I. The Anti-kickback Statute

- 42 USC § 1320a-7b(b)(2)
- It is unlawful to knowingly and willfully offer or pay any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person - -
  
  a) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

  b) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program
The Anti-kickback Statute

- What it all means? – Prohibits anyone from purposefully offering, soliciting, or receiving anything of value to generate referrals for items or services payable by any Federal health care program.

- 42 states and D.C. have enacted their own anti-kickback statutes.

Elements

- Remuneration

- Offered, paid, solicited, or received

- Knowingly and willfully

- To induce or in exchange for Federal program referrals
Remuneration

- Anything of value
- “In-cash or in-kind”
- Paid directly or indirectly
- Examples: cash, free goods or services, discounts, below market rent, relief of financial obligations

Offered, Paid, Solicited, Or Received

- Different perspectives – payers and payees
- “It takes two to tango”
- Old focus: payers subject to prosecution
- New focus: payers and payees (usually doctors)
To Induce Federal Program Referrals

- Any Federal health care program
- A nexus between payments and referrals
- Covers any act that is intended to influence and cause referrals to a Federal health care program
- One purpose test and culpability can be established without a showing of specific intent to violate the statutory prohibitions

Fines And Penalties

- The Government may elect to proceed:
  
  **Criminally:**
  
  - Felony, imprisonment up to 5 years and a fine up to $25,000 or both
  - Mandatory exclusion from participating in Federal health care programs
  - Brought by the DOJ
Civilly:

- A violation of the Anti-Kickback Statute constitutes a false or fraudulent claim under the Civil False Claims Act
- Penalties are same as under False Claims Act (more later)
- Controversial, yet common basis for FCA liability (more later)

Administratively:

- Monetary penalty of $50,000 per violation and assessment of up to three times the remuneration involved
- Discretionary exclusion from participating in Federal health care programs
- Brought by the OIG
Many harmless business arrangements may be subject to the statute

Approximately 24 exceptions (“Safe Harbors”) have been created by the OIG

Compliance is voluntary

Must meet all conditions to qualify for Safe Harbor protection

Is substantial compliance enough?

Many courts have held under an express or implied certification theory that a violation of AKS is actionable under the False Claims Act

- Allows for significant penalties
- Allows for whistleblowers to bring actions

The following language in the Statute presents as follows:

“In addition to the penalties provided for in this section, . . ., a claim that includes items or services resulting from a violation of this section (i.e. Anti-Kickback Statute) constitutes a false or fraudulent claim for purposes of the [False Claims Act].” § 1128B9g) (Emphasis added)
Guidance On The Anti-kickback Statute

- Advisory Opinions from the OIG
  - A party may request advice on the law, concerning (1) remuneration within the meaning of the law, (2) whether they are meeting one of the law’s exceptions or safe harbors, or whether their arrangement warrants the imposition of a sanction
  - General guidance and notice on compliance matter, but not precedential law

Guidance On The Anti-kickback Statute (Cont’d.)

- Fraud Alerts and Special Advisory Bulletins
- Preamble to the Safe Harbor Regulations
- Compliance Program Guidance’s
- www.oig.hhs.gov
Foreign Corrupt Practices Act

- Offers of payment of a bribe to a foreign government official to obtain a business advantage
- Pharmaceutical and medical device manufacturers
- Others who do business in foreign countries (i.e. hospitals).

The Stark Law

- Section 1877 of the Social Security Act, 42 U.S.C. 1395nn
- The law is complicated and consists of the original statute (Stark I in 1989) and the amended provisions (Stark II in 1996)
- Stark regulations have gone into effect in phases (I, II and III) in 2002 and 2004, 2008 and 2009, but some are still pending.
The Stark Law

- A prohibition on physician self-referrals
- If a physician (or immediate family member) has a direct or indirect financial relationship (ownership or compensation) with an entity that provides designated health services (“DHS”), the physician cannot refer the patient to the entity for DHS and the entity cannot submit a claim for the DHS, unless the financial relationship fits an exception.

Difference Between Anti-kickback Statute And The Stark Law

- Physician referrals only
- No “knowingly and willfully standard” – strict liability
- Involves Designated Health Services (“DHS”)
Types Of Designated Health Care Service (“DHS”)

- Clinical laboratory
- Physical therapy
- Occupational therapy
- Radiology and Imaging Services (MRI, CAT, scan, ultrasound)
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment and supplies
- Prosthetics, orthotics and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

What Is A Financial Relationship?

- Nearly any type of investment or compensation agreement between the referring physician and the DHS entity will quality as a financial arrangement under the Stark law

Examples:
- Stock ownership
- Partnership interest
- Rental contract
- Personal service contract
- Salary

- Compensation agreements can be direct or indirect
  - Exceptions for certain indirect compensation arrangements
Exceptions

- Compliance is mandatory
- Types of exceptions:
  - In-office ancillary services
  - Personal physician services by member of group practice
  - Pre-paid health plan
  - Certain publicly traded securities
  - Rural provider (investment interests)
  - Hospital ownership (must be in the “whole” and not “specialty” hospital)
  - Rental of office space and equipment
  - Bona fide employment
  - Personal services arrangement
  - Physician recruitment

Closer Look At Stark Exceptions

- **In Office Ancillary Services** (an exception that applies to both ownership and compensation)
- The **Physician Services Exception** (an exception that applies to both ownership/investment interests and compensation)
- The **Rural Provider** exception (an exception that applies to only ownership/investment interests)
- The **Rental of Office Space and Equipment** exception (a compensation only exception)
- The **Personal Services Arrangements** exception (a compensation only exception).
Other Stark Exceptions (Cont’d.)

- The exception for *Electronic Health Records* (a compensation only exception).
- The exception for *Electronic Prescribing* (a compensation only exception)
- The exception for *Technology Provided as part of a Community-wide Information System* (a compensation only exception)
- There are also a number of other Stark Law exceptions. Each of the Stark Law exceptions has specific and technical requirements that must be met.

Part I: The False Claims Act

- **31 USC § 3729** – The False Claims Act (“FCA”) sets forth seven bases for liability. The most common ones are:
  1. Knowingly presenting, or causing to be presented, to the Government a false or fraudulent claim for payment
  2. Knowingly making, using, or causing to be made or used, a false record or statement material to get a false or fraudulent claim paid
  3. Conspiring to commit a violation of the False Claims Act
  4. Knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or avoiding or decreasing an obligation to pay or transmit money or property to the government
- Obligation defined as an established duty, whether or not fixed, arising...from retention of any overpayment
Elements Of An FCA Offense

- The Defendant must:
  - Submit a claim (or cause a claim to be submitted)
  - To the Government
  - That is false or fraudulent
  - Knowing of its falsity
  - Seeking payment from the Federal Treasury
  - Damages (maybe).

Knowing & Knowingly

- No proof or specific intent to defraud is required
- The Government need only show person:
  - had “actual knowledge of the information”; or
  - acted in “deliberate ignorance” of the truth or falsity of the information; or
  - acted in “reckless disregard” of the truth or falsity of the information.
**Qui Tam Actions & Government Intervention**

- A private person (“Relator”) may bring a False Claims Act action under the *qui tam* provisions of the FCA – The Whistleblower
- Government may intervene in a suit brought by Relator
- The relationship between Relator and Government

**FCA Statistics**

- If the Government intervenes and obtains recovery, the Relator receives between 15% and 25% of the proceeds
- Since 1986, of all of the *qui tam* actions filed, the average yearly intervention rate has been about 20-25%
- Recoveries have increased (higher penalties and greater publicity); $6.8 billion since 2009 and over $35 billion (in excess of $23 billion in health care) overall since 1986
- Whistleblower protection is provided to those that take lawful actions in furtherance of the *qui tam* suit, including investigation, initiation, testimony for, or assistance in the action (Anti-Retaliation Provision and Cause of Action)
Recent False Claims Act Amendments

- Liability for overpayments and failure to return a known overpayment within 60 days from identification-return of known overpayment an affirmative and express obligation
- Claims for payment from government contractors, grantees or other recipients if money is spent on government's behalf or to advance a government program or interest
- Materiality requirement for False Claims Act liability

Application Of Fraud And Abuse Laws To Private Exchange Insurers and Other Commercial Health Insurance Plans

- Authority to implement any measure or procedure appropriate to eliminate fraud or abuse
- Federal payments to private insurance exchanges subject to False Claims Act
- Medicare Advantage Plans – Part C & D
Role Of The OIG In FCA Cases

- May assist in the investigation
  - Settles as client agency on behalf of HHS
  - Permissive exclusion authority
  - May waive exclusion authority in exchange for Corporate Integrity Agreement
    - Monitoring and annual reports
    - Successor liability

United States ex rel. Baklid-Kunz v. Halifax Medical Center (M.D. Fla.)

- Halifax Hospital is in Daytona Beach, Florida
- In 2014, paid $86 million to settle alleged Stark Law and Anti-Kickback violations, brought by a *qui tam* Relator.
  - The Relator was a Halifax compliance officer turned whistleblower.
  - Hospital/Physician Compensation Arrangements
- The government alleged that the prohibited referrals resulted in the submission of 74,838 claims and overpayment of $105,366,00.
United States ex rel. Baklid-Kunz v. Halifax Medical Center (M.D. Fla.) (Cont’d)

- Executed contracts with six medical oncologists that included an incentive bonus that improperly included the value of prescription drugs and tests that the oncologists ordered and Halifax billed to Medicare.
  - Bonus Pool = 15% of Halifax Hospital’s "operating margin" from outpatient medical oncology services (i.e., pool includes revenue from "designated health services" referred by oncologists)
  - Does not comply with Employment Exception (1) FMV and (2) Volume/Value referral prohibition
  - Share of pool paid to individual oncologists is based on each individual physician's personal productivity, not referrals
  - However, pool includes "profits" from services referred, but not personally performed by oncologists.

United States ex rel. Baklid-Kunz v. Halifax Medical Center (M.D. Fla.) (Cont’d)

- Relator filed qui tam alleging Stark Law and AKS violations and that hospital improperly billed short-stay cases
- Government intervened in Stark Law allegations
  - Bonus payments to six oncologists that allegedly varied with or took into account volume/value of referrals
  - Compensation to three neurosurgeons set at 100% of collections with a guaranteed minimum was in excess of FMV and took into account volume/value of referrals
Halifax – Oncologists’ Arrangement

- New Compliance Officer attended HCCA conference in 2008 and after returning concluded that the oncology arrangements violated Stark Law
- Compliance Officer sent memo to Associate General Counsel expressing her views
- GC sought advice of outside counsel in October 2008
- February 2009, outside counsel opined:
  - The bonus arrangement does not take into account, or vary with, volume or value of referrals or other business generated by the physicians
  - What matters is that the bonus pool was not allocated based on volume or value of referrals
  - This conclusion was essential to satisfying the employment exception
  - “[W]e believe thee is a reasonable argument that the Contingent Bonus qualifies for the ... exception. However, given the preamble language set forth above, we cannot provide any assurances that CMS or a court would more likely than not concur with that analysis”.
- June 2009 – qui tam filed

Halifax-DOJ motion for partial summary judgment on claims based on oncologists’ arrangements

- DOJ: the bonus payments to oncologists were an indirect compensation relationship and did not fit an exception
- Evidence hospital acted “knowingly”
  - Former Compliance Officer sent internal Stark Law informational memos in 2001 and 2004
  - Compliance Officer
  - Outside counsel’s memo too weak to rely upon
  - Prospective change to neurosurgeons’ agreement
- Sought summary judgment of about $350 million
United States ex rel. Baklid-Kunz v. Halifax Medical Center (M.D. Fla.) (Cont’d)

Halifax’s Response to Motion to Summary Judgment

- Bonus did not vary with volume or value of referrals for reasons stated by outside counsel, that what matters is how the bonus pool is allocated
- Argued that there was a direct compensation arrangement, apparently to enable it to argue that bonuses may be based on physician’s personally performed services
- Hospital did not act “knowingly” because it relied on advice of counsel

United States ex rel. Baklid-Kunz v. Halifax Medical Center (M.D. Fla.) (Cont’d)

Halifax – Court grants Government’s summary judgment in part (11/13/13)

- Direct or indirect compensation analysis not resolved
- Hospital violated the Stark Law – oncologists’ bonuses varied with, and took into account, value or volume of referrals
- Outside legal opinion is irrelevant to common law claims, since Stark Law is strict liability
- Physician’s inclusion as “attending” or “operating” physician on UB-04 is evidence of a referral
- Grants partial SJ as to liability on common law claims
United States ex rel. Baklid-Kunz v. Halifax Medical Center (M.D. Fla.) (Cont’d)

Halifax – Ruling on Government’s MSJ
- Denies summary judgment on FCA claims because of genuine issue of material fact as to whether Hospital acted “knowingly”
- FCA liability and damages issues reserved for jury

Halifax – Other MSJ motions denied
- Halifax’s MSJ denied
  - Disputed issue of fact whether neurosurgeons paid consistently with FMV
  - In some years, compensation was twice the 90th percentile
  - Productivity figures touted as supporting the high compensation included bills submitted under their names for NP and PA work
  - “The propriety of the neurosurgeons’ compensation under the Stark Act is a matter for the jury to decide
- Relator’s MSJ denied under AKS employment safe harbor

United States ex rel. Baklid-Kunz v. Halifax Medical Center (M.D. Fla.) (Cont’d)

Halifax
- March 2014 set for trial
  - Short-stay issues (summary judgment motion pending)
  - Damages and FCA liability on Stark Law/oncologists issue issue
  - All issues on neurologists

Halifax settlement
- Potential $1.14 billion judgment
- More than $22 million in defense costs
- $85 million settlement plus extensive corporate integrity agreement
- Relator’s claims for attorney’s fee
- Settlement is more than eight times the hospital’s operating margin and 18% of its $480 million annual revenue. Source: Modern Healthcare
United States ex rel. Drakeford v. Tuomey, 792 F.3d 364 (4th Cir. 2015)

- In 2005, Dr. Michael Drakeford, an orthopedic surgeon, sued Tuomey under the False Claims Act (FCA). The United States intervened in 2007.
- In 2010, the case went to trial in the U.S. District Court for the District of South Carolina.
  - The jury found that Tuomey violated the Stark Law but not the FCA.
  - The district court set aside the jury’s verdict and ordered a new trial, but entered a $45 million judgment against Tuomey.
- In 2012, Tuomey appealed to the Fourth Circuit which vacated the monetary judgment and ordered a new trial.
- In 2013, the case was retried in district court and the jury found that Tuomey violated the Stark Law and FCA and awarded $237,454,195 to the U.S.
- Tuomey appealed for a second time and the Fourth Circuit affirmed the judgment against Tuomey on July 2, 2015.

United States ex rel. Drakeford v. Tuomey, 792 F.3d 364 (4th Cir. 2015) (Cont’d)

- Tuomey Healthcare System was a nonprofit hospital in Sumter, South Carolina.
- Sumter is a federally-designated medically underserved area.
- Tuomey was concerned about doctors who previously performed outpatient surgery at the hospital now performing the surgeries at other off-site facilities.
- Tuomey sought to negotiate part-time employment contracts with physicians to perform outpatient surgeries at the hospital.
- Physician compensation exceeded FMV, not commercially reasonable and based on volume and value of referrals.
The terms of the physicians’ contracts:

- Physicians were to perform all outpatient surgeries at Tuomey for a 10 year term.
- Upon termination, the contracts had a non-compete provision for 2 years within 30 miles of Tuomey.

Physicians’ compensation varied with the number of referrals made to Tuomey, implicating the Stark Law.

Tuomey was found to have submitted 21,730 false claims.

Tuomey

- GI and other specialists considering investing in ASC, moving procedures there
- In response, Tuomey proposed part-time employment contracts. Physicians would be employees while they performed outpatient procedures at Tuomey facilities.

Tuomey-Part-time employment terms

- Physician required to perform outpatient procedures at Tuomey
- Physician assigns professional fees to Tuomey and Tuomey would bill for professional services and facility fee
United States ex rel. Drakeford v. Tuomey, 792 F.3d 364 (4th Cir. 2015) (Cont’d)

Tuomey – Part-time employment terms (Cont’d)

- Compensation
  - Base salary
  - “Productivity bonus” equal to 80% of collection of fees for professional services for outpatient procedures
  - Performance bonus based on quality measure
  - Benefits
- Ten-year term and non-compete for contract term plus two years after expiration
- Outside counsel for hospital approved the compensation model, relying on consultant’s opinion on FMV and commercial reasonableness
- Average pay for physicians would be 19% over professional fee collections, but opined that physicians’ compensation was consistent with fair market value and reasonable

Tuomey CEO advised Board that although the employment agreements would cost the hospital $1-2MM each year, employing the physicians would save millions in the long run by preserving facility fees that would otherwise be lost

Tuomey approaches many physicians for part-time employment

9/04 – Dr. Michael Drakeford (orthopedic surgeon) refuses

Through 5/05 – Tuomey enters into part-time employment agreements with 19 specialists

After Drakeford’s lawyer persists with objections, Tuomey and Drakeford jointly retain Kevin McAnaney for a legal opinion
United States ex rel. Drakeford v. Tuomey, 792 F.3d 364 (4th Cir. 2015) (Cont’d)

Conference call with McAnaney

- Fair Market Value opinion from consultant is not enough
  - “it’s just not common in my experience to hire physicians and pay them substantially above even their collections, much less their collections minus expenses.”
  - “it would be very hard to sell” FMV
  - Expecting to pay more than collections would be a “red flag”
- Cannot justify losing money on part-time contracts by saying that they were “making it up on other business they were generating.”
- Other hospitals have settled cases based on similar facts
- Context important – luring physicians from investing in an ASC

Conference call with McAnaney (Cont’d.)

- Stringent non-compete and contrived part-time employment agreement are additional red flags
- “Government would find this to be an easy case to successfully prosecute.”
- Doesn’t pass the “red face” test
- Consultant powerpoints: “Government’s Exhibit 1.”
Tuomey

July 2005 – Dr. Drakeford sends letter to Tuomey Board chairman requesting meeting with Board

In response, Tuomey Board adopts policy:

- Requiring that anyone requesting to speak with the Board first present to the chairman and the CEO
- That is shall be in the discretion of the chairman to decide if the full Board or any committees should hear the issue
- Prohibiting any requester to have legal counsel present

Drakeford’s counsel asked McAnaney to put his opinion in writing, but Tuomey’s counsel tells him not to

August 2005 - Tuomey retains another law firm that opines that the arrangements are legal, again deferring to consultant’s FMV opinion

Law firm’s opinion did not consider whether compensation “took into account” the volume or value of referrals

Tuomey

October 2005- Drakeford files qui tam

First trial – March 2010

- Judge excluded evidence of McAnaney call
- Verdict: Tuomey violated the Stark Law, but not liable under FCA
- Judge entered judgment for approximately $44.9 million on Government’s common law claims

Fourth Circuit reversed because hospital entitled to jury determination of damages

Forth Circuit held that “take into account” “value or volume of referrals” includes anticipated referrals
Tuomey Retrial (May 2013)

- Jury verdict
  - $39.3 million in "single" damages and 21,730 false claims
  - Hospital liable under FCA

- Tuomey moved for retrial on grounds, inter alia, that: (1) the compensation did not take into account or vary with volume/value of referrals, (2) did not prove Hospital acted knowingly

Tuomey Motion for New Trial

Did physician contracts constitute an indirect financial relationship under Stark Law?

- An indirect compensation agreement exists if, inter alia, the referring physician receives aggregate compensation that “[1] varies with, or [2] takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing” services. 42 C.F.R. § 411.354(c)(2)(ii)

Tuomey – “Vary with volume or value of referrals”

- Tuomey: Variable component of compensation was based solely on collections for personally performed services and not based on facility fees received by the hospital, so it did not vary with volume or value of referrals

- Government:
  - All the services provided under employment agreement consisted of performing procedures which necessarily involved referrals
  - “One-to-one relationship” between each physician’s aggregate compensation and the physician’s referrals of facility components to the hospital
  - Each time a physician performed a procedure on a Medicare patient at Tuomey pursuant to contract, the physician’s compensation would increase
United States ex rel. Drakeford v. Tuomey, 792 F.3d 364 (4th Cir. 2015) (Cont’d)

Tuomey – Vary with volume or value of referrals

“the Government presented evidence of a one-to-one relationship between each doctor’s aggregate compensation and the volume or value of each doctor’s referrals of technical components to the hospital. The Government presented testimony wherein Tuomey acknowledged that each time one of the physicians performed a legitimate procedure on a Medicare patient at Tuomey’s facility pursuant to his or her agreements, the physician’s compensation would increase. In addition, the Government presented testimony that each time one of the physicians referred a patient to Tuomey’s facility, Tuomey received a facility fee for the services that the hospital provided in connection with the referral.

... A reasonable jury could have found the physicians’ compensation varied with [the] volume and value of the physicians’ referrals to Tuomey.”

(10/2/13 opinion).

United States ex rel. Drakeford v. Tuomey, 792 F.3d 364 (4th Cir. 2015) (Cont’d)

“Take into account” the volume or value of referrals

- Government’s argument:
  - Cejka valued the non-compete provision based on anticipated lost facility fee revenue and used those figures as a “benchmark” in developing the compensation plans
  - Tuomey COO: “That salary is derived and defended by the analysis of the value of the work that the hospital may lose if the surgeons were to work elsewhere and the value of having them sign an exclusive arrangement with the hospital to do the work only at our place.”
  - Hospital told surgeons that anesthesiologist and radiologists were not offered similar contracts because “y’all create the volume.”
  - Hospital wanted to provide an economic incentive to physicians “who have been and continue to be loyal to Tuomey in terms of referrals”
  - Hospital wanted to “reward you economically” for using hospital facilities
“Take into account” the volume or value of referrals:

- “The court notes that the Government presented evidence from ... witnesses tending to show that Tuomey took into account the volume or value of referrals ... A reasonable jury could have found that Tuomey took into account the volume or value of referrals in establishing physicians’ compensation...”

Tuomey – Proof of referrals

- Inclusion of physician as “admitting physician” or “operating physician” on UB claim form was evidence that physician made a referral under the Stark Law

Tuomey – FCA “Knowledge”

- Jury could find that Tuomey acted “knowingly” in light of its reaction to the McAnaney conference call
- Jury’s calculation of damages and number of false claims implies that it found that Tuomey acted “knowingly” beginning in September 2005 (when McAnaney’s engagement was terminated)
- Court entered judgment of $237,454,195 in favor of Government (Oct. 2, 2013)
  - Treble damages (3 x $39,313,065)
  - Penalties of $5,500 x 21,730
- Tuomey has spent $18 million on defense costs and anticipates another $5 million (including CIA compliance)
Tuomey Settlement?

- Terminating CEO and COO and severing relationship with outside general counsel, were condition precedent to continued settlement negotiations
- Tuomey settles for approximately $70 million and is subsequently sold to another health system

Other Cases and Settlements

- U.S. ex rel Reilly v. North Broward Hospital District, et al (S.D. Fla.)
- U.S. ex rel Barker v. Columbus Regional Healthcare (M.D. Ga.)
- U.S. ex rel Singh v. Bradford Regional Medical Center (W.D. Pa.)

And Many Others
Advice of Counsel Defense

- Defendant fully disclosed all relevant facts before receiving advice
- Relied on advice and acted in strict accordance with the advice
- Defense not available for advice secured to facilitate a crime or fraud
- Waiver of privilege and disclosure of all facts relied on for advice
- Can be a risky and often futile defense
- The success or failure of the advice of counsel defense often requires consideration by a jury during trial with all the attendant uncertainties

“Good Faith Defense”

- “Good Faith” can be inconsistent with intent or willingness necessary to establish criminal or civil liability
- “Good Faith” encompasses the belief or opinion honestly held, an absence of malice or ill will and no intention to take advantage of another
- Did defendant act with intent to defraud or with “good faith” to act in accordance with the law
- May also require waiver of privilege and may only be put forth at trial
THE END