Many healthcare purchase and sale transactions are intended to help providers achieve economies of scale or otherwise position themselves to pursue value-based reimbursement and other goals. Increased quality, lower costs and improved access to care are required to successfully move from fee for service payments to the new reimbursement models.

These transactions cover a wide spectrum in the healthcare industry, including hospital mergers and consolidations, health system acquisitions of physician practices and ancillary providers and suppliers, physician practice joint ventures, and private equity investments in healthcare provider groups.

Critical role of due diligence
Through due diligence, a buyer can gather information about a seller and evaluate the information within the context, planned structure, and proposed terms of the transaction. Then the terms and value of the transaction may be adjusted based on the information obtained. The buyer will also have a better understanding about the historical operation of the seller’s business, which can aid the buyer in developing a strategic plan for the seller’s assets or equity that are being acquired.

Typical due diligence areas of inquiry cover a broad range of topics:

1. Organizational matters
2. Contracts
3. Real property
4. Corporate compliance
5. Litigation, claims and investigations
6. Financial information
7. Insurance
8. Tax matters  
9. Personal property assets  
10. Employment and employee benefits  
11. Information technology  
12. Intellectual property

Healthcare transactions themselves are unique because healthcare is one of the most highly regulated industries in the country, on both a state and federal level. Considerations not necessarily present in other industries are at the forefront of an acquisition in the healthcare sector, including:

• Multiple government agency oversight  
• Regulation of referral relationships  
• Complex revenue sources and patient relationships  
• Threats to cash flow from payer reimbursement trends  
• Potential for successor liability

As a result, due diligence in healthcare transactions is particularly important—especially from a compliance perspective. Buyers and sellers alike need an in-depth understanding of compliance-related matters of a seller, including:

• Compliance with Medicare Conditions of Participation  
• Federal and state fraud and abuse laws and regulations (e.g., Anti-Kickback Statute, Stark Law)  
• Billing and coding regulations  
• Federal and state licensure requirements

A seller that understands its compliance status in advance of a transaction can be better positioned to obtain a more financially attractive offer and ensure a more efficient closing process. Due diligence can help a buyer avoid unforeseen compliance liabilities that can destroy its investment.

Some key areas in a healthcare transaction where due diligence is particularly important are shown in Exhibit 1.

The failure of a seller to be in material compliance with applicable healthcare regulations can have a negative impact on the value of the investment. Successor liability, independent claims by the OIG, CMS or DOJ, or negative market effect because of public perception or mistrust in the healthcare system can be significant.

Transaction evaluation

Three general stages of review cover the buyer’s assessment of the risks of the transaction.

Stage 1

The first stage relates to the due diligence process itself. The buyer’s compliance team should evaluate the nature of the transaction, and identify the compliance risks of the seller’s business activity. The risk assessment should seek to identify potential liabilities, known problems, and potential sources of unknown problems.

The buyer’s team should then use this risk assessment to develop a checklist based on the key areas outlined in Exhibit 1. The buyer’s team has a responsibility to understand the purpose and use of the checklist and be well-versed in the general background information about the substantive areas being evaluated.

After the due diligence process, the team should review the findings, highlight concerns and decide next steps, which could include remediation before the transaction closes, canceling the deal or planning to fix the problem after the transaction closes. An integration checklist should be prepared and should include remediation of issues discovered during due diligence.

Stage 2

Activities in this stage involve reviewing and assessing the effectiveness of the seller’s compliance program as a tool
to prevent, detect and remediate problems in specific risk areas. The review should include:

- Oversight and operational structure of the compliance plan
- Actual operation of the compliance program
- Periodic evaluation of the compliance program’s effectiveness

Strong internal controls and a seller that devotes appropriate attention, resources and personnel to ensuring its compliance program is effective are often good signs of regulatory compliance. The buyer should consider, based on the level of compliance with the program, whether pre-closing education is needed for the seller’s staff.

The buyer should document differences between the buyer’s and seller’s compliance policies, procedures and risk areas to decide what integration changes are necessary after the transaction closes. The integration checklist should include combining compliance policies and procedures.

**Stage 3**

Next, the buyer should consider a coding and billing review. The parties should agree on a probe or discovery sample that will give a sense of whether the error rate is sufficiently low to show regulatory compliance. The sample

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**Exhibit 1 – Key compliance areas in due diligence**

<table>
<thead>
<tr>
<th>1. Physician contracting and compensation</th>
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<tbody>
<tr>
<td><em>Are the terms of employment agreements, independent contractor agreements, medical director agreements, and medical staff appointment arrangements consistent with applicable regulatory requirements?</em></td>
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<tr>
<td><em>Where required, is the compensation commercially reasonable, at fair market value, and not based on the volume or value of referrals?</em></td>
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<tr>
<th>2. Material contracts and related party contracts</th>
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<tbody>
<tr>
<td><em>Are contracts regarding referral relationships consistent with applicable regulatory requirements?</em></td>
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<th>3. Government investigations</th>
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<tbody>
<tr>
<td><em>Is the seller party to any Corporate Integrity Agreements?</em></td>
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<tr>
<td><em>Are any investigations pending, or has the seller received any notifications regarding investigations from the DOJ, OIG or CMS?</em></td>
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<tr>
<td><em>Is the seller engaging in any activity that is an investigation focus of government agencies?</em></td>
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<th>4. Billing and coding review and audits</th>
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<tbody>
<tr>
<td><em>Does the seller perform its coding and billing in-house or is it contracted out?</em></td>
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<tr>
<td><em>Does the seller conduct regular internal or external billing and coding audits?</em></td>
</tr>
<tr>
<td><em>Is the seller compliant with the 60-day rule regarding any Medicare and Medicaid overpayments?</em></td>
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<th>5. Licensure, certifications, accreditations, and regulatory compliance programs</th>
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<tbody>
<tr>
<td><em>Does the seller have appropriate compliance programs in place?</em></td>
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<td><em>Are staff trained in relevant compliance areas?</em></td>
</tr>
<tr>
<td><em>Are the seller’s policies and procedures in practice consistent with the terms of the compliance programs?</em></td>
</tr>
<tr>
<td><em>Are licenses, certifications and accreditations up to date?</em></td>
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<tr>
<td><em>Have procedures for Medicare’s Change of Ownership Rules been reviewed and implemented?</em></td>
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<table>
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<tr>
<th>6. HIPAA/HITECH and privacy matters</th>
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<tbody>
<tr>
<td><em>Have regular risk assessments been conducted?</em></td>
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<tr>
<td><em>Have any required Office of Civil Rights notifications occurred?</em></td>
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<table>
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<tr>
<th>7. Tax matters for nonprofit healthcare providers</th>
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</thead>
<tbody>
<tr>
<td><em>Does the seller engage in any activities, directly or through subsidiaries, that may have a negative effect on tax exempt status?</em></td>
</tr>
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</table>
does not need to be large enough or random enough to be statistically significant.

Identifying compliance issues in the due diligence process can impose obligations on a seller even before the transaction is closed. CMS requires providers and suppliers to return and report an overpayment within 60 days of its identification (60-Day Rule).1 Failure to return overpayments on time can lead to additional liability under the Federal False Claims Act.

Due diligence in healthcare transactions is particularly important from a compliance perspective.

The 60-Day Rule is especially relevant in due diligence activities involving reviews of billing and coding issues to test regulatory compliance. The rule also applies to contract reviews under the Anti-Kickback Statute and the Stark Law that give rise to disallowance of Medicare or Medicaid payments based on impermissible referral relationships. Seller has an affirmative obligation to repay within 60 days of the seller’s identification of the overpayment. To avoid potential repayment risks, a review could be limited to claims not yet billed by the seller.

The buyer and seller should agree on who will conduct the review, such as an outside consultant or law firm. A decision should also be made as to whether seller’s counsel will engage the reviewer to protect the work under the attorney-client privilege. Doing so, however, can limit the seller’s ability to give the results of the review to the buyer or their representative, unless a common interest or joint defense relationship is established between the parties.

However it is structured, the buyer will want to require the seller to resolve any compliance issues discovered in due diligence prior the transaction’s closing.

Sample follow-up
A sample of claims for billing and coding compliance can reveal whether a risk exists in the form of overpayments or other billing irregularities. For overpayments, the first question is whether the sample has isolated overpayments that can be refunded at once, or whether the overpayments signal a pattern or practice.

In the event the sampling shows signs of a pattern or practice, the buyer should be looking to the seller to engage in a broader claims review to address the root cause of the errors. Then the seller will be able to implement corrective actions to fix the underlying causes and to return all overpayments in a timely manner.

If the billing and coding errors are significant, the buyer should consider if:

- The valuation of the seller’s business is affected
- The errors affect how the seller’s accounts receivable are handled post-closing
- The indemnification provisions of the deal are sufficient
- The deal should be completed considering the audit findings

From the seller’s perspective, if a sample of claims raises concerns, performing the root cause analysis and addressing all identified overpayments in an appropriate manner may allow the transaction to continue and close. In the event the transaction does not proceed, taking these actions will minimize the seller’s amenable risk.

Seller’s preparations
Every seller should consider performing defensive due diligence well in advance of a potential transaction to proactively review its operations for compliance with fraud and abuse laws. A comprehensive compliance review prior to a buyer’s due diligence provides the seller the opportunity to reconcile any issues discovered early in the process. The seller will seem more trustworthy and the buyer will be more amenable to paying the agreed price. Identifying issues up front can better position the company for a more efficient transaction.

An integration checklist should include remediation plans for issues discovered during due diligence.

In contrast, if the buyer identifies regulatory issues late in the due diligence process, then the momentum established in the transaction can erode and potentially delay or derail the entire transaction.

Compliance as deal savers
Compliance professionals are often overlooked or viewed as obstructionist during due diligence activities. This viewpoint

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1 CMS 6037-F
Most compliance officers are savvy at identifying and addressing provider-specific risk areas.

may stem from outdated compliance program models in which compliance functioned as the “police,” or from individuals who believe that mitigating compliance risk is a barrier to advancement.

As the healthcare compliance profession has matured, however, many compliance officers have transitioned from a policing focus to a solution-oriented viewpoint. Compliance officers still identify areas of risk, but now commonly aid providers in developing solutions, alternatives, and corrective actions. In fact, a well-seasoned compliance officer can often save the deal for both the seller and buyer.

A good indication of regulatory compliance is a seller that devotes appropriate attention to its compliance program.

Given their role in provider organizations, most compliance officers are savvy at identifying and addressing provider-specific risk areas. Thus, sellers are prudent to include their compliance officer when identifying potential risk areas to explore further prior to the due diligence process.

The compliance officer’s assistance is also valuable to the buyer when assessing the potential effect of risks uncovered during due diligence review. Specifically, the compliance officer can tailor the compliance due diligence checklist and sample coding audit to focus on specific healthcare industry risks presented by the transaction.

Buyers can also rely on the compliance officer to examine the seller’s compliance program structure, staffing, documentation, and culture to help integrate the acquired operations into the buyer’s system. If a buyer does not have compliance staff, the buyer should consider retaining a reputable consulting firm to assist with pre-closing due diligence and appraisal of the seller’s compliance program.

Addressing challenges
A robust due diligence process during a healthcare transaction will often unearth risks. For the seller, these challenges need to be addressed so the transaction can be completed. For the buyer, the exposure must be analyzed to decide if the seller can fully address or minimize the risks.

While the risks to a transaction are always fact-specific, a number of questions can be raised to assist sellers and buyers, including:

1. Does the risk need to be addressed prior to closing?
2. Can the risk be addressed prior to closing?
3. If the risk cannot be addressed prior to closing, how does this affect the buyer?
4. Does this affect the value of the deal?
5. Will the buyer be assuming the risk if the deal closes?
6. Are there any overpayments that need to be refunded?
7. Are there pending investigations or regulatory enforcement actions that may carry consequences for the buyer after closing?
8. Will any issues discovered affect the entity’s ability to participate in federal or state healthcare programs?

Conclusion
While healthcare transactions are complex and raise unique challenges, risks can be managed if due diligence is conducted in a thorough manner. Whether buyer or seller, pulling together a team including executive leadership, compliance professionals, internal auditors and the legal staff to examine the unique characteristics of the deal can reduce risk for both sides. NP

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Failure has to be an option...No important endeavor that required innovation was done without risk.
~James Cameron