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KAYE SCHOLER

**Government Investigations and Compliance
Matters: Roadmap for In-House Counsel and
Compliance Professionals**

21st Compliance Institute
Health Care Compliance Association
Washington, D.C.
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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

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|  <p style="text-align: center;">U.S. Department of Justice Office of the Deputy Attorney General</p> <hr/> <p style="text-align: center;">Washington, D.C. 20530 September 9, 2015</p> <p>MEMORANDUM FOR THE ASSISTANT ATTORNEY GENERAL, ANTI-TRUST DIVISION THE ASSISTANT ATTORNEY GENERAL, CIVIL DIVISION THE ASSISTANT ATTORNEY GENERAL, CRIMINAL DIVISION THE ASSISTANT ATTORNEY GENERAL, ENVIRONMENT AND NATURAL RESOURCES DIVISION THE ASSISTANT ATTORNEY GENERAL, NATIONAL SECURITY DIVISION THE ASSISTANT ATTORNEY GENERAL, TAX DIVISION THE DIRECTOR, FEDERAL BUREAU OF INVESTIGATION THE DIRECTOR, EXECUTIVE OFFICE FOR UNITED STATES ATTORNEYS ALL UNITED STATES ATTORNEYS</p> <p>FROM: Sally Quillian Yates  Deputy Attorney General</p> <p>SUBJECT: <u>Individual Accountability for Corporate Wrongdoing</u></p> <p><small>Fighting corporate fraud and other misconduct is a top priority of the Department of Justice. Our nation's economy depends on effective enforcement of the civil and criminal laws that protect our financial system and, by extension, all our citizens. These are principles that the Department lives and breathes—as evidenced by the many attorneys, agents, and support staff who have worked tirelessly on corporate investigations, particularly in the aftermath of the financial crisis.</small></p> <p><small>One of the most effective ways to combat corporate misconduct is by holding accountability from the individuals who perpetrated the wrongdoing. Such accountability is important for several reasons: it deters future illegal activity, it incentivizes changes in corporate behavior, it ensures that the proper parties are held responsible for their actions, and it promotes the public's confidence in our justice system.</small></p> | <ul style="list-style-type: none"> ▪ 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. ▪ 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. ▪ Determine if allegations are sufficiently serious to merit retaining outside counsel: <ul style="list-style-type: none"> ▪ 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 not make referral to entity for designated health service (“DHS”) and entity may not 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 complaint 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?
- 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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