

**HEALTH CARE COMPLIANCE
ASSOCIATION**

**AVOIDING QUI TAM ACTIONS:
ISSUES AND CONSIDERATIONS**

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FALSE CLAIMS ACT

37 U.S.C. §3729 - 3730

§§3729(a)(1)(A) and (B) set forth liability for any person who

- knowingly submits a false claim to the government or causes another to submit a false claim to the government or

- knowingly makes a false record or statement to get a false claim paid by the government.

§§3729(a)(1)(G) - reverse false claims section

- knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government

“KNOWINGLY”

- (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;
- requires no proof of specific intent to defraud;

“OBLIGATION”

- an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment;

EXAMPLES OF FCA VIOLATIONS

False record or statement
Have you considered these??

CMS-1500 FORM – page 2

SIGNATURE OF PHYSICIAN OR SUPPLIER
(MEDICARE, CHAMPUS, FECA AND BLACK LUNG)

In submitting this claims for payment from federal funds, I certify that :

- 1. the information is true, accurate and complete;

"the billing staff determines the E&M level..."

"we service drug treatment providers, when the physician fails to provide a diagnosis code, the billing department uses either F11.129 or F19.120. We have never had a claim denied because of these diagnosis codes."

CMS-1500 FORM – page 2

2. I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor;

"what is an LCD..."

"The MAC in Oregon never required that information..." *D. L. Jones, new CFO for NY health provider*

"Medicare Learning Network? I never heard of that!"

"Our compliance programs concentrate on proper documentation so we can get paid. I've never attended a session about the law." *Dr. Jim O'Doe, Anytown Hospital*

CMS-1500 FORM – page 2

3. I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision,

"when the physician fails to provide a diagnosis code, the billing department uses either F11.129 or F19.120."

Upon CMS's request, laboratories that have submitted claims must be able to provide documentation demonstrating that the services for which they seek reimbursement were reasonable and necessary. 42 C.F.R. 410.32(d)(3)(i).

CMS-1500 FORM – page 2

4. this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and programs instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law;

"The sales staff was urged by the company to get physicians hooked on the extra income they could make by: 1) billing nine to twelve units for a single POCT cup and 2) to significantly increase the number of patients they were testing and the frequency of the testing for each patient."
Regional Sales Manager, XYZ Laboratories

CMS-1500 FORM – page 2

4. this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and programs instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law;

If the Doctor's office "failed to check the box concerning the use of the custom profile, customer support personnel would either provide the physician's office with requisition forms that had the "Use Custom Profile" box already checked off, or they would go the physician's office and check the box on the requisition forms themselves."
Sales Person, XYZ Laboratories

STATUTORY REVIEW

Complaint and Disclosure Statement

- (2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) [1] of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

Complaint and Disclosure Statement

the Court’s “first to file” analysis focuses on whether the relator “provided the government sufficient notice that it was the potential victim of fraud worthy of investigation.” *Heineman-Guta*, 718 F.3d at 33. Because written disclosures outside the complaint are a required component of the “notice” that a relator must provide for the government, the Court’s analysis would be incomplete if it did not consider such documents.

Disclosure Statement

List of Individuals with Knowledge of the Rituxan Scheme

Carole Doe is Vice-President of Revenue Cycle at XYZ. She has held this position since the beginning of 2010. Prior to this Ms. Doe was Vice-President of Revenue Cycle at Brady Health System in Dallas, Texas (2005 – 2010) and Director of the Revenue Cycle Division at University Medical Center of Oregon in Portland, Oregon (2001 – 2005). <http://www.linkedin.com/pub/carole-doe/83/867/6b0>.

Susan Doeperson is a Senior Consultant at LLT Consulting. She has held this position since 2011. Prior to this she was a Senior Consultant at Make More Consulting from 2007 until March 2011. Before that she was the Manager of Revenue Systems, for the Medical University of New Jersey, a position she held from 2002 until 2007. <http://www.linkedin.com/pub/susan-doeperson/11/8b3/76>.

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IMPORTANCE OF FIRST TO FILE

The “first to file” rule of the FCA states

[w]hen a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action. 31 U.S.C. § 3730(b)(5).

IMPORTANCE OF FIRST TO FILE

The provision precludes the filing of subsequent qui tam cases once a relator has notified the government of a specific fraud, preventing copycat relators from bringing claims simply to gain a portion of the relator’s share. See United States ex rel. Heineman-Guta v. Guidant Corp., 718 F.3d 28, 35 (1st Cir. 2013).

FACTORS DRIVING AMOUNT OF REWARD

If the government proceeds with an action brought by a person under subsection (b), such person shall... receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action.

FACTORS INCREASING AMOUNT OF REWARD

- 1) The relator reported the fraud promptly.
- 2) When he learned of the fraud, the relator tried to stop the fraud or reported it to a supervisor of the Government.
- 3) The qui tam filing, or the ensuing investigation caused the offender to halt the fraudulent practices.
- 4) The complaint warned the Government of a significant safety issue.
- 5) The complaint exposed a nationwide practice.
- 6) The relator provided extensive, first-hand details of the fraud to the Government.
- 7) The Government had no knowledge of the fraud.

FACTORS INCREASING AMOUNT OF REWARD

- 8) The relator provided substantial assistance during the investigation and/or pretrial phases of the case.
- 9) At this deposition and/or trial, the relator was an excellent, credible witness.
- 10) The relator's counsel provided substantial assistance to the Government.
- 12) The case went to trial.
- 13) The FCA recovery was relatively small.
- 14) The filing of the complaint had a substantial adverse impact on the relator.

FACTORS DECREASING AMOUNT OF REWARD

- 1) Relator participated in the fraud.
- 2) Relator substantially delayed reporting the fraud or filing the complaint.
- 3) Relator, or relator's counsel, violated FCA procedures.
- 4) Relator had little knowledge of the fraud or only suspicions.
- 5) Relator's knowledge based primarily on public information.
- 6) Relator learned of the fraud in the course of government employment.

FACTORS DECREASING AMOUNT OF REWARD

- 7) Government already knew of the fraud.
- 8) The relator, or relator's counsel, did not provide any help after filing the complaint, hampered the Government's efforts in developing the case, or unreasonably opposed the Government's position in litigation.
- 9) Case required a substantial effort by Government to develop the facts to win the lawsuit.
- 10) Case settled shortly after the complaint was filed or with little need for discovery.
- 11) FCA recovery was relatively large.

COMPLIANCE PROGRAMS

Common Issues in Most Qui Tam Actions

False Statements

Express Certifications

Failure to timely investigate and repay

Stark and Anti-kickback violations

COMPLIANCE OFFICER

Where do you sit in the scheme of things?

GENERAL STATEMENT OF DUTIES AND RESPONSIBILITIES

- The Chief Compliance Officer is responsible for the implementation and ongoing operation of the XYZ corporate compliance program that includes the XYZ Medical Center Corporation (the "Hospital") and its subsidiary corporations Faculty Practice Group, Inc. and XYZ Health Plan, Inc. The Chief Compliance Officer is responsible for taking all necessary action under the Compliance Program to enforce standards/programs adopted pursuant to the Compliance Program by means of auditing, training, mandating compliance and corrective action, and recommending necessary disciplinary action.

DUTIES AND RESPONSIBILITIES

- Establish, maintain and revise compliance policies and procedures reasonably capable of preventing unethical, illegal, or other conduct not complying with Hospital policy or compliance standards/procedures, and otherwise carrying out the policy and purpose of the Compliance Program.

DUTIES AND RESPONSIBILITIES

- Take all necessary steps to communicate compliance standards and procedures to all employees, with a special emphasis on training and the dissemination of training materials.

DUTIES AND RESPONSIBILITIES

- See that remedial actions and systems are designed and implemented to ensure that no unethical, illegal, or other conduct not complying with Hospital policy or Hospital compliance standards/procedures occurs in the future.

WHAT DRIVES WHISTLEBLOWERS?

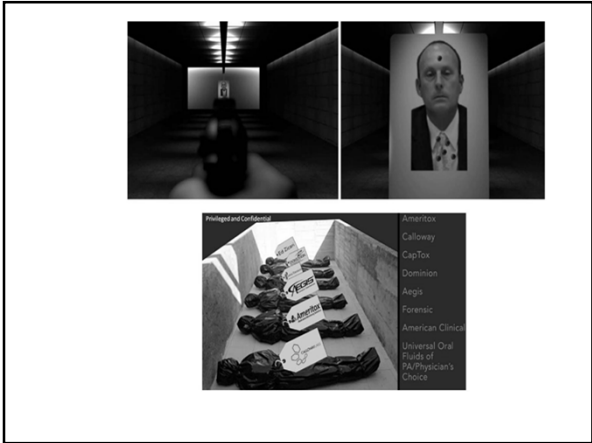
1. "I will be the scapegoat"
2. "No one is taking my complaint seriously"
3. Paying only a portion of the money owed
4. Limiting the lookback period
5. Ineffective communication
6. Potential relator's fee
7. Outrageous practices.

Beware of Retaliation

- 31 USC 3730(h): Relator can bring FCA action for retaliation
- Relief includes reinstatement with seniority, 2x back pay, costs and fees
- Recent example: TRM Case
 - Physical therapist at nursing home brought whistleblower action
 - Company settled
 - Whistleblower brought separate action for retaliation
 - Jury deadlocked

UNITED STATES' COMPLAINT IN INTERVENTION

- Millennium’s General Counsel gave a presentation, nominally on “compliance” entitled “Taking Over.” During the presentation, Millennium’s General Counsel showed an animated slide of a former employee whom Millennium had sued. The former employee’s face was shown on a target range being shot repeatedly, and another slide depicted Millennium’s competitors and the former employee in body bags:



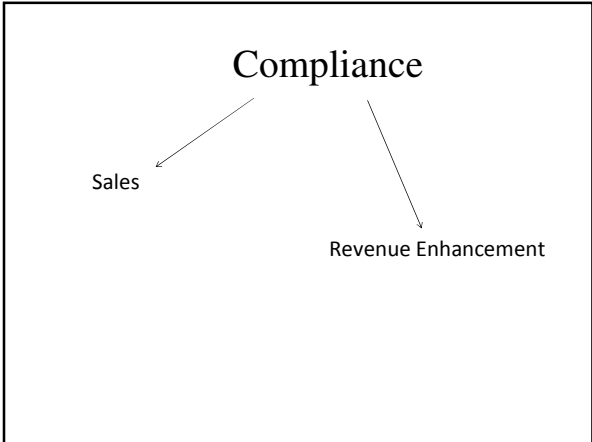
UNITED STATES' COMPLAINT IN INTERVENTION

188. The emphasis on sales came from the top. Millennium’s VP of Sales wrote an email to all Millennium sales representatives in November 2011 that stated: “let’s not forget our primary mission - to sell, sell, sell.” Exhibit 52 (emphasis in original).

COMPLIANCE PROGRAM GOALS

Compliance Program Elements

1. Standards, Policies, and Procedures
2. Compliance Program Administration
3. Screening and Evaluation of Employees, Physicians, Vendors and other Agents
4. Communication, Education, and Training on Compliance Issues
5. Monitoring, Auditing, and Internal Reporting Systems
6. Discipline for Non-Compliance
7. Investigations and Remedial Measures



Government's perspective

Important Factors to Prosecutors

- 1st Questions Asked: Visibility and Presence of Compliance Department?
 - Record of active monitoring, investigating, and consequences for violations
 - Reporting Chain
- Bone Growth Investigation examples
- Compliance Officer/lawyer considerations
- Voluntary disclosures and cooperation

Recent DOJ Cases

- Pharmakon Pharmacy
 - Compounding pharmacy in Indiana
 - 6/17: Owner and compliance officer charged criminally with distributing over-potent and under-potent drugs (morphine, fentanyl)
 - Charges: Conspiracy to defraud U.S.; distributing adulterated drugs
 - Infants injected with over-potent drugs
 - Compliance officer received notice of potency issues and lied to FDA during inspections.

Recent DOJ Cases

- Pacific Alliance Medical Center, Inc.
 - Acute Care hospital in Los Angeles
 - Whistleblower action
 - Stark/Anti-Kickback Allegations
 - Above-market rates to rent space in referring physicians' offices
 - Marketing arrangements providing undue benefit to referring physicians
 - \$42M settlement

Recent DOJ Cases

- U.S. ex rel. Ruckh v. CMC II, LLC
 - Whistleblower case against 2 Florida SNFs, management groups, rehab company
 - Allegations: false certifications that skilled therapy services were medically necessary. Upcoding & placing patients in highest therapy level.
 - DOJ did NOT intervene
 - Trial featured 600 sample Medicare/Medicaid claims
 - Defendants convicted. Damages extrapolated and trebled, with penalties. \$347M verdict

Recent DOJ Cases

- Biodiagnostics Laboratory Services, LLC
 - Clinical blood laboratory in NJ
 - Kickbacks investigation
 - Cash, private jet trips, prostitutes, strip clubs
 - Sham lease and consulting agreements
 - 50 criminal convictions (36 doctors) to date
 - >\$100 million in Medicare payments to BLS

Recent DOJ Cases

- EClinicalWorks
 - Electronic health records vendor
 - Certified to allow HCPs to participate in HITECH incentive program
 - Allegations: falsely represented that it met each “meaningful use” module; kickbacks
 - \$155M False Claims Act settlement

Going After Individuals

- Yates memo
- 2017 examples in FCA Cases
 - Ohio hospice FCA settlement: \$19.5M from company + 2 executives
 - EClinicalWorks FCA settlement: \$155M from company + 6 individuals
 - Curo Health Services: \$12.2M kickbacks settlement; intervened vs. 2 executives
 - Berkeley HeartLab: \$6M kickbacks settlement; intervened vs. 3 executives
