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Reports of Non-Compliant Activity, Internal Investigations, Resolutions and Self Disclosure

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Compliance, Internal investigations and Self- Disclosure: Building the Team, Process and Resolution; Learning Objectives

- Response to reports of non-compliant activity
- Organizational governance and internal investigations; authority and practical considerations
- Methodology for internal investigations; establishment, personnel and resources, probable cause and preponderance of evidence, privilege and findings of fact
- Practical tips; investigation workplan, conducting interviews, collecting documents and e-data, establishing facts and final report
- Resolution; remedial action and self-disclosure and managing the risk
- Compliance professionals and best practices

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Follow-up Response to Reports of Non-Compliant Activity

- Responding to reports of non-compliant activity and proliferation of Federal and State Government initiated investigations have led organizations to consider a response to and a strategy for such events and “internal investigations” are a central feature of an organization’s ability to effectively deal with these situations.



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Conducting an Internal Investigation (cont’d.)

- The initiation of an internal or parallel investigation is critical with reference to allegations raised against the organization or in connection with an internal compliance matter
- It is important for an organization’s resolution of an external enforcement investigative matter
- It is also important for an organization’s compliance strategy and compliance program and resolution of internal matters
- No substitute for the facts regarding a resolution of external and internal matters.

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The Duties and Rights of Employers and Employees Related to Internal Investigations

- The duty of an organization to investigate compliance matters
- The duty of loyalty and fair dealing for employees and the organization
- The duty of an employee to cooperate with an organization investigation
- The employee's rights to privacy and to work free from unreasonable interference and harassment
- The right to have your reputation protected.

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Legal Standards in Investigations

- A reasonable, fair, thorough, and prompt investigation which reaches reasonable conclusions usually protects employers against claims
- The investigation process should be consistent throughout the organization
- An investigation can only be sustained if there is probable cause and/or reliable and credible evidence of non-compliant conduct
- An ultimate factual conclusion must be based on a preponderance of the evidence (i.e. more than 50% probability)
- Right of employee to generally know results of investigation and best practice, but no right to review privileged investigation report
- The attorney-client privilege does not necessarily apply to factual findings of internal investigation, but does apply to advise of lawyer based on the factual findings.

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Legal Standards in Interviews

- Employees cannot refuse to cooperate and/or be interviewed by organization representatives without risking continued employment
- Do employees have Miranda rights?
- Employees have a basic right to fairness and this would be organization's "best practice"
- The employees right to be confronted with the proof and the opportunity to respond
- The prohibition against retaliation
- Confidentiality of the interview, subject to waiver of privilege
- The right to counsel
- Proper instructions protect the evidence.

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Evidence Collection in Investigations

- You must prove each element of an allegation by preponderance of evidence
- Proper evidence is relevant
- Proper evidence is material
- Proper evidence is competent
- Proper evidence is authentic/original
- Proper evidence can be direct or circumstantial
- You can use hearsay evidence-statements against interest and business records – statements by third parties – appropriate weight accorded to evidence.

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Legal Claims When Things Go Wrong

- Defamation of an employee
- Retaliation for cooperating with the investigation
- False imprisonment in interviews
- Intentional infliction of emotional distress
- Assault and battery
- Invasion of privacy
- Malicious prosecution

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When Must You Investigate?

- Any time there is:
 - A report of improper conduct or non-compliant activity
 - An allegation of a violation of law
 - A potential for a government overpayment
 - A potential for an overpayment by any other third-party payor
 - A potential for whistleblower activity

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Validate and Investigation "Work Plan"

- Validation of the original compliance report is essential and is the reason for an internal investigation
- Avoid rush to judgment
 - Measured investigative response
 - Avoid siege mentality-define scope and develop "work plan"
 - Don't rely on unverified information
- You rarely end up where you thought you would upon initiation of an internal investigation
- Do not ignore privileges and protections
- Do the work and find out the facts

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Doing Nothing is Risky

- Increased likelihood of diversion of attention from core business activities
- Greater potential for harm to reputation
- Greater potential for harm to individuals
- Potentially greater financial penalties and sanctions (i.e. suspension and/or exclusion) as issues walk out the door
- Lawsuits, including individual defendants
- Increased fees for counsel, consultants, experts
- Compliance with a government request for information (even if ill-founded) can be expensive and resource intensive under any circumstances
- Need to do the work and get a handle on situation before it becomes unwieldy and out of control and ends up in the hands of third parties, including enforcement and regulatory authorities

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Key Purposes for Your Investigations

- You must determine the facts and the back story
- You must determine the root causes of the non-compliant activities for corrective action
- Your findings must establish accountability and those involved in the non-compliant activity-individuals
- Your findings must maximize the decision-making process for management
- Your findings must help the bigger needs of the business. This includes avoiding and mitigating damages
- The investigation must be done timely both for practical reasons as well as to prove there was no cover-up of improper conduct

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Actual Failures Due to Lack of Investigation

- Compliance issues walk out the door-whistleblowers
- Demotions, counseling and bad evaluations after compliance issues reported
- Promotions of employees who caused non-compliance
- Complaints dismissed because employee was rude, incompetent, lazy, fill in the blank
- CFO knew of issue and commented, "if anyone finds out, we'll all go to jail"
- Multiple internal audit reports identified the issue and management ignored it
- Administrator looked the other way because the physician was a high admitter

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Practical Initial Questions

- Differing agendas in integrated settings?
- Conflicts of interest?
- What is the time period at issue?
- What if there are collateral issues?
- Who are the people internally to report to?
- Who is and who is not on the investigative team?
- How to preserve privilege?
- Who are interview candidates? Who are custodians of relevant documents and data?
- How much to reserve or escrow?

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Scope Of The Internal Investigation and “Work Plan”

- What is the scope of the subject matter to be addressed?
- Who will be directing the internal investigation and/or compliance investigative team and who will they be accountable to within the client organization
- The scope of the internal investigation and the proffer of fact and/or legal conclusions
- Notification of initial investigation to management
- Issues, individuals and documents and data
- Revise “Work Plan” when necessary

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Stakeholders Removed From Process

- Independence
- Objectivity
- Candor
- Credibility
- Fairness
- Effective compliance program
- Anti-retaliation

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How Much Must You Investigate?

- Depends on the facts
- Initially, need to investigate enough to gauge the credibility of the allegation and to advise client as soon as possible
 - Reliable and credible evidence and preponderance of evidence
- Dollar amount of potential exposure impacts practical decisions regarding scope, depth, and personnel involved in investigation
- Tailored Investigation vs "Boiling the Ocean"

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Who Should Investigate?

- Different categories of problems are best investigated by different personnel:
 - Human resources issues (such as sexual harassment or discrimination) should generally be investigated by the HR Department and/or employment counsel
 - Other general issues (non-criminal in nature, unlikely to result in substantial civil liability) can be initially investigated in-house
 - Need to consider whether attorney-client privilege may be important – involve counsel (in-house and/or outside)

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Who Should Investigate?

(Cont'd.)

- Different categories of problems are best investigated by different personnel:
 - Criminal issues or issues likely to result in significant civil liability (whistleblower situations, high dollar overpayments, systemic problems) should not be investigated without the assistance of competent and experienced legal counsel and investigative team
 - Attorney-client privilege important – may want outside counsel involved to strengthen application of attorney-client privilege

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Getting Outside Counsel Involved

- Expertise in white collar and health care compliance
- Familiarity with government enforcement and regulatory personnel
- Conflicts of interest and objectivity and independence
- Government's perception and credibility of organization
- Familiarity with industry compliance matters
- Cost
- Disruption to ordinary business activities
- Availability

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Considerations with Consultants

- Scope of engagement- Define and manage scope of investigation
- Qualifications for specific assignment
- Privilege and work product protection
- Flow of information and coordination with counsel and organization personnel

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Investigation Roadmap

- Investigations generally should follow the same basic roadmap:
 - Identify potential issues – those already identified, others that should be investigated
 - Identify individuals likely to have information, both inside and outside the company
 - Identify potentially relevant documents and institute document “holds” to prevent destruction or disposal
 - Identify individuals best suited to conduct investigation (in-house resources or outside counsel and/or consultants)
 - Prepare investigation plan – the more serious the issue, the more detailed the plan

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Risks and Benefits

- What are the potential risks and benefits of an investigation?
 - Risks include costs and disruptions to ordinary course of business – can be managed
 - Risk/benefit of potentially uncovering unknown additional issues and/or misconduct
 - Benefits include potential advantages of early disclosure, cooperation with any government investigation and potential for preferred treatment in charging decisions and under civil penalty provisions and sentencing guidelines
 - No substitute for knowing the facts

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Identify Investigative Personnel

- Investigations of serious issues (large amounts at stake, criminal issues) should be managed by counsel
- Who should direct counsel?
 - Senior management (CEO, COO, General Counsel?), but not “stakeholders”
 - Board of Directors
 - Audit or other independent committee of the Board of Organization

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Attorney-Client Privilege

- Attorney-client privilege protects communications between an attorney and client
 - Which were intended to be confidential
 - Which were made for the purpose of obtaining legal advice (not business advice)
 - As to which confidentiality has not been waived by disclosures to third parties or otherwise
- More difficult to demonstrate that communications to in-house counsel meet each prong of this test – Advantage of using outside counsel

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Attorney-Client Privilege/Consultants & Others

- Attorney-client privilege extends to agents retained by the attorney to assist in providing legal advice to the client
 - Applies to secretaries and clerks
 - Also applies to investigators, interviewers, technical experts, accountants, consultants, and other specialists
- Attorney-client privilege applies to communications with agents as if communications had been with attorney
 - Between client and agent
 - Between agent and attorney

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Evaluating the Evidence

- You owe it to the company, the investigation process, and the people involved to get done quickly
- Determine whether your gathered information matches your scope
- The burden of proof is the preponderance of the evidence
- Determine the credibility of the witnesses
- Don't be afraid to get a second opinion

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Investigation Complete

- Counsel should report to client, including
 - Discovered facts
 - Remaining unknowns
 - All implicated or potentially implicated laws, and
 - Counsel's analysis of the facts (and unknowns) in light of those laws
- Report must remain confidential-limit circulation of report-oral report preferred
- Oral or written

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Fix the Problem

- Using the report, identify corrective action needed to fix the problem
- Need to assess compliance process and policies to identify deficiencies in existing compliance programs and reporting mechanisms (i.e. "root cause analysis")
- Responsible employees should be disciplined, as appropriate
- Additional policies, procedures, or reporting layers should be added as necessary to promote future compliance

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Now What- - Voluntary Disclosure?

- Need to discuss with client:
 - Whether the past conduct involves liability to third parties, including the government and whether it needs to be resolved.
 - Options of self-disclosure – to whom? Department of Justice, Office of Inspector General of Health and Human Services, Center for Medicare and Medicaid Services, Attorney General?

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Self Disclosure Process

1. Investigation and Evaluation
2. Consider the Benefits and Risks
3. Consider Which Entity to Disclose to
4. Submit a Timely, Complete and Transparent Disclosure
5. Anticipate Government Validation
6. Resolution – Strategies and Options

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Is it “Voluntary?”

- Misprision of a Felony – 18 U.S.C. § 4 provides that “whosoever...having knowledge...of a felony...conceals and does not as soon as possible make known the same...shall be fined...imprisoned...or both
 - Requires active concealment
- Medicare Statute – 42 U.S.C. § 1320a-7b(a)(3) arguably makes it a felony to conceal or “fail to disclose” facts affecting right to receive payment

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Is it “Voluntary?”

- False Claims Act – Amendments to the FCA made as part of Fraud Enforcement and Recovery Act of 2009 (FERA) – 31 U.S.C. § 3729(a)(1)(G)
 - Illegal to “knowingly conceal...or knowingly and improperly avoid...or decrease...an obligation to pay or transmit money or property to the Government...”
- Presentment of claim not essential for False Claims Act Liability under Affordable Care Act
- Affordable Care Act establishes “obligation” to report “identified” overpayment within sixty (60) days

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Disclosure Considerations

- Decision to disclose should be made in conjunction with counsel, but is a business decision – weighing potential risks and benefits
 - Where available, self disclosure may offer protections too significant to pass up and is it really voluntary
 - Useful for substantial violations of law and whistleblower risk
 - Leaves as an open question more minor or isolated violations – time + expense + minimum settlement may make minor disclosures prohibitively costly
 - Continuing focus on compliance programs, good faith cooperation and prompt disclosure

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Weigh Pros and Cons With Counsel

- “Potential advantages of self-disclosure:
 - Goodwill with government
 - Limiting possibility of external investigation
 - Expediting process of resolution
 - Reducing criminal and civil liability
 - Neutralizing whistleblower threat and lawsuits
 - Lessening overall damages and penalties

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Weighing Pros and Cons (cont'd.)

- Potential disadvantages of self disclosure:
 - Financial loss – government motivated by recovery whether discovered or disclosed
 - Increased government scrutiny – validation process
 - No immunity from liability or prior commitments
 - Possible penalties for conduct that may have remained undiscovered.

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Choosing A Government Entity

- Self-disclosure can be made to:
 - Office of Inspector General of the Department of Health and Human Services (**OIG-HHS**) – Self Disclosure Protocol (SDP)
 - Centers for Medicare and Medicaid Services (**CMS**) – Self Referral Disclosure Protocol (SRDP)
 - Department of Justice, U.S. Attorney's Office (**DOJ**)
 - State Attorney General's Office

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General Guidelines

- Disclose billing errors and mistakes to entity processing claims and payment
- Disclose matters indicating civil liability under Civil False Claims Act to DOJ and/or OIG-HHS
- Disclose matters indicating criminal liability to DOJ and/or OIG-HHS
- Where, when and how to voluntarily disclose involves careful considerations

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OIG Self-Disclosure Protocol (SDP)

- Full cooperation and complete disclosure
- Submission violates laws, not a “mistake”
- Minimum settlement amount of \$50,000
- Submit within 60 days from discovery
 - False Claims Act - 30 days limits damages
- Ongoing fraud scheme = more immediacy
- Physician self-referral matter with colorable anti-kickback statute violation
- Follow Self-Disclosure Protocol, done in 3 months

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CMS' Stark Self-Referral Disclosure Protocol (SRDP)

- Report and return overpayment 60 days from identification or from when cost report due
- Follow CMS' Protocol - SRDP
- Open access to all financial records, including work product
- Intended to resolve physician self-referral matters ("Stark" law) without extraordinary financial liability
- When no anti-kickback matter exists, use CMS' Protocol
- When anti-kickback matter exists, must choose either CMS or OIG for disclosure, not both

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Settlement Factors

- CMS may consider the following:
 - (1) the nature and extent of the improper or illegal practice;
 - (2) the timeliness of the self-disclosure;
 - (3) the cooperation in providing additional information related to the disclosure;
 - (4) the litigation risk associated with the matter disclosed; and
 - (5) the financial position of the disclosing party

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Self-Disclosure to DOJ

- DOJ is a law enforcement agency
- Unlike OIG and CMS, No formal protocol
- Criminal jurisdiction and civil authority under the False Claims Act
- Ability to release organization from liability

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Agency Coordination

- OIG confers with DOJ before acceptance
- OIG confers with DOJ before resolution
- OIG resolution not binding on DOJ
- Disclosing party can request DOJ or OIG presence in settlement discussions to resolve parallel liability
- CMS or Fiscal Agents can refer matters to OIG and DOJ

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Many Possible Settlement Factors

- Effectiveness of pre-existing compliance program
- Nature of the conduct and financial impact
- Ability to repay
- First-time offender, isolated and distinct incident
- Low-level bad actors
- Efforts to correct problem
- Successor liability under former management
- Period of conduct
- How matter was discovered
- Level of cooperation, candor, flexibility
- Relationships
- Etc.

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Final Advice

- There is no “one size fits all” approach to voluntary self-disclosure
- These decisions should be made with the assistance of competent and experienced counsel

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Key Takeaways

- Establish Policy and Procedure for Organization Response to Reports of Non-Compliant Activity
- Internal Investigation Capability is Important for Governance and Compliance Program Effectiveness
- Internal Investigations are Critical to the Organization Response and Resolution of Reports of Non-Compliant Activity
- Establish Organizational Acceptance and Standards for Conducting Internal Investigation
- Remedial Action and/or Self-Disclosure is Important for Management of Risk
- Experience and Best Practices are Important for Effective Internal Investigations and Avoidance of Risk

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THE END

QUESTIONS?

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