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# Katten's Seventh Annual Women's In-House Counsel and Compliance Officer Program

# Tackling the Tough Issues in Health Care Law and Compliance


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# How the Supreme Court's Recent *Escobar* Decision Impacts FCA Exposure and Reporting Obligations Under the 60-Day Rule

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# Presentation Overview

- FCA Refresher
- 7th Circuit Law Prior to *Escobar*
- Facts and Allegations in *Escobar*
- Holding
- Impact on FCA Liability
- Impact on Application of 60 Day Rule
- Practical Pointers for Reducing Risk

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# False Claims Act Refresher

- False Claims Act (FCA) prohibits a person from knowingly:
  - Presenting a false or fraudulent claim to the government for payment or approval, or
  - Making or using a false record or statement material to a false or fraudulent claim, or
  - Retaining overpayments (including payments for DHS billed in violation of the Stark Law).
- FCA imposes a civil penalty per violation *plus* up to triple the amount of damages.
- Stark Law and AKS violations may serve as a predicate for claims.

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# 7th Circuit Law Prior to *Escobar*

- The 7th Circuit had consistently held that, where a FCA action is "premised upon a false certification of regulatory compliance, the relator must also prove that the certification was a condition of or prerequisite to payment by the government."[1]
  - The 7th Circuit rejected the implied certification theory, requiring an expressly false certification or statement.
- FCA cases in this circuit were routinely dismissed where they failed to allege compliance with a regulation that was a condition of payment, suggesting that failure to satisfy a condition of participation ("COP") that is not a condition of payment does not give rise to FCA liability.[2]
- This is consistent with CMS guidance.
  - The Medicare Program Integrity Manual instructs MACs and ZPICs "not to analyze provider compliance with Medicare rules that do not affect Medicare payment. Examples of such rules include violations of the conditions of participation..."
  - The MPIM instructs contractors to refer COP violations to the CMS regional office and applicable State survey agency but not to deny payment solely based on COP violations.

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1 *E.g., United States ex rel. Crews v. NCS Healthcare of Ill., Inc*., 460 F.3d 853, 858 (7th Cir. 2006)

2 *United States ex rel. Kennedy v. Aventis Pharmaceuticals*, 610 F.Supp. 938, 940 (N.D. Ill. 2009).

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# Facts and Allegations in the *Escobar* Case

- The *qui tam* relators were the parents of a patient who received treatment at a Universal Health Services mental health facility over a 5-year period.
- Only 1 of 5 "professionals" who treated the patient was properly licensed.
- The patient had an adverse reaction to a medication prescribed by a purported doctor after she was diagnosed with bipolar disorder.
- The patient's condition worsened; she suffered seizures and died.
- The "doctor" who diagnosed bipolar disorder held herself out as a psychologist with a Ph.D., but her degree was from an unaccredited internet college and Massachusetts rejected her psychologist license application.
- The practitioner who prescribed the drugs was held out as a psychiatrist, but was a nurse who lacked authority to prescribe medications without supervision.
- The relators lodged complaints with various state agencies resulting in a finding that the facility violated over a dozen Massachusetts Medicaid regulations related to the licensing and supervision.
- The relators alleged that the filing of Medicaid claims without disclosing the lack of licensure and supervision violated the FCA under an implied false certification theory of liability.
- Notably, the Government declined to intervene.

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# *Escobar* Holding

The Court in *Escobar* overrides 7th Circuit law in two important respects by holding that:

1. The implied false certification theory can be a basis for FCA liability when a defendant submitting a claim makes specific representations about the goods or services provided, but fails to disclose noncompliance with material statutory, regulatory, or contractual requirements that make those representations misleading with respect to those goods or services, and

2. FCA liability for failing to disclose violations of legal requirements does not turn upon whether those requirements were expressly designated as conditions of payment.

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# Materiality Standards Under *Escobar*

The *Escobar* ruling does not establish a bright line test for when a regulatory violation constitutes a false claim but provides the following guidance:

- A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the FCA.
- A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular requirement as a condition of payment.
- Nor is the Government's option to decline to pay if it knew of the defendant's noncompliance sufficient for a finding of materiality.
- Materiality also cannot be found where noncompliance is minor or insubstantial.
- If the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.
- The FCA does not apply to insignificant regulatory violations.
  - A provider must have misrepresented its compliance with requirements that are so central to the provision of the provided services that the Government would not have paid the claims had it known of the violation.

The Court did not rule on whether the alleged regulatory violations were sufficiently material to provide a basis for FCA liability, concluding that "respondents may well have adequately pled a violation . . . . But we leave it to the courts below to resolve in the first instance."

# Impact on FCA Liability

The *Escobar* ruling significantly increases health care provider exposure to FCA claims.

- The Court's holding that FCA liability need not be predicated on a condition of payment vastly increases the array of regulations that can serve as the basis for an FCA claim.
- Likewise, the Court's acceptance of the implied certification theory as a basis for FCA liability exacerbates risk by eliminating the need for the plaintiff to demonstrate an express certification of compliance with the specific standard at issue.
- The need for a materiality analysis makes it much harder to prevail at the motion to dismiss stage, and generally makes litigation more complex, expensive and unpredictable.

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# 60-Day Rule: Statutory Requirements

- Section 6402 of the Affordable Care Act ("ACA") provides that, if an entity has received an overpayment, it is required to report and return the overpayment to the Secretary or the State Medicaid Agency or the appropriate contractor and with the reason for the overpayment.
- The overpayment must be reported and returned within 60 days of the date on which the overpayment was ***identified***, or the date any corresponding cost report is due (if applicable), whichever is later.
- Any overpayment retained past the deadline is an "obligation" under the reverse false claims provision of the False Claims Act ("FCA").
  - FCA penalties are not less than $5,500 nor more than $11,000 per claim plus treble damages.
- "Overpayment'' is defined in Section 6402 of the ACA as any funds a person receives or retains under Medicare or Medicaid to which the person, "after applicable reconciliation," is not entitled.

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# Impact on 60 Day Rule Obligation to Report and Refund

- Because COP and other regulatory violations may be a predicate for a FCA claim, it is logical that payments received in connection with such claims will be considered "overpayments" for purposes of the 60 day rule.
  - However, this has yet to be litigated.
- Accordingly, when an investigation or audit identifies claims filed in connection with services that materially violated Medicare or Medicaid requirements, the provider arguably has a report and refund obligation.
  - This is true even if the regulation at issue is not a condition of payment.

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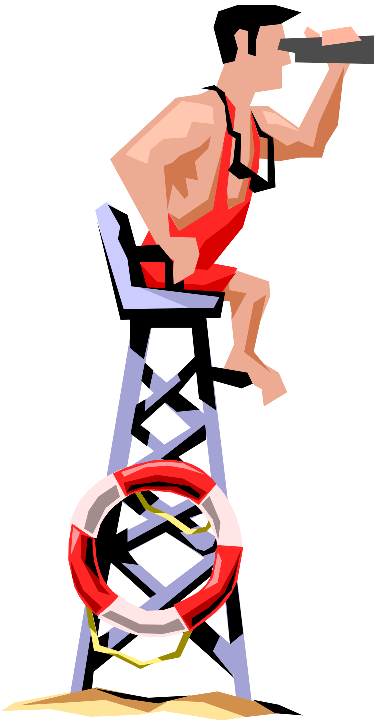
# Practical Pointers for Reducing Risk

- Take reports of suspected compliance and Medicare survey findings seriously.
  - Promptly investigate all reports of suspected noncompliance.
  - Review all adverse audits and investigator's findings.
  - Conduct a materiality analysis.
- Consider audits of prior periods when violations are material.
- Consider reports and refunds under IDHFS and OIG protocols, to USAO or directly to contractors in appropriate cases.
- Consider compliance program effectiveness review in light of new FCA standards.

# Internal Compliance Enforcement with Top Executives and Board Members

# Key to Compliance: Education on Corporate Leadership Responsibility



- Corporate directors have an obligation to act as fiduciaries for the organization.
- This duty includes an obligation to ***actively monitor organizational performance, processes and systems***.
- Failure to monitor organizational performance may result in liability for the corporation and its officers and directors.

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# Tips on Compliance Education

- Ensure that officers and directors understand their fiduciary duties as they related to compliance.
- Educate on primary legal/compliance parameters relating to the business and policies addressing those parameters.
- Ensure that education is scenario-based.
- Educate on what attendees ***can do*** – not just on what they ***can't do****.*
- Consider using new developments like *Escobar* or a compliance program effectiveness review as an impetus for education.

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# Tips on Enforcement

- Determine if your organization has clear compliance policies in place covering primary risk areas to promote compliance.
- If not, develop new policies and educate on those policies.
- Foster a culture and, if possible, implement policies requiring legal/compliance to be consulted before actions are taken or arrangements are entered within risk areas.
  - Encourage leadership to view you as their partner in minimizing institutional and personal risk.
- An effective compliance program requires uniform discipline for compliance violations, including those committed by the leadership team.
  - The Yates memo requires companies to disclose relevant facts to the Government regarding individual responsibility for corporate misconduct in order to receive cooperation credit.
  - While the memo makes it more difficult to jointly represent the company and management after a violation occurs, the risk or personal liability drives compliance.
- Be aware of Illinois Rule of Professional Conduct 1.13 in advising your company.

# Organization as Client (Rule 1.13)

- A lawyer employed or retained by an organization represents the organization acting through its duly authorized constituents.
- If a lawyer for an organization knows that an officer, employee or other person associated with the organization is engaged in action, intends to act or refuses to act in a matter related to the representation that is a violation of a legal obligation to the organization, or ***a crime, fraud or other violation of law*** that reasonably might be imputed to the organization, and that is likely to result in ***substantial injury to the organization***, then the lawyer ***shall*** proceed as is ***reasonably necessary in the best interest of the organization***.
  - Normally, this involves referral to a higher authority within the organization.
  - However, referral may not be necessary if a constituent had an innocent misunderstanding of law and reconsiders action on advice of counsel.
  - If highest authority within organization refuses to address action that is clearly a ***crime*** or ***fraud***, lawyer ***may*** reveal information reasonably necessary to prevent substantial injury to the organization but ***not*** if information arose from lawyer's involvement in an investigation or defense of client.
- In dealing with an organization's directors, officers, employees or other constituents, a lawyer shall explain the identity of the client when the lawyer knows or reasonably should know that the organization's interests are adverse to those of the constituents with whom the lawyer is dealing..

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# Ransomware: Your Money or Your PHI

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# Your Money or Your PHI

- What is Ransomware?
  - Malicious software that attempts to deny access to a user's data, usually by encrypting it with a key known only to the hacker until a ransom is paid.
- 4000 daily ransomware attacks since 2016 (300% increase over 2015).
- Ransomware attacks have become more sophisticated and destructive.

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# Agenda

- How do HIPAA Privacy, Security and Breach Notification Rules address ransomware?
- What steps can Covered Entities and Business Associates take now to prevent and mitigate the harm associated with ransomware attacks?

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# An Ounce of Prevention…

- Malware (including ransomware) should be part of your HIPAA security risk analysis and addressed via the HIPAA risk management program.  Considerations include (but are not limited to):
  - Have we implemented procedures to guard against and detect malware, including ransomware?
  - Are our users trained to detect and report suspected malware?
  - Have we limited access to ePHI to only those persons/software programs requiring access?
  - How do we address risks of network devices running on obsolete firmware?

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# An Ounce of Prevention…

- The HIPAA Security Rule requires organizations to have a data backup plan (as part of a broader Contingency Plan addressing business continuity, disaster recovery and emergency operations). Questions particularly relevant to ransomware include:
  - How frequently is data backed up?
  - Do we regularly test our data recovery process to see if it actually works?
  - Is it feasible to maintain backups offline/unavailable from the network?

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# An Ounce of Prevention…

- A suspected ransomware attack will trigger your Data Incident Response Plan and Contingency Plan. It may also trigger your Crisis Communications Plan.
  - These plans should be regularly tested and validated/refined via Table Top Exercises or Incident Simulations.

# Key Considerations – DIR Plan

- Having an “actionable” Data Incident Response Plan is a key step to being able to rapidly and effectively respond to a ransomware or other major data incident.
- Typical elements include:
  - Team members (internal and external), roles & responsibilities (including contact info)
  - Procedures for detection, reporting and initial analysis of an incident
  - Process for escalation based on severity

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# Key Considerations – DIR Plan

- Procedures to contain/mitigate/eradicate and restore the lost data/resume business as usual
- Procedures to collect and preserve evidence
- Process and logistics for confidential/secure communications (including if the network is compromised)

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# Key Considerations – DIR Plan

- Identifies the panel of potential outside experts with which the organization has agreements in place (i.e., outside counsel, forensics, crisis communications, notice/call center vendor, credit monitoring vendor, etc.)
  - Other experts are generally retained through outside counsel to maximize privilege
  - Engagement in advance allows for rapid deployment on more favorable terms
- Contains draft scripts/holding statements, FAQs for rapid revision and deployment.

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# Key Considerations – DIR Plan

- Protocol for coordinating with law enforcement
- Protocol for notifying insurer (Note: consider a cyber-extortion endorsement)
- A plan to identify, track and manage the maze of potential notifications and communications (proactive and reactive) with stakeholders, including: Board, CEO, employees, providers, regulators, attorneys general, affected individuals, customers, media, contractual parties, vendors, insurers, threat-sharing organizations, elected officials, etc.

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# Key Considerations – DIR Plan

- Plan for responding to investigations, audits and/or litigation
- Post mortem/corrective actions

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# Is Ransomware a HIPAA Breach?

- HIPAA defines "Breach" as the acquisition, access, use or disclosure of PHI in a manner not permitted by the Privacy Rule which compromises the privacy or security of the PHI. 45 C.F.R. 164.402. Fact specific, but per OCR:
  - When ePHI is encrypted as a result of a ransomware attack, a breach has occurred because the ePHI encrypted by the ransomware was acquired and thus is a "disclosure" not permitted by the HIPAA Privacy Rule.
  - Unless the Covered Entity/Business Associate demonstrates a "low probability of compromise," breach is presumed.

# HIPAA Breach Risk Assessment

- To demonstrate low probability of compromise, consider:
  - Nature and extent of PHI involved
  - Nature of unauthorized recipient
  - Whether PHI actually acquired or viewed
  - Extent to which risk has been mitigated
- Burden is on the Covered Entity/Business Associate to demonstrate compliance.

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# Other Considerations

- What other factors might come into play?
  - High risk of unavailability of data
  - High risk to the integrity of the data
  - Evidence of exfiltration
- What if the ePHI was already encrypted per HHS Guidance before the attack?
  - Take a close look before concluding breach notification does not apply.

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# Further Guidance

- United States Government Interagency Guidance Document, *How to Protect Your Networks from Ransomware,* available at https://www.justice.gov/criminal-cips/file/872771/download).
- United States Department of Health & Human Services Fact Sheet, *Ransomware and HIPAA*, available at http://www.hhs.gov/blog/2016/07/11/your-money-or-your-phi.html).

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## Internal Compliance Enforcement

## Practical Pointers on Restrictive Covenants

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# Non-Competition and Non-Solicitation Agreements in Illinois

- Illinois Supreme Court in 2006: Restrictive covenant agreements with physicians do not violate the state's public policy.
- Recent events suggest an evolution of basic standards courts will apply to determine enforceability:
  - Legitimate business interest
  - Adequate consideration
- Changing market conditions could affect courts' analysis:
  - More demand, less supply
  - Competition for market share

# Not Against Illinois Public Policy

- ***Mohanty v. St. John Heart Clinic*, 225 Ill.2d 52 (2006)**
  - "We have strictly adhered to the position that public policy of the state is not to be determined by the varying opinions of laymen, lawyers or judges as the demands of the interests of the public." (internal quotations and citations omitted)
  - "[P]laintiffs have failed to show that physician restrictive covenants are contrary to the constitution, statutes or judicial decisions of this state. Nor have they shown that these covenants are manifestly injurious to the public welfare."
  - Apply standard reasonableness test regarding enforceability.
  - Legislature has not changed its position since 2006.

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# Enforceability of Restrictive Covenants

- **Refresher on the basic standards for evaluating enforceability:**
  - Generally disfavored; agreement alone is not enough
  - A non-competition or non-solicitation agreement is typically enforceable if that agreement:
    - Is ancillary to a valid employment contract/relationship;
    - Is supported by adequate consideration; and
    - Only imposes reasonable restrictions.

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# Are the Restrictions Reasonable?

- **Three-prong "Rule of Reason":** The covenant (i) is no greater than necessary to protect the legitimate business interest of the employer; (ii) does not impose an undue burden on the former employee; and (ii) is not injurious to the public.
- *Reliable Fire Equipment Co. v. Arredondo*, 2011 IL 111871 (2011): "Whether a legitimate business interest exists is based on the ***totality of the facts and circumstances*** of the individual case. . . . No factor carries any more weight than any other, but rather its importance will depend on the specific facts and circumstances of the individual case."
  - More than near-permanent relationships and misappropriation
  - Time and place
  - Changing market conditions?

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# What is Adequate Consideration?

- *Fifield v. Premier Dealer Services, Inc.*, 2013 IL App (1st) 120327.
  - "Illinois courts have repeatedly held that there must be at least two years or more of continued employment to constitute adequate consideration in support of a restrictive covenant."
  - Does not matter if the employee resigned or was terminated.
  - Cert denied.
- *Prairie Rheumatology Associates v. Francis*, 2014 IL App (3d) 140338.
- *McInnis v. OAG Motorcycle Ventures, Inc.*, 2015 IL App (1st) 142644.
- *Fifield* rejected by federal courts in the Seventh Circuit (2016).

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# Enforcing Your Restrictive Covenants

- Revisit language of existing agreements
- Integrate new physicians/practice groups
- Provide additional consideration where possible
- Be prepared for additional challenges
- Understand that discovery may be more burdensome
- Require and police return of all information and devices

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# Protecting Yourself Against Liability for Violating Restrictive Covenants

- Obtain all agreements with prior employers
- Interview employees about contacts with patients, clients
- Interview employees about documents, devices taken
- Do not permit employees to add any materials that pre-date employment to system

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# Settlement of Restrictive Covenant Disputes

- **If you decide that settlement is the best option, consider:**
  - Breadth of Restriction
  - DO NOT POACH Provisions
  - Antitrust Implications

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Laura Keidan Martin is the national head of the firm's Health Care practice and a member of the firm's Board of Directors. She counsels health care industry participants including health systems, national ancillary service providers and life sciences companies, helping them structure their transactions, sales/marketing practices and physician compensation arrangements to meet state and federal regulatory requirements. Laura regularly assists clients with government and internal investigations and advises on corporate integrity and deferred prosecution agreements. She also helps clients develop and update their compliance programs and policies, provides compliance education and conducts compliance program effectiveness reviews.

Ms. Martin also serves as lead counsel on complex transactions, often involving multiple parties and creative deal structures. Her broad-based antitrust practice includes antitrust compliance advice and representation through pre-merger reviews and investigations conducted by the Federal Trade Commission and Department of Justice.

Ms. Martin earned her BA in economics from the University of Michigan and her J.D. from Harvard Law School. She is past president of the Illinois Association of Health Attorneys. Her recognitions include *Chambers USA: America's Leading Lawyers for Business* for both health care and antitrust, *Best Lawyers'* 2012 Lawyer of the Year for Chicago Health Care Law, and *Leading Lawyers Network's* "Top 10 Leading Women Lawyers in Illinois."

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Dawn M. Canty represents corporate clients who are the targets of regulatory enforcement actions and serves as Deputy General Counsel to the firm's Chicago office. She has conducted investigations and defended clients against Federal Trade Commission and state attorney general actions claiming unfair or deceptive acts or practices on the part of her clients in product marketing or advertising. She has an extensive national federal court practice, routinely litigating complex commercial disputes and civil regulatory enforcement and consumer redress actions in courts across the country. Dawn also frequently assists clients in resolving complex commercial disputes, including intercreditor disputes, lender liability claims, real estate litigation, fraud and breach of contract. Her practice includes the defense of securities and consumer fraud class action litigation.

Dawn routinely advises financial institutions, insurance companies and clients in the transportation, technology, manufacturing and communications sectors. Dawn is a counselor who attempts to avoid—rather than foster—litigation and, to that end, routinely engages in preventative business counseling of clients. She has engaged extensively in mediation and unique pre-litigation dispute resolution techniques. When negotiations fail, however, Dawn is a fierce advocate who has proven consistent in courtroom success.

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Megan Hardiman is a partner in the firm's Health Care practice and co-head of the firm's Privacy, Data and Cybersecurity group. She regularly counsels clients on privacy practices, information security, and data breach planning and response. In particular, Megan devotes a significant portion of her practice to helping health care industry clients understand and meet the requirements of the Health Information Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and state privacy and data breach laws. Megan closely follows related industry and regulatory agency developments and has advised on numerous complex information-sharing arrangements. Her deep knowledge of key privacy laws helps her clients mitigate risk in today's enhanced enforcement environment.

In addition, Megan has significant experience advising health care clients on a wide range of regulatory and transactional matters. Her transactional experience includes sales, acquisitions and affiliations involving a wide variety of health care industry clients, such as hospitals and health systems, home infusion companies, senior housing providers, urgent care centers, physician practice management companies and medical colleges. She has also represented tax-exempt health systems in structuring complex joint operating agreements and affiliations with unrelated health systems and has obtained favorable rulings from the Internal Revenue Service on the consequences of these and other transactions among tax-exempt organizations.

Megan frequently speaks and authors articles on privacy, data breach planning and response, and a range of other health care regulatory matters.

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Jennifer C. Ryan, practices in the areas of complex commercial and real estate litigation, serving public and private companies and executives in a variety of industries, including lending, real estate investment, financial services and health care. With a master's degree in business administration, she has a unique sensitivity to, and appreciation for, her clients' business considerations in resolving disputes, which she utilizes in developing effective litigation and non-litigation strategies.

Jennifer has represented clients in a variety of disputes, including foreclosing on retail, hotel and single-family home development projects. Additionally, she has represented clients in connection with golf courses in multiple states; defending against mechanics lien claims; negotiating and preparing pre-negotiation agreements, forbearance agreements and deeds in lieu of foreclosure; conducting internal investigations in response to tips, complaints and regulatory inquiries; defending publicly traded companies and their directors and officers in various types of actions, including breach of contract, breach of fiduciary duty, ERISA and securities fraud cases; negotiating and drafting settlement agreements; and analyzing draft contracts to identify and avoid language that could create litigation exposure.

Whether Jennifer is filing or opposing motions to dismiss and motions for summary judgment, managing the discovery process, preparing for arbitration, mediation or trial, or negotiating a settlement, she utilizes her keen attention to detail and advocacy skills to successfully pursue her clients' objectives.

Jennifer is co-chair of the firm's Chicago Committee of the Women's Leadership Forum.

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