Applying a Clinical Model of Care to Transaction Due Diligence

This white paper is derived from the original publication in the American Health Lawyers Association 2019 Health Care Transactions Resource Guide.

A patient lies in a hospital bed surrounded by a team of clinicians with diverse specializations. The clinicians are ***collaborating*** on the patient's condition and treatment. The Mayo Clinic calls this approach its "Model of Care," and it is foundational to the organization's superior reputation for collaborative patient care and satisfaction. According to Mayo, the key success factors for the model include the following:

- A team of experts focuses on one patient at a time.
- Physicians embody the organization's values of collaboration, compassion, and innovation.
- Knowledge is translated to clinical practice.
- Patient care is delivered with respect, quality, and excellence.[1]

This practice contributes to high-quality clinical services and enhanced outcomes that define the Mayo brand and experience. This same collaborative approach leads to success in virtually every other discipline or process. For example, replace "physician" with "transaction advisor" and "patient" with "client," and this model becomes a best practice for use in conducting transaction due diligence.

A transaction advisory firm that aspires to such a model must be able to effect a collaborative and evidence-based approach, leveraging multiple areas of expertise, to produce a "holistic" assessment of the target organization's health. To accomplish this aspirational goal, the due diligence team must represent a collaboration of experts from healthcare audit, tax, clinical coding compliance, physician compensation arrangements, compliance programs, governmental payer reimbursement programs, clinical operations, information technology (IT) infrastructure and security, real estate, managed care contracting, and revenue cycle operations, among others. A tall order, to be certain, but well worth the effort given the risk buyers assume in healthcare transactions.

1 Mayo Clinic, Mayo Clinic Model of Care, https://www.mayoclinic.org/giving-to-mayo-clinic/our-priorities/mayo-clinic-model-of-care (last visited Mar. 6, 2019).

A Collaborative Viewpoint of Risk

When an organization considers a transaction, the level of due diligence contemplated should have a direct relationship to the assessed level of risk—more specifically, enterprise risk. Enterprise risk is multi-faceted, including the following specific areas:[2]

- Operational
- Clinical/Patient Safety
- Strategic
- Financial
- Human Capital
- Legal/Regulatory
- Technology
- Hazard

Typically, if the risk tolerance exhibited by a particular buyer or for a particular transaction is low, broader and deeper diligence is needed to satisfy concerns and identify potential risk areas. Often, however, due diligence is fragmented between multiple experts. For example, one organization may perform financial due diligence, while another, unrelated organization reviews clinical coding practices. Yet another entity may evaluate the IT infrastructure and security protocols, while other entities assess nuanced programmatic compliance issues. Finally, a healthcare valuation firm may round out the convention of due diligence firms, charged with reviewing physician contracts and compensation to understand whether remuneration to referral sources is commensurate with fair market value (FMV), and the arrangements are commercially reasonable (CR). This disjointed approach often results in "siloed" perspectives and discrete evaluations of risk, which are difficult for clients to assimilate into a comprehensive enterprise risk assessment presented as a result of the transaction.

This white paper further explores how the assembly of a comprehensive team of experts, who work together to assess risk, results in a more complete and collaborative due diligence process for transactions, incorporating the "spirit" of Mayo's Model of Care.

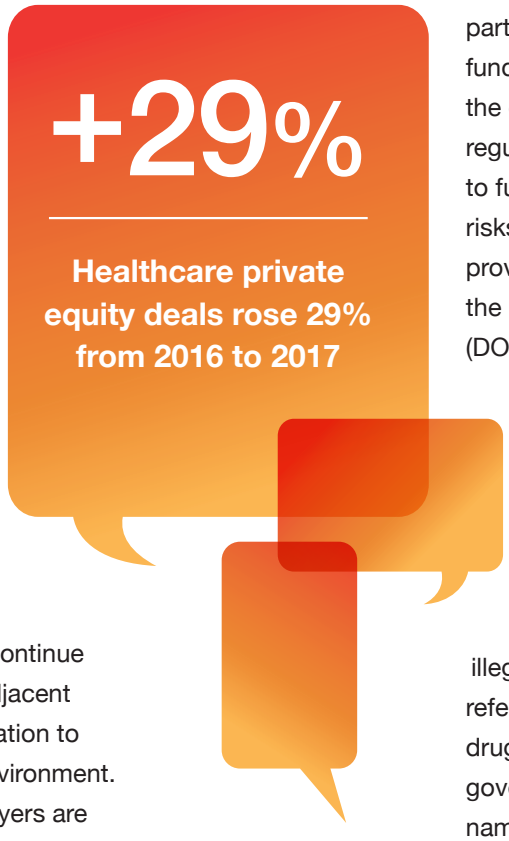
2 Roberta L. Carroll et al., *Enterprise Risk Management: A Framework for Success,* AM. SOC. FOR HEALTHCARE RISK MGMT. (2014), https://www.ashrm.org/sites/default/files/ashrm/ERM-White-Paper-8-29-14-FINAL.pdf.

Environmental Considerations

In order to understand why a collaborative approach to due diligence is so important, particularly in the current healthcare environment, we first must appreciate the pace of consolidation within the industry and which entities are participating in transactions.

The current healthcare environment has created a space ripe with investment opportunities. Investment is often driven by entities looking to rapidly create scale in order to generate efficiencies and become more competitive in the marketplace. Healthcare providers—be they hospitals, health systems, physician practices, post-acute care, ambulatory care, behavioral health organizations, or others—continue to consolidate and/or acquire providers in adjacent segments, which better positions an organization to succeed in a value-based reimbursement environment. Providers who traditionally have not been payers are also venturing into those risk-bearing endeavors through partnerships and acquisitions.

Additionally, the increased influx of private equity funding into the healthcare market is leading to consolidations of platforms across multiple segments of the industry. This enhanced competition for the same resources essentially results in an "arms race" to see who can quickly attract the best providers. For example, there were 265 healthcare private equity deals in 2017, representing a 29% increase from 2016, with 44% of the healthcare-deal value occurring in the provider sector, totaling $18.9 billion.[3] The pace increased with the closing of 487 private-equity-funded healthcare deals in the first three quarters of 2018. It is expected that number could increase to 750 in 2019.[4]



Some of those organizations participating in private-equity-funded transactions do not have the depth of expertise in healthcare regulatory and compliance issues to fully appreciate the potential risks inherent to healthcare provider organizations. In fact, the Department of Justice (DOJ) recently named a private equity firm as a defendant in a False Claims Act suit, whereby one of the private equity firm's portfolio companies—a compounding pharmacy—was accused of paying illegal kickbacks in exchange for referrals for certain compounding drugs that were reimbursed by a governmental payer.[5] The DOJ named the private equity firm as a defendant, in part, because it managed and controlled the compounding pharmacy.

The increased number of non-traditional buyers in the healthcare marketplace has the potential to increase risk, not just at the transactional level, but for the entire industry itself. Risk is further accentuated by the pace and volume of the transactions. Therefore, a key component in achieving a successful transaction is the completion of thorough due diligence. Given the fragmented expertise needed to evaluate these sectors, a collaborative approach to due diligence is the preferred course of action.

3 Kara Murphy & Nirad Jain, *Global Healthcare Private Equity and Corporate M&A Report 2018,* Bain & Company (Apr. 18, 2018), https://www.bain.com/ insights/ global-healthcare-private-equity-and-corporate-ma-report-2018/ (last visited Mar. 9, 2019).

4 Alex Kacik, *Healthcare Organizations Turned to Unexpected Partners in 2018,* MODERN HEALTHCARE (Dec. 26, 2018), https://www.modernhealthcare.com/ article/20181226/NEWS/181219923/2018-year-in-review-healthcare-sees-unconventional-partnerships-rise (last visited Mar. 6, 2019).

5 United States ex rel. Medrano v. Diabetic Care Rx, LLC d/b/a Patient Care America et al. (S.D. Fla. No. 15-62617-civ).

What Constitutes "Due Diligence?"

In addition to various components of legal due diligence, which are performed by attorneys, acquirers often use the term "due diligence" when referring to an analysis of financial results. Many transactions focus the majority of due diligence efforts on the financial reporting and earnings of the potential acquisition entity, often referred to as the "target," determining if historical revenue and expenses appear to be stated correctly. This is typically referred to as a quality of earnings analysis. While analyzing financial reporting is a critical area to understanding the financial health of an entity, the economic drivers impacting financial statements also need to be assessed. For example, clinical coding practices, changes in reimbursement strategies or policies specific to a market, market factors affecting changes in volume, contingent liabilities resulting from lacking compliance posture, etc., all affect the results reported in financial statements.

So, when assessing an entity's purchase price—often expressed as a multiple of revenue or earnings before interest, taxes, depreciation, and amortization (EBITDA)—an organization must consider the risk these economic and activity drivers pose to the target's future financial performance and evaluate them in concert with the typical analyses performed.

To effectively approach a collaborative due diligence effort, a transaction advisor should:

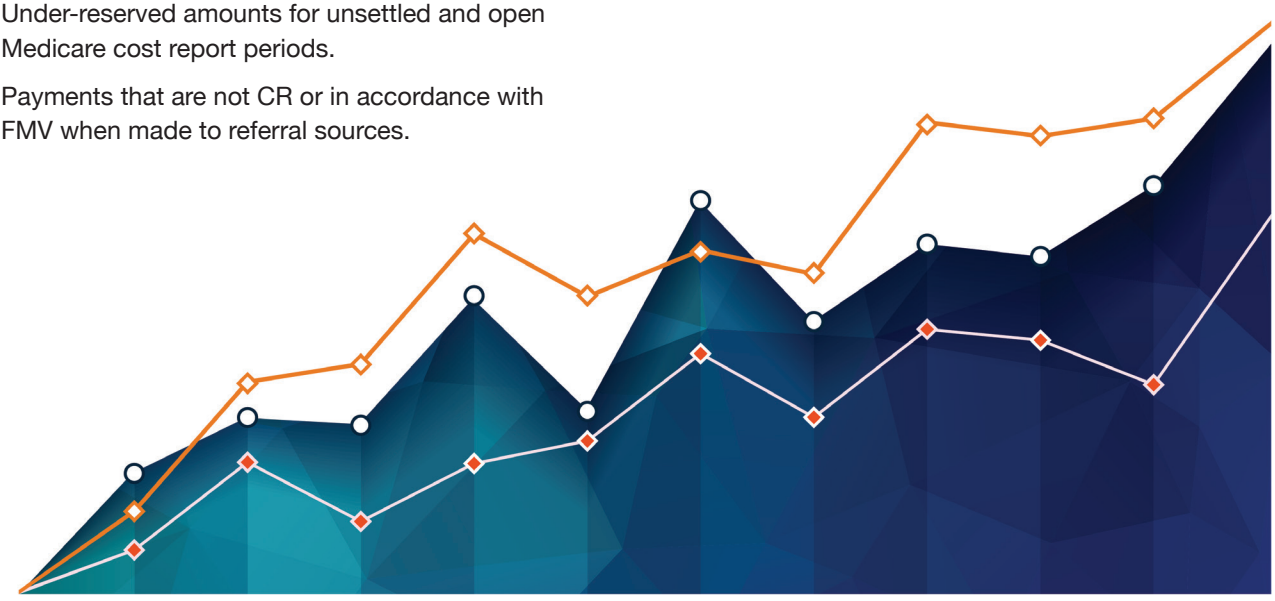
- Thoroughly understand the proposed transaction and its potential risk areas.
- Develop an appropriate scope of work to address those concerns by identifying specific focus areas across a spectrum of disciplines, including accounting/financial, tax, clinical coding, compliance, IT, provider contracts, management care contracting, revenue cycle, supplier contracting, real estate, human resources, and operations.
- Obtain and analyze information for all disciplines, utilizing subject matter experts specific to that discipline.
- Implement a project team structure that includes a centralized project manager to serve as an aggregator of findings and a central communication channel to the client, with oversight and direction from long-standing healthcare transaction executives throughout the process.
- Prioritize focus areas with a higher risk profile (may be specific to the transaction).
- Identify risks emerging from the review process.
- Communicate findings, as they are identified throughout the process, to the client.
- Collaborate on interdependent implications of identified risks to other disciplines.
- Assess enterprise risk, considering findings across all disciplines.
- Identify action plans with the client to mitigate risks.

The first step in the collaborative due diligence effort is to understand the specific structure of the merger or acquisition in order to define an appropriate scope for the due diligence process. In transactions structured as an acquisition, a transaction advisor must understand if the transaction is a stock or asset acquisition. Buyers may pursue an asset acquisition to shield the acquiring entity from pre-acquisition liabilities. However, the healthcare industry presents a complicating factor to that strategy—the provider's Centers for Medicare & Medicaid Services (CMS) Certification Number (CCN). When an acquirer assumes the CCN and underlying provider agreement of the target through a change of ownership (CHOW), the liabilities associated with that CCN—relating to all interactions with Medicare—are also assumed, including, but not limited to:

- Billing to Medicare for:
  - Professional services coded higher than the appropriate and medically necessary procedure.
  - Inappropriate patient status, particularly related to inpatient and observation admissions.
  - Services, including, but not limited to, outpatient services for which appropriate documentation does not support the medical necessity of the service rendered.
- Under-reserved amounts for unsettled and open Medicare cost report periods.
- Payments that are not CR or in accordance with FMV when made to referral sources.
- Penalties associated with deficient compliance programs of a hospital and/or certain service lines.
- Inability to meet certain safe harbors/exceptions related to physician employment, real estate and equipment leases with referral sources, joint ventures, physician recruitment in underserved areas, and risk-sharing arrangements, among others.

The alternative to assuming the existing CCN is obtaining a new one. However, in many instances, this approach presents an economically untenable situation for the acquirer due to the often-elongated process of obtaining a new CCN from CMS.

When the transaction structure involves the assumption of the CCN, an integrated approach to due diligence is even more imperative. Therefore, a comprehensive scope that considers interdependencies between various due diligence focus areas must be deployed. The remainder of this white paper delves further into these issues and also provides relevant examples of unmitigated risks to highlight how various aspects of due diligence can affect financial results. This integrated approach enhances the ability to assess risk at the enterprise level.



High-Impact Due Diligence Areas

1. *Financial Reporting*

First and foremost, a key activity in any affiliation, merger, or acquisition is an assessment of the target's financial position. This assessment not only informs financial risk, but often uncovers risk areas in operations, human resources, regulatory, and strategy, among others. A focused and thorough financial due diligence effort is vital to establishing a baseline understanding of future sustainability, deterioration, or improvement of historically reported operating results and financial position. A thorough financial due diligence process includes analyses of the target's accounting policies and procedures. It also includes detailed analysis of revenue attributes, including revenue sources, revenue trends, key operating statistics, accounts receivable aging, bad debt reserves, contractual adjustments, payer mix, and the policies and procedures surrounding revenue recognition employed by the target. An analysis of the target's operating-expense trends and key statistics, along with allocated overhead expense, is warranted. From this analysis, assessments are made of significant fluctuations in reporting to identify normalization adjustments and eliminate non-recurring items from pro forma financial statements. Finally, analyses of the balance sheet are required to understand working capital, key contingent liabilities, debt, and factors affecting future earnings.

An area of financial due diligence that consistently bears significant risk to healthcare organizations is the accounts receivable reserve methodology. A healthcare entity's reserves must be reviewed per payer, including self-pay accounts receivables. A detailed collections-to-net-revenue analysis can also be used to assess the effectiveness of reserve methodologies. Under-reserved accounts overstate the value of the accounts receivable acquired, and potentially overstate revenue. Adjustments to accounts receivable balances—which often lead to net revenue adjustments—can materially affect normalized and projected earnings, resulting in adjustments to the target's value and the agreed-upon purchase price.

2. *Clinical Coding and Documentation*

A clinical coding and documentation review has direct correlation with financial, operational, clinical/patient safety, and legal/regulatory risk areas in a transaction. A review should be conducted within a due diligence assessment to ensure compliance with appropriate coding and regulatory standards, including medical necessity (discussed later within), which can affect the corresponding payments received for claims previously filed and adjudicated. Often, revenue or balance sheet abnormalities or trends noted in the financial review can alert the due diligence team to the need for specific or enhanced clinical coding due diligence.

a. *Provider Coding and Documentation Review:* A well-performed provider coding and documentation review can help identify areas of miscoding that may lead to misaligned payments. Coding that results in payments higher than what can be justified through the patient record documentation (i.e., "overcoding") can result in the need for repayment and/or self-reporting to third-party payers. Conversely, coding that is too conservative based on patient record documentation (i.e., "undercoding") can lead to revenue results that are understated for the resources (expenses) invested to treat the target's patient population. Miscoded patient encounters are often due to a lack of education on the part of the provider, lack of appropriate documentation, errors in the utilization of the electronic medical record, or many other factors.

b. *Facility Coding and Documentation Review:* If the target is a hospital, or a physician who admits patients to inpatient status, there is also significant value to reviewing a sampling of inpatient admissions to evaluate if appropriate place of care was billed based on the documentation provided (inpatient versus observation), and if appropriate documentation is present to support the billed diagnosis-related group (DRG). There is significant regulatory scrutiny regarding patient status in these situations, often referenced as the "Two-Midnight Rule." Additionally, errors in diagnosis code capture may impact the DRG, ultimately creating a material financial impact.

c. *Medical Necessity Review:* Regulatory/legal and clinical/patient safety risks are inherent when health services that the patient may not clinically need are provided. In such circumstances, there is also downstream financial risk to historically reported earnings due to overstated revenue or unrecorded contingent liabilities. The concept of medical necessity applies to all clinical services, including those provided in facility (hospital) inpatient and outpatient settings, physician practices, ambulatory surgery centers, and behavioral health and post-acute care settings.

   Medical necessity reviews include review of a sample of medical records and focus on the patient's clinical state leading to the treatment. Often with a clinical background, the reviewer evaluates to assess whether the care provided meets acceptable clinical practices and protocols appropriate for the patient's condition.

   For each of these reviews, if the sampled records contain errors, omissions, or other concerns, the due diligence team must work with the buyer, or the buyer's counsel, to determine whether additional testing and sampling is necessary to normalize the target's revenue. In addition, negative financial impacts include potential repayment to payers—especially if the provider is submitting claims for payment while concurrently not following the payer's billing or care guidelines—and possible additional penalties or fines. A tangential benefit of these types of reviews is that the results quickly seed a post-acquisition work plan to address findings on a go-forward basis once the entity is under the buyer's control.

3. *Cost Reports*

Cost report reviews are always critical components of collaborative due diligence engagements. An understanding of a provider's Medicare and Medicaid reimbursement is imperative to assessing financial position. Buyers unaware of under-reserved obligations to governmental payers, or over-accrued receivables for anticipated funding from governmental programs, bear the risk of loss if the provider number is assumed, absent indemnification for such specific circumstances from the legacy entity. If the purchase agreement does not adequately protect the buyer, the result could be an implied, unintentional premium for the hospital. While most Medicare and Medicaid reimbursement methodologies are prospective in nature, there are many historical recoupments every year for numerous reasons, as part of the typical cost report life cycle. Therefore, a thorough analysis of prior cost reports and the calculations used to assess and record accruals is important.

Furthermore, certain entities, such as critical access hospitals (CAH) and rural health clinics (RHC), are reimbursed allowable and incurred costs, rather than amounts determined via a predetermined fee schedule, like other Medicare providers. Likewise, some states reimburse for Medicaid patients in a similar fashion. In these instances, proper identification and filing of allowable costs and cost reports is extremely important in determining reimbursement for the entities. Accuracy has a significant financial impact on year-end cost reporting, and experts should be consulted to ensure appropriate allowable costs are utilized.[6] Understanding the specific risks and potential liabilities requires the due diligence team to include experts experienced with these types of entities.

6 RHIhub, *How Does Medicare Reimburse RHCs?,* https://www.ruralhealthinfo.org/topics/rural-health-clinics#medicare (last visited Mar. 9, 2019).

4. *Compliance Program Deficiencies*

All covered healthcare entities are required to develop and implement a compliance program as a condition of enrollment in Medicare, Medicaid, and the Children's Health Insurance Program. The Office of Inspector General (OIG), DOJ, and other federal and state agencies see a compliance program as the minimum standard a healthcare entity should maintain.

Key components of a high-quality compliance program include detection and prevention of inappropriate conduct, as well as commitment to the organization's legal and ethical values. The Federal Sentencing Guidelines detail seven elements of an effective compliance program.[7] A successful compliance program is the result of a combination of clinical and regulatory expertise to assess risk in these areas. A thorough due diligence process should ensure that a strong compliance program exists, and reasonable means are undertaken to enforce it.

In addition to the compliance program required for all participants in major governmental programs, participation in specific clinical services or discount programs may also come with more rigid compliance standards. For example, entities that qualify for, and participate in, the 340B Drug Discount Program are subject to additional compliance scrutiny. Failure to comply with the program's rules can result in manufacturer repayments and may ultimately impact program participation.

Amid concerns of excessive pricing, diversion, and other abuses of the 340B Program, and at the recommendation of the Government Accountability Office, the Health Resources and Services Administration (HRSA) has increased its regulatory oversight of Covered Entities (CE). Additionally, the expansion of a contract pharmacy network for many CEs has created added scrutiny in the industry. Given this increased oversight, it is important for CEs to demonstrate routine auditing and monitoring, including an independent, objective external assessment. Upon an audit, if compliance is deemed unacceptable, drug manufacturer repayment or suspension of program participation could be necessary. Lost 340B drug pricing due to compliance issues could have a materially negative impact on an entity post-acquisition. Therefore, the multi-disciplinary team performing due diligence on a target participating in the 340B Program must include compliance professionals with expertise in this complex program.

5. *IT Security and Compliance*

No due diligence process can be deemed credible without a thorough review of IT and security compliance. The onerous Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations, the accompanying high compliance costs, and extensive time commitments necessary to implement the processes have made HIPAA compliance a major challenge for virtually every provider. HIPAA rules and regulations require providers to update and address new areas of HIPAA compliance regularly.

The omission of appropriate HIPAA security standards—usually assessed through a HIPAA security risk assessment—can result in significant liabilities and losses for an entity in the event of a breach. According to a 2017 study by the Ponemon Institute, the average cost of a data breach for incidents with less than 10,000 compromised records was $1.9 million.[8]

7 EFFECTIVE COMPLIANCE AND ETHICS PROGRAM, 2018 GUIDELINES MANUAL, U.S. SENTENCING COMM'N, 18 U.S.S.C. § 8B2.1, https://www.ussc.gov/guidelines/2018-guidelines-manual/2018-chapter-8#NaN.

8 Framework Offers Companies Solution for Cybersecurity Risk, PYA (2018), https://pyapc.com/wp-content/uploads/2018/05/Framework-Offers-Companies-Solution-for-Cybersecurity-Risk-PYA.pdf.

In addition to IT compliance considerations, an assessment of the costs to implement IT systems—be it electronic medical records systems, financial systems, various clinical support systems, performance improvement technology, etc.—is frequently required. All of these areas represent significant costs that need assessment in concert with the purchase price to better understand the total cost of a transaction. Such an assessment requires an inventory of the various technology systems of both the acquired entity and the acquirer in order to establish which systems are vital to operations; determine a strategy for conversion; and assess license, ongoing subscription, and professional services costs to convert systems. Specific expertise is required for this due diligence effort to successfully identify potential risks and costs to be assumed by the buyer. No comprehensive due diligence exercise is complete without specific assessment of IT security and functionality risk. All buyers should be certain their due diligence team has the requisite expertise to tackle these highly complex and technical areas of risk.

6. *Real Estate*

Healthcare transactions may or may not include real estate. Often, for example, a physician practice owner(s) may also own the medical office space or building that the practice (and others) occupy. The common owner may structure ownership terms or set rental rates to effect a tax benefit for the owners. In such cases, the rental rate(s) charged may not represent FMV between two willing and informed parties in an "arm's-length" transaction. Upon entering into an arrangement (through a practice acquisition), ownership structure and the value of acquired real estate, as well as the leases for space occupied by the target, will need to be reviewed to understand if the value of the property or the rental rate(s) are in accordance with FMV standards.

In transactions involving a hospital, where property is purchased from a referral source(s), or leases with referral sources are assumed, it is crucial to review all property matters to ensure appropriate documentation exists and the arrangement is at FMV. Absence of appropriate documentation or remuneration that is not commensurate with FMV could present significant legal/regulatory risk. A lease listing (i.e., rent roll) should be obtained to identify payments from any referral sources in order to evaluate the terms and the rate of each lease, paying specific attention as to whether the terms and rates are CR and can be defended as representative of FMV.

Supporting documentation for the lease agreement, including current and executed amendments, should also be reviewed. To identify potential risks, a review should be performed on the actual lease contracts, and a reconciliation should be performed to issued Internal Revenue Service Forms 1099, documenting annual payments to independent entities.

7. *Provider Contracts and Compensation*

As the number of employed and contracted providers continues to increase, the regulatory and legal compliance of provider compensation arrangements looms larger, drawing further scrutiny from oversight agencies. Negative regulatory, brand, and financial impacts abound in the physician compensation space, as potential inappropriate payment arrangements to referral sources will jeopardize any referrals from those sources and can create substantial fines and penalties.

In order to conduct an effective due diligence review, targets must be able to detail all payments to potential referral sources, including the production of contracts documenting arrangements with non-employed providers, and 1099s detailing any payments to those providers. The due diligence team will then assess compensation paid, considering local market information and relevant benchmarks in order to evaluate the reasonableness of individual—and stacked—compensation components, such as base salary, productivity bonuses, call coverage arrangements, and administrative compensation. Issues identified during due diligence, such as payments outside of FMV and/or insufficient contract documentation, may result in the need for the target entity to self-disclose under the CMS Voluntary Self-Disclosure Protocol.[9] In such cases, the acquirer should try to include an indemnification in the purchase agreement to protect against liabilities associated with self-disclosure.

In addition to the FMV of a contract with a provider, the CR should also always be considered. As there is no universally accepted definition of CR, buyers should be aware of, and understand, referral relationships to provide sound justification for any transactions that may occur within business arrangements involving referral sources.

9 Self-Referral Disclosure Protocol, CMS, https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/self_referral_disclosure_protocol.html (last visited March 24, 2019).

Conclusion

While this white paper is not inclusive of *all* potential risk areas, the areas highlighted herein have significant impact on enterprise risk and the decision of whether to pursue a particular transaction. As many entities without deep healthcare knowledge continue to invest in the industry, the importance of engaging an experienced due diligence team and acting in a collaborative manner to assess multiple areas of enterprise risk continues to increase. An appropriate due diligence approach can ultimately help an entity recognize, understand, and mitigate potential risks. Armed with this knowledge, buyers make more informed decisions.

How PYA Can Help

PYA is committed to employing a collaborative approach to due diligence services, not unlike the clinical model of care Mayo Clinic provides its patients. Bringing a collaborative team of experts from multiple disciplines, including healthcare audit and tax, healthcare operations, clinical coding, managed care and governmental payer reimbursement, real estate, IT, valuation, and regulatory compliance, differentiates PYA in its approach to providing due diligence services to meet the needs of its clients. PYA coordinates services with its engagement principals who have deep experience in healthcare transactions, affording clients and their legal counsel a single point of contact and centralized project management across these multiple disciplines.

This approach allows for streamlined communications and alleviates burdensome client oversight, isolated risk assessments, and divergent due diligence reports as are typical of engaging several firms to perform various due diligence services spanning multiple disciplines. Our seasoned transaction advisory executives welcome the opportunity to help you assess transaction risk across the spectrum of due diligence initiatives.

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