terms
- Collateral

Health Care Transactions – Letter of Intent/Term Sheet

- No-Shop
- Non-solicitation
- Publicity
- Closing Date
- Contingencies
- Choice of law
- Confidentiality
- Binding Provisions

Federal and State Regulatory Challenges

- Understand the Flow of Funds
- Understand Referral Patterns between the Parties
- Compliance with AKS Safe Harbors
- Compliance with Stark Exceptions
- Fair Market Value
- Commercial Reasonableness
- Beware Civil False Claims Act

Navigating the Regulatory Challenges of Health Care Transactions

- Health Care is a Highly Regulated Industry
  - FTC/DOJ/AG increasingly focused also on hospital acquisitions of physicians and other vertical transactions. Agencies generally believe that most savings and improvements can be accomplished without full acquisition/merger of competitors
  - Federal/State Stark(like) and Anti-Kickback Laws
  - Federal Income Tax
  - State Corporate Practice of Medicine
  - State Licensure Laws

Federal and State Health Care Laws

- Medicare/Medicaid Billing and Reimbursement Requirements
- State Licensing and Certification Requirements (Entities and Individuals)
- Industry Accreditation Requirements
- Federal and State Anti-Kickback Laws
- Beneficiary Inducement Prohibitions (Civil Monetary Penalties -CMP)
- Stark Law and State Self-Referral Prohibitions
- Federal and State False Claims Acts
- HIPAA and State Privacy Laws
- State Corporate Practice of Medicine Prohibitions
- State Fee Splitting Laws
- Antitrust Laws
- FDA Requirements

Federal and State Fraud Abuse Laws

- Federal and State fraud and abuse laws are always a main focus of any regulatory review in health care transactions – Primarily Federal AKS, Stark and FCA (BUT do NOT overlook State laws).

- AKS – Safe Harbors intended to protect the financial arrangement from prosecution. Failure to comply with an applicable Safe Harbor does not mean the transaction is illegal – must look to the intent of the parties.

- Stark Exceptions – If Stark applies, MUST meet ALL elements of an exception.

- Significant with complying with both AKS and Stark is FMV and "Commercial Reasonableness." While a question of fact and not law, it has significant legal consequences when structuring a transaction between health care providers and potential referral sources.

Federal and State Fraud Abuse Laws -- Valuation and FMV

- Fact NOT Law
- Legal Significance
  - Tax
    - Tax-Exemption
    - Allocation of Purchase Price
  - Fraud and Abuse
    - Stark
    - Anti-Kickback Statute
- FMV v. Commercially Reasonable
- Review -- Do Not ASSUME Accuracy

Corporate Practice of Medicine Restrictions

- Many States Prohibit the "Corporate Practice of Medicine"
- Public Policy is Primary Rationale Behind Most States' CPOM Doctrines
  - Theory: Corporate employment of licensed physicians should be prohibited because such a relationship "tends to the commercialization and debasement of those professionals."
  - General concern that physician's independent medical judgment will be compromised and physician-patient relationship will be undermined.
  - Even in most restrictive CPOM states, there are always a number of exceptions to the rule – e.g., hospitals, HMOs, ASCs, other licensed entities
- Penalties for Violating CPOM
  - Can be subject to **criminal** and **civil** penalties.
  - All contracts potentially **VOIDABLE** – Employment Agreements, Non-Competes, etc.

Corporate Practice of Medicine Restrictions

- If the state has a corporate practice of medicine prohibition alternative deal and operating structures must be considered, for example utilization of "captive PC."
- Where alternative structures involve Management Agreements, parties must consider state fee-splitting laws.
  - Some states have strict fee-splitting laws that prohibit physicians from sharing fees with non-professionals – e.g., Illinois, New York.
  - In such states, management fees may not be based on a percentage of revenues.

Fee Splitting

I. "Fee-Splitting" refers generally to state law restrictions that prohibit physicians or other medical professionals from sharing professional fees or, more specifically, from sharing professional fees in exchange for referrals.

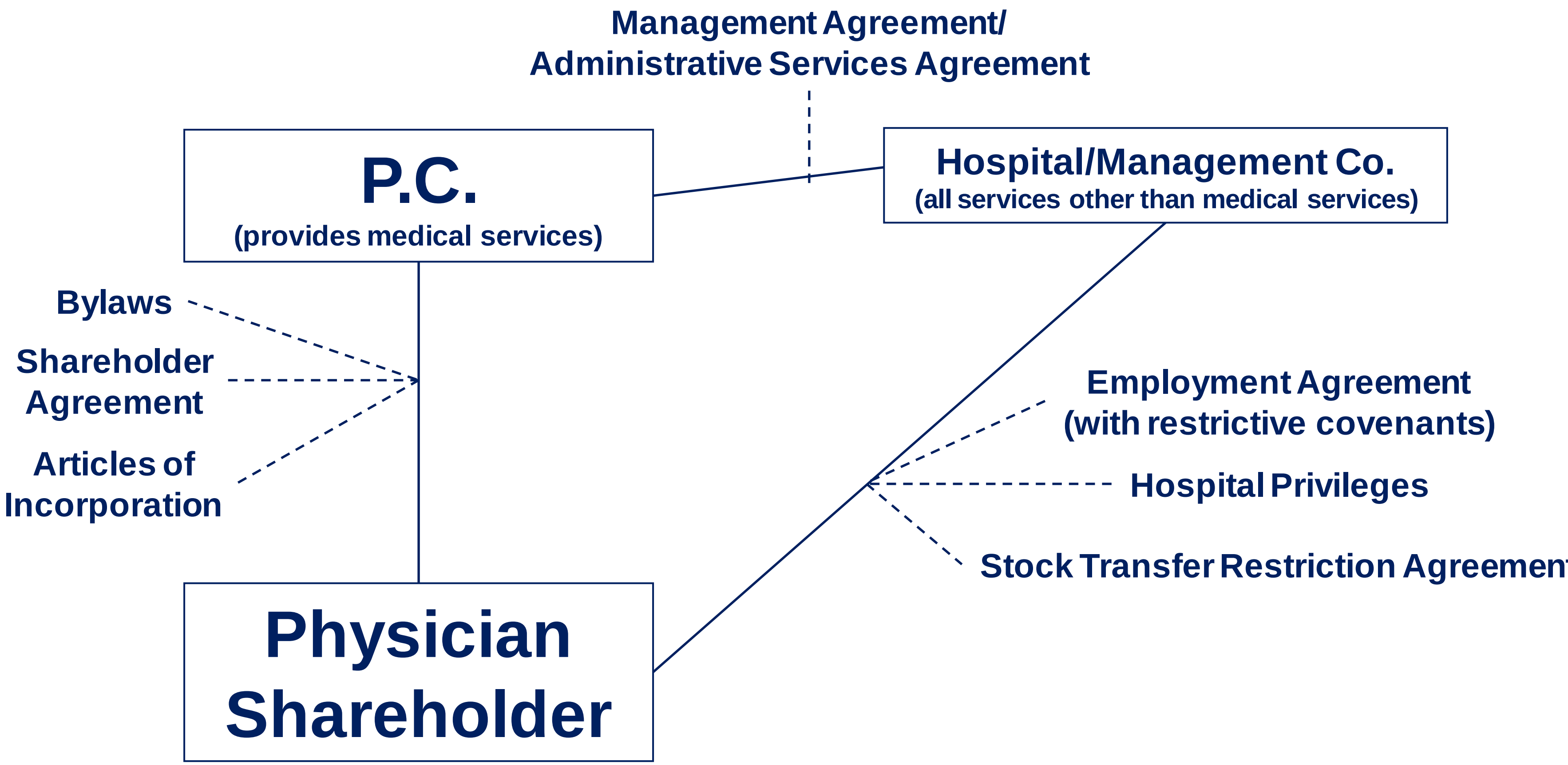
   A. Distinct concept from the CPOM doctrine and State kickback prohibitions

      1. **CPOM Doctrine**: Proposition that some corporations are "unfit vehicles" for the practice of medicine

      2. **Fee-Splitting Prohibitions**: Govern if and how professional fees may be split among professional shareholders of a corporation properly formed to operate medical practices and employ physicians.

   B. Must be considered even if a corporate arrangement does not implicate a particular State's CPOM prohibition

The Captive Professional Corporation



Captive Definitive Documents

I. Captive Professional Corporation

A. Structure

1. “Friendly Doc” – Consider TWO
2. Management Company – Management Agreement
3. Shareholders Agreement – restrictions on transfers
4. Stock – Legend citing restriction on transfer
5. Option exercised by management company or its “licensed designee”
6. Pledge
7. Physician Employment Agreements – Restrictive Covenants

Effective Due Diligence

What is Due Diligence?

- It is the process of obtaining and reviewing information about a company and using that information in the context of a specific transaction.
- Due to the multi-layered regulatory environment, targeted, thorough, and thoughtful diligence is necessary in all health care transactions.
- Generally
  – It's all about Disclosure
- Identification of Assets/Business
  – Tangible Assets
    – fixtures, furniture, equipment, cash, a/r, deposits, bank accounts, leases, real estate, inventory, supplies, software
  – Intangible Assets
    – Goodwill, name, telephone #, website, intellectual property

Why is Due Diligence Conducted?

- Evaluate overall transaction, value, and purchase price
- Identify risk areas
- Identify issues that must be addressed in the Purchase Agreement
- Ensure proper disclosures by Seller
- Understand Seller's operations
- Evaluate financing and structure of transaction
- Plan for post-closing integration

Common Areas of Focus for Health Care Regulatory Due Diligence

- Identification of Liabilities
  - Lines of Credit, Loans
  - Equipment & real estate leases
  - Accounts Payable
  - Compliance Audits
  - Environmental Issues
  - Employment Issues
- Identification of Agreements
  - Leases
  - Consulting and Employment
  - Payer/Hospital Agreements
  - Personal Guarantees
  - Assignability

Common Areas of Focus for Health Care Regulatory Due Diligence

- Corporate Books and Records
- Licenses/Permits
- Compliance Program
- Government Correspondence and Investigations
- Litigation (pending/threatened)
- HIPAA Compliance
- Billing and Coding
- Marketing Materials

When reviewing these com consider…

- Regulatory Issues
  - Governmental/CMS Required Approvals (CHOW, State AG/Court, State Licenses)
  - Anti-Trust (HSR Threshold = $70.9 Million)
  - Tax-Exemption
  - Fraud & Abuse Issues -- Existing Relationships
    - Space Leases - expired, unsigned, undated, etc.
    - Physician Employment Agreements
    - Other Relationships with Physicians - medical director arrangements, unwritten financial relationships
    - Relationships with other referral sources

When reviewing these com… consider…

- Contractual Arrangements
  - Understand the referral pattern between/among the transaction parties -- Does the arrangement potentially implicate the AKS or Stark Law?
  - Follow the Money ($) -- Is the arrangement used to improperly move money from a regulated entity to an unregulated entity?
  - Is it structured to comply with a safe harbor and/or exception?
  - Are the services provided legitimate?
  - FMV payments?
  - Are the payments “commercially reasonable?”
  - Are the management services and fees set up to comply with corporate practice of medicine prohibitions?
  - Does the compensation structure improperly incentivize increased services or increased coding?

When reviewing these com consider…

- Corporate Books and Records
  - Does the structure comply with the corporate practice of medicine?
  - Is money transferred between affiliated entities in a proper way?
- Licenses/Permits
  - Does the seller have all of the required approvals?
  - Do employees have all required licenses?
  - What governmental filings are necessary as a result of the transaction?

When reviewing these com consider…

- <u>Compliance Program</u>
  - Is the seller an entity that is required to have a Medicare compliant compliance program?
  - Does the program comply with CMS guidance and Federal Sentencing Guidelines?
  - Is it effective and updated regularly?
  - Does the seller regularly screen employees and contractors against the OIG exclusion list?
  - Is there a compliance hotline? What issues have been reported?
  - Who receives annual training?

When reviewing these com consider…

- <u>Government Correspondence and Investigations</u>
  - How is the seller's relationship with the government?
  - Are there any pending investigations or audit findings?
  - Has the seller received any warning letters?
- <u>Litigation</u>
  - Health care fraud and abuse related litigation?
  - Any recent departures from the company?
  - Does the company conduct exit-interviews?

When reviewing these com… consider…

- <u>HIPAA Compliance</u>
  - Has the seller implemented proper safeguards and security systems along with comprehensive HIPAA policies, procedures, and training?
  - Regulators will assume lack of documentation equates to a lack of compliance.
  - Are there existing breaches or complaints that will create post-closing liability?
  - Are IT security procedures adequate?
    - Consider post-closing costs of implementing new or upgrading existing systems.

When reviewing these com consider…

- Billing and Coding
  - May require outside consultant review.
  - Are billing and coding procedures in compliance with applicable law?
- Marketing Materials
  - Are the Medicare Marketing Guidelines applicable to the seller? If so, has the seller complied with them?
  - Does the seller adequately train and supervise its sales force?
  - Are the seller's materials truthful and accurate? State consumer protection laws reach much further than the federal AKS and state kickback laws – has the Seller complied with them?

Outcome of Due Diligence Review

- Based on the due diligence review, be prepared to adjust the transaction structure, documents, and price
  - Representations and Warranties
  - Indemnification/Caps/Holdback/Escrow
  - Disclosure Schedules
  - Conditions Precedent to Closing
  - Adjustments to Purchase Price
  - Legal Opinion

Outcome of Due Diligence Review

- Regulatory Issues
  - What do you do if you identify a potential problem?
    - Indemnification provisions – may not be practical depending upon parties involved or structure of transaction.
    - Self-disclose prior to closing – close over or await resolution
- Reps and Warranties NOT a substitution for due diligence

How do the due diligence findings affect the value of the transaction/venture?

- Has the Seller conducted business in a manner that may create risk under health laws (or other laws)?
- Will a self-disclosure need to be made? If so, how much money may need to be re-paid?
- Are the Seller's financial projections based on its past faulty billing procedures?
- Are the financial projections based on relationships and arrangements that violate the AKS or Stark Law?
- Are the Seller's facilities about to have their licenses revoked?
- Will the Seller's payor contracts be terminated as a result of the transaction?

Valuation Review Checklist

Valuation Review Checklist: Legal

- ✓ In the health care industry, an arrangement (i.e., service agreements, leases, acquisitions) that is not priced to be consistent with fair market value can raise significant red flags under fraud and abuse laws and is unable to fall within an AKS safe harbor or a Stark Law exception.
- ✓ Fair market value is not just an issue of the price paid to acquire an entity, it often impacts every arrangement for health related services that is reviewed in due diligence.
- ✓ Although legal counsel is generally not in a position to determine FMV, it should be on the look out for problematic compensation structures or unsubstantiated valuations.

Valuation Review Checklist: Fair Market Value vs. Investment Value

✓ Under the fair market value standard, an appraiser cannot account for what a specific buyer brings to the table (i.e., synergies specific to a single buyer), only what the most likely hypothetical buyers could operationally adjust. To the extent an appraisal includes financial considerations specific to the acquirer of the proposed interest, the appraiser must be in a position to defend the use of the assumptions from the context that any buyer could bring similar opportunities to the table.

  – Example #1: Hospital proposes to purchase a 51% interest in a physician-owned ASC. Within the hospital, physicians employed by the hospital perform 1,500 cases per year that could be performed in an ASC setting.

  – Example #2: Private equity group proposes to purchase 10 diagnostic imaging centers from radiology group. Private equity group owns 25 other centers in the regional area and has 15% higher managed care reimbursement than the radiology group.

Valuation Review Checklist: Billing and Coding Assessments

- ✓ As part of the valuation process, valuators should perform a review of the sellers coding, when applicable.
  - Volumes are compared to Medicare or other benchmarks
    - What is the distribution of patient visit codes?
    - What is the use of ancillary services as a percent of total services?
- ✓ Significant variance between the entity's billing and coding patterns relative to those of a sample of comparable entities may indicate unsustainable revenue, potential legal issues, or poor practice management.
- ✓ If deemed necessary, valuators can either adjust revenue by "normalizing" the entity's distribution of codes or by increasing the discount rate (i.e., the return on investment that a hypothetical buyer would require with an investment in the subject entity). Both adjustments have the same impact of lowering the value of the underlying entity.

Valuation Review Checklist: Adjusting Historical Financial Statements

✓ When reviewing a valuation, it is important to identify that all of the adjustments made to the historical and projected income statements are proper and aligned with the subject interest (i.e., minority or control).

- Removal of Non-Recurring Expenses
  - Implementation of EMR
  - Consideration of meaningful use payments
- Removal of Discretionary Expenses
  - Personal automobile (generally discretionary, although for several specialties, such as nephrology, a portion of this expense may be necessary)
- Removal of Non-Operating Income
- Additional Expenses to Account for Growth
  - Space and staff needed to support growth

Valuation Review Checklist: Capacity Constraints

- ✓ Example: When performing an income approach, most valuation practitioners will prepare a discrete projection (generally 5 years) followed by a terminal projection into perpetuity. During the discrete period projection, keep an eye out of unrealistic projections that violate the entity's current capacity. If capacity constraints would cap volume projections, be sure the valuation has considered the necessary capital expenditures and operating expenses necessary to support growth.
  - – Example: Physician practice owns a sleep lab and proposes to sell the lab to the local hospital. The sleep lab has two beds. Practice currently performs 650 sleep studies of which 200 require CPAP.

	Growth Rate	5.0%	5.0%	5.0%	5.0%	5.0%

CPT code	Historical	Year 1	Year 2	Year 3	Year 4	Year 5	Capacity
Total	650	683	717	753	791	831	730
95811	200	210	220	231	243	255	
95805	450	473	497	522	548	576	

Valuation Review Checklist: Terminal Value

- ✓ At the end of the projection period, the valuator will develop an amount projected into perpetuity (generally the point where the company matures). Be sure the assumptions used to develop the terminal value are realistic if forecasted into perpetuity.
  - Example #1: Hospital proposes to purchase 20 physician cardiology group. Five of the physicians are 55 or older. As part of the negotiations, physician propose to reduce compensation by 15% to drive more value to the purchase price.
  - Example #2: Rehabilitation hospital opened in March 2016 with brand new equipment and furniture. As part of the valuation, the valuator projects capital expenditure for the next five years of $25,000 per year.

Valuation Review Checklist: Terms of the Asset Purchase and Employment Agreements

- ✓ The valuator MUST know the terms of the transaction and tie back to the terms prior to the execution of the deal. The appraiser should always connect with counsel after issuance of the draft appraisal and before execution of the asset purchase agreement to be sure the purchase price is supportable under the terms of the proposed agreement.
  - Example #1: Hospital proposes to purchase a physician practice. As part of the deal, the parties negotiate whether the hospital will assume the practice's debt. The valuator determines that assets purchased equate to $1 million. The practice has $200,000 in debt, which the hospital assumes upon execution of the transaction. Effectively, the hospital has paid $1.2 million in consideration.
  - Example #3: Hospital purchases physician practice. Hospital proposes to purchase certain tangible and intangible assets. In addition, physicians will earn higher compensation post transaction than earned when they owned the practice.

Valuation Review Checklist: Market Approach

✓ Understanding the comparable transactions is critical to the application of the market approach.

- Personal service businesses should generally not be valued based on a revenue multiple when the owners of the business remain employees.
- Application of an earnings before interest, taxes, depreciation, and amortization (EBITDA) multiple or any other “market” defined multiple is only meaningful if the factors considered by the market are considered when applying the multiple.

Strategies to Minimize Regulatory Risks

Transaction Structure

- Asset versus Stock
  - In an asset transaction, the Buyer can limit the assumed liabilities. Although certain liabilities may follow the assets even if not expressly assumed:
    - Tort Liabilities
    - Medicare Billing/Coding (Assumed Medicare Contract)
    - Tax Liabilities
    - Environmental Liabilities
  - In stock transaction all liabilities are included (known and unknown, contingent or otherwise).
    - Accordingly, due diligence, representations and warranties, and indemnification protections are critical.

Regulatory Compliance

- Address Regulatory Compliance in Reps & Warranties
  - Non-compliance can impose significant successor liability and potentially large penalty assessments for fraud and abuse violations.
  - Typical Health Care Representations & Warranties
    - Licenses and Permits
    - Legal Proceedings
    - Compliance with Laws
    - Payment Programs
    - HIPAA
  - Other Considerations – Definitions, Material Contracts, Absence of Certain Events, No Undisclosed Liabilities

Hidden Risks of Boilerplate Provisions

- Say what you mean, mean what you say!
  - Assignment
  - Compliance with Laws
  - Survival of Representations and Warranties
  - Choice of Law
  - Forum
  - Amendment
  - Waiver
  - Notice
  - Entire Agreement
  - Third Party Rights
  - Indemnification
  - Arbitration

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Indemnification – Holdbacks and Escrows

- Buyers can use holdbacks and escrows to address and allocate regulatory risks.
- Typically tied to performance, revenue, or compliance benchmarks.
- Holdbacks and Escrows
  - Portion of purchase price held back or placed in an escrow account for a period of time to secure indemnification obligations or to address regulatory non-compliance.
  - Mitigates risk for Buyer.
  - Recent surveys estimate that 10% is reasonable – but depends on non-compliance the escrow/holdback is intended to address.

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Survival and Indemnification

- Survival Periods for Reps and Warranties
  - Create "classes" of reps and warranties.
  - "Standard" versus "Fundamental"
    - Health care representations and warranties as "Fundamental"
- Caps and Baskets
  - Limit and apply to only certain reps and warranties.
  - Exclude Fundamental reps and warranties.
- Sandbagging
  - Protection against recovery due to constructive knowledge.

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Survival and Indemnification

- Additional Practice Considerations:
  - Indemnification is NOT a substitute for due diligence
  - Rights to Set Off
  - Impact of Insurance
  - Joint and Several Liability
  - Differentiation Between Covenants and Representations and Warranties
  - Conflicting Indemnification Provisions Throughout Agreement
  - Other Limitations on Liabilities