Health Care Compliance Association Orlando Regional Healthcare Compliance Conference Friday, January 31, 2020

Recent Developments and Physician Compensation Arrangements

Gabriel L. Imperato, Esq.

Board Certified Healthcare Lawyer



False Claims Act

- 31 USC § 3719, 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

False Claims Act (cont'd.)

- 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
 - Person acted in "deliberate ignorance" of the truth or falsity of the information; or
 - Person acted in "reckless disregard" of the truth or falsity of the information

Penalties

- ☐ Three times the amount of damages which the Government sustained
- ☐ Civil penalty from \$5,500 to \$11,500 per false claim (going up to \$10,781.00 to \$21,563.00)

Qui Tam Actions & Government Intervention

- A private person ("Relator") may bring a False Claim Act action under the qui tam provisions of the FCA – The Whistleblower
- Government may intervene in a suit brought by Relator
- Relationship between Relator and Government
 - Collaborators in recovery of money
 - Rewards for whistleblowers

Repayment Obligation and The 60 Day Rule

Creation of the 60 Day Repayment Requirement

- The Affordable Care Act required providers to report and return any overpayment within 60 days after <u>identification</u> (or the date any corresponding cost report is due), whichever is later Section 1128 J(d) of the Social Security Act
- "Overpayment" is defined as any funds that a person receives <u>or retains</u> from Medicare or Medicaid to which the person, after any applicable reconciliation, is not entitled
- Overpayments include payments received for claims submitted in violation of the Stark Law or the Anti-Kickback Statute
- Any overpayment retained after the repayment deadline is considered an obligation for purposes of False Claims Act liability

The 60 Day Rule (Medicare Parts A & B)

- Final regulations for the 60 Day Rule (Medicare Parts A & B) published on February 12, 2016 (81 Fed. Reg. 7654)
- The regulations:
 - Clarify when an overpayment is identified
 - Establish a six-year lookback period
 - Describe options for reporting and returning identified overpayments
- There is no minimum monetary threshold; all identified overpayments must be returned

- "[A]person has identified an overpayment when the person has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment." (emphasis added)
- "Reasonable diligence" includes both (1) proactive compliance activities and (2) reactive investigations conducted in a timely manner in response to credible information of a potential overpayment

- "Minimal compliance activities to monitor the appropriateness and accuracy of claims would be a failure to exercise reasonable diligence"
- Identification of a single overpaid claim requires further investigation
- "Part of identification is quantifying the amount, which requires a reasonably diligent investigation."

- The 60 day time period for reporting / returning begins when either:
 - The reasonable diligence is completed; or
 - On the day the provider received credible information of a potential overpayment (if the provider fails to conduct reasonable diligence)
- For an investigation to be conducted in a "timely" manner, providers typically must <u>complete the</u> <u>investigation within 6 months</u> from receipt of credible information indicating there may be an overpayment
 - 6-month timeframe may potentially be extended under "extraordinary circumstances"
 - 8 months generally the maximum total time to return overpayments.
- The government recommends that providers maintain records documenting "reasonable diligence"

Six-year lookback period

Sometimes possible to use a shorter period depending on the facts at issue

Amount to be repaid

 May vary depending on the method used to report / return, e.g., Medicare administrative contractor ("MAC") v. self-disclosure

Overpayment notification

 After receiving an overpayment notification from the government, you should investigate for related overpayments, e.g., other time period.

Voluntary Disclosure Process

- 1. Investigation and Evaluation
- 2. Consider the Benefits and Risks
- 3. Consider Which Entity to Disclose to
- 4. Submit a Timely, Complete and Transparent Disclosure
- 5. Anticipate Government Validation
- 6. Resolution Strategies and Options

Is it "Voluntary?"

- Misprision of a Felony 18 U.S.C. § 4 provides that "whosoever...having knowledge...of a felony...conceals and does not as soon as possible make known the same...shall be fined...imprisoned...or both
 - Requires active concealment
- Medicare Statute 42 U.S.C. § 1320a-7b(a)(3) arguably makes it a felony to conceal or "fail to disclose" facts affecting right to receive payment

Is it "Voluntary?"

- □ False Claims Act Amendments to the FCA made as part of Fraud Enforcement and Recovery Act of 2009 (FERA) 31 U.S.C. § 3729(a)(1)(G)
 - Illegal to "knowingly conceal...or knowingly and improperly avoid...or decrease...an obligation to pay or transmit money or property to the Government...
- Presentment of claim not essential for False Claims Act Liability
- Affordable Care Act established "obligation" to report "identified" overpayment within sixty (60) days

Disclosure Considerations

- Decision to disclose should be made in conjunction with counsel, but is a business decision – weighing potential risks and benefits
 - Where available, disclosure may offer protections too significant to pass up
 - Useful for substantial violations of law and whistleblower risk
 - Leaves as an open question more minor or isolated violations time + expense + minimum settlement may make minor disclosures prohibitively costly
 - Continuing focus on compliance programs, good faith cooperation and prompt disclosure

Weight Pros and Cons with Counsel

- "Voluntary" vs. Essential Disclosures
- Potential advantages of disclosing:
 - Goodwill with government
 - Limiting possibility of external investigation
 - Expediting process of resolution
 - Reducing criminal and civil liability
 - Neutralizing whistleblower threat and lawsuits
 - Lessening overall damages and penalties

Weighing Pros and Cons (cont'd.)

- Potential disadvantages of disclosing:
 - Financial loss government motivated by recovery whether discovered or disclosed
 - Increased government scrutiny validation process
 - No immunity from liability or prior commitments, except under OIG-SDP
 - Possible penalties for conduct that may have remained undiscovered.

Choosing A Government Entity

- Self-disclosure can be made to:
 - Office of Inspector General of the Department of Health and Human Services (OIG-HHS) – Self Disclosure Protocol (SDP)
 - Centers for Medicare and Medicaid Services (CMS) Self Referral Disclosure Protocol (SRDP)
 - Department of Justice, U.S. Attorney's Office (DOJ)
 - State Attorney General's Office

General Guidelines

- Disclose billing errors and mistakes to entity processing claims and payment
- Disclose matters indicating civil liability under Civil False Claims Act to DOJ and/or OIG-HHS
- Disclose matters indicating criminal liability to DOJ and/or OIG-HHS
- Where, when and how to voluntarily disclose involves careful considerations

Many Possible Settlement Factors

- Effectiveness of pre-existing compliance program
- Nature of the conduct and financial impact
- Ability to repay
- First-time offender, isolated and distinct incident
- Low-level bad actors
- Efforts to correct problem
- Successor liability under former management
- Period of conduct
- How matter was discovered
- Level of cooperation, candor, flexibility
- Relationships
- Etc.

- 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 professional responsible for physician relations who became a 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.

- 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.
 - O 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)
 - Stark Employment Exception (1) FMV and (2) Volume/Value referral prohibition, but (3) payment not prohibited if in the form of a productivity bonus based on services performed personally by a physician
 - Share of pool paid to individual oncologists is based on each individual physician's personal productivity
 - However, pool was created by the volume and value of physicians referrals for oncology services performed by the hospital and not personally performed by the oncologists.

- Paid three neurosurgeons more than fair market value for their work.
 - Bonus = 100% of collections after covering base salary, no expense sharing
 - Total Compensation = As much as double neurosurgeons at 90th percentile of FMV.

- Relator alleged Stark Law and AKS violations and also that hospital improperly billed short-stay cases
- Government initially declined, but later 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

- Relator attended HCCA conference in 2008 and after returning concluded that the oncology arrangements violated Stark Law
- Relator 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
 - o 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
 - o "[We] believe this 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".
 - o Hospital continued paying the oncologists in accordance with the terms of the original compensation arrangement
- June 2009 qui tam filed

DOJ motion for partial summary judgment on claims based on oncologists' arrangements

- Evidence hospital acted "knowingly"
 - Chief Compliance Officer sent internal Stark Law informational memos in 2001 and 2004
 - Associate General Counsel addressed Stark application to physician compensation arrangements and raised compliance concerns.
 - Compliance Officer Deposition Testimony
 - Outside counsel's memo too weak to rely upon
 - Prospective change to neurosurgeons' agreement
- DOJ sought summary judgment for about \$350 million

Halifax's Response to Motion for 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 employment compensation arrangement under the Stark law which provided for bonuses based on physician's personally performed services
- Hospital did not act "knowingly" because it relied on advice of counsel

Court grants Government's summary judgment in part

- Hospital violated the Stark Law oncologists' bonuses varied with, and took into account, volume or value of referrals
- Outside legal opinion is irrelevant to common law claims since Stark Law is strict liability and Court grants partial Summary Judgment as to liability on common law claims (i.e. overpayment claims)
- Physician's inclusion as "attending" or "operating" physician on UB-04 is evidence of a referral by that physician

Ruling on Government's MSJ cont'd

- 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

Other MSJ motions denied

- Halifax's MSJ denied
 - Disputed issue of fact whether neurosurgeons paid consistently with FMV
 - o 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
 - o "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

Case set for trial

- Short-stay issues (summary judgment motion pending)
- o Damages and FCA liability on Stark Law/ oncologists 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.
 - o The jury found that Tuomey violated the Stark Law but not the FCA.
 - o 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

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

- 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

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

- Compensation
 - Base salary
 - o "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 — Part-time employment terms (Cont'd)

- 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

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:
 - o Requiring that anyone requesting to speak with the Board first present to the chairman and the CEO
 - o That is shall be in the discretion of the chairman to decide if the full Board or any committees should hear the issue
 - o 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 opins 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
 - o Judge excluded evidence of McAnaney call
 - Verdict: Tuomey violated the Stark Law, but not liable under FCA
 - o 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

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).

"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)
 - o 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

U.S. ex rel. Bookwalter M.D., Sclabassi M.D., Anna Mitina v. UPMC; University of Pittsburgh Physicians (3rd Circuit, September 2019)

- Hospitals/Physician Compensation Arrangement Potentially Violates Stark
 Law
- Allegation of Referral for Designated Health Services; A Compensation Arrangement; A Medicare Claim for the Referred Services Survives Dismissal and Provides Enough "Smoke" to Survive 9(b) and Go to Discovery to Determine if There Is Any "Fire"
- Neurosurgeons Compensation Based on Personally Performed Services (WRVU's) Resulted in Referrals to Hospital for Surgery

U.S. ex rel. Bookwalter M.D., Sclabassi M.D., Anna Mitina v. UPMC; University of Pittsburgh Physicians (cont'd.)

- Potentially violates prohibition on payment based on the volume or value of referrals
- "The surgeons pay was facially based only on the services they personally performed, but every time they "performed a surgery or other procedure at UPMC Hospitals, they made a referral for associated hospital claims."
- Decision places most physician/hospital compensation arrangements at risk for Stark Law and False Claims Act liability

[See Pg. 11-13 of Concurring Opinion]

Other Cases and Settlements

- United ed States ex rel. Kosenske v. Carlisle HMC, Inc., (3rd Cir.)
- United States v. Borrasi, (7th Cir.)
- U.S. ex rel Reilly v. North Broward Hospital District, et al (S.D. Fla.)
- U.S. ex rel Payne, et al v. Adventist Health System/Sunbelt, Inc., et al (W.D. N.C.)
- U.S. ex rel Barker v. Columbus Regional Healthcare (M.D. Ga.)
- U.S. ex rel Bisk, et al v. Westchester Medical Center, et al (S.D. N.Y.)
- U.S. ex rel Parikh, et al v. Citizens Medical Center, et al (S.D. Tx.)
- U.S. ex rel Singh v. Bradford Regional Medical Center (W.D. Pa.)

And Many Others



Contact Information



Gabriel L. Imperato

Partner

Fort Lauderdale, FL
(954) 745-5223

gabriel.imperato@nelsonmullins.com