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*Theories of Liability and Defenses under the False  
Claims Act*

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## THE CIVIL FALSE CLAIMS ACT

31 USC § 3729, the False Claims Act ("FCA") sets forth seven bases for liability. The most common ones are:

- Knowingly presenting, or causing to be presented, to the Government a false or fraudulent claim for payment
- Knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid
- Conspiring to defraud the Government by getting a false or fraudulent claim allowed or paid
- Knowingly makes, uses, or causes 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 conceals or knowingly and improperly avoids or decreases an obligation (including by definition the retention of any overpayment) to pay or transmit money or property to the Government

## 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)

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## 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

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## Penalties

- Civil penalty from \$5,500 to \$11,500 per false claim
- Three times the amount of damages which the Government sustained
- Potential collateral administrative consequences for Medicare and Medicaid program participation-Exclusion/Integrity Agreement

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## 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
- Relationship between Relator and Government
  - Collaborators in recovery of money

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## FCA Statistics

- If the government intervenes and obtains recovery, the Relator receives between 15% and 25% of the proceeds
- Since 1986, of all the *qui tam* actions filed, the average yearly intervention rate has been about 25% (approximately 200-300 cases per year)
- \$1-2 billion in health care FCA recoveries per year are from whistleblowers
- Recoveries have increased (higher penalties and publicity)
- Whistleblower protection is provided to those that take lawful actions in furtherance of the *qui tam* suit, including initiation, investigation, testimony for, or assistance in the action
  - Separate cause of action under FCA for retaliation against a whistleblower

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## Types of FCA Cases

- Unbundling (billing bundled service as if one service)
- Services not rendered, but claimed, or not provided as claimed (upcoding)
- Billing for items or services that are not covered
- Duplicate billing
- Submitting false or inflated cost reports-historical liability in health care
- Quality of care (“standard of care claims” or “worthless claims”)
- Research Grant and Clinical Trial Fraud
- Actions under the Food, Drug & Cosmetic Act
  - Misbranding and adulteration of drugs and promotion of off label use
- False Claims Act cases based on violations of the Stark Law and/or the Anti-Kickback Statute (“tainted claims”)

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## Making a Case under the FCA

### ➤ Claims Under the FCA

- Defendant submitted or caused another person to submit a claim for payment to the Federal government
- False or fraudulent and/or the Defendant made or used a false or fraudulent record or statement to obtain payment or approval of the false or fraudulent claim
- Person submitting claim had actual knowledge of its falsity or acted in reckless disregard of its falsity

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## Making a Case Under the FCA (cont'd.)

### ➤ 1998 Memorandum to Department of Justice Attorneys

- Notice to the Provider. Was the provider on actual or constructive notice, as appropriate, of the rule or policy upon which a potential case would be based?
- The Clarity of the Rule or Policy. Under the circumstances, is it reasonable to conclude that the provider understood the rule or policy?
- The Pervasiveness and Magnitude of the False Claims. Is the pervasiveness or magnitude of the false claims sufficient to support an inference that they resulted from deliberate ignorance or intentional or reckless conduct rather than mere mistakes?
- Compliance Plans and Other Steps to Comply with Billing Rules. Does the health care provider have a compliance plan in place? Is the provider adhering to the compliance plan? What relationship exists between the compliance plan and the conduct at issue? What other steps, if any, has the provider taken to comply with billing rules in general, or the billing rule at issue in particular?

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## Making a Case Under the FCA (cont'd.)

- Past Remedial Efforts. Has the provider previously on its own identified the wrongful conduct currently under examination and taken steps to remedy the problem? Did the provider report the wrongful conduct to a government agency?
- Guidance by the Program Agency or its Agents. Did the provider directly contact either the program agency (e.g. CMS) or its agents regarding the billing rule at issue? If so, was the provider forthcoming and accurate and did the provider disclose all material facts regarding the billing issue for which the provider sought guidance? Did the program agency or its agents, with disclosure of all relevant, material facts, provide clear guidance? Did the provider reasonably rely on such guidance in submitting the false claims?
- Have There Been Prior Audits or other Notice to the Provider of the Same or Similar Billing Practices?
- Any Other Information that Bears on the Provider's State of Mind in Submitting the False Claims?

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## Conditions of Participation vs. Conditions of Payment

- Hospitals must comply with specified standards pertaining to administration, staffing, quality assurance, nursing services, medical services, and physical environment
- Long-term care facilities must abide by standards for nutrition, hydration, wound care, staffing, medication, resident rights, and a variety of other areas of long term care

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## Conditions of Participation vs. Conditions of Payment (cont'd.)

- Compliance with established conditions of participation is not an explicit condition of receiving payment for providing services to Federal health care beneficiaries
- Provider's are not immediately excluded or refused payment unless it is determined that there is an immediate threat to the health or safety of a patient
- Substantial performance
- Providers given a chance to remedy the situation in the administrative process through the submission of a plan of corrective action
- Allowed to continue providing services to patients and submit claims to the Federal government for the services provided during this administrative process.

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## "Classic" False Claims

- United States v. Krizek, 111 F.3d 934 (D.C. Cir. 1997)
  - The Court found that because of a "seriously deficient" system of recordkeeping the Krizeks "submitted bills for 45-50 minute psychotherapy sessions... when Dr. Krizek could not have spent the requisite time providing services, face-to-face, or otherwise."
  - 21 hours of patient treatment within a 24-hour period
  - False statements
  - Were not "mistakes" nor merely negligent conduct
  - Acted with reckless disregard as to the truth or falsity of the submissions

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## “Classic” False Claims (cont’d.)

- United States v. Cabrera-Diaz, 106 F.Supp. 2d 234 (D.P.R. 2000)
  - 1994 Cabrera billed for 99,270 minutes of anesthesia time, when the evidence (hospital records) provided to Triple S only supported 21,371 minutes for a difference of 77,899 minutes
  - 1995 Cabrera billed for 90,930 minutes of anesthesia time, when the evidence provided to Triple S only supported 20,987 minutes for a difference of 69,943 minutes
  - The amount overpaid to Dr. Cabrera based on the overstated, falsely reported undocumented or unsupported anesthesia time was \$75,338.75 in 1994 and \$56,448.99 in 1995
- United States v. Mackby, 261 F.3d 821 (9<sup>th</sup> Cir. 2001)
  - Claims submitted using a physician’s Medicare provider number who never saw or treated patients at the clinic
  - Claims were false in stating physician provided service

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## “Standard of Care” or “Quality of Care” False Claims Cases

- United States ex rel. Mikes v. Straus, 78 F.Supp. 2d 223 and 84 F.Supp. 2d 427 (S.D.N.Y. 1999), Aff’d. 274 F.3d 687 (2<sup>nd</sup> Cir. 2001)
- United States ex rel. Swafford v. Borgess Med. Ctr., 24 Fed. Appx. 491 (6<sup>th</sup> Cir. 2001)
- United States v. NHC Health Care Corp., 164 F.Supp. 2d 1051 (W.D.Mo. 2001)
- United States ex rel. Swan v. Covenant Care, Inc., 279 F.Supp 2d 1212 (E.D. Cal 2002)

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## “Tainted Claims” Cases

- Federal Anti-Kickback Statute
- Stark Self-Referral Law
- False Claims Act Liability

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## Defenses to False Claims Act Cases

- Presentment of claim (i.e. to managed care organization; to Fiscal Intermediary or Carrier)
- Facts mitigating Scienter (i.e. state of mind)
  - Ambiguity of rule
  - Government knowledge of claims
  - Mistake or knowingly and willfully
  - Falsity
    - Matter of scientific dispute or competing expert opinions
    - Technical violators of law
    - Condition of participation or payment?
    - Reasonable interpretation of “ambiguous” regulations (i.e. ambiguity defense)
    - Common “regulatory behavior” without knowing and willful conduct

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## Defenses to False Claims Act Cases (cont'd.)

- Materiality or nexus to claim
- Obligation to pay
- Jurisdictional Defenses
  - Public disclosure and original source
  - Statute of Limitations
- Damages
  - Financial loss to Government?

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## Retaliation Claims Against Whistleblower under the False Claims Act

- Employee or other party (i.e. contractor or subcontractor or other agent) engaged in conduct protected under FCA (i.e. investigating fraudulent activities related to potential false claims)
- Employer aware of conduct or that it was being undertaken to investigate fraudulent activities and
- Employee discriminated against in the terms and conditions of employment because of the protected conduct and a potential FCA claim existed

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## Negotiation Strategies in False Claims Act Cases

- Negotiation strategies designed to achieve a reasonable resolution of the case (i.e. damages and penalties) while avoiding exclusion from Federal and/or state health care programs
  - Internal investigation
  - Negotiation and resolution and discovery
  - Compliance (i.e. Integrity Agreements) and administrative sanctions (i.e. exclusion)
  - Fixing damages and limiting collateral liability

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## Internal Investigation

- Determining the facts that underlie the whistleblower's and/or the government's allegations
- No substitute for knowing the facts for negotiation and/or defense
- Investment vs scope of liability

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## Negotiation Strategies

- A discussion with government representatives and discovery of Relator and/or government evidence
- A review of government evidence is of great value when assessing the degree of culpability which might be established and degree of exposure for physician or provider

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## Compliance Issues and Administrative Sanctions

- Exclusion and Integrity Agreements

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## Minimizing Damages and Limiting Collateral Liability

- Multiples of damages
- Penalties
- Ability to pay – financial disclosure

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## Alternative Dispute Resolution

- Government not always willing despite policy
- Sometime effective
- Can work both ways

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