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

Privileged & Confidential
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.
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:
- Criminal
- Civil
- Administrative/Overpayment
Dealing with costs, requests for individual counsel
Complications of settlement including CIA

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
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**
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?

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?
- 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.
Questions

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