GARVEY SCHUBERT BARER

STATE OF REFORM

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Consolidations, Mergers, and Acquisitions Heightened Scrutiny and Risk Mitigation

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Healthcare Transactions and the Affordable Care Act

- Providers look to lower costs and increase value and accountability
- Government agencies work to finalize regulations to implement the Affordable Care Act
 - Regulatory compliance is even more difficult for healthcare providers, payors, and vendors
 - Buyers are focused on regulatory compliance during due diligence
 - Regulatory compliance affects structure of the transaction

Ever-Evolving Regulatory Landscape

- Changes in fraud and abuse provisions create additional risks of government investigations and litigation
 - Both the anti-kickback statute ("AKS") and the False Claims Act ("FCA") now reach even further
 - Threat of penalty of exclusion from federal healthcare programs emphasizes need to for heightened diligence
- Healthcare transactions face increased antitrust scrutiny
- Increased risk in healthcare transactions surrounding data privacy and security issues

Affordable Care Act Expands Exposure and Liability

- Affordable Care Act amends AKS to relax the specific intent requirement
- Violation of AKS constitutes a false or fraudulent claim under the FCA
- Section 6402 provides that identified overpayments must be reported and returned within 60 days to the applicable government contractor, intermediary, or carrier
 - Any delay in processing known overpayments creates the potential for FCA liability
 - CMS has proposed a 10-year look-back period for an overpayment

Heightened Antitrust Scrutiny of Healthcare Transactions

- Healthcare transactions face increased scrutiny by FTC and DOJ
 - Antitrust enforcement officials increasing scrutiny of transactions that "appear to have a competitive concern"
 - FTC and DOJ use the same analytical framework to scrutinize a healthcare transaction's effects as they do for other mergers

Increased Risk Data Privacy and Security Issues

HIPAA Omnibus Act

- Directly regulates Business Associates that receive protected health information ("PHI"), including subcontractors
- Covered entities and business associates face civil and criminal liabilities for noncompliance
- Expands the duty to give notice to individuals when there has been a breach of unsecured PHI
- Increase in providers' use of electronic health record systems
 - Increased risk of data breaches, theft, accidental disclosures and losses

Mitigating Risk in Healthcare Transactions

- Review and Assess Organization Fit
 - Structure of the transaction
 - Disincentive to reject assignment of seller's Medicare provider agreement
 - Parties should familiarize themselves with the antitrust laws and guidelines
 - Identify and document the pro-competitive effects of the transaction

Mitigating Risk in Healthcare Transactions

Heightened Diligence

- Review all agreements with physicians and physician-owned entities for compliance with AKS and physician self-referral laws
- Review coding and payment issues for appropriate documentation to support reimbursement claims.
 - Determine whether there is a pattern and practice of submitting inappropriate claims
- Review HIPAA policies, procedures and privacy log. Identify breaches, which may result in post-closing liabilities for the successor
- Review medical staff issues

Mitigating Risk in Healthcare Transactions

Drafting Considerations

- Parties should require representations and warranties regarding the other parties' compliance with healthcare laws
 - Survival periods, use of caps, baskets and deductibles
- Earn-outs, escrows, and holdbacks can mitigate some buyer risk
- Representation and warranty insurance
- Indemnification for losses arising from inaccuracies in a representation or warranty
 - Party's knowledge of a breach or inaccuracy does or does not affect its right to seek indemnification
- Alternative dispute resolution

Transition

- Planning for Transition Issues
 - Address risks associated with noncompliance
 - Remediation prior to close
 - Self disclosure / repayment / CIA
 - Adjust transaction if necessary
 - Involve compliance officers prior to closing
 - Integration with compliance program
 - Understand how the cultures of the two organizations will interact (i.e., for-profit and not-for-profit, faith-based and non-faith-based)

• Questions?



About the Speaker

Rachael Ream has significant expertise and experience representing healthcare clients on compliance and regulatory matters, including government investigations and *qui tam* actions, defense of Medicare fraud and abuse accusations, Stark and Anti-Kickback law compliance, HIPAA, and corporate governance. Rachael graduated *magna cum laude*, Order of the Coif, from Case Western Reserve University and earned a Ph.D. in Biological Sciences from Stanford University.

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