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

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

<table>
<thead>
<tr>
<th>Violation</th>
<th>No Violation</th>
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<td>Specific intent to violate the FCA</td>
<td>Belief in a plausible (if erroneous) legal interpretation</td>
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<td>Actual knowledge of the falsity of the claim</td>
<td>Reasonable legal interpretation of a vague law</td>
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<td>Constructive knowledge of the falsity of the claim (“reasonable person”)</td>
<td>Reasonable minds can disagree about the propriety of the claim</td>
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<td>Deliberate ignorance or reckless disregard of (i) the truth of the claim</td>
<td>Reliance on a practice generally accepted by the medical or professional community</td>
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<td>(ii) clear regulations or contract terms</td>
<td>Reliance on medical or scientific literature</td>
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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")
- Conducting audits that only address underpayments and never address overpayments
  - SCAN Health Plan Settlement Agreement
Unique Features of the FCA

FCA

Qui Tam

Other Laws
Reliance on Other Laws

Legal/Contractual Violation

FCA Violation

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

- Anti-Kickback Statute
- Stark Law
- CMP - Beneficiary Inducement
- CMP - Exclusion

FCA

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

  – 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)


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

  – 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

  – 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

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<td>Studies indicate savings of hundreds of billions</td>
<td>Relators’ counsel aggressive in forming novel theories of liability</td>
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<td>Relators have incentive to not report violations internally and file suit</td>
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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
  - 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).”

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
  – 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)
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!