Presentation Overview

• The Applicable Law
  – Anti-Kickback Statute
  – Physician Self-Referral Law (“Stark Law”)
  – False Claims Act (“FCA”)
• DOJ and OIG Focus on Physician Compensation
  – June 2014 Fraud Alert
  – Recent Cases
  – Enforcement Trends
• Best Practices for Compliance & Investigation Responsiveness
The Applicable Law

The Applicable Law:

Anti-Kickback Statute

- **Criminal penalties** for physicians and entities “who knowingly and willfully solicit[] or receive[] any remuneration” in exchange for patient referrals from federal health care programs.

- Remuneration includes anything of value, including:
  - rent
  - staffing compensation
  - excessive compensation for medical directorships or consultancies

- Potential consequences of violation:
  - **Jail terms** of up to five years
  - Fines of up to **$25,000 per violation**
  - Expulsion from participation in federal health care programs
  - Penalties of up to **$50,000 per kickback plus three times the amount of remuneration**
The Applicable Law:
Safe Harbor

- Safe harbor provisions were developed “to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements.” 56 FR 35952, 35958 (July 29, 1991).
- Safe harbor payments include:
  - Returns on investment interests, such as dividends or interest income
  - Space or equipment rentals
  - Personal service and management contracts
  - Payments made in connection with the sale of a practice
  - Payments for referral services or practitioner recruitment
  - Discounts or other price reductions

The Applicable Law:
Physician Self-Referral Law (“Stark Law”)

- Prohibits physicians who have a financial relationship, including compensation arrangements, with a health care entity from referring patients to that entity to receive “designated health services” billed to federal health care programs.
- Mandates that all payments made to referring physicians be at fair market value for the services rendered.
- Potential consequences of violation:
  - Denial of payments
  - Refund of payments
  - A $15,000 per service civil penalty
  - Civil assessments of up to three times the amount claimed
The Applicable Law: Exceptions to the Stark Law

- Akin to the safe harbor provisions of the Anti-Kickback Statute, there are a number of statutory exceptions to the Stark Law, including:
  - Payments as part of ownership or investment interests
  - Bona fide compensation arrangements for employment and personal service arrangements
  - Physician recruitment
  - Payments for space or equipment rentals

The Applicable Law: False Claims Act (“FCA”)

- Prohibits submission of fraudulent claims for payment to federal health care programs.
  - Claims that violate the Anti-Kickback Statute and/or the Stark Law may also render the claims fraudulent under the FCA.

- Civil penalties include fines of up to three times the program’s loss plus $11,000 per claim filed.
DOJ and OIG Focus on Physician Compensation

DOJ and OIG Focus: June 2015 Fraud Alert

- Increasing focus on subjecting both health care companies and individual physicians to criminal and civil penalties.
- On June 9, 2015, HHS-OIG issued a special fraud alert cautioning that physicians who enter into compensation arrangements “must ensure that those arrangements reflect fair market value for bona fide services the physicians actually provide.”
- “[E]ven if one purpose of the arrangement is to compensate a physician for his or her past or future referrals of Federal health care program business,” an otherwise legitimate compensation arrangement may violate the anti-kickback statute.
- The HHS-OIG placed the onus on physicians to “carefully consider the terms and conditions” of their compensation arrangements before entering into them.
DOJ and OIG Focus: “Fair Market Value”

- **Hospitals**
  - *Adventist Health System* (September 21, 2015)
    - $115 million settlement.
    - Physician bonuses allegedly calculated based on “bottom line” and “pay for play” formulas that took into consideration number of tests and procedures ordered by referring physician.
    - Physicians’ compensation also allegedly exceeded fair market value and was commercially unreasonable.
    - $74 million settlement to resolve $237 million judgment.
    - Contracts with 19 specialist physicians that allegedly required the physicians to refer their outpatient procedures to Tuomey and, in exchange, paid them compensation that far exceeded fair market value.

- **Hospitals (cont.)**
  - *North Broward Hospital* (September 15, 2015)
    - $69.5 million settlement.
    - Hospital engaged in allegedly improper financial relationships with referring physicians:
      - Compensation formulas allegedly considered volume and value of physician referrals.
    - Payment of compensation to nine physicians purportedly exceeded the fair market value of their services.
  - *Columbus Regional Healthcare System* (September 4, 2015)
    - $25 million settlement and additional contingent payments of up to $10 million.
    - Alleged payment of excessive salary and directorship payment to physician.
DOJ and OIG Focus: “Fair Market Value”

- Hospitals (cont.)
  - Citizens Medical Center (April 21, 2015)
    - $21.75 million settlement.
    - Alleged payment of compensation and bonuses to several cardiologists exceeded the fair market value of their services and improperly took into account the value of their cardiology referrals.
  - Tri-City Medical Center (January 15, 2016)
    - $3.2 million settlement.
    - Center allegedly maintained 97 financial arrangements with physicians and physician groups that did not comply with the Stark Law.

- Hospitals (cont.)
  - Westchester County Health Care Corporation (May 14, 2015)
    - $18.8 million settlement.
    - Alleged advanced payment of money to cardiologist group for services as “consultants” to open practice for sole purpose of generating referrals to hospital.
    - Hospital allegedly allowed cardiologist group to use hospital fellows free of charge (contrary to historic practice).
  - Aria Health Systems, Inc. (December 23, 2015)
    - $2.5 million settlement.
    - Alleged Payment of compensation to cardiac thoracic physician and purchase of a trademark name in acquisition of orthopedic group exceeded their fair market value.
DOJ and OIG Focus: “Fair Market Value”

- Skilled Nursing Facilities
  - Hebrew Homes Health Network, Inc. (June 16, 2015)
    - $17 million settlement.
    - Alleged payment of referral fees to physicians for patient referrals. Involved an allegedly sophisticated kickback scheme where doctors were hired as “medical directors” with no real job responsibilities in order to cover kickback payments.
    - “[L]argest settlement involving alleged violations of the Anti-Kickback Statute by skilled nursing facilities in the United States.”
    - Individual consequences: Executive Director agreed to resign and no longer be an employee of the company.

DOJ and OIG Focus: What Constitutes a Kickback?

- Hospitals
  - Millennium Health (October 19, 2015)
    - $256 million settlement.
    - Alleged provision of free drug test cups on the express condition that the physicians return the specimens to Millennium for hundreds of dollars’ worth of additional testing.
  - Mercy Medical Communities (August 13, 2015)
    - $5.5 million settlement.
    - Allegations that physicians received bonuses based on a formula taking into consideration the value of the physicians’ referrals to the clinics.
DOJ and OIG Focus: What Constitutes a Kickback?

- **Laboratories**
  - Berkeley Heart Lab, Inc. (April 9, 2015)
    - $48.5 million settlement.
    - Alleged payment of processing and handling fees of $10 to $17 per referral and routine waiver of patient co-pays and deductibles.

- **Pharmaceutical Companies**
  - Daiichi Sankyo, Inc. (January 10, 2015)
    - $39 million settlement.
    - Alleged excessive speaker fees (e.g., “speaking” on duplicative topics) and lavish entertainment (e.g., expensive dinners).
  - Physician Pharmacy Alliance, Inc. (May 6, 2015)
    - $5 million settlement.
    - Allegedly gave physicians “improper” gift cards and routinely waived co-payments to induce referrals.
DOJ and OIG Focus: What Constitutes a Kickback?

- Medical Device Companies
  - NuVasive, Inc. (July 30, 2015)
    - $13.5 million settlement.
    - Promotional speaker fees.
    - Alleged honoraria and expenses relating to physicians’ attendance at events sponsored at “Society of Lateral Access Surgery,” an organization owned and funded solely by NuVasive.
  - Olympus Corp. of the Americas (March 1, 2016)
    - $623.2 million settlement. Foreign subsidiary to pay $22.8 million.
    - Allegedly won new business and rewarded sales by giving doctors and hospitals kickbacks, including consulting payments, foreign travel, lavish meals, millions of dollars in grants, and free endoscopes.
    - Required to adopt several compliance measures to remedy its problems.

DOJ and OIG Focus: Conditions of Employment and Grants

- Hospitals
  - South Shore Physician Hospital Organization (January 20, 2015)
    - $1.775 million settlement.
    - Terms of grant to physicians allegedly required that grant recipients refer patients to participating providers.

- Laboratories
  - Family Dermatology of Pennsylvania, P.C. (April 21, 2015)
    - $3.2 million settlement.
    - Dermopathology laboratory/clinic operator employed dermatologists as independent contractors and allegedly routinely required them to use in-house pathology lab, resulting in improper self-referrals.
DOJ and OIG Focus: Other Notable Cases

- **Hospitals**
  - Memorial Health, Inc. (December 23, 2015)
    - $9.895 million settlement.
    - Alleged financial incentives for referrals.
    - Largest civil health care fraud recovery in the history of the United States Attorney’s Office for the Southern District of Georgia.

Enforcement Trends: Individual Liability

- **Focus on Individual Liability (“Yates Memo”)**
  - U.S. Department of Justice issued a memorandum in September 2015 confirming DOJ’s increasing and public focus on individual prosecutions for fraud.
  - Companies under investigation must report individuals involved in the fraud in order to be eligible for any cooperation credit.
Enforcement Trends: Individual Liability

- **Individual Liability in Action:**
  - Sacred Heart Hospital (July 31, 2015)
    - Former executives and physicians convicted and sentenced to prison terms for alleged role in orchestration and participation in unlawful kickback compensation schemes.
  - Hebrew Homes Health Network, Inc. (June 16, 2015)
    - Skilled nursing facility paid $17 million to settle Anti-Kickback Statute claims alleged against it; its Executive Director agreed to resign and no longer be an employee of the company.

- **Individual Liability in Action (cont.):**
  - Former Owner, Mark T. Conklin (March 2, 2016)
    - Former owner, operator, and sole shareholder of Recovery Home Care Inc. agreed to pay $1.75 million to settle lawsuit alleging illegal kickbacks to doctors who agreed to refer Medicare patients.
    - Conklin allegedly paid dozens of physicians thousands of dollars per month to serve as sham medical directors who supposedly conducted quality reviews of patient charts but often performed little work.
  - Physician Assistant, Kyle D. Gandy (January 12, 2016)
    - Sentenced to 14 months in prison and two years of supervised release for accepting $1,000 in illegal kickbacks for referring patients to medical clinics, physical therapy clinics, and a home health care agency.
    - Ordered to pay $18,030.17 in restitution, representing the amount of the referred services paid by Medicare and Medicaid.
    - Excluded from participating with the Medicare and Medicaid programs for at least five years.
Enforcement Trends: Corporate Integrity Agreements

- HHS-OIG are increasingly using Corporate Integrity Agreements ("CIAs") to ensure provider compliance with Medicare.
- Health care providers under investigation may agree to a CIA as part of settlement.
  - Over 50% of the CIAs currently in effect were entered into over the past two years.

Enforcement Trends: Corporate Integrity Agreements

- CIAs can be rigorous and may require a provider to:
  - establish training and compliance programs;
  - retain independent monitors to oversee and audit compensation agreements;
  - retain independent advisors to assess effectiveness of compliance programs;
  - provide periodic reports to OIG regarding compliance; and
  - agree to other terms as necessary to target a provider’s alleged violation(s).
Best Practices for Compliance & Investigation Responsiveness

Best Practices: Minimizing Exposure

- *Reasonable* measures, not perfection: A strong internal compliance program may not prevent a rogue employee from committing fraud, but it may defeat scienter.
- Adopt a formal business ethics compliance program and internal control system.
  - Develop standards and procedures to prevent, detect, and respond to improper conduct.
  - Monitor compliance through regular internal and external audits.
  - Create a compliance hotline and conduct formal investigations into complaints.
  - Conduct employee compliance training and consistently inform employees of outlets for grievances.
Best Practices: Comparative Compliance

- Compliance cannot be executed in a vacuum. A strong internal compliance program is further strengthened through the utilization of:
  - Third-party benchmarks
  - Third-party valuations
  - Independent auditors and/or consultants

Best Practices: Risk Assessment

- Monitor government interactions.
  - Understand express certifications in government contracts and programs.
  - Account for use of government contract funds and grants.
  - Evaluate business partners, especially government subcontractors.
  - Document the government’s knowledge, awareness and ratification of contractual and programmatic deviations.
- Take care in responding to billing inquiries as incorrect explanations may be used as evidence of fraud.
- Documentation and transparency are key.
**Best Practices: Investigation Responsiveness**

- Critical to know of FCA complaints as soon as possible.
- Whistleblower warning signs:
  - HR issues; exit interview statements
  - Unexpected audits
  - Requests for billing explanations
  - Increased web activity
  - Former employees contacted
- Contact and present your case to DOJ and USAO.
  - The most critical juncture is the government’s intervention decision.

---

**Whistleblowers**

Of the 22 cases in this presentation, 18 were *qui tams*.

Relators:
- 7 were doctors
- 8 were employees
- 4 were executives

Many *qui tam* suits follow a termination of employment.
Once in litigation:

- File motion to dismiss:
  - Rule 12(b)(6): Theories of liability
  - Rule 12(b)(1): Jurisdictional arguments (e.g., public disclosure, first-to-file, etc.)
  - Rule 9(b)
- Consider privilege and potential waiver issues early on.
- Identify “sources of corporate knowledge”: Whose scienter matters?
- Conduct a damages analysis.
- If government declines intervention, keep lines of communication open.
  - Ability to settle often depends on the government.
Best Practices: Privileged Internal Investigation

- Internal investigation **must include an attorney to preserve privilege.**
  - Work should be performed at the direction of the attorney.
  - Employees should receive *Upjohn* warning in interviews.
  - Consider retaining independent counsel for employee-witnesses and employees who may face individual exposure.
- *Barko v. Halliburton* (D.D.C. March 2014): Certain reports generated by in-house counsel’s internal investigation were not privileged because they were created as part of a routine investigation required by regulatory law and company policy.
- *In re Kellogg, Brown & Root, Inc.* (D.C. Cir. June 2014): Overturned *Barko* in holding that internal investigation materials were privileged “[s]o long as obtaining or providing legal advice was one of the significant purposes of the internal investigation.”

---

Winston Y. Chan is a partner in Gibson, Dunn & Crutcher’s San Francisco office. He is an experienced trial and appellate attorney, and is a member of the firm’s White Collar Defense and Investigations Practice Group. He regularly represents entities and individuals in criminal and civil False Claims Act matters, and conducts internal investigations and compliance reviews for healthcare and life sciences companies.

From 2003 to 2011, Mr. Chan served as an Assistant United States Attorney in the Eastern District of New York, where he investigated and prosecuted a wide range of matters as part of that office’s Business and Securities Fraud Section, including False Claims Act matters, Foreign Corrupt Practices Act violations, hedge fund improprieties, insider trading, accounting fraud, market manipulation, and fraudulent offerings of securities. Mr. Chan served in a number of supervisory roles and received a variety of departmental awards and commendations. In particular, he served as that office’s Healthcare Fraud Coordinator, overseeing all *qui tam* and whistleblower investigations involving allegations of FCA violations, kickbacks, misbranding and off-label promotion.

Mr. Chan earned his undergraduate degree, *magna cum laude*, from Yale University, and his Juris Doctor from Yale Law School. In 2014, Mr. Chan was named in Law360 as one of just five nationwide “Rising Stars” in the government enforcement defense and investigations field.
William J. Harrington

Mr. Harrington is a partner at Goodwin Procter in New York City. A former federal prosecutor, Mr. Harrington is an experienced trial lawyer and appellate advocate. He specializes in government civil and regulatory actions, criminal defense, and internal investigations. Mr. Harrington is an expert in federal civil fraud suits and medical kickback cases under the False Claims Act.

Mr. Harrington worked in the Criminal Division of the U.S. Attorney’s Office for the Southern District of New York from 2006 through 2012. In his last two years at the U.S. Attorney’s Office, Mr. Harrington regularly worked on parallel investigations with the Civil Division of the U.S. Attorney’s Office, including the management of criminal investigations based on qui tam complaints. He served as the S.D.N.Y.’s Criminal Health Care Fraud Coordinator, responsible for fraud investigations and prosecutions involving health care providers and pharmaceutical companies.

Mr. Harrington earned his B.A., magna cum laude, from Yale College, and his J.D. from Yale Law School. Mr. Harrington is currently recognized as a top rated white collar lawyer by Super Lawyers, one of the world’s leading white collar crime lawyers by Euromoney’s Expert Guides: White Collar Crime Lawyers, and a leading white collar lawyer by Legal 500. He is also listed in Global Investigations Review 100, a guide to the world’s leading firms for corporate investigations.

Jeffrey Marcus

Jeffrey Marcus is a co-founder and partner of Marcus Neiman & Rashbaum in southern Florida. Jeff is an experienced trial lawyer and former federal prosecutor. His practice focuses on white collar criminal defense, complex civil litigation, qui tam litigation and internal investigations. He has a niche specialty in representing clients in qui tam False Claims Act cases in such areas as healthcare, pharmaceuticals, and government contracting.

Jeff has been recognized by a wide range of peer groups and publications for his litigation prowess. Chambers USA describes Jeff as “very smart” “with a keen eye for understanding the dynamics and strategy of a case,” observing that peers praise him for his “thorough and conscientious approach.”

Jeff was a federal prosecutor in the Southern District of Florida’s Criminal Division where he successfully tried more than 25 cases to verdict and never lost a case as lead counsel. As a prosecutor, Jeff specialized in economic crimes, with an emphasis on healthcare and pharmaceuticals, and led numerous investigations involving corporations and their officers and employees.

Raised in Miami, Florida, Jeff earned his B.A., magna cum laude and Phi Beta Kappa (early selection) from Yale University and his J.D. from The Yale Law School.