Navigating the Perilous Waters of the False Claims Act From Medical Necessity to the Anti-Kickback Statute and Beyond

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Financial Disclosure Statement

- None of The Panelists Have Any Relevant Financial Relationships With Commercial Interests To Disclose

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Goals

- Overview of the Federal False Claims Act
- Explore How the FCA is Used and What Drives DOJ Decision-Making
- Discuss Specific Examples of How the FCA Can Impact Providers, Particularly MDs
- Provide Real-World Guidance on How To Mitigate/Prevent FCA Exposure
The False Claims Act
31 U.S.C 3729 et seq.

- Originally enacted during the Civil War (1863)
- Redresses fraud involving federal government programs
- Prohibits false claims, records or statements involving U.S. money
- Treble damages
- Penalties of $5,500 to $11,000 for each false claim or statement
- Joint and several liability for defendants
- Qui Tam Provisions
  - Sealed Period
  - Relator Works With Government to Develop Case
  - Proper Relator Shares in Recovery (% Based on whether government intervenes and other considerations)

- The Act is Applied Broadly:

"Congress wrote [the FCA] expansively, meaning 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'" (Cook County v. United States ex rel. Chandler, 538 U.S. 119, 129 (2003)).
The False Claims Act:

- It’s always a good idea to look into the law.

- No telling what you might find in there.
The False Claims Act
31 U.S.C. 3729 et seq.

“Any person who **knowingly** presents, or causes to be presented, a false or fraudulent claim for payment or approval ... is liable to the United States ... for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted ... plus 3 times the amount of damages which the Government sustains because of the act of that person”

The terms “knowing” and “knowingly” mean that a person, with respect to information —

(i) Has actual knowledge of the information;
(ii) Acts in deliberate ignorance of the truth or falsity of the information; or
(iii) Acts in reckless disregard of the truth or falsity of the information.

✓ No Specific Intent to Defraud is Required
The False Claims Act

Recoveries

• **For Fiscal Year 2014:**
  - Total Recoveries = $5.7 billion
  - Total Health Care Recoveries = $2.3 billion
  - Total Health Care Qui Tam Recoveries = $2.2 billion
  - Total New Qui Tam Filings = 713
  - Total New Qui Tam Health Care Filings = 469

  - Historically, DOJ has intervened in approximately 25% of the qui tam cases in which it makes an intervention decision (some cases get dismissed pre-election).
U.S. DOJ False Claims Act Investigation Toolkit
Actual Photograph of a Real FCA Investigation In Progress
The False Claims Act

Anatomy of An FCA Case

- Most start with relators, though not required
- Filed under seal, on relator’s behalf and for the government
- Sealed Period, With Extensions
- Investigating Agencies
  - OIG (various agencies), FBI, MFCU, DCIS among many others
- Limitations Period:
  - 6 years from date of claim, record or statement OR 3 years from date of discovery by an official with authority to act, but in no event more than 10 years after the submission of the claim
  - NOTE: Case now pending in the Supreme Court relating to the application of the Wartime Statute of Limitations Act to the FCA
- Who Can Be Sued?
  - Individuals, Corporations (under respondeat superior and apparent authority doctrines),
  - Not the Federal Government
  - Not state entities in cases by relators (Vermont v. United States ex rel. Stevens, 529 U.S. 765 (2000))
The False Claims Act

Anatomy of An FCA Case

• Key Elements
  ✓ Claims
  ✓ Falsity
  ✓ Knowledge
    ✓ Actual Knowledge
    ✓ Deliberate Ignorance
    ✓ Reckless Disregard
  ✓ Materiality
  ✓ Damages (actually not required but almost always present)
  ✓ Causation
    ✓ The FCA is directed not merely at those who submit false claims but also at those who "cause" false or fraudulent claims to be submitted. ("Relator has presented evidence showing that it was foreseeable that Parke-Davis’s conduct... would ineluctably result in false Medicaid claims"). United States ex rel. Franklin v. Parke-Davis, 2003 WL 22048255, at *5 (D. Mass. Aug. 22, 2003)
The False Claims Act

**Intervention Decision**

- After Its Investigation, the United States May Choose to Intervene and Take Over the Litigation. This is a Critical Juncture for Defendants. Though Relators May Proceed Without the Government, 80-85% of Non-intervened Cases Do Not Go Forward.

- **Key Drivers in Government’s Decision:**
  - The strength of the case and the evidence
  - The magnitude of the associated damages
  - Non-monetary issues such as patient health or safety, and other quality of care concerns
  - Whether the conduct is part of a pervasive practice that the government wants to address
  - The potential for individual liability
  - The potential deterrent value of the case

*Not a key driver:* Relator’s personal baggage
The False Claims Act

Categories of False Claims Potentially Affecting Physicians

- Billing For Goods or Services Not Provided
  - Quality of Care Cases

- Billing for Ineligible Goods or Services
  - Medical Necessity Cases

- Inflated Billings
  - Hospitalist Cases

- False Certification Cases
  - Kickback and Stark Cases
The False Claims Act
Billing For Goods or Services Not Provided

- An Entity May Not Bill The Government For Non-Existent, Worthless or Substandard Products or Services

- “...in a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent to no performance at all.” U.S. ex rel. Mikes v. Strauss, 274 F.3d 687 (2d Cir. 2001).

- U.S. Files Suit Against Georgia Medical Center and Physician; Allegedly Submitted Claims for Worthless Services to Federal Health Care Programs (July 27, 2010)
  - The United States alleged that operative procedures performed by a general surgeon and related hospital services were not reasonable and necessary, were incompatible with standards of acceptable medical practice, were of no medical value and endangered the lives of federal health care program beneficiaries.
  - The physician was a general surgeon by training. The hospital allowed him to perform highly specialized endovascular procedures in the cath lab. The physician lacked specialized training to perform such procedures, was not qualified or competent to perform such procedures, had never performed such procedures before at any of the hospitals where he had been on staff, and did not even have privileges to perform the procedures.
  - Allegations of resulting patient harm included seriously injury and the death of one patient from hemorrhagic shock following an endovascular procedure during which the physician perforated a renal artery.
The False Claims Act:

Claims For Services Not Rendered

- Medical College of Wisconsin, Inc. Pays $840,000 to Settle Alleged False Claims for Neurosurgeries

- MCW knowingly billed federal healthcare programs for neurosurgeries involving residents who did not receive the required level of supervision from teaching physicians.
  - In similar cases over the years, Attending Physicians signed as “present” and available when they were not

- Medicare already pays resident salaries through Part A. Medicare will pay through Part B for a teaching physician’s services during a surgery performed by a resident only if he was present for the surgery’s key parts and either remained immediately available throughout the surgery or else arranged for a back-up surgeon to be available.

- MCW allegedly billed for teaching physicians’ services even though they were responsible for multiple overlapping surgeries and did not satisfy those supervision requirements.
The False Claims Act

Billing for Ineligible Goods or Services

Medical Necessity

Social Security Act
“Section 1862 (42 U.S.C. § 1395y) - (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services (1)(A) which, except for items and services described in a succeeding paragraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member....”
The False Claims Act: Medical Necessity

- Kentucky Hospital Agrees to Pay Government $16.5 Million to Settle Allegations of Unnecessary Cardiac Procedures (January 29, 2014):
  - The government alleged that doctors working at Saint Joseph Hospital performed numerous invasive cardiac procedures, including coronary stents, pacemakers, coronary artery bypass graft surgeries and diagnostic catheterizations, on Medicare and Medicaid patients who did not need them, and that the hospital was aware of these unnecessary procedures.
  - One cardiologist working at the hospital performed many of the medically unnecessary coronary stents. That doctor plead guilty to a federal health care fraud offense and has been sentenced to serve 30 months in prison.
  - The government also intervened in a separate lawsuit alleging False Claims Act violations by two other physicians who referred patients for and performed the unnecessary procedures and tests, and their practice group.
  - The government actions stem from a whistleblower complaint filed by three Lexington, Ky., cardiologists pursuant to the *qui tam* provisions of the False Claims Act.
  - The Relators, Drs. Michael Jones, Paula Hollingsworth and Michael Rukavina, received a total of $2.46 million of the $16.5 million settlement with the hospital.
The False Claims Act:
Medical Necessity and Transmittal 541

CMS Manual System, Department of Health & Human Services (DHHS), Transmittal 541,
EFFECTIVE DATE: September 8, 2014, SUBJECT: Claims that are Related
SUMMARY OF CHANGES: The purpose of this CR is to allow the MACs and ZPICs the
discretion to deny claims that are "related" and provide approved examples of such situations.

- When the Part A Inpatient surgical claim is denied as not reasonable and necessary, the MAC may recoup the surgeon’s Part B services. For services where the patient’s history and physical (H&P), physician progress notes or other hospital record documentation does not support the medical necessity for performing the procedure, post payment recoupment may occur for the performing physician’s Part B service.

- Nothing New Here: The essential “relatedness” of the Part A and Part B claims has always formed the basis for liability of both the physician and the hospital when there is a demonstrable lack of medical necessity. This just allows real-time administrative denial.
The False Claims Act: Inflated Billings

The Hospitalist Case

- Government Intervenes in False Claims Lawsuit Against IPC the Hospitalist Co. Inc. Alleging Overbilling of Physician Services
  - FCA lawsuit alleges that IPC physicians sought payment for higher and more expensive levels of medical service than were actually performed – a practice commonly referred to as “upcoding.”
  - IPC encouraged its physicians to bill at the highest levels regardless of the level of service provided, trained physicians to use higher level codes and encouraged physicians with lower billing levels to “catch up” to their peers.
- Lawsuit filed by a former IPC physician, under the qui tam provisions of the FCA.
- The lawsuit compares physician level-of-care reporting before and after physicians affiliated with IPC.
- Lawsuit uses time compilations to allegedly illustrate how hospitalists claimed to have spent more than 24 hours in a single day performing medical services with the knowledge and encouragement of IPC.
The False Claims Act: 
False Certification Cases- *Stark and AKS*

How the FCA Intersects With Stark and the AKS

**Stark Statute:** Civil rule that prohibits a physician from referring a Medicare patient for certain designated health care services ("DHS") to an entity with which the physician (or immediate family member) has a financial relationship, unless an applicable exception protects the referral.

**Anti-Kickback Statute:** Criminal statute that prohibits the exchange (or offer to exchange) of anything of value if one purpose is to induce (or reward) the referral of federal health care business.

- Under the “False Certification” theory, False Claims Act liability can attach to claims where a government payee falsely certifies compliance with a statute or regulation-- like Stark or the Anti-kickback statute -- that is a prerequisite to government payment.

- If a claim for payment grows out of a prohibited Stark relationship, or the claim is “tainted” by an intent to induce federal program business, it is *false* for purpose of the FCA.
The False Claims Act:
False Certification Cases- Stark and AKS

- Two Florida Couples Agree to Pay $1.13 Million to Resolve Allegations that They Accepted Kickbacks in Exchange for Home Health Care Referrals (Feb. 23, 2015)

  - Medical doctors and their wives settled FCA allegations that they violated the Act when their wives accepted sham marketer salaries in exchange for their husbands’ referrals.

  - Company paid spouses of referring physicians for sham marketing positions in order to induce patient referrals.

  - Spouses were required to perform few, if any, of the job duties they were allegedly hired for and instead, the spouses’ salaries were intended as an inducement for the husband physicians to refer their Medicare patients

  - One physician also received sham medical director payments as part of company’s scheme to obtain his referrals and he attempted to hide those payments from the United States.
The False Claims Act:  
*False Certification Cases- Stark and AKS*

- **United States Settles False Claims Act Allegations Against Patient Safety Consultant and His Companies** (Mar. 2, 2015)
  
- Physician pays the United States $1 million to settle allegations that he violated the False Claims Act by soliciting and accepting kickbacks.
  
- The physician received monthly payments from a company while serving as the co-chair of the Safe Practices Committee of the National Quality Forum, which reviews, endorses and recommends standardized healthcare performance measures and practices.
  
- The physician solicited and received payments in exchange for influencing the recommendations of the National Quality Forum (a “not-for-profit, nonpartisan, membership-based organization that works to catalyze improvements in healthcare”) and for recommending/promoting/arranging for the purchase of the company’s product.
  
- The United States alleged that this conduct *caused the submission* of false or fraudulent claims for the company’s product to federal health care programs.
The False Claims Act:  
False Certification Cases- Stark and AKS

- **Illinois Physician Pleads Guilty to Taking Kickbacks from Pharmaceutical Company and Agrees to Pay $3.79 Million to Settle Civil False Claims Act Case** (Feb. 13, 2015)
  
  - Physician pleaded guilty to receiving illegal kickbacks totaling $600,000 from pharmaceutical companies in exchange for regularly prescribing the company’s anti-psychotic drug to his patients.
  
  - Physician also paid the United States and the state of Illinois $3.79 million to settle a parallel FCA lawsuit alleging that, by prescribing the drug in exchange for kickbacks, the physician *caused* the submission of false claims to Medicare and Medicaid.
  
  - The scheme began in 2003 when the physician agreed to switch his patients to generic clozapine if the company paid him $50,000 plus other benefits under a one-year “consulting agreement.”
  
  - In addition to direct payments, the company also provided all-expenses paid trips to Miami for the physician and his wife and various employees. The physician quickly became the largest prescriber of generic clozapine in the country.
The False Claims Act: False Certification Cases - Stark and AKS

- Government Intervenes in Lawsuit Against Florida Cardiologist Alleging Unnecessary Peripheral Artery Interventions and Payment of Kickbacks

- The government intervened in two lawsuits against a Florida cardiologist and his physician group alleging that the physician and his company billed Medicare for medically unnecessary peripheral artery interventions *and paid kickbacks to patients* by waiving Medicare copayments irrespective of financial hardship.

- Physician allegedly induced patients to undergo the unnecessary procedures by routinely waiving the 20 percent Medicare copayment regardless of the patients’ financial need.
QUESTIONS? COMMENTS? REFUNDS?

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