

Effective Internal Investigations

Healthcare Law & Compliance Institute

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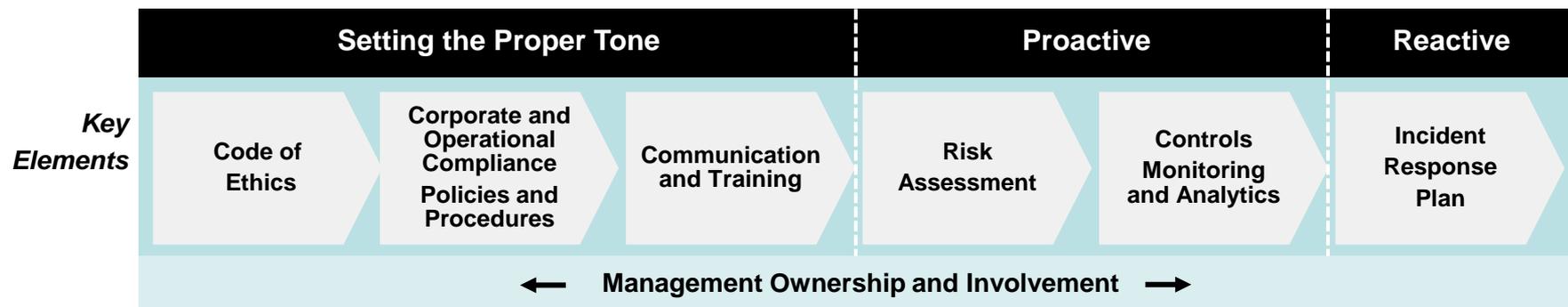
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Whistleblower Findings⁽¹⁾

- Only one in six reporters reported externally.
 - Of those, 84% tried to report internally first.
- Only 2% reported solely outside the company and only 3% of reports were made externally first.
- Only 5% of individuals would be motivated by a monetary award.
- Reporting rates are impacted by:
 - Awareness and recognition of misconduct.
 - Whether or not employees feel that they can make a difference by reporting.
 - Whether employees feel financially secure and safe from retaliation.
 - Available support from management and coworkers and support systems outside of work.

(1) Ethics Resource Center, *Inside the Mind of a Whistleblower*

Importance of a Strong Compliance Program



Key Benefits

- Raises awareness of compliance requirements
- Establishes clear guidance for employees and others acting on the Company's behalf
- Promotes proactive identification of potential compliance risks
- Facilitates timely and effective investigation and mitigation of compliance violations

Advantages of Robust Investigations Policy

- By establishing a clear policy for logging, conducting and documenting investigations, an organization:
 - Minimizes delays associated with the scramble to determine how to handle investigations on an *ad hoc* basis.
 - Promotes thorough and uniform investigations.
 - Ensures that all investigation steps, findings and corrective actions are appropriately documented.
 - Promotes root cause analysis and corrective actions that reduce risk of future violations.
 - Reduces risk that reporter will turn to third party reporter channels or file a *qui tam* suit.
 - Enables company to proactively self-disclose when appropriate, qualify for “cooperation credit” and minimize penalties.
 - Facilitates compliance with “60 day rule” for reporting/refunding overpayments.

60 Day Rule Implications for Investigations

- 60 Day Rule requires providers to report and refund overpayments within 60 days of “identification.”
- An overpayment is “identified” when a person has or should have, through the exercise of reasonable diligence, determined that an overpayment was received.
 - “Reasonable diligence” is demonstrated by timely, good faith investigation, which CMS indicates is at most 6 months from the receipt of credible information regarding a potential overpayment absent extraordinary circumstances.
 - An overpayment is not “identified” until it is quantified (unless a provider fails to exercise reasonable diligence).
 - Overpayments identified by a probe sample need not be returned until the full overpayment amount is identified.
- Failure to exercise reasonable diligence to investigate credible information regarding a potential overpayment will result in a violation of the 60 Day Rule under the “should have known” standard if an overpayment was received.
- CMS advises providers to maintain records of their reasonable diligence efforts.

The Yates Memo: DOJ's Increased Focus on Individual Accountability

The 6-pronged memorandum regarding “Individual Accountability for Corporate Wrongdoing” issued by Deputy Attorney General Sally Quillian Yates to federal prosecutors on September 9, 2015 changed DOJ’s policy on the resolution of criminal *and civil* cases.

1. To be eligible for any cooperation credit, corporations must provide to the Department all relevant facts about the individuals involved in corporate misconduct.
 - Failure to conduct a robust investigation may disqualify the company for credit.
2. Both criminal and civil corporate investigations should focus on individuals from the inception of the investigation.
3. Criminal and civil attorneys handling corporate investigations should be in routine communication with one another.
4. Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.
5. Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires and declinations as to individuals in such cases must be memorialized.
6. Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual’s ability to pay.

Elements of an Effective Investigations Policy

Multiple Reporting Channels/ Triggers

- At least one anonymous reporting option (e.g., hotline encouraging check-ins in case additional information is needed)
- Adverse audit results and employee exit interviews also should trigger investigations
- Explicit obligation for supervisors to report concerns raised by employees
- Link to non-retaliation policy
- Widely publicize to employees, vendors and the public via code of conduct posters in employee common areas, intranet and internet

Log And Triage

- Capture relevant data: source, all involved persons, location, timeframes, etc.
- Consider subject matter codes to aid data analytics
- Process for determining whether to refer to HR or Quality (with documentation of referral)
- Assessment of institutional risk level and designation of lead investigator
- Process for determining whether to investigation under privilege and, if so, whether to refer to outside counsel

Investigation Plan

- Determine need for document holds and preservation tactics
- Identify and obtain any governing policies/SOPs.
- Interviews
- Document reviews

Investigation

- Track all investigation steps
- Linkage of all documents reviewed and interview summaries to investigation tracking systems
- Mechanism to segregate privileged materials

Close Out

- Require clear findings of fact/basis for concluding report is substantiated or unsubstantiated
- Mechanism for appropriate legal input (non-lawyers should not determine if laws were violated)
- Root cause analysis and corrective action plan where report is substantiated
- Incorporate or cross reference “report & refund” policy when overpayments are identified

Corrective Action

- Actions to remediate violations
- Actions to address root cause of violation and safeguards against future violations
- Mechanism to track to completion

Follow Up

- Self-disclosures when appropriate
- Communications to key constituencies
- Follow up with reporters

Triage Process

Who Should Investigate?

- Compliance Office
 - Independently v. Under Direction of Counsel
- Managers with Compliance Office Oversight
- In-House Counsel
- Outside Counsel
 - Regular v. Special Counsel?

Factors to Consider

- Scope of Allegation?
- Likelihood of Whistleblower?
- Are Company Officers Implicated?
- Is Reporting to Government Likely?
- Will You Want “Cooperation Credit”?
- Potential Litigation related to Subject of Investigation?

Guidelines for Preserving Privilege of Investigations Conducted by In-House Counsel

- Document that the investigation purpose is to obtain legal advice from the outset.
- Investigation tracking system should clearly identify the investigation as privileged.
- Place privilege label on all investigation-related communications, interview summaries and reports.
- Segregate documents in privileged hard copy or electronic files.
- Any third party experts/auditors should be engaged by counsel and act under the direction and control of counsel.
- If compliance is assisting with the investigation, legal counsel should issue formal written request for assistance in conducting a privileged investigation under the direction and control of legal counsel.
 - Subsequently, **EVERY** investigation step – every interview, email search, document review and analysis – should clearly be conducted at the direction of counsel (as memorialized by investigation plan or email).
- Provide interviewees with *Upjohn* warnings.
- Investigation reports should be issued by counsel and state the purpose of and reflect legal advice.

The Investigation Plan

- Large organizations should consider utilizing investigation plan template to promote consistent and uniformly detailed plans.
- Determine need for document holds, imaging of hard drives, disabling email delete functions and other document preservation strategies.
- Identify and obtain any governing policies/SOPs.
- Identify and obtain other key documents through:
 - Document requests to individuals
 - Email searches
 - Review of centralized files/repositories
 - Sharepoint access
- Determine need for audits/data analysis and engagement of outside experts.
- Determine role (if any) of HR, IT, corporate security, internal audit, business unit management and executive team.
- Identify key interviewees in prioritized tranches.
 - Use 2-person interview team (consider non-attorney “prover” in event of litigation).
- Periodically revisit investigation plan and adapt as facts evolve.

Upjohn and *Zar* Warnings

- “*Upjohn* warnings” must be given in privileged investigations to put interviewee on notice that:
 - Attorney is conducting investigation for purpose of providing legal advice
 - Attorney represents the Company – not the individual
 - Conversation is privileged and confidential – privilege belongs to the Company and may not be waived by interviewee.

Yates memo’s focus on individual responsibility for corporate wrongdoing makes it essential to indicate that counsel represent the Company and not the individual.

- *Zar* warning also should be given if there is potential for Government self-disclosure.
 - Employees may be indicted for obstruction of justice based on false statements in interview with Company counsel.

ABA Criminal Justice Section “Best Practices”

- “I am a lawyer for or from Corporation A. I represent only Corporation A, and I do not represent you personally.

I am conducting this interview to gather facts in order to provide legal advice for Corporation A. This interview is part of an investigation to determine the facts and circumstances of X in order to advise Corporation A how best to proceed.

Your communications with me are protected by the attorney-client privilege. But the attorney-client privilege belongs solely to Corporation A, not you. That means that Corporation A alone may elect to waive the privilege and disclose this discussion to such third parties as federal or state agencies, at its sole discretion, and without notifying you.

- In order for this discussion to be subject to the privilege, it must be kept in confidence. In other words, with the exception of your own attorney, you may not disclose the substance of this interview to any third party, including other employees or anyone outside of the company. You may discuss the facts of what happened, but you may not discuss this discussion.

Do you have any questions? Are you willing to proceed?”

Can I Get my Own Lawyer?

- Remind the witness that you do not represent him and cannot provide legal advice, including on this point.
 - Yates memo makes this more important.
- Consider offering to postpone the interview until employee determines whether to engage own lawyer.
- Organization may want to offer to provide and pay for individual counsel.
- Remind employee of Company policies regarding cooperation and that failure to cooperate could lead to discipline
 - See *In re Grand Jury Subpoena*, 274 F.3d 563, 571 (1st Cir. 2001) (employee has duty to assist company counsel with investigation and defense of corporation's business affairs).

Memorialize the Interview

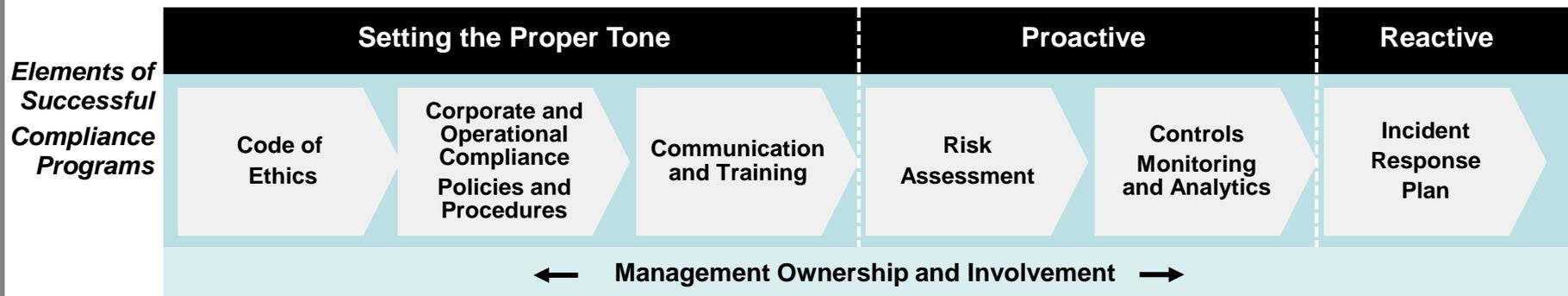
- Interview Memorandum in form of attorney-client communication.
- Quoting witnesses – pros and cons.
- Consider using separate sections for mental impressions and facts.
- Include Attorney Work Product/Disclaimer:

This memorandum is a summary and analysis of the discussion that occurred during the interview, and is neither a verbatim nor a chronological transcription of it. I have incorporated into this memorandum my thought processes and analyses, including factual interpretations, mental impressions, and the choice of which questions and answers were important to memorialize. This memorandum contains privileged communications and constitutes attorney work product created in contemplation of potential litigation. This memorandum has not been shown to, reviewed by, approved, or adopted by WITNESS.

- Keep your notes!

Concluding the Investigation

Root Cause Analysis

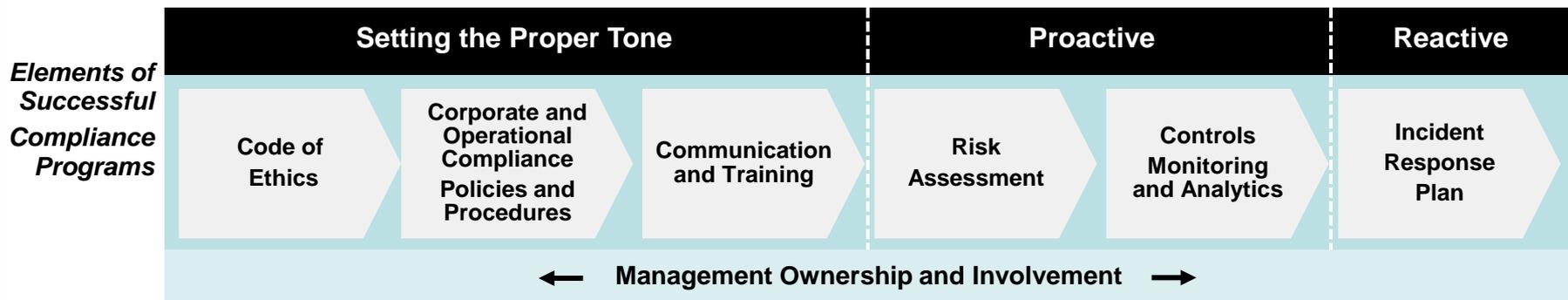


Key Questions

- Was written guidance available, accurate and well publicized?
 - Were implicated parties trained on the guidance?
 - Was management direction consistent with written guidance?
 - Did performance metrics and compensation support compliance with the guidance?
- Was the issue considered during routine risk assessment activities?
 - Is monitoring or auditing of the activity performed on a regular basis?
- Was internal reporting method used?
 - Was response timely and complete?
 - Was matter correctly escalated?

Concluding the Investigation

Corrective Action Plan and Remediation



Key Actions

- Additional /updated guidance
 - New or revised policies/SOPs
 - Education/training
 - Additions to code of conduct
 - Messaging from leadership
 - Individual counseling
- Future audits to monitor performance improvements
 - Proctoring/shadowing of involved individuals
 - Competency testing
 - System changes
- Discipline managers/employees who participated in violation or who knew but failed to report
 - Report and refund any overpayments in accordance with applicable law and payor requirements
 - Consider formal self-disclosure

Never simply issue a corrective action plan and trust that it will be implemented – monitor implementation to completion.

Avoiding Investigation Pitfalls

Common Investigation Pitfalls	Potential Risk Mitigation Strategies
<ul style="list-style-type: none"> • Failure to appreciate seriousness of issue and need for legal involvement at front end of investigation 	<ul style="list-style-type: none"> • Require analysis of risk level and benefits of privileged investigation during triage process • Compliance should consult with Legal during triage process when appropriate
<ul style="list-style-type: none"> • “Buzz Factor” undermines investigation integrity 	<ul style="list-style-type: none"> • Emphasize need for confidentiality when scheduling interview and issuing document requests • Re-emphasize during interviews • Review privilege at the outset and conclusion of interviews, if applicable • No ambiguous voicemails or emails • Adopt policy against undermining integrity of investigations/subject violators to discipline
<ul style="list-style-type: none"> • Lack of robust investigation documentation in a centralized repository 	<ul style="list-style-type: none"> • Invest in robust compliance investigation tracking system • Hardwire in linkages to relevant documents/interview summaries • Provide templates that prompt investigators to document each interview/ investigation step and basis for findings/ program tracking system to preclude close out absent essential inputs
<ul style="list-style-type: none"> • Investigation delays due to: <ul style="list-style-type: none"> • Difficulty scheduling interviews/cancellations • Delays in document request responses • Heavy workload for investigators 	<ul style="list-style-type: none"> • Include cooperation with investigations in employee code of conduct and/or compliance policies • Make compliance (including cooperation with investigation) an element of performance reviews • Establish escalation procedures with timeframes if employees fail to respond or make themselves available for interviews • Ensure adequate resources to conduct timely investigations • Use auto-reminders/calendar ticklers to check in on investigation status • Require periodic status reports

Avoiding Investigation Pitfalls

Common Investigation Pitfalls	Potential Risk Mitigation Strategies
<ul style="list-style-type: none"> • Variability in effectiveness/thoroughness of investigations among investigators 	<ul style="list-style-type: none"> • Establish quality control (QC) process <ul style="list-style-type: none"> • Competency testing • Spot checks • Centralized review before closeout • Periodic shadowing of investigators • Require periodic training/education
<ul style="list-style-type: none"> • Failure to address root cause of violations and take steps 	<ul style="list-style-type: none"> • Require root cause analysis prior to investigation close out when reports are substantiated (ideally via mandatory care in tracking system) • Require corrective action plans that include steps to prevent recurrence (e.g. education, policy changes, system updates)
<ul style="list-style-type: none"> • Failure to ensure that corrective action plans are implemented 	<ul style="list-style-type: none"> • Corrective action plans should identify the responsible party for each action step and target completion dates – The business needs to “own” the plan • Track and document implementation dates • Rationale for delays should be documented • Use auto-reminders and require status reports to monitor to completion

Self-Disclosure Options

- Updated OIG Self-Disclosure Protocol (SDP)
- CMS Self-Referral Disclosure Protocol (SRDP)
- State Provider Self-Disclosure Protocols
- Department of Justice/U.S. Attorney
- Routine Report and Refund Channels

OIG Self-Disclosure Protocol

Potential Benefits of SDP

- Presumption against corporate integrity agreements
- Lower damages multiplier
- Suspends “60-day rule”
- Mitigates FCA exposure
- Nearly always releases parties from permissive exclusion

OIG Self-Disclosure Protocol

Background

- Conduct that may violate federal criminal, civil or administrative laws for which civil monetary penalties (CMPs) are authorized.
 - Does not include matters exclusively involving overpayment or errors.
 - Does not include “Stark only” disclosures.
 - Requires additional disclosures.
 - Internal investigation and corrective action must be completed within 90 days of submission (subject to extension).
 - Requires disclosing party to screen all current employees and contractors against LEIE before making “excluded persons” disclosures.

OIG Self-Disclosure Protocol

Baseline disclosure requirements

- Information regarding disclosing party.
- Concise statement of conduct disclosed, including conduct giving rise to the matter, time period, and the names of implicated parties, including an explanation of their roles in the matter.
- Statement of the federal criminal, civil or administrative laws that are potentially violated by the disclosed conduct.
- Federal health care programs affected by the disclosed conduct.
- Damages estimate.
- Description of corrective action taken upon discovery of the conduct.
- Whether the disclosing party has knowledge that the matter is under current inquiry by a Government agency or contractor.
- Name of individual authorized to enter into a settlement agreement on behalf of the disclosing party.
- Certification statement.

OIG Self-Disclosure Protocol

Additional disclosure requirements

- New requirements for false billing disclosures, including a minimum sampling requirement of 100 items.
- Excluded persons disclosures.
- Greater detail regarding why disclosed conduct potentially violated the AKS and Stark Act, if applicable (*e.g.*, why arrangement was not commercially reasonable).
 - Also requires estimate of amount paid by federal health care programs for services associated with and total remuneration paid under unlawful arrangement.

OIG Self-Disclosure Protocol

Settlement Parameters

- \$10K floor for non-AKS disclosures/\$50K floor for AKS disclosures.
- 1.5 times multiplier presumed.
- Damages in false billing disclosures based on all affected claims or random sample, without “netting” of underpayments .
- AKS/Stark settlements typically based on multiplier of remuneration conferred by referral recipient to referral source.
- Previously refunded amounts will be credited.
- Presumption against corporate integrity agreements.
- Criminal matters referred to DOJ for resolution.
- Financial inability to pay must be documented with assessment of how much can be paid.

CMS Self-Referral Disclosure Protocol

Resolution

- CMS has the authority to accept a reduced overpayment (*i.e.*, less than 100%).
- CMS is clear to point out that it is under no obligation to accept the disclosing party's calculation of its financial liability or to compromise the overpayment at all.
- There are no limits on the reduction that CMS may make.
 - Theoretically, CMS may reduce the overpayment to \$0.

CMS Self-Referral Disclosure Protocol

Limitations

- Parties have no guarantee of acceptance into the SRDP.
- CMS will not waive the “refund to individuals” requirement in section 1877 of the Social Security Act which requires refund of any amounts collected that were billed in violation of the Stark law.
- Does not prohibit intervention by law enforcement.

Tips For Handling Self-Disclosures

- Adopt and implement policies to ensure satisfaction of the 60 day rule.
- Define “identification” of overpayments to occur following investigation and validation that overpayment was received and determination of the amount of the overpayment.
- Develop timely investigation and audit plan that avoids need to report and refund on a rolling basis to satisfy the 60 day rule when possible.
- Investigate “root cause” of overpayments to determine if they arose from intentional misconduct or reckless disregard of applicable law (ideally before quantifying damages).
- Limit investigation/audit scope to arrangements/claims where there is reason to believe that violations may have occurred.
- Consider pros and cons of reporting under a protocol v. to USAO or through routine channels.
- Ensure that disclosures satisfy all requirements and anticipate Government concerns.



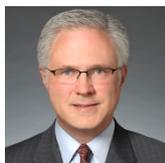
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Laura Keidan Martin is the national head of the firm's Health Care practice and a member of the firm's Board of Directors and Executive Committee. She counsels health care industry participants including health systems, national ancillary service providers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

Laura 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.

Laura 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 Lawyer of the Year 2012* for Chicago Health Care Law, and Leading Lawyers Network's "Top 10 Leading Women Lawyers in Illinois."



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W. Kenneth Davis, Jr. helps his health care industry clients design, structure and grow their businesses. Ken represents physicians, hospitals, ancillary service companies and other health care and e-health providers and businesses in transactional and regulatory matters.

Ken counsels clients as they form new businesses, joint ventures, management and other service relationships, networks and other relationships aimed at integrating and improving the efficacy of the health care process. His work involves a myriad of matters including initial structuring and business model development, analysis of regulatory and reimbursement issues, private equity, debt-based and lease-hold financing, and mergers and acquisitions. He also regularly provides health care compliance counsel for clients.

He is “highly regarded for his physician and managed care work” according to *Chambers USA*.

Ken advises clients on many changing health care regulations, including the Affordable Care Act, the Stark Act, Health Insurance Portability and Accountability Act (HIPAA), the Federal Anti-Kickback Statute and several state laws and tax regulations. He counsels clients on financial matters such as reimbursement issues and private equity, debt-based and lease-hold financing.

Prior to joining Katten, Ken served as vice president and general counsel for Princeps Inc., a Nashville, Tennessee-based physician practice management company focused on diagnostic radiology services. The company was the result of a merger between Healthcare Resource Management Inc. and Princeps Medical Practice Management Inc., which Ken co-founded and for which he served in dual capacities as chief operating officer and general counsel.

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