2019 Alabama Healthcare Fraud Summit

Navigating Qui Tam/ Whistleblower Actions

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Introduction: Lots of Activity

- Over $2.8 billion recovered in FCA cases in FY 2018
  - 10th consecutive year recoveries exceeded $2 billion
  - Largest industry target was healthcare ($2.5 billion)
  - Total recoveries since Jan. 2009 exceed $37 billion
- Sharp incline in whistleblower suits
  - Almost 650 new qui tam cases filed in FY 2018
  - Compare with 2000-2009, only 300 to 450 filed per year
  - $2.1 billion related to qui tam cases in FY 2018

Agenda

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False Claims

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Elements and Theories

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Elements and Theories

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The Federal False Claims Act (FCA)

Liability for submission of false claims extends to one who:

"knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."

31 USC § 3729(a)(1)(A)

"knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim"

31 USC § 3729(a)(1)(B)

"conspires to commit [an FCA violation]."

31 USC § 3729(a)(1)(C)

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

31 USC § 3729(a)(1)(G)

Damages and Penalties

- Damages
  - 3 times amount claimed
- Penalties
  - Currently $11,181 to $22,363 per claim
  - Increase yearly based on inflation
- Reasonable attorneys' fees and costs

Elements

- Existence of a Claim
- Falsity
- Knowledge
- Materiality
- Damages?
  - Penalties may be recovered even in the absence of damages
  - But alleged actions must have some potential impact on the U.S. Treasury

Falsity

What is “false?”

- Factually false
  - Services not provided
  - Services not provided as described
  - Worthless services
- Legally false
  - Express false certification – falsely certifying compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment
  - Implied false certification – the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment

What is “fraudulent?”

- Fraudulent inducement

Falsity – Kickbacks

- Affordable Care Act amends Anti-Kickback Statute (AKS) to state:

> "In addition to the penalties provided for in this section . . . a claim that includes items or services resulting from a violation of this section [the AKS] constitutes a false or fraudulent claim."
>
> 42 U.S.C. § 1320-7b(g)

Knowledge

- "Knowingly" defined as
  - Actual knowledge of the falsity of the information
  - Acting in deliberate ignorance
  - Acting with reckless disregard
    - "an extension of gross negligence or an extreme version of ordinary negligence." *Urquilla-Diaz v. Kaplan University*, 780 F.3d 1039, 1058 (11th Cir. 2015).

Materiality

- "Material" defined as
  - Having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property
- Demanding standard that turns on the likely or actual behavior of the recipient of the alleged misrepresentation

Universal Health Services, Inc. v. U.S. ex rel. Escobar, 136 S. Ct. 1989 (June 16, 2016)

- Supreme Court upholds "implied certification" theory of falsity.
  - Limited to "at least where two conditions are satisfied"—
    - (1) a claim makes specific representations about a good or service (as opposed to merely requesting payment) and
    - (2) the defendant's failure to disclose noncompliance with material statutory, regulatory or contractual requirements makes those specific representations "misleading half-truths."
  - Since ruling, DOJ and defendants disagree as to whether these two elements are necessary or merely sufficient

- Supreme Court emphasizes the "demanding" nature of the materiality standard.
  - Turns on the "likely or actual behavior of the recipient of the alleged misrepresentation"
  - Not enough to show "government would be entitled to refuse payment were it aware of the violation."
  - Govt's past practices in paying such claims are relevant to the determination
  - Govt's designation of a requirement as a "condition of payment" is relevant but not dispositive

Reverse False Claims

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Reverse False Claims

Liability for reverse false claims extends to anyone who:

"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 to pay or transmit money or property to the Government."

31 USC § 3729(a)(1)(G)

Reverse False Claims: "Obligation" Defined

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

31 USC § 3729(b)(3)

Overpayments

- Affordable Care Act imposes an affirmative obligation to report and return overpayments.
- "Overpayment" means "any funds that a person receives or retains under [Medicare or Medicaid] to which the person, after applicable reconciliation, is not entitled."
- Overpayments must be reported and returned by the later of
  - 60 days after overpayment is "identified"; or
  - The date any corresponding cost report is due, if applicable
- An overpayment not timely reported and returned is an "obligation" under the FCA.

42 U.S.C. § 1320a-7k(d)

When Does the Clock Start?

- When are overpayments "identified" to start the 60-day repayment clock?
- "[W]hen the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment." 81 Fed. Reg. 7654, 7661
- Reasonable diligence for these purposes includes both proactive compliance activities and investigations conducted in response to receiving "credible information" of a potential overpayment. *Id*.
- Reasonable diligence is demonstrated through the timely good faith investigation of credible information, "which is at most 6 months from receipt of the credible information, except in extraordinary circumstances." 81 Fed. Reg. at 7662

US ex rel. Keltner v. Lakeshore Med. Clinic, Ltd. No. 11-cv-00892 (E.D. Wis. March 28, 2013)

- Action brought by former billing employee alleging failure to repay overpayments.
- Alleged that defendant discovered in an annual audit that two physicians had upcoding error rates greater than 10%.
- Hospital repaid the specific identified overpayments, but did not go back to review other claims from the physicians. Also, ceased auditing these physicians going forward.
- Court denied defendant's motion to dismiss.
  - Relator "plausibly suggest[ed] that [Lakeshore] acted with reckless disregard for the truth and submitted some false claims."
  - Lakeshore "intentionally refused to investigate the possibility that it was overpaid" and "may have unlawfully avoided an obligation to pay money to the government."

Enforcement / Whistleblowers

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Variety of Potential Legal Remedies

- Several different statutory bases for false claims liability
- Several different types of liability
  - Criminal
  - Civil
  - Administrative

Variety of Potential Enforcers

- Civil AUSAs
- Criminal AUSAs
- OIG
- State AGs/Medicaid Fraud Control Units
- Qui Tam Relators (whistleblowers)

Qui Tam Provisions

- Action may be brought by a relator (whistleblower) on behalf of the U.S. government
- 60 or more days for government to investigate and intervene
  - But there are cases that remain “under seal” for years
- If government intervenes, relator comes along for the ride
- Relator share of recovery
  - 15% to 25% if government intervenes
  - 25% to 30% if government does not intervene

Public Disclosure / Original Source

In civil actions for false claims, "[t]he court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were **publicly disclosed—**

> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
>
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
>
> (iii) from the news media

unless the action is brought by the Attorney General or the person bringing the action is an **original source** of the information."

31 U.S.C. § 3730(e)(4)(A)

Public Disclosure / Original Source

- The term "**original source**" means "an individual who either
  - (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or
  - (2) has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section."

31 U.S.C. § 3730(e)(4)(B)

A Selection of Recent Cases

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Objective Falsity

- *United States v. AseraCare, Inc.*, Case No. 16-13004 (11th Cir. Sept. 9, 2019)
  - Rare case to go to trial (August 2015)
  - Government alleges that AseraCare submitted false claims to Medicare for patients who were not eligible for the Medicare hospice benefit.
  - Law and guidance base hospice eligibility on the physician's clinical judgment.
  - At trial, each side presented physician experts to provide opinions on individual AseraCare patient medical records.

Objective Falsity (*continued*)

- *United States v. AseraCare, Inc.*, Case No. 16-13004 (11th Cir. Sept. 9, 2019)
  - "Nothing in the statutory or regulatory framework suggests that a clinical judgment regarding a patient's prognosis is invalid or illegitimate merely because an unaffiliated physician reviewing the relevant records after the fact disagrees with that clinical judgment."
  - "All the legal framework asks is that physicians exercise their best judgment in light of the facts at hand and that they document their rationale."
  - "[T]he claim cannot be 'false'—and thus cannot trigger FCA liability—if the underlying clinical judgment does not reflect an objective falsehood."

Ambiguous Regulation

- *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281 (D.C. Cir. 2015)
  - No FCA violation where:
    - The law or regulation at issue is ambiguous;
    - The defendant's interpretation is reasonable; and
    - The agency issued no formal guidance indicating that the defendant's interpretation was wrong
  - Rejected argument that defendant acted recklessly by not seeing the agency's legal opinion

Ambiguous Regulation

- *U.S. ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148 (11th Cir. May 26, 2017)
  - "Although ambiguity may be relevant to the scienter analysis, it does not foreclose a finding of scienter. Instead, a court must determine whether the defendant actually knew or should have known that its conduct violated a regulation in light of any ambiguity at the time of the alleged violation."
  - "Scienter is not determined by the ambiguity of a regulation, and can exist even if a defendant's interpretation is reasonable."
  - Granted summary judgment for defendants because relators failed to present sufficient evidence of scienter.

Resolving FCA Matters

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Dynamics of FCA Litigation

- DOJ has enormous settlement leverage
  - Astronomical damages/penalties; extreme sanctions
  - Threat of public unsealing/filing of “fraud” claims
- Companies often choose to settle
  - Tens or hundreds of millions
  - Corporate Integrity Agreements
  - Avoid exclusion or debarment at all costs
- Opportunities to reduce or eliminate liability come early
  - Presentations during the investigation phase
  - Motions to Dismiss

Questions?

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