Private Enforcement of Healthcare Fraud & Abuse Laws

Thursday, June 21, 2018

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- Brad represents health care clients in complex litigation, government and internal corporate investigations, enforcement proceedings, whistleblower suits, and payor audits
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Agenda

- Overview of Enforcement Agencies
- Summary of Fraud and Abuse Laws
- Expansion of Federal Travel Act allegations in Healthcare Enforcement
- Developments in Private Enforcement of Fraud and Abuse Laws
- Conclusion & Questions
DOJ, continued

- Commitment to prosecute healthcare fraud
  - Criminal/Civil/Antitrust Divisions
  - Consumer Protection Branch
  - FBI/DEA
  - Healthcare Fraud Unit Coordinators within 94 United States Attorneys' Offices
  - Yates Memorandum

- Relationships with federal & state enforcement agencies with distinct funding sources
- Partnerships with private payors
Other Enforcement Players

- Centers for Medicare and Medicaid Services (CMS)
- TRICARE Management Authority
- Offices of Inspectors General Federal and State
- Medicaid State Agencies
- Medicaid Fraud Control Units
- Licensing Boards
- Local District Attorneys
- Federal/State Contractors
- Commercial “Special Investigative Units”
- Whistleblowers
- Private Litigants

Summary of Fraud and Abuse Laws
Health Care Fraud Statute (18 U.S.C. § 1347)

- Federal criminal statute for public AND private health care fraud
- Knowingly and willfully execute/attempt a scheme or artifice to:
  - Defraud health care benefit program; or
  - Obtain by false or fraudulent pretenses property under custody/control of program in connection with delivery or payment for items or services
- 10-year imprisonment, restitution, and fine

False Claims Act (31 U.S.C. § 3729)

- A false claim or statement (or conspiracy) for payment to the United States
- Claim must be submitted "knowingly"
  - Actual knowledge
  - Deliberate ignorance
  - Reckless disregard
  - No specific intent to defraud required
- “Reverse” false claims is the knowing retention of a known overpayment
- AKS and Stark are bases for liability
Anti-Kickback Statute (42 U.S.C. §1320a-7b(b))

- Federal criminal statute
- Prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration for recommending/arranging items/services paid for by a federal healthcare program
- Remuneration is anything of value
- One purpose test
- Includes non-clinicians

AKS, continued

- Advisory Opinions address industry concerns, not precedential
- Violation is a felony, punishable by:
  - Criminal fines of up to $25,000 per violation
  - Imprisonment for up to 5 years
  - Civil monetary penalties
  - Exclusion
- Penalties and criminal liability apply to both sides of the arrangement
- Violation can also be the basis of an FCA claim
- State analogs may limit kickbacks in cash / private plans
AKS, continued

- Several statutory exceptions and regulatory safe harbors including:
  - Personal services and management contracts
  - Bona fide employees
  - Investment interests
  - Space and equipment rentals
  - Discounts
- Generally, must be commercially reasonable and fair market value (FMV)

AKS, continued

- If no safe harbor, the totality of the facts and circumstances are analyzed
- FMV / commercial reasonableness generally means less risk
- OIG’s principal concerns in assessing potential risk are:
  - Overutilization
  - Increased federal healthcare program costs
  - Interference with clinical decision-making
  - Patient safety and quality of care concerns
  - Decrease in patient freedom of choice
  - Unfair competition
Stark Law (42 U.S.C. §1395)

- Prohibits physician self-referrals
  - Must involve physician referral
  - Ownership interest or compensation arrangement
  - Designated health services (e.g., outpatient drugs, DME)
  - Medicare and Medicaid only
- Strict liability – Must fully satisfy statutory or regulatory exception
- Remedy is payment disallowance for entire period of noncompliance
- Exclusion and CMP liability
- May be violation of FCA
- State law may limit non-Medicare business agreements

Stark Law, continued

- Stark exceptions include:
  - Publicly traded securities and mutual funds
  - Bona fide employment relationships
  - Personal service arrangements
  - Rental of office space and equipment
  - Fair market value compensation
  - Indirect compensation arrangements
- Must meet every requirement of a Stark exception
- Generally must be commercially reasonable and FMV
Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a(a))

- HHS-OIG administrative remedy
- Permissive exclusion and money damages for specific violations, including:
  - Beneficiary inducement
  - Payment or receipt of illegal kickbacks
- Mirrors FCA but not governed by civil rules of procedure or evidence
  - Limited discovery
  - Hearsay admissible
- OIG usually releases this authority in exchange for Corporate Integrity Agreement

State Fraud and Abuse Statutes

- Many states have enacted their own anti-kickback statutes, which vary widely
- Other state healthcare laws include:
  - Self-referral prohibitions/restrictions (i.e., “mini-Stark” laws)
  - False claims (“mini-FCA” or similar statutes)
  - Worker’s compensation
  - Commercial bribery
  - Consumer protection
  - Out-of-Network (OON) billing and collection co-pays
Growth of Federal Travel Act Allegations in Healthcare Enforcement

The Federal Travel Act (18 U.S.C. § 1952)

- Anti-racketeering statute used to prosecute AKS violations
  - Prevents use of mail or interstate/foreign travel or commerce with intent to “promote, manage, establish, carry on, or facilitate the promotion, management, establishment, or carrying on, of any unlawful activity”
  - “Unlawful activity” includes “bribery...in violation of the laws of the State in which committed or of the United States”
- Can transform a state misdemeanor (commercial bribery) that is seldom prosecuted separately in state court into a federal felony
- Penalties include imprisonment up to 5 years, fines, or both
Travel Act, continued

**USA v. Forest Park Med. Ctr., No. 3:16-cr-00516 (N.D. Tex)**

- Physician-owned, out-of-network hospital
- Alleged scheme involved $40M in kickbacks, bribes, and other inducements (e.g., copayment waivers) for referrals to FPMC
  - $200M in claims paid from 2009 to 2013
  - Federal payors included TRICARE, Federal Employees Health Benefits (FEHB) Program, Federal Employees’ Compensation Act (FECA) program
- FPMC agreed to pay around $475K to settle kickback allegations relating to TRICARE and FECA referrals
- 21 executives and doctors charged December 2016
  - Conspiracy to pay and receive healthcare bribes and kickbacks under AKS and Travel Act
- Multiple parties have pleaded guilty to Travel Act violations, including the anesthesiologist/founder

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Travel Act, continued

**Biodiagnostic Laboratory Services, LLC (D.N.J.)**

- More than 50 convictions, including 36 physicians, in connection with a scheme operated by BLS, a New Jersey blood-testing lab
- Payments to physicians included bribes, sham lease, and consulting payments
- In June 2016, BLS pleaded guilty to one count of conspiracy to violate the AKS and the Travel Act and one count of conspiracy to commit money laundering
- Multiple physicians have pleaded guilty to Travel Act and AKS violations, money laundering, and other charges
- In March 2017, a federal jury convicted a physician of conspiring to violate and actual violations of the AKS and the Travel Act, as well as wire fraud

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**GT Greenberg Traurig**
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Travel Act, continued

**Pacific Hospital (C.D. Cal.)**
- Hospital allegedly paid tens of millions of dollars in illegal kickbacks to doctors and others for referring patients
- Patients underwent spinal surgeries that led to more than $580M in fraudulent bills being submitted over eight years
- Former CFO pleaded guilty to participating in a conspiracy that engaged in, among other things, paying or receiving kickbacks and violating the Travel Act (specifically, interstate travel in aid of a racketeering enterprise)
- Orthopedic surgeon pleaded guilty to conspiracy to commit mail fraud, honest services fraud, and violations of the Travel Act, as well as a separate, substantive Travel Act violation

Developments in Private Enforcement of Fraud and Abuse Laws
Private Enforcement

Qui tam actions under FCA

DOJ New Civil Matters – Qui Tam v. Non Qui Tam Actions

Relators’ Share of Qui Tam Settlements & Judgments
Private Enforcement, continued

2017 FCA Settlements & Judgments

- Healthcare $2,400,000,000
- Non-Healthcare $1,300,000,000

Private Enforcement, continued

- **Providers, suppliers, and others alleging illegality to terminate contracts**
    - DME supplier agreed to pay an independent marketer a percentage of DME sales it generated
    - When marketer sued for breach of contract, DME supplier defended on the ground that the agreement was illegal under the federal anti-kickback statute
    - A Florida appeals court affirmed the trial court’s conclusion that the agreement was illegal and unenforceable
Private Enforcement, continued

- **Beneficiaries suing commercial payors**
  - Potential class action by UnitedHealth members arguing that their plans did not permit UnitedHealth to charge more for copays than their prescriptions actually cost and pocket the difference
  - Example: Pharmacy charged $11.65 for a prescription, customer paid a $50 copay, and UnitedHealth allegedly kept the $38.35 difference
  - Alleged violations of ERISA, RICO, breach of contract, fraud, and state laws, including consumer protection and insurance laws

Private Enforcement, continued

- **Commercial payors suing providers to recoup/avoid tainted payments**
    - Mississippi hospital allegedly entered into contract with labs that allowed them to submit claims using the hospital’s name and billing number for services not performed at or by the hospital
    - $9.8M in claims paid by Blue Cross (in network)
    - In May 2017, Blue Cross sued the hospital for breach of contract and the labs for fraud, civil conspiracy, negligent misrepresentation, and unjust enrichment
    - Blue Cross asked the court to enjoin further submission of misrepresented claims and for a declaration that it is not required to pay for pending misrepresented claims
    - The claims were settled
Private Enforcement, continued

  - Similar suit involving the same laboratories
  - Allegedly acquired control over a financially-vulnerable Oklahoma hospital and caused Anthem to pay $21.6M in claims between January 2016 and April 2017
  - Increase from an average of 6 claims/month to 834 claims/month
  - Civil RICO, fraud, negligent misrepresentation, money had and received, unjust enrichment, civil conspiracy, tortious interference, injunctive relief
  - Ongoing

  - Allegations:
    - Defendants used a 15-bed hospital in Missouri to bill BCBS plans for lab tests performed by various labs for patients who were never present at the hospital, were never seen by providers credentialed at the hospital, and were located outside the hospital’s service area
    - Since August 2016, Defendants billed Plaintiffs more than $258M for lab testing purportedly performed at the hospital, causing Plaintiffs to reimburse the hospital more than $91M
    - Resulted in “staggering” increase in urine drug testing claims, from 85 in the first six months of 2016, to more than 37,000 in the first six months of 2017
  - Fraud, negligent misrepresentation, tortious interference, civil conspiracy, unjust enrichment, money had and received, ERISA, injunctive relief
  - Ongoing
Private Enforcement, continued

  - Aetna sued network of ASCs for fraud, intentional interference with contractual relations, and unjust enrichment
  - Out-of-network overbilling and kickback scheme
  - In 2016, a California jury awarded Aetna $37.4M in damages

  - Similar kickback case against Texas hospital
  - In 2016, a federal court awarded Aetna $41.4M
  - Hospital prevailed in a similar lawsuit brought by Cigna
Private Enforcement, continued

- **Cigna v. Sky Toxicology, No. 9:15-cv-80994-WJZ (S.D. Fla.)**
  - Cigna sued Texas-based out of network diagnostic laboratories which provide testing on urine samples, alleging a widespread fraudulent scheme causing Cigna to incur over $20 million in damages, in violation of federal and state law
  - Sky Labs engaged in alleged “fee forgiveness” scheme, failing to bill patients for their required cost-share obligations, and promising not to seek reimbursement from the patients for any other portion of its bill that the plan does not cover
  - Sky Labs also allegedly induced physicians and drug treatment centers to refer patients to its OON labs by offering kickbacks
  - The claims were settled

- **United Healthcare v. Sky Toxicology, et al., Case No. 9:16-cv-80649-RLR (S.D. Fla.)**
  - United sued Sky Toxicology and other defendants, alleging medical testing lab executives cost it $50 million by offering kickbacks in the form of partnership shares to treatment facilities and doctors in exchange for often-unnecessary urine test referrals, disguising payments as partnership distributions
  - The lab defendants allegedly encouraged addiction treatment facilities and pain management physicians to refer large quantities of urinalysis tests, which the labs then billed to United without requesting payment from the insureds
  - The action was dismissed without prejudice after the court concluded that the plaintiffs lack standing to assert ERISA claims
Private Enforcement, continued

  - United sued Next Health and its subsidiaries, Texas-based companies which perform drug and genetic lab testing
  - Labs allegedly paid bribes and kickbacks to referral sources in exchange for test orders, improperly utilized standing test protocols regardless of patients’ conditions or needs and performed and billed for testing services that were neither necessary nor ordered
  - Complaint asserted claims for fraud, conspiracy, unjust enrichment, and violations of the Texas Theft Liability Act and Lanham Act
  - Case remains pending

Private Enforcement, continued

  - State Farm alleged that accident referral service (“1-800-Ask-Gary”) orchestrated a fraudulent referral scheme to lure automobile accident victims to the referral service owner’s Florida clinics
  - According to the Complaint, Defendants unlawfully collected accident victims' PIP and medical benefits, in violation of the Anti-Kickback Statute, Patient Brokering Act, and Patient Self-Referral Act
  - In addition to the statutory claims, State Farm sought declaratory judgment that it is not liable for any bills submitted by the defendants, and asserted common law claims for fraud and unjust enrichment, with damages of at least $480,000 in fraudulent bills
  - The Court denied the motion to dismiss, and matter was subsequently settled
Conclusion & Questions

- Attendees can submit questions via the chat feature on the webinar interface