The False Claims Act (FCA) – What Every Managed Care Compliance Department Needs to Know

HCCA Managed Care Conference
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Agenda

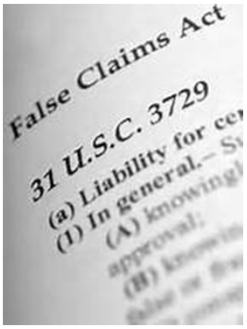
- FCA Elements
- Unique Features
- Changes under the Affordable Care Act
- State Law
- Compliance Department Issues

Types of Fraud

Criminal Fraud	Embezzlement, kickbacks, bribery, extortion
	Jail + fine "Beyond a reasonable doubt" (98%)
Civil Fraud	FCA violation
	Fine only "Preponderance of the evidence" (51%)

Importance of the FCA

- The government's oldest and primary litigation tool for combating fraud



Expansion of the FCA

Amendments	• 1986 Amendments • 2009 - FERA Amendments • 2010 - Patient Protection and Affordable Care Act (ACA)
Fines	• Since 1986, lawsuit volume is stable but fines have expanded dramatically • 2013: $3.8 billion • 2014: $5.7 billion
Enforcement	• Expanding theories of liability • Increased targeting of MCOs • New state laws and increased use

FCA – The Three Arrows

31 USC § 3729(a)(1)	• A person knowingly presents, or causes to be presented, to the US Government a false or fraudulent claim for payment or approval
31 USC § 3729(a)(2)	• A person knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the US Government
31 USC § 3729(a)(3)	• A person conspires to defraud the US Government by getting a false or fraudulent claim allowed or paid

FCA Damages

Direct	Indirect
Treble (triple) the amount of each false claim	Potential exclusion from Medicare and Medicaid (ACA § 6402)
Civil penalty of $5,000 - $11,000 per claim	Legal costs of defense during the investigation (Columbia HCA)
	Costs of an outside monitor
	Plunging stock prices (WellCare)
	Criminal indictment of executives

FCA Elements

Claim	• A claim is presented to the Government
Falsity	• The claim/record is false or fraudulent
Knowledge	• The person causing submission knows the claim is false

What is a "Claim?"

1. Any request or demand
   - Any document or other communication that reasonably could be expected to cause the Government to make or approve a payment
2. For any money, property, or service
3. To any government employee or contractor

What is "Presented?"

- Person who "causes" a false claim to be presented, even if not the actual presenter of the claim, may be liable
- The person actually presenting the claim need not know it is false
- Potentially applies to anyone who touches federal funds
- Potentially applies to a recipient who did not know the Government was the ultimate purchaser of goods
- Failing to prevent submission of a false claim if you had a duty to prevent fraud
- Failing to return a payment later discovered to be erroneously received ("reverse false claim")

What is "Knowing?"

Violation	No Violation
Specific intent to violate the FCA	Belief in a plausible (if erroneous) legal interpretation
Actual knowledge of the falsity of the claim	Reasonable legal interpretation of a vague law
Constructive knowledge of the falsity of the claim ("reasonable person")	Reasonable minds can disagree about the propriety of the claim
Deliberate ignorance or reckless disregard of (i) the truth of the claim or (ii) clear regulations or contract terms	Reliance on a practice generally accepted by the medical or professional community
	Reliance on medical or scientific literature

Lance Armstrong Accused of Defrauding U.S. in Complaint

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By Tom Schoenberg | Apr 26, 2013 1:06 PM PT | 11 Comments Email Print

(Corrects list of defendants in second paragraph in story published April 24.)

Lance Armstrong, the former champion cyclist, defrauded the U.S. by using banned substances, the government said in a complaint filed under the False Claims Act that joins a lawsuit brought by his ex-teammate Floyd Landis.

GOV'T SUES ARMSTRONG FOR FALSE CLAIMS

April 24 (Bloomberg) -- Bloomberg's Sara Eisen reports that the U.S. government has filed a complaint against former champion cyclist Lance Armstrong, alleging he defrauded the U.S. by using banned substances during sponsorship of his team by the U.S. Postal Service. She speaks on Bloomberg Television's "Bloomberg Surveillance."

The **Justice Department**, in the complaint filed yesterday in federal court in Washington, brought six counts of false claims, fraud and unjust enrichment against Armstrong, his team manager **Johan Bruyneel** and team owner Tailwind Sports Corp. An additional breach of contract claim was brought against Tailwind. Tailwind founder Thomas Weisel, one of several additional defendants in Landis's suit, wasn't named in the U.S. complaint.

Common FCA Violations

- Billing for services that were never provided
- Performing inappropriate or unnecessary medical procedures
- Unbundling – using multiple billing codes instead of the correct bundled code in order to increase payment
- Bundling – billing more for a panel of services when a single service was appropriate
- Double Billing – charging more than once for the same goods or services
- Up-Coding – inflating bills by using diagnosis billing codes that suggest a more expensive illness or treatment
- Billing for Brand – billing for brand-named drugs when generic drugs were actually provided
- Billing for non-covered drugs or services
- Forging physician signatures when such signatures are required for reimbursement

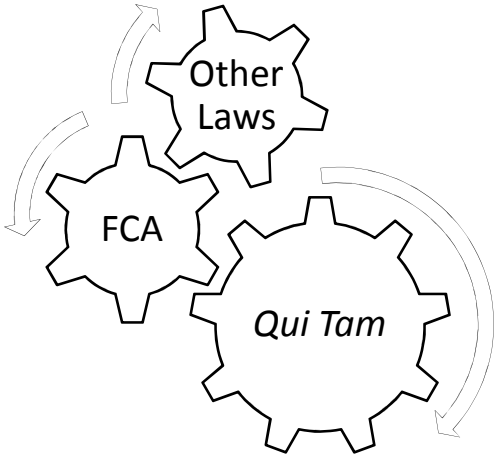
Common FCA Violations – Managed Care

- Cherry-picking healthy enrollees
- Refusing to enroll individuals with likely upcoming expenses
- Falsifying enrollment information to support higher capitation rates
- Reporting patients as eligible when they are not
- Dis-enrolling expensive patients
- Delaying eligibility determination on newly discharged hospital patients
- Denying medically necessary care

Common FCA Violations – Managed Care

- Contracting with unlicensed or unqualified providers
- Submitting false data to the government
- Inflating risk scores
- Passing excessive costs to government programs
- Retaining erroneous payments ("reverse false claim")
  - U.S. ex rel. Schaengold v. Mem'l Health, Inc., (S.D. Ga., 2014)
- Conducting audits that only address underpayments and never address overpayments
  - SCAN Health Plan Settlement Agreement

Unique Features of the FCA



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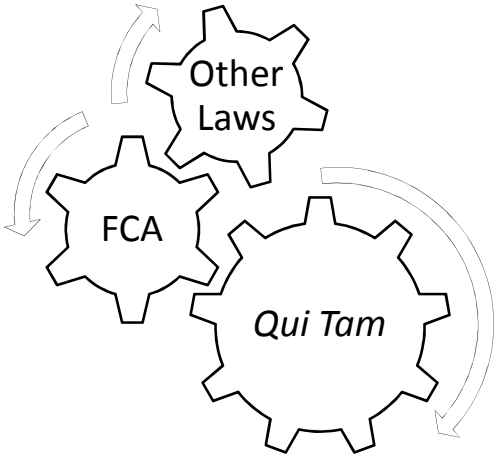
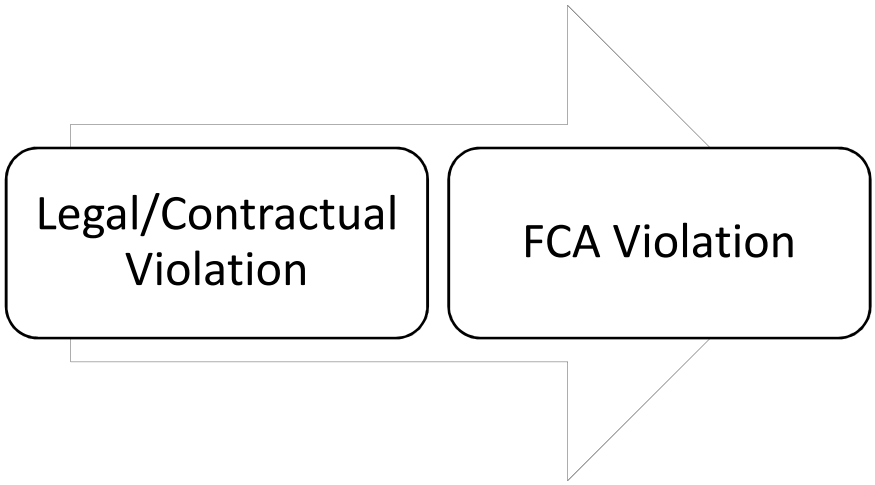


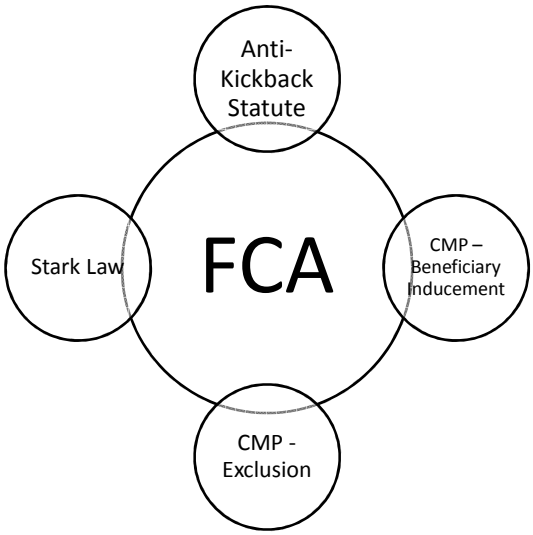
Reliance on Other Laws



Other Legal/Contractual Violations

- Defendant certifies compliance with other laws as part of being eligible to receive program payments
  - No overt act or statement by defendant (no "submission")
  - Violation of other law forms basis of FCA claim
    - Defendant warrants compliance with law
      - As part of demonstrating eligibility to participate in the program
      - In a government contract provision
    - The government would not have paid the claim if it had been aware of the legal violation
  - Implied certification; conditions of payment; conditions of participation

Other Legal Violations



The Anti-Kickback Statute

(42 USC §1320a-7b)

- Prohibits the offer or receipt of remuneration in return for referrals or recommendations to purchase products or services reimbursable under government health care programs
- Criminal law
- Willful knowledge
- Managed care safe harbor (42 CFR §1001.952(t))

The Anti-Kickback Statute

(42 USC §1320a-7b)

- United States ex rel. Wilkins v. United Health Group, 659 F.3d 295 (3d Cir. 2011)
  - FCA claim based upon offering of kickbacks to physicians to recommend patients to United's plan
- United States ex rel. Hutcheson v. Blackstone Medical, Inc. (694 F.Supp.2d 48 (D. Mass. 2010)
  - FCA claim based on kickbacks to physicians to increase use of its medical devices in spinal surgeries

Civil Monetary Penalties Law – Beneficiary Inducement

(Social Security Act, 42 § 1320a-7a)

- Civil penalties for offering or giving remuneration to any beneficiary of a FHCP likely to influence the receipt of reimbursable items or services

Civil Monetary Penalties Law – Beneficiary Inducement

(Social Security Act, 42 § 1320a-7a)

- Osheroff v. Humana, Inc., No. 13-15278 (11th Cir. 2015)
  - FCA claim that Humana promoted a variety of free services (transportation, meals, massages, salon services) for patients and health plan members without regard for medical purpose or financial need

Civil Monetary Penalties Law – Exclusion

(Social Security Act, 42 § 1320a-7a)

- Civil penalties for arranging for reimbursable services with an entity which is excluded from participation from a FHCP

Civil Monetary Penalties Law – Exclusion

(Social Security Act, 42 § 1320a-7a)

- United States v. Caremark, Inc., 634 F.3d 808 (5th Cir. 2011)
  - An insurer may potentially be liable under the FCA if it processes a claim for services rendered, ordered, or prescribed by a provider that the issuer knew or should have know was excluded

The Stark Law

(42 USC § 1395nn)

- Prohibits physician referrals of certain services for Medicare & Medicaid patients if the physician has a financial relationship with the entity receiving the referral
- Strict liability

Stark Law

(42 USC § 1395nn)

- United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr., No. 6:09-cv-1002, 2013 U.S. Dist. LEXIS 161718 at *6-34 (M.D. Fla. 2013)
- United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc., No. 3:05-2858, 2013 U.S. Dist. LEXIS 141316 at *5-20 (D.S.C. 2013)
- United States ex rel. Singh v. Bradford Reg'l Med. Ctr., 752 F. Supp. 2d 602 (W.D. Pa. 2010)

Dilemmas

- Absence of the classic false claim
- Different standards of culability
- No private right of action
- Some provisions extremely complicated and vague

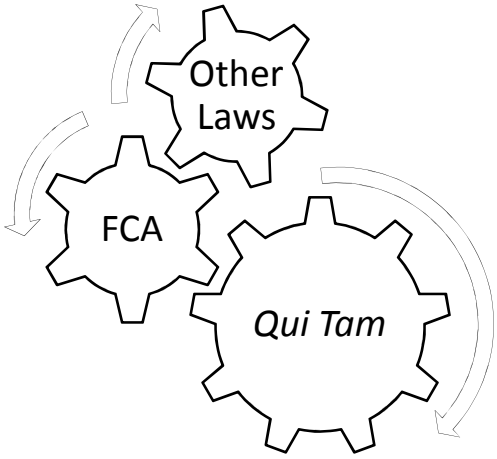
Other Laws, Regulations & Government Contract Provisions

- United States v. Americhoice of Pennsylvania, Inc. (E.D. Pa June 30, 2005)
  - FCA claim for failure to timely process medical claims & for reporting inaccurate claims processing data in violation of state Medicaid rules and state contract
  - $1.6 million settlement
- Keystone Mercy Health Plan settlement, 2006
  - FCA claim for collecting overpayments from Medicaid providers and then retaining them past regulatory and contractual deadlines before remitting payments to the state

Other Laws, Regulations & Government Contract Provisions

- United States ex rel. Tyson v. Amerigroup Illinois, Inc. 488 F. Supp. 2d 719 (N.D. Ill. 2007).
  - FCA claim based on theory that Medicaid MCO fraudulently induced Illinois to sign a Medicaid MCO agreement by falsely promising during contracting not to discriminate against any beneficiaries

Unique Features of the FCA



Qui Tam Provisions of the FCA

"For every thousand hacking at the leaves of evil, there is one striking at the root."

- Henry David Thoreau

Qui Tam Provisions

- Writ of *qui tam* – one "who sues in this matter for the king as well as for himself."
- Whistleblower – a person who reveals fraud or corruption ("relator")
  - Suit brought in the name of the United States
  - Government has option to intervene at any time
  - Government must approve any settlement

Qui Tam Provisions

- Relator's bounty:
  - 15% - 25% if the government intervenes
  - 25% - 30% if the government does not
  - FY 2014
    - 700 FCA whistleblower suits files
    - $3B in recoveries, $435M to relators
- Relator must be the original source of the information ("Original Source Requirement")
- Relator's information must not have been previously disclosed ("Public Disclosure Bar")

Qui Tam Provisions – Good and Bad

Good	Bad
Studies indicate savings of hundreds of billions	Relators' counsel aggressive in forming novel theories of liability
	Relators have incentive to not report violations internally and file suit

Qui Tam Provisions

- Non-retaliation (31 USC § 3730(h))
  - "any employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done by the employee on behalf of the employee or others in furtherance of the action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole…."
- Reinstatement, back pay x2, special damages, attorney fees and litigation costs
  - United States ex rel. Koch v. Gulf Region Oncology Ctrs., Inc. (N.D.Fla. 2013)(relator that was a leased employee still entitled to protection)

Affordable Care Act Changes to the FCA

(March 23, 2010)

- Changes to the Public Disclosure Bar
  - The federal government now must approve of a court's dismissal based upon the Bar
  - Public disclosure must occur by news media or the federal government (not the state)
- Changes to the Original Source Requirement
  - A relator can be an original source if s/he has information that materially adds to publicly disclosed information
- Overpayments
  - Overpayments under Medicare and Medicaid must be reported and returned within 60 days of discovery, or the date a corresponding hospital report is due

Affordable Care Act Changes to the FCA

(March 23, 2010)

- Application of the anti-kickback statute (AKS)
  - Language of the AKS changed to provide that claims submitted in violation of the AKS automatically constitute false claims for purposes of the FCA
  - AKS mental state no longer requires actual knowledge or specific intent to violate the law
- Health Insurance Exchanges
  - Risk adjustment mechanism
  - FCA applies
- Mandatory Compliance Programs for Providers
  - Upon issuance of rules
- Exclusion
  - authorizes the OIG to exclude from FHCPs entities that provide false information on any application to enroll or participate in a FHCP

State False Claims Acts

- 36 states and District of columbia have enacted false claims laws
  - 13 specifically address health care programs
  - 29 allow whistleblower suits
- Deficit Reduction Act of 2005 (Pub. L. No. 109-171, (2006))
  - Creates a financial incentive for states to adopt false claims laws modeled after the federal FCA
  - Directed toward recovery of Medicaid funds

The Compliance Department

"Plaintiffs have sufficiently alleged that Medco submitted its false claims knowingly under this definition. At the very least, the Government has claimed that Medco's compliance programs were either non-existent or insufficient, in satisfaction of the 'reckless' requirements of sec. 3729(b)."

United States of America ex rel George Bradford Hunt et al. v. Merck-Medco Managed Care, 336 F.Supp.2d 430 (E.D. Pa. 2004)

FCA & the Compliance Department

- FCA fines do not factor in the existence or efficacy of a compliance program, but….
  - "knowingly"
    - The government will review compliance program materials – early decision points, audits, hotline logs, complaints, responses
  - Deferred prosecution/settlement
  - Never entering the kitchen
    - Whistleblowers and the value of culture

FCA & the Compliance Department

- Policy elements:
  - Federal (and state?) FCA policy
  - Duty to report & reporting channel
  - Contractors/vendors
  - Inclusive non-retaliation policy
    - United States ex rel. Koch v. Gulf Region Oncology Ctrs., Inc. (N.D.Fla. 2013)(relator that was a leased employee still entitled to protection)
  - Address in the Code of Conduct

FCA & the Compliance Department

- Maintain a center of knowledge
  - Federal FCA
    - Relevant state FCAs
  - The anti-kickback statute
    - Relevant state anti-kickback statutes
  - Civil Monetary Penalty Provision
  - The Stark law
  - Exclusion rules
  - Criminal fraud laws

FCA & the Compliance Department

- FCA-specific training
  - Leadership
    - WellCare Health Plans, Inc. settlement - $320M
      - CEO, CFO, General Counsel & 2 Vice Presidents
  - External Affairs Department
    - U.S. ex rel. Health Dimensions Rehabilitation Inc. v. RehabCare Group Inc., et. al., (E.D. Mo.)(CEO mentions "therapist recruiting fee", fines of $30 million).
  - Legal Department
  - Compliance Department
  - Medicare/Medicaid/government contracting departments
  - Audit Department
  - Billing/Claims Processing Departments
    - "reverse" false claims & the new ACA 60 day rule
  - Vendors/contractors
  - Workforce
- Combination with anti-corruption or anti-fraud?

FCA & the Compliance Department

- Vendor/contractor relationships
  - Compliance Department vetting at contract execution or renewal
  - Contractual protections/obligations
    - To report suspected FCA issues promptly
    - To facilitate your investigations
    - To timely respond to government inquiries
    - To comply with law/comply with the FCA
  - Existence of training
  - Acknowledgement of shared exposure

FCA & the Compliance Department

- Risk assessments & operational audits
  - Annual fraud risk assessment
    - "Sponsors are required to investigate potential FWA activity to make a determination whether potential FWA has occurred. Sponsors must conclude investigations of potential FWA within a reasonable time period after the activity is discovered" (CMS Medicare Managed Care Manual)

Instructions	
Complete the FRA following the instructions (also provided in the workbook tab titled "Instructions") below and return it to this mailbox (Corporate Compliance) by EOD Tuesday, December 16, 2014.	
Step 1. Find your Business Unit (Col A).	
Step 2. Insert new (or modify existing) Potential Fraud Scenarios (Col B) faced by your business unit. Each unique fraud risk must have its own cell in column A.	
Step 3. Assess the likelihood of that particular fraud risk occurring (Col C - enter a value of High, Medium, or Low)	H= High Risk M= Medium Risk L= Low Risk
Step 4. Assess the severity of harm to BSC (including to BSC's members, employees, business partners, or brand) if that particular fraud risk actually occurs (Col D - enter a value of High, Medium, or Low)	
Step 5. List out all existing anti-fraud controls your business unit currently has in place to control or mitigate that particular fraud risk (Col E)	
Step 6. Evaluate the effectiveness of the current controls at preventing that particular fraud risk from occurring (Col F - enter a value of High, Medium, or Low). Once you enter a value in the "Effectiveness of Existing Anti-Fraud Controls" (Col F), the Overall Fraud Risk Score (Col G) for that scenario will be automatically calculated	
Step 7. Enter optional additional comments in Column H, if you feel they are helpful.	
Examples of Anti-Fraud Controls	
1. Comprehensive, updated Policies and Procedures	
2. Self auditing program to identify fraud scenario red flags	
3. Proactive versus reactive management monitoring	
4. Ability to run appropriate reports for trends and outlier analysis	
Please keep in mind there are no right or wrong answers to the questions and the information gathered will be more useful to us if you candidly share with us your work-related concerns.	

FCA & the Compliance Department

- Risk assessments & operational audits
  - Application of the AKS safe harbor & state laws
  - Kickback/corruption audits
    - Health care providers
    - Beneficiaries
    - Agents/brokers

FCA & the Compliance Department

- Risk assessments & operational audits
  - Audits risks:
    - Audit may form the basis of "knowledge"
    - General findings extrapolated to specific knowledge
      - U.S. v. Vitas Hospice Servs., LLC (W.D. Mo. 2013)
      - United States ex rel. Stone v. OmniCare, Inc. (N.D. Ill. 2011)
    - Audit process biased
      - SCAN Health Plan Settlement Agreement
    - Audit proper but follow-up inadequate

Thank you!