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Whistleblowing Under the False Claims Act

Session 303, March 9, 2018

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**Phillips
& Cohen**

FIGHTING FOR
WHISTLEBLOWERS
FOR 30 YEARS

Conflict of Interest

Colette G. Matzzie, JD

Has no real or apparent conflicts of interest to report.

Conflict of Interest

Brendan Delaney

Has no real or apparent conflicts of interest to report.

Agenda

- Background on the False Claims Act.
- How a whistleblower lawyer evaluates a potential case.
- Considerations for whistleblowers before bringing a qui tam suit.
- Potential Violations of the FCA for Health IT Industry

Learning Objectives

- Explain the federal False Claim Act whistleblowing provisions and how they apply to the health IT industry
- Identify what practices the US federal government may see as violations of the False Claims Act and other considerations for would-be whistleblowers
- Discuss what information-and-technology-vendor employees, customer employees, and contractors can do if they see a potential problem
- Discuss experience of being a whistleblower and working with the Government in law enforcement

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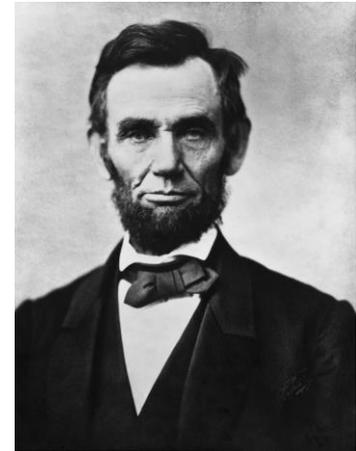
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History of the False Claims Act

The Health IT Industry's Newest Compliance Tool

Background on the False Claims Act

- Known as “Lincoln’s Law.”
 - Originally enacted during the Civil War to combat fraud by companies that sold supplies to the Union Army.
- Key provisions of the law were strengthened in 1986, 2009, and 2010, vastly increasing the law’s reach from Lincoln’s day.
- “Qui Tam” is from the Latin phrase, “Qui tam pro domino rege quam pro se ipso in hac parte sequitur.”
 - “Who pursues this action on our Lord the King’s behalf as well as his own.”



SUCCESS OF THE FCA

- \$56 billion in federal civil recoveries as of 2017.
 - Since 1987, the federal False Claims Act has returned over \$56 billion in civil recoveries to the federal government.
- Over \$9 billion in criminal fines as of 2016.
 - Federal FCA lawsuits have also resulted in over \$7 billion in associated criminal fines.
- Over \$10 billion has gone back to the states as of 2016.
 - Federal FCA lawsuits have also returned over \$6 billion to state Medicaid programs.

Sources: <https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017>; <https://taf.org/IMAGES/fcabrief16.pdf>

SUCCESS OF THE FCA

False Claims Act Recoveries by Industry, 2009-2017

- **Healthcare fraud: \$22.08 billion**
- **Defense contractor fraud: More than \$1.7 billion**
- **Housing and mortgage fraud: More than \$7.5 billion**
- **Non-healthcare or defense fraud: \$10.6 billion**

SUCCESS OF THE FCA

Top Healthcare Recoveries of 2017

- Healthcare providers
 - Life Care Centers of America (\$145 million)
- Pharmaceutical/medical device
 - Mylan (\$465 million)
 - Shire Pharmaceuticals (\$350 million)
- Health IT
 - eClinicalWorks (\$155 million)



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How a Qui Tam Lawyer Evaluates a Potential Case

What makes a False Claims Act violation?

Elements of an FCA Violation

A False Claims Act violation must:

- Be false or fraudulent.
- Present a false “claim” to the government.
- Be “material.”
- Be done “knowingly”.

Elements of an FCA Violation

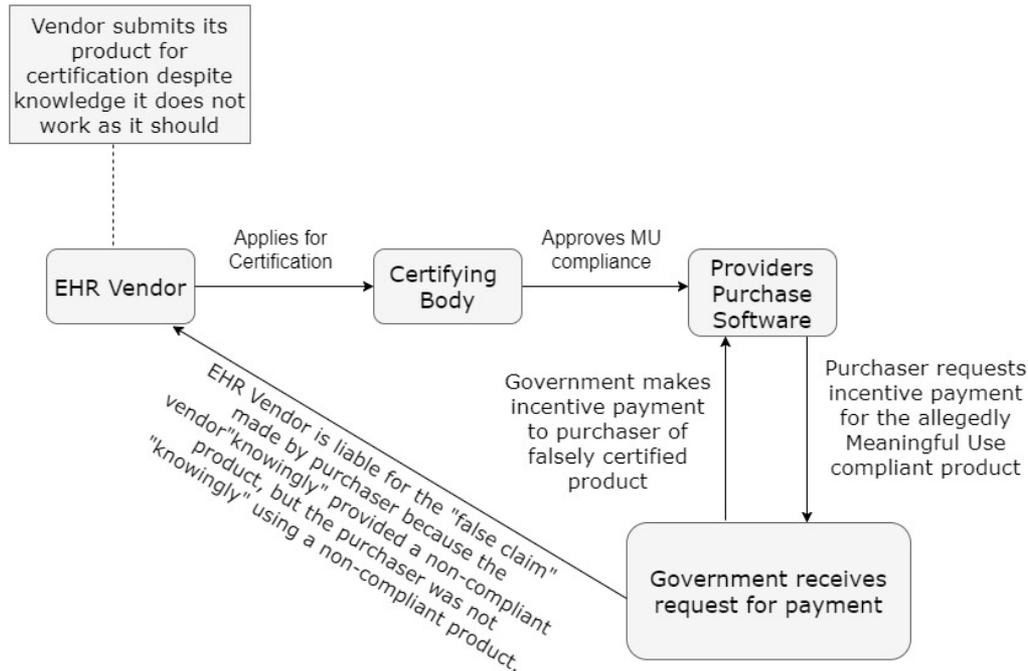
- **False or Fraudulent.**
 - Providing products that do not conform to requirements.
 - Misrepresentations to induce a contract or grant award.
 - Not limited to express false statements.
 - Includes misrepresentation by omission.

- What is a “**claim**” under the False Claims Act?
 - Any request for money or property to be spent or used on the Government’s behalf or to advance government interest, and funds provided or reimbursed by the Government.

Elements of a FCA Violation

- **“Cause to be presented”**
 - An entity or individual who causes another to present a false claim to the Government, or agents of the Government, is liable.
 - An EHR vendor could be liable for false claims presented to CMS by a health care practitioner using the vendor’s software, even if the EHR vendor didn’t directly make that specific false claim.

“Cause to be Presented” Example



Elements of a FCA Violation

- **“Materiality.”**
 - The claim has a natural tendency to cause payment.
 - The false claims must be a significant violation of the contract or law.
 - Consider: Will Government agencies (ONC/CMS/OIG/DOJ) support these allegations as “material”?
- **“Knowingly.”**
 - Mistakes and mere negligence not enough.
 - Government knowledge not a defense but can be relevant.

Whistleblower's Considerations

- Do I have a strong case?
- Are patients at risk because of what I am alleging?
- Will I be willing to assist the Government investigation?
- Can I handle the stress of a long investigation under seal?
- What are the litigation risks?
- Can I strengthen my case by joining with another relator (whistleblower)?
- Am I prepared for retaliation and the possible risks to my career?

Additional Considerations by a Lawyer

- What information does the relator (whistleblower) have?
- What is the relator's background?
- Has the fraud been publicly disclosed?
- What evidence exists to prove the fraud?
- Has a similar case been filed?
- Does the Government know about the allegations?
- What are the damages?
- Can the defendant pay?

Whistleblower Protection in the FCA

- Protects “any” employee, contractor or agent,
- Who is in “any” manner “discriminated against in the terms and conditions of employment,”
- Because of “lawful acts” in support of qui tam, or to stop FCA violation taken by the individual or “associated others.”
- Not limited to discrimination by the defendant.
- Relief: Double back-pay, interest on back-pay, reinstatement, special damages, litigation costs and reasonable attorneys’ fees.
- Statute of limitations: 3 years.

Mechanics of Filing a Qui Tam Case

- All False Claims Act cases are filed under seal.
 - Under seal means nobody knows about the lawsuit except the gov't.
 - Whistleblower's identity is not revealed publicly until court lifts the seal.
- Lawsuit is served on a US Attorney's Office and to DOJ.
 - NOT directly served on the company or individual.
- Intervention decision.
 - Will the government join the lawsuit?
- Possible litigation and role of relator.

Whistleblower Assistance with a Government Investigation

- Government interviews the whistleblower.
- Witnesses are identified.
- Whistleblower produces relevant, non-privileged documents.
- Civil administrative subpoenas or civil investigative demands.
- Deposition of current employees.
- Assistance with criminal investigation.

Enforcement Remedies

False Claims Act lawsuits can result in civil or criminal charges, which can result in:

- Damages and civil penalties.
- Criminal fines and restitution.

- Role of the Office of Inspector General
 - Civil monetary penalties
 - Corporate Integrity Agreements

Whistleblower Awards

- FCA Whistleblowers are entitled to financial rewards if their case is successful.
 - Given for “substantial contribution” to the case.
 - Relators can be awarded between 15% and 30% of the total recovery.
- Attorneys’ fees, costs and expenses for the relator are paid by the defendant when there is a settlement.
 - This figure is often in addition to (i.e. not included in) the announced settlement agreement on DOJ’s website.

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Potential Violations of the FCA

Implications for Health IT

Potential Qui Tam Cases in Health IT

- Fraudulent meaningful use certification
 - False statements and fraudulent conduct.
 - Software not MU compliant and/or patient safety risks.
 - MU stage 2 & 3.
- Failure to perform required functionality
 - RxNorm, SNOMED CT, CVX, and LOINC codes.
 - CPOE issues.
 - CQM issues.

Potential Qui Tam Cases in Health IT

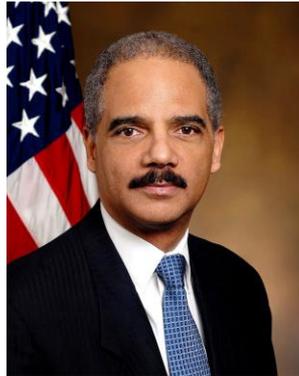
- Violations of the Anti-Kickback Statute
 - Improper payments to purchasers.
 - Payments to/from providers including pharmaceutical companies, pharmacies, medical device vendors, home health or rehab or other providers, even billing services.

Potential Qui Tam Cases in Health IT

- Upcoding/overbilling
 - Clinical decision support/use of order sets.
 - Provider schemes for overutilization/misuse of system.

“...There are troubling indications that some providers are using this technology to game the system, possibly to obtain payments to which they are not entitled...There are also reports that some hospitals may be using electronic health records to facilitate ‘upcoding’ of the intensity of care or severity of patients’ condition as a means to profit with no commensurate improvement in the quality of care.”

- 2012 letter to several hospital associations from then-HHS Secretary Kathleen Sebelius and Attorney General Eric Holder.



Potential Qui Tam Cases in Health IT

WHAT COMES NEXT?

Potential Qui Tam Cases in Health IT

- Population-based health tools
 - Data integrity.
 - Predictive analytics.
 - Clinical decision support/risk stratification/case management.
- Quality-based payment and managed care payment systems
 - MIPS, ACOs, star ratings.

Questions

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