U.S. v. Sulzbach: Government Theories, Potential Defenses, and Lessons Learned

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Background

- June 1994: National Medical Enterprises, Inc. (NME) settles health care fraud allegations (paying for referrals, billing for medically unnecessary services, double billing, denying necessary services):
  - $346 Million civil fine
  - $33 Million criminal fine
  - 5-year Corporate Integrity Agreement (signed by Ms. Sulzbach)
- 1995: NME and American Medical Holdings, Inc. merge, Tenet Healthcare Corporation (Tenet) is formed
- Tenet operates under CIA until 1999

Background

- Sulzbach:
  - In-house counsel for NME
  - Assoc. General Counsel, Corporate Integrity Program Director for Tenet
  - General Counsel for Tenet
- For 15 years, Tenet has been under Federal scrutiny
  - Redding Medical Center: allegations of unnecessary cardiology procedures
  - Alvarado Hospital: allegations of improper physician recruitment arrangements
  - $920 Million global settlement last year pertaining to allegations of improper billing of “outlier” services, among other allegations
- Sulzbach resigned in September, 2003

The Corporate Integrity Agreement

- Obtain approval of outside counsel to review physician agreements
- Establish Corporate Integrity Program
- Investigate employee reports of misconduct, notify DOJ / HHS of such reports, outcomes of such investigations
- Provide annual "Compliance Reports," including certification that, to the best of the certifier's knowledge and belief, Tenet was in compliance or non-compliance with (1) the terms of the CIA; (2) the anti-kickback statute; and (3) "other federal program legal requirements"
- Compliance Reports must include summary of ongoing investigations, legal proceedings involving compliance with Federal program legal requirements

The Underlying Alleged Illegalities

- 1993/1994: North Ridge Medical Center, a Tenet hospital in Florida, employed 12 physicians with compensation in excess of fair market value
  - Pre-hire financial analyses showed that North Ridge would "suffer significant annual losses"
  - However, losses minimized / eliminated when North Ridge factored in revenues from the physicians' clinical lab referrals
  - Compensation nearly doubled physicians' previous income
  - Post-hire referrals soared
- If true, potential Stark Law violations
  - Exception for employment arrangements requires that compensation be fair market value, commercially reasonable, and not take into account the volume or value of referrals

Six Months in 1997

- February, 1997: Tenet executive Bennett writes memo to his boss, expresses concern that physician contracts at North Ridge violated the Stark Law
- Bennett's boss forwards the memo to Sulzbach
- Sulzbach retains McDermott, Will & Emery to review the issues raised by the Bennett Memo
- May 13, 1997: Sal Barbera, Tenet employee, files FCA *qui tam* suit under seal: alleges, among other things, that North Ridge violated Stark Law by billing Medicare while maintaining unexcepted relationships with physicians
- May 27, 1997: McDermott draft report highlights improprieties of North Ridge's physician agreements

Six Months in 1997, cont'd.,

- June 23, 1997: McDermott produces final report; same conclusions as draft report
- June 27, 1997: Tenet submits Compliance Report to HHS; Sulzbach certifies that, to the best of her knowledge and belief:
  - Tenet in compliance with the terms of the CIA
  - Tenet in compliance with the anti-kickback statute
  - Tenet in compliance with "other federal program legal requirements"
- July 31, 1997: Sulzbach writes memo re: physician agreements, asks Bennett's boss to implement corrective actions identified by McDermott Reports or a disclosure to HHS may have to be made

1998 To Present

- January, March 1998: Four of twelve physicians at issue cease employment with North Ridge
- June, 1998: Tenet submits annual Compliance Report; Sulzbach makes same certification
- November, 1998 – August, 1999: other eight physicians at issue cease employment with North Ridge
- As late as 1999, North Ridge continues to submit claims to Medicare for services rendered to patients referred by the physicians at issue
- 2001: Barbera *qui tam* complaint unsealed, amended to rely on Bennett Memo
- 2003/4: In Barbera litigation, Tenet denies that North Ridge physician arrangements violated Stark, settles for $22.5M
- 2006: As part of $920M settlement, Tenet produces McDermott Reports and Sulzbach's July, 1997 memo (previously asserted to be privileged)

Government's Case Against Sulzbach

- Stark Law violations are the predicate
- Under Stark, Tenet forfeited the right to bill Medicare for services rendered pursuant to prohibited referrals and was required to refund any payments that it received
- Claims submitted in violation of Stark also violate the FCA, exposing the violator to treble damages and penalties of $10,000 per claim
- When Tenet settled the Barbera qui tam suit, the settlement agreement excluded claims against individuals

Government's Damage Causation Allegations

- U.S. was damaged by Sulzbach's:
  - 1997 and 1998 submission of false Compliance Report certifications
  - Failure to stop Tenet from violating the Stark Law
  - Failure to report Tenet's violations
  - Permitting Tenet to receive payments to which it was not entitled
  - Obstruction of the Government's efforts to discover and recover the improper payments

The Applicable Liability Provisions of the FCA

The Government alleges that Sulzbach violated the FCA by

A) Causing false claims to be presented in violation of 31 U.S.C. §3729(a)(1)

B) Using a false statement to get a false claim paid in violation of 31 U.S.C. §3729(a)(2)

C) Using a false statement to avoid or decrease an obligation to pay the U.S. in violation of 31 U.S.C. §3729(a)(7)

FCA Statute of Limitations Provisions

- FCA suit must be filed either within 6 years of the alleged violations or within 3 years from when "*facts material to the right of action*" are known or should have been known by the U.S. official charged with the responsibility to act but in no event more than 10 years after the violation
- U.S. will argue that it filed within 3 years of its 2006 discovery of the 1997 McDermott Reports and these are material to Tenet's "knowing" submission of false claims
- Sulzbach can argue that the U.S. knew all the facts upon which the McDermott Reports based their Stark Law conclusions, at least by the time of the Government's February, 2001 intervention in the Barbera *qui tam* suit
- U.S. will counter that it didn't know Sulzbach's role and level of knowledge until 2006 and that she's the defendant now, not Tenet

Damages

- The U.S. alleges that there are 70,000 "individual payments" totaling $18 million for which Sulzbach is legally responsible; these have to be North Ridge claims submitted from the date of the 1997 McDermott Reports to the final submissions in 1999
- Sulzbach can argue again that the U.S. knew all the underlying facts upon which the McDermott Reports were based, and already collected all its damages in the Barbera *qui tam* settlement
- The U.S. will counter that it compromised its claims in Barbera because of the usual challenges it faced in proving the FCA "knowing" element; that challenge would have been diminished if it had known of Tenet's awareness of the McDermott Reports' conclusions
- The Government's settlement strategy and calculations may be fair game for Sulzbach's lawyers to explore; what was the Government's starting point in dollars and claims in Barbera negotiations?; Sulzbach's single damages shouldn't be more than the difference between that starting point and settlement
- Is the Government right that the Barbera settlement payment is only applied to its Sulzbach damages after they've been trebled?

Points of Contention

- FCA Causation
- Were Medicare's payments to North Ridge conditioned on the accuracy of the Sulzbach Compliance Reports' certifications?
- Did Sulzbach/Tenet really use the Compliance Reports' certifications to obtain payment of the North Ridge claims or to later avoid paying more in the Barbera settlement?
- What would the Government have done differently if Tenet had disclosed the potential Stark Law violations in 1997?
  - The Government knew of the Stark Law violations alleged in the 1997 Barbera *qui tam* lawsuit

Key Lessons Learned

- ***First:*** Government views False Claims Act authority very broadly; any certification at risk of linkage to a "claim"
- ***Second:*** Try to negotiate a Corporate Integrity Agreement that is reasonable under the circumstances and imposes obligations with which you can comply.
- ***Third***: If you are under a CIA, take obligations it imposes seriously and establish reliable procedures to comply with those obligations.
- ***Fourth:*** Plan your CIA compliance efforts taking into account your reporting obligations (e.g., audits, investigations)
- ***Fifth***: Consider how (or whether) your entity will "protect" individual certifier

The CIA Itself

- Executing the CIA is only the beginning.
- A CIA is a contract with the Government. When negotiating terms, contemplate future performance problems.
- Common terms of a CIA
  - Multi-year term
  - Implement corporate integrity program
  - Annual compliance reports that are certified based on best knowledge and belief
  - Engage independent review organization or other third party to perform compliance reviews
- What may be negotiable: Wordsmithing is crucial
  - Entities and/or persons covered
  - Obligations regarding specific allegations
  - Reportable events: “a reasonable person…may consider a potential violation of law”
  - Opportunities and process to identify issues and cure (Stark violations unusual in this sense)
  - Timeframes to report
- Borderline Issue
  - Attorney-client privilege

Know Your CIA and Implications Regarding Certification

- Among the requirements, CIA at issue in *Sulzbach* required Tenet to:
  - Engage external legal counsel to review contracts involving payments to physicians; maintain opinions
  - "Investigate" any potential misconduct and report existence of investigations to Government
  - Take appropriate corrective action
- Potential performance issues
  - Identifying the existence of an "investigation"
  - Recognizing its implications concerning CIA obligations
  - Establishing response process for dealing with employee complaints
  - Considering process – if any – that would permit resolution of Stark issue without triggering notice obligations

Who's Affected by *U.S. v. Sulzbach*?

- *U.S. v. Sulzbach* should be a wake-up call nationally for any MCO or provider operating under a CIA, but its implications are far broader
- Other parties to certification of Compliance Agreements also affected
- Government contractors are also required to self-report violations
  - FEHBP contractors must report to OPM on the results of its mandatory fraud and abuse detection efforts.
  - CMS proposed rule would require Medicare Advantage Organizations and Part D Plan Sponsors to self-report potential fraud or misconduct to appropriate government authority.

Who's Affected by *U.S. v. Sulzbach*?

- MCOs and providers that file certifications with the Government:
  - Medicare fee-for-service providers
    - Cost reports
    - UB-92
    - Medicare participating provider agreements
  - FEHBP contractors' certificates of accurate pricing
  - Medicare Advantage / Part D certifications including:
    - Enrollment and Payment Data
    - Risk Adjustment Data
    - Prescription Drug Event
  - Medicaid MCOs
    - Encounter Data
  - Government uses false certifications as basis of False Claims Act cases against MCOs and providers. *Sulzbach* highlights the potential exposure of those who sign those certifications.

Who's Affected by *U.S. v. Sulzbach*?

- MCOs / providers that conduct internal investigations
  - Although there is no general obligation to self-disclose violations, MCOs / providers should not conduct internal investigations unless they intend to correct any detected violations.
    - Findings may bear on ability to certify to best knowledge and belief
    - Findings could be used by *qui tam* plaintiff
    - Findings could end up in the Government's hands
- Important question raised by case is how should results of internal investigations be communicated
  - Detailed written report vs. oral presentation of findings
- Dual role of general counsel and compliance officer causes additional difficulties

Thank you for your participation

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