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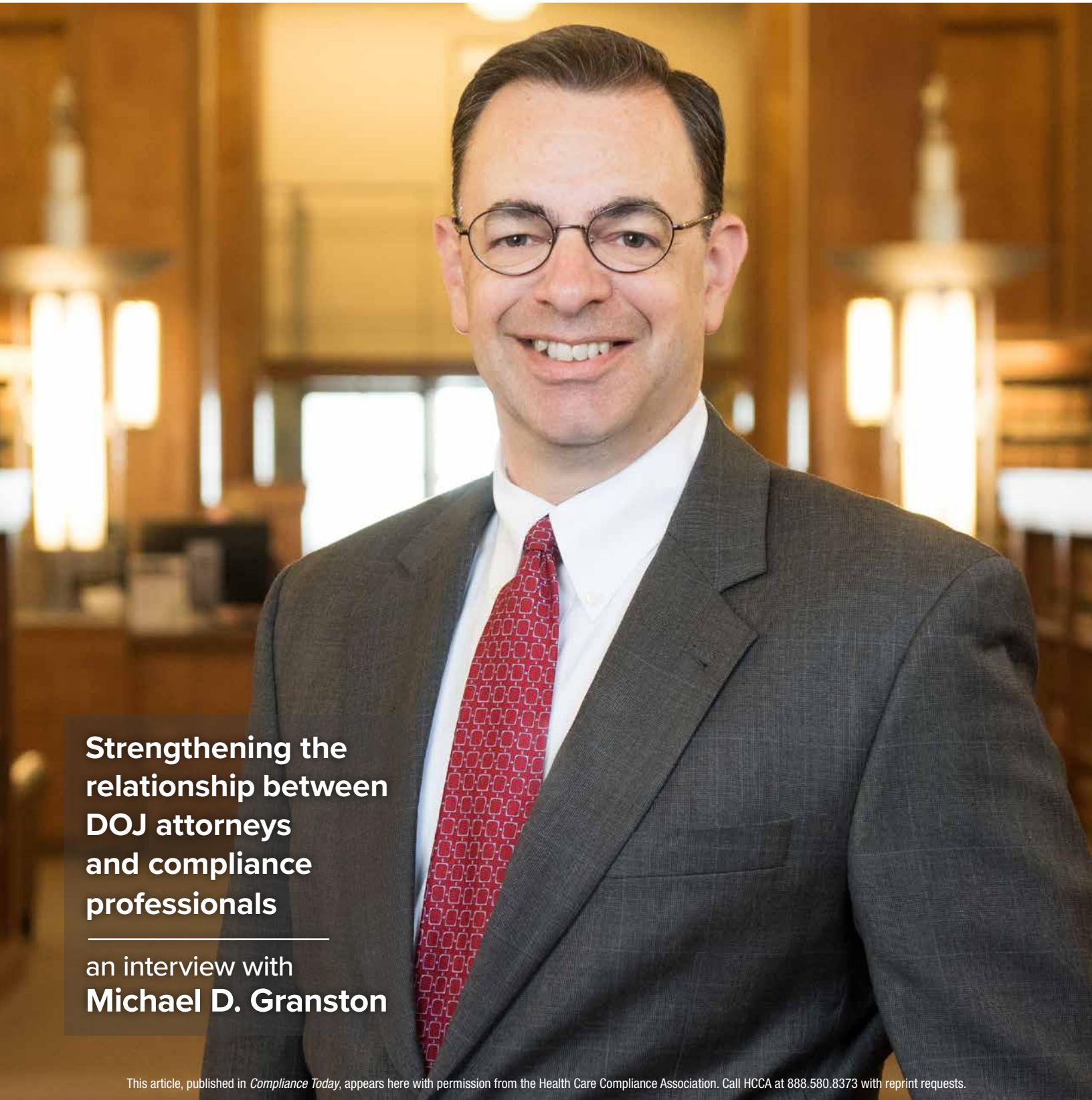

Strengthening the relationship between DOJ attorneys and compliance professionals

an interview with
Michael D. Granston

> Healthcare providers have come to realize that not only are strong compliance programs good for business by enhancing employees' awareness of their legal obligations, but they also promote internal reporting by giving potential whistleblowers a mechanism to voice their concerns.

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VOLUME 20, ISSUE 9

by Saud Juman and Shawn DeGroot, CHC-F, CCEP, CHRC, CHPC

Compliance due diligence for a merger and acquisition

» Implement proactive measures to improve your compliance program and/or prepare for a merger and acquisition.
» Perform a self-assessment to create a path to improvement.
» Identify risks and gaps in a compliance program and/or process.
» Conduct risk mitigation with process improvement.
» Collaborate with key stakeholders.

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Today's medical business landscape is driving hospitals, systems, and smaller physician groups to partner with other organizations to gain a competitive edge and/or improve efficiency. Almost all these entities will, at some time, consider the possibility of consolidation. Mergers and acquisitions (M&A) in particular are viewed as opportunities to manage cost pressures, improve market position, increase capital access, and bolster infrastructure.

For these partnerships to succeed, however, both the acquirers and acquirees must complete a full, top-to-bottom self-assessment, taking into consideration many aspects of their current operations. One area that is too often overlooked is the process of compliance due diligence. Risk exists without performing compliance due diligence during an M&A, and indeed when entering into any organizational partnership. Furthermore, when companies do not address such matters efficiently, the consequences can be severe, ranging from reduced valuations, legal suits, and government fines. Most important is reputation capital or the erosion of consumer confidence and trust.

Juman

DeGroot

Minor infractions, major complications

Minor infractions uncovered during due diligence may include a pending billing issue already under review by the Centers for Medicare & Medicaid Services (CMS), Medicare Administrative Contractors (MACs), or the Office of the Inspector General (OIG). Another infraction might be a privacy breach that the organization hasn't yet discovered, or one that has been reported to the Office for Civil Rights (OCR) and not yet reported to the entity. Usually such problems can be addressed as they arise; however, an accumulation of issues, or the emergence of more extensive problems, can impact valuation and lead to greater difficulties regarding accountability and liability.

For instance, if the appropriate coding and billing documentation review isn't performed and a system's value is overstated due to upcoding, lack of documentation, or an inappropriate hard code in the charge master, overpayments and associated regulatory

consequences may be the outcome. More importantly, when the term agreements are based on flawed earnings numbers, the value of the acquisition may be overstated. In all of these scenarios, the question becomes, "Who owns the liability and who is going to pay?"

The non-negligible likelihood of the above scenarios makes it critical to include contract language that clarifies the liability or a waiver of liability for any impropriety discovered within 90 days of the contract effective date. Even with such language in place, compliance due diligence cannot provide a 100% guarantee of identifying *all* areas of risk.

In the due diligence process, the Legal department plays a key role in protecting an organization by examining pending legal matters against an organization, limitations of liability, and associated concerns in contracts. Conversely, Compliance plays a crucial role in identifying risks and/or gaps within a process or compliance program. If an organization is reliant on manual processes, the compliance due diligence task can be quite daunting. Properly identifying risk and liability can be a complicated process and can lead to delays of the M&A; therefore, collaborating with Legal by establishing clear lines of communication to and from Compliance is key to continue forward movement. If an operation is clearly unorganized, mismanaged, and lacks effective compliance program oversight, the speed of completing due diligence may also lead to a delay with the M&A. Both are at risk of real consequences if accurate information isn't forthcoming or isn't detected.

One element that often complicates the due diligence process is when one or both sides do not have adequate time and resources to review important elements thoroughly. In the area of compliance, for example, the review process is more time-consuming when a system is not consolidated within their operational structure. If entities within a system operate independently or in siloes, and the programs, processes, contracts, and policies are de-centralized, additional time will need to be allocated for the compliance review. Modern approaches that include automated management systems that are accessible across a health system can dramatically improve the speed and accuracy of these crucial reviews.

Who owns the liability and who is going to pay?

Plan and prepare

Document collection is certainly a primary step in the due diligence process. However, documents can only describe the "intent" of what is expected and do not equate to an effective compliance program. Reviewing the practical application of the policies and procedures, contract management, and documentation of compliance issues, investigations, corrective actions, etc., based on the *process* within the organization, will provide a more complete picture of the culture of an organization. How can both the acquirer and the acquiree better prepare? The following steps can be taken proactively whether the effort is to prepare for an M&A or the organization simply desires to enhance their current compliance program.

Contracts

Effective, consistent due diligence is aided immensely by a contract checklist that includes, but is not limited to, legal entity name, payment amount, exclusion verification, license and/or tax ID validation, and

responsible stakeholder. These items are reviewed by Legal, Finance, Compliance, and Materials Management, as well as other departments as appropriate. The checklist can be manual and/or automated within a compliance tracking tool. Areas that need further review can be added to the checklist by any of the program areas listed above.

Secondly the review of the contract management process performed as a "spot check" audit and/or statistically valid audit that may include, but is not limited to, the following steps:

1. **Validate the contract dates:** If management is reliant on a manual process, a contract could be expired, and payments may have continued.
2. **Verify terms of payment:** Validate Accounts Payable data to the contract terms of payment. Occasionally, rates or payments are raised, and the contract terms are incongruent with the payment. Also validate whether a payment is directed to an individual provider, another payment is made to the same individual as a partner, and another payment is made to them as a contracted medical director.
3. **Review pre-payment documentation:** Review additional documentation requirements and/or quality measures required to receive payment. Federal reimbursement is tied to the quality of care, and accurate data is critical. If a requirement exists for documentation of a service provided or quality measures are to be met prior to payment, the required documentation should be validated, or validate that a process even exists to review the required documentation.[1]
4. **Check for exclusion:** Confirm that the individual who is receiving payment is not on the OIG Exclusion List.[2]
5. **Conduct a policy review:** Review the current policies and procedures with the contract process.
6. **Take corrective action:** If gaps are identified in any of the previous steps, verify:
   (a) whether the subject matter experts have been trained on the applicable policies and procedures of the contract process, or
   (b) implement a corrective action plan to improve.

Equally important to identifying issues is to document the corrective action, including active monitoring.

Tracking

Review the compliance tracking system or process for compliance issues, concerns, and findings. Dependent on the size of the organization, internal Excel or Access spreadsheets can be used as a manual approach or a third-party vendor tracking system can be contracted. Either way, the tracking system should provide trends of incidents, issues reported, and corrective action along with associated documentation such as regulatory standards, policies and procedures, contracts, contract checklists, trends, investigations, audit findings, and more. Conflict of interest is another key area of review that may be documented in the compliance tracking system or may be in a separate repository. Equally important to identifying issues is to document the corrective action, including active monitoring.

An example of crucial information in a compliance tracking system is related to the

HIPAA Privacy Rule[3] and HIPAA Security Rule.[4] The OCR can impose civil penalties for organizations that fail to comply with the HIPAA rules. The state attorney general may also bring civil actions on behalf of state residents for violations of the HIPAA rules. This authority was grated to state attorneys general in the Health Information Technology for Economic and Clinical Health (HITECH) Act.[5] Any violations of privacy and/or security standards and their associated corrective actions should be documented. Although Security may not be a direct report to Compliance, it is crucial that the privacy and security officers maintain healthy communication on current issues and incidents as they relate to the security safeguards, breach standards, and privacy, which are all outlined in the OCR Audit Protocol.[6] The OCR Audit Protocol specifies the required policies and procedures needed to support a privacy program. Documented timely response upon discovery of an issue, production of the supportive documentation, and corrective action will reduce risk during an external government audit or review.

Both privacy and security programs must monitor that security safeguards are in place to assure that the IT infrastructure is secure during the M&A transition and transmission of protected health information (PHI). Access and navigation-related nuances of transferring data and the repository of historical data are also crucial to a successful M&A.

Although compliance due diligence may identify and/or detect new issues, there is no guarantee of discovering *all* issues. Nevertheless, the due diligence process promotes transparency, maintains integrity, and adds value to all M&A stakeholders. Investors, surveyors, potential partners, and especially the board of directors no longer assume that a company is compliant; all desire a fundamental understanding of the culture, the process of identifying and reducing risk, and that an effective compliance program exists.

Whether your organization maintains manual or automated processes, where possible, non-automated compliance systems can challenge your ability to secure deals. According to Kevin Meek, President of Meek Clinical Partners, LLC and former VP of Patient Care Services, Clinical Operations and Corporate Compliance Officer at Adeptus Health:

> I believe that we had a larger hurdle to overcome with partnerships prior to our automating a compliance management system. Not being able to demonstrate compliance in a timely manner, even when we were in fact compliant, proved to be a real challenge.

Although compliance due diligence may identify and/or detect new issues, there is no guarantee of discovering *all* issues.

On the other hand, he says, when his former company was entering into a restructure, they had a capital company investing and guiding the company through the process, and:

> by showing our completeness of compliance it brought credibility to the company. We were able to show the investors any-policy and share it with them literally within minutes. This was very impressive to them and their auditors, and contributed to an efficient, collegial and trusting working environment. Had we taken more time to get those documents it

would have raised red flags and called into question our efficiency and the true level of compliance.[7]

Conclusion

It is in the interest of both parties to ensure the highest degree of transparency during an M&A compliance due diligence. Teams on both sides of the transaction must be enlisted to identify all risk factors. Rather than designing and implementing a process during an acquisition negotiation, proactive organizations improve efficiency, mitigate risk, and save time and resources in advance. As Eleanor Roosevelt so eloquently stated, "It takes as much energy to wish as it does to plan."

1. See OIG: Health care Fraud Prevention and Enforcement Action Team (HEAT): "A Toolkit for Health Care Boards" Available at https://bit.ly/2lLwNdw
2. See OIG: Exclusion Program. Available at https://bit.ly/2tN85wY
3. 45 CFR Part 160 and Subparts A and E of Part 164 (HIPAA Privacy Rule) Available at https://bit.ly/2DhI0Jb
4. 45 CFR Part 160 and Subparts A and C of Part 164 (HIPAA Security Rule). Available at https://bit.ly/2yFAda4
5. HHS.gov: HITECH Act Enforcement Interim Final Rule. Available at https://bit.ly/2tGoq7r
6. See HHS.gov: Phase 2 HIPAA Audit Program – Updated April 2016. Available at https://bit.ly/2Kn71Lz
7. Per phone conversation with Kevin Meek.