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Due Diligence in Healthcare Private Equity Transactions

Minimizing Regulatory, Corporate Practice of Medicine and Other Risks

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Why the Need for Due Diligence?

- Past non-compliance with laws (particularly health care laws)
- Do compensation plans, services rendered and other contractual terms comply with health care laws?
 - Violations could result in treble damages as well as possible criminal punishment
- Does the ownership structure comply with health care laws?
 - Violations could result in recoupments of reimbursement payments as well as additional penalties
- Are change of ownership or change of information filings required to be made with state or federal agencies?
 - Failure to make timely and correct filings could jeopardize reimbursement

Why the Need for Due Diligence?

- Imprisonment
- Loss of license
- Exclusion from governmental health care programs
- Fines
- Damages
- Recoupment
- Corporate Integrity Agreements
- Lost revenue for liabilities
- Illusory revenue

General Due Diligence

- Non-Disclosure Agreement
- Scope of requests
 - Financial records
 - Organizational documents
 - Litigation, investigations and audits
 - Contracts
- Private equity analysis
 - Successor liability
 - Compliance and reimbursement
 - Post-closing business and operations

Regulatory Due Diligence

- Similar to regular M&A diligence done between two healthcare organizations, but with added emphasis on future earnings and efficiencies
- May be fitting together investments in complementary service lines (antitrust implications)
- Level of PE management involvement post-closing is dependent on the company and purpose of the deal
- Confirm authority to operate as is, or as contemplated
- Identify legal impediments that could affect timing of the deal
- Determine what liabilities each party would be undertaking in order to negotiate appropriate indemnity and other protections

Regulatory Due Diligence

- Obtain information necessary for various filings/approvals
- Review all remuneration relationships and arrangements
- Perform internal assessments and internal/external audits; assess the status of repayments and other corrective actions and/or pending appeals and request additional information as needed
- Understand the billing and coding system of the entity and identify any potential risks or compliance issues
- Identify and quantify potential exposure on compliance issues
- Consider the appropriateness of disclosures and settlements pre- (or post-) closing
- Understand the risks of sharing legal analyses relative to attorney-client privilege and work product protection; facts are not privileged

Health Care Business Due Diligence Considerations

- Risk of post-merger exodus
- Have the physicians bought in (culture)?
- What are the reimbursement methodologies?
- Physician practice's long-term strategy
- Ancillary service developments

Due Diligence Structure and Implementation

- Private Equity investment in healthcare has increased dramatically over the past 10 years
- Investments have not just been health systems and hospitals but niche ancillary providers such as practice management, digital health, laboratories, behavioral health, freestanding emergency and urgent care centers and revenue cycle management
- Investments in these areas involve common due diligence concerns due to the similar regulatory framework shared among them
- The Physician Practice Management Company, or “PPMC” provides the best vantage point to review both the business and healthcare aspects of due diligence

Due Diligence Structure and Implementation

- The PPMC is also commonly referred to as a Management Services Organization, or “MSO”
- PPMCs are common to the healthcare industry and serve as a vehicle for Private Equity to invest in an entity that is affiliated with a physician group and capitalize on opportunities generated by the physician practice
- This arrangement may address concerns related to the Corporate Practice of Medicine Doctrine and may insulate the PPMC from certain liability
- Large PPMCs are usually specific to a medical specialty

Due Diligence Structure and Implementation

PPMC Private Equity Transaction

- PPMC will purchase the assets of a medical group and continue to lease certain key operational assets from third parties necessary to operate the medical group
- The medical group may continue to operate as the employer of the physicians and other licensed healthcare providers or another PPMC-affiliated medical group, known as a “Friendly Practice” or “Captive Practice”, may employ them
- The medical group used may be dependent upon payer agreements, hospital affiliations or other operational or liability concerns

Due Diligence Structure and Implementation

PPMC Private Equity Transaction

- PPMC will hire identified nonmedical personnel of the medical group
- The physician practice will execute a long-term Management Services Agreement with the PPMC for it to provide administrative and management services to the physician practice
- The transaction may involve Real Estate and Equipment Leases that are acquired by the PPMC and leased back to the physician practice

Due Diligence Structure and Implementation

PPMC Private Equity Transaction

The PPMC Private Equity Transaction must consider two entirely different areas of Due Diligence: (i) general business concerns and (ii) healthcare industry specific concerns

- Generally, there is no “one size fits all” set of requests for information in healthcare
- The transaction type and size, geographic concerns and business and industry considerations impact the information requested
- The level of regulatory involvement is important to consider
- The timing of the transaction and source of funding

Due Diligence Structure and Implementation

PPMC Private Equity Transaction

There are certain subject matters common to the general corporate Due Diligence that involve private equity. The basic areas of Due Diligence include:

- Organizational/Business Records of the Target Entity and its Related Entities
- Securities Issuances and Stockholder Information
- Information on Directors, Officers and Key Management
- Employees and Employee Benefit Plans
- Credit Arrangements
- Operational Documents such as key agreements, leases and other material contracts
- Real Property and Environmental Matters
- Intellectual Property

Due Diligence Structure and Implementation

PPMC Private Equity Transaction

- Joint Ventures and Partnerships
- Franchises and Licensing
- Insurance
- Financial Information
- Tax Matters
- Regulatory Matters
- Litigation
- Miscellaneous matters such as press releases, appraisals, surveys, valuations and other significant documents

Due Diligence Structure and Implementation

PPMC Private Equity Transaction

Due to the nature of the healthcare industry and its heightened risks, the following Due Diligence of are particular importance:

- Employment and Independent Contractor Agreements
- Agreements with between parties where referrals are made
- Marketing arrangements
- Joint Ventures or other agreements between market participants
- Regulatory Matters
- Intellectual Property
- Material Litigations (including claim notifications)
- Real Property and Environmental Issues
- Compliance Programs

Due Diligence Structure and Implementation

PPMC Private Equity Transaction

The Private Equity Due Diligence team will usually include the following parties:

- Legal and Financial Counsel
 - Regulatory Specialists
 - Valuation Specialists
 - Risk Management and Compliance Specialists
- It is advisable that in a healthcare transaction all of these parties have considerable experience in the healthcare industry due to significant regulatory and liability concerns so as to be able to recognize problematic areas

Due Diligence Structure and Implementation

PPMC Private Equity Transaction

Recommendations for the Due Diligence team

- Treat Due Diligence just as important as negotiating the transaction because the Due Diligence responses may drive the negotiations including governance concerns, representations and warranties and indemnification
- Develop a game plan on how to approach it and assign responsibilities and time lines
- Be in constant contact with the parties regarding the delivery of Due Diligence materials, holes in materials provided or questions related to same
- The Target company should have already prepared for the Private Equity partner's Due Diligence before entering into negotiations

Successor Liability

- Asset transactions are typically designed, in part, so that the buyer does not assume the liabilities of the seller
 - Common health care exceptions: Medicare and Medicaid provider agreements
- State common law exceptions to the “disclaimer of liabilities” in an asset transaction:
 - the transaction is a fraudulent effort to avoid liabilities of the seller
 - the buyer expressly or impliedly assumes the obligations of the seller
 - the transaction is a de facto merger
 - the successor is a mere continuation of the seller

Successor Liability

- The transaction is a de facto merger:
 - continuity of ownership
 - cessation of ordinary business and dissolution of the seller as soon as possible
 - assumption by the buyer of the liabilities ordinarily necessary for the uninterrupted continuation of the business of the seller
 - continuity of management, personnel, physical location, assets, and general business operation

Pending or Threatened Litigation

- May damage relationships with important third parties
- The buyer may inherit liability and an obligation for legal fees
- Review all filings and documents involved with ongoing litigation
- Speaking with counsel for the seller handling all such matters
- Review all correspondence and documents that might lead to possible litigation
- The review should include all documents and correspondence with government agencies, including subpoenas

Pending or Threatened Litigation

- Diligence on this point continues right up to closing
- Should include threatened litigation to the transaction itself
- Is any litigation, pending or threatened, sufficient to put the deal itself at risk?
- Consider special indemnification, holdback or escrow

Fraud and Abuse Concerns

FIVE IMPORTANT FEDERAL FRAUD AND ABUSE CONCERNS IN THE PRIVATE EQUITY HEALTHCARE TRANSACTION

- Physician Self-Referral Law (Stark Law)
- Anti-Kickback Statute
- False Claims Act
- Exclusion Authority
- Travel Act

Fraud and Abuse Concerns

Physician Self-Referral Law (“Stark Law”)

- Prohibits physicians from referring patients to receive "designated health services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies
- Financial relationships include both ownership/investment interests and compensation arrangements
- Exceptions – Important to ensure compliance since the Stark Law is a strict liability law

Fraud and Abuse Concerns

Federal Anti-Kickback Statute (“AKS”)

- Prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs
- AKS covers those who solicit, pay or receive kickbacks as well as those who arrange them
- Safe Harbors – Similar to Stark Law Exceptions however the statute is in intent based allowing for consideration of the purpose of the transaction

Fraud and Abuse Concerns

False Claims Act (“FCA”)

- Knowingly and willfully makes or causes to be made any false statement or representation of a material fact or knowledge or concealment of relating to a Federal health care program
- Similar False Claims Act statute referred to as the “Lincoln Law” which applies to such acts related to federal programs in general
- Violations of FCA often result in violations of other Federal fraud and false statement statutes as well as Wire and Mail Fraud, Money Laundering and RICO
- Whistleblower actions

Fraud and Abuse Concerns

Exclusion Authority

- The Federal Government has the authority to exclude those who have committed certain criminal offenses and acts contrary to the law such as Federal Healthcare Program Fraud, patient abuse or neglect and unlawful manufacture, distribution, prescription, or dispensing of controlled substances
- Mandatory and permissible exclusion
- Important part of Due Diligence

Fraud and Abuse Concerns

The Travel Act

- New concern in reviewing operations for fraud and abuse issues
- Originally enacted to prosecute organized crime
- A violation of state law that involves interstate commerce
- The state law violation is commonly extortion or bribery
- The new method by which the Federal Government gets jurisdiction over a state law claim
- Recent successful prosecutions in New Jersey and Texas

Fraud and Abuse Concerns

Fraud and Abuse Due Diligence Concerns

- A proper review of any Arrangement between those involved in the making and receiving of referrals amongst themselves
- Valuations of Fair Market Value and Commercial Reasonableness (also important if involving not for profit entities)
- Documentation sufficient to meet Stark Exceptions and AKS Safe Harbors
- Review of compliance-related complaints and concerns
- Exclusion List

HIPAA:

Why the Increased Vigilance on Diligence?

- OCR enforcement continues to increase
- The HIPAA Omnibus Final Rule expanded applicability to business associates and subcontractors
- OCR audits are increasing
- Data breaches are increasing
- The number of complaints to OCR are on the rise
- Increased awareness of HIPAA and sensitivity around the privacy of patient medical information

HIPAA

- Investigation requests, demands and responses
- Policies and Procedures
- Security Protocols
- Forms
- Risk Assessments
- Business Associate Agreements
 - Template
 - Review all potential PHI relationships
- Data Use Agreements

HIPAA

- Use of Mobile Devices
- Training Programs
- Government Correspondence

Compliance Plans

- Many health care entities do not have compliance plans
- Others have compliance plans that are collecting dust on shelves
- A small amount have compliance plans that are reviewed on a regular basis and actually implemented
- A robust compliance plan is customarily symbolic of how serious an organization takes compliance and may result in less risk for a buyer
- If a disclosure is made to the government or an issue is discovered down the line, showing the government that the organization has a robust compliance plan may less the penalties

Compliance Plans

- Buyer should consider conducting a coding audit and possibly an audit of the seller's compliance plan
- Utilize an experienced vendor to ensure that the audit provides the necessary feedback
- Buyer's counsel should have a dialogue with Seller's compliance officer
- The parties must remain mindful of privileged information and remember that the audit results will not be privileged

Regulatory Concerns

Medicare/Medicaid Change of Ownership (“CHOW”)

- The structure of the transaction will determine if it is a CHOW, a Change of Information or requires new Medicare Enrollment
- Important to determine which category the transaction falls under because it may impact the need and timing of regulatory notices and approvals, successor liability and the possibility in billing and payment complications
- CHOWs occur when a new legal entity becomes an owner or operator of a Medicare-enrolled provider such as through a merger or consolidation of parties or a change in partners if it is a partnership

Regulatory Concerns

Medicare/Medicaid Change of Ownership (“CHOW”)

- Home Health Agency CHOW - the “36-month rule”
- Change of Information does not involve a change of ownership but rather it allows for the continuation of the enrollment but that the enrollment information for the provider needs to be updated
- New enrollment occurs if the transaction is not a CHOW or a Change of Information
- Recognize that many times filings will be required prior to the actual effective date of the transaction

Regulatory Concerns

Licenses

- Medical providers such as physicians and physician extenders, dentists, chiropractors, pharmacists and therapists
- Hospitals, Ambulatory Surgery Centers, Freestanding Medical Emergency Facilities, Skilled Nursing, Long Term Acute Care, Imaging and Radiation Centers
- Special care facilities such as Comprehensive Outpatient Rehabilitation Facilities, Mental Health and Substance Abuse Centers, Birthing Centers, Dialysis Providers
- Laboratories, Pharmacies, Ambulances and other ancillary providers

Regulatory Concerns

Permits

- Permits are often required at the Federal, State and Local level
- Common at the State and Local levels
- Building and Zoning (especially important with facilities)
- Health
- Fire
- Hazardous Waste
- Food

Regulatory Concerns

CHOW/Licenses/Permits

- Review early in Due Diligence to determine notification and application deadlines
- Anticipate the need for appropriate extensions in the anticipated Closing Date to address deadline concerns
- Do not be afraid to reach out to the appropriate authority to ask questions or guidance (but do not reveal the health care entity that you are asking about unless absolutely necessary)
- Consider using subject matter experts

Thank You

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