Government Investigations and Compliance Matters: Roadmap for In-House Counsel and Compliance Professionals 21st Compliance Institute Health Care Compliance Association Washington, D.C. 29 March 2017 BASS BERRY+SIMS. Overview

- DOJ Direction to target responsible individuals
- Legal standards
- Anti-Kickback Statute
- Stark law
- False Claims/Statements
- Role of compliance professionals
- Employee reports and hotline calls
- Who needs individual counsel
- How to investigate allegations of fraud and abuse
  - Documents
  - Witnesses
  - Reporting results

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## Direction to Target Responsible Individuals Deputy Attorney General Yates -- Sept. 9, 2015



- · Yates Memo direction is not new. In Civil FCA investigations, companies receive no credit for cooperation without providing "all relevant facts relating to" responsible individuals.
- responsible individuals.

  In FCA practice, DOJ refuses to identify issues and individuals of interest during initial meetings.

  Involve counsel early in process to outline legal standards and issues.
- legal standards and issues.

  Determine if allegations are sufficiently serious to merit retaining outside counsel:

  Criminal

  Civil

  Administrative/Overpayment
- Dealing with costs, requests for individual counsel
- Complications of settlement including CIA

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#### Legal Standards -AKS

- Anti-Kickback Statute prohibits knowingly & willfully paying, offering, soliciting or receiving remuneration in return for referral
- Safe Harbors & exceptions similar to Stark exceptions (space & equipment rental, personal services & mgmt. contracts, sale of practice, bona fide employment, physician recruitment, etc.)
- "One Purpose" rule

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#### Legal Standards - Stark Law

- Stark law: If physician (or immediate family member) has financial relationship with entity (e.g. hospital), physician may <u>not</u> make referral to entity for designated health service ("DHS") and entity may <u>not</u> submit claims for such services.
- "Designated Health Services" = Lab services, therapy services, radiology/imaging, DME, prosthetics & orthotics, home health services, outpatient Rx drugs, inpatient & outpatient hospital services.
- "Financial relationship" under Stark? Any ownership or investment interest; Any compensation arrangement (defined as "any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity" with certain very limited exceptions..
- "Referral" is defined very broadly, and includes: A request for, or ordering of, DHS; Establishment of a plan of care, etc.
- Safe Harbors and Exceptions: Rental of office space & equipment, Bona fide employment, Personal service arrangements, Physician recruitment, Isolated Transactions, Remuneration unrelated to DHS, etc.

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## Legal Standards - FCA

- False Claims Act prohibits, among other things:
  - Knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval
  - Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim
  - Knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the government
    - · Retention of overpayment
    - 60-day rule
- Qui tam actions

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# Role of Compliance, In-House and Outside Counsel to Company

- Whistleblowers work with government to identify and prosecute cases
- Does the entity have an effective compliance program?
- Will it be necessary to conduct employee interviews?
- Who will handle them?
- How will interviews be memorialized?
- Will the company retain counsel for employees if requested?
- How will the company handle a refusal to cooperate?

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## Investigation

- Take every compliant and allegation seriously.
- What are the issues?
- What is the applicable legal standard?
- Who at company/entity decides whether compliance will conduct initial investigation?
- What are the risks of compliance acting without direction of counsel?
- $\bullet \quad \text{Making yourself a witness/accomplice/co-conspirator.} \\$
- Cost of outside counsel vs. cost of foregoing outside counsel.
- Pitfalls: waived privileges, binding admissions, payment suspension, loss of licenses or privileges, penalties, imprisonment, and government-wide exclusion.

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# Questions

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