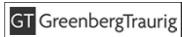


Recent Enforcement Trends: Examples from AKS and Stark to Private Enforcement



Law Office of
Sean McKenna

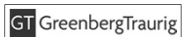
Sean McKenna

sean@seanmckennalaw.com | 786.973.3762

- Former 10-year Assistant U.S. Attorney, Attorney with U.S. Office of Counsel to the Inspector General for HHS and U.S. Department of HHS, Office of General Counsel
- Now represents healthcare providers in all manner of litigation, regulatory, and enforcement matters



2



Law Office of
Sean McKenna

Nathan Fish

fishn@gtlaw.com | 214.665.3657

- Nathan counsels health care clients on regulatory matters, including fraud and abuse, Medicare/Medicaid enrollment and reimbursement, and licensure
- Nathan also has wide-ranging experience with health care transactions, internal investigations, and compliance reviews, and government enforcement actions, investigations, and audits



3



Law Office of
Sean McKenna

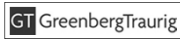
Brad Smyer

brad.smyer@alston.com | 214.922.3400

- Brad represents health care clients in complex litigation, government and internal corporate investigations, enforcement proceedings, whistleblower suits, and payor audits
- Brad frequently draws on his unique industry experience, including a multi-year position with the U.S. Federal Judiciary, a Certification in Healthcare Compliance (CHC), and his experience working for a large hospital system, to help clients prevent and resolve regulatory compliance issues



4

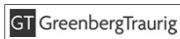


Law Office of Sean McKenna

Agenda

- Key Fraud & Abuse Laws
- Healthcare Enforcement Trends
- Conclusion & Questions

5



Law Office of Sean McKenna

Key Fraud & Abuse Laws

6

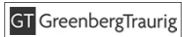


Law Office of Sean McKenna

Federal 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

7

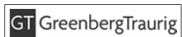


Law Office of Sean McKenna

False Claims Act (31 U.S.C. § 3729)

- A false claim, statement, or conspiracy for payment from the *United States*
- Claim must be submitted "knowingly"
 - Actual knowledge
 - Deliberate ignorance
 - Reckless disregard
 - No specific intent to defraud required
- "Reverse" = knowing retention of overpayment
- AKS and Stark are bases for liability
- 3X damages, penalties, exclusion

8



Law Office of Sean McKenna

Texas Medicaid Fraud Prevention Act (Tex. Hum. Res. Code § 36.001 et seq.)

- False statement, misrep of material fact, or conspiracy for payment from Medicaid (or knowing obstruction of investigation)
- Same "knowingly" standards
- 2X damages, FCA-level penalties, exclusion
- Patient Solicitation Act and Administrative Penalties Statute can form basis of claim

9



Law Office of Sean McKenna

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 or services* paid for by a *federal healthcare program*
- *Remuneration* is anything of value
- Substance not form of arrangement matters (e.g., commonly owned entity)
- One purpose test; no specific intent required
- Includes non-clinicians

10



AKS, penalties

- 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

11



AKS, referrals

- The AKS is broad, and prohibits not just referrals, but “arranging for or recommending purchasing, leasing or ordering”
 - Sales and marketing activities
 - Purchase of devices by physicians, hospitals, etc.
 - Patient self-referrals (i.e., choosing a particular provider, supplier, product)
 - Physician certification or recertification of the need for care

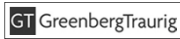
12



AKS, items or services

- *Items and services include:*
 - Diagnostic tests
 - Devices
 - DME
 - Ancillary services
 - Imaging
 - Physician services
 - Inpatient and outpatient hospital services

13



AKS, federal healthcare program

- *Federal healthcare program includes:*
 - Medicare
 - Medicaid/CHIP
 - TRICARE (for active military)
 - Veterans Health Administration (for military veterans)

14



AKS, remuneration

- The transfer of *anything of value*, directly or indirectly, overtly or covertly, in cash or in kind
 - Meals, trips, gifts
 - Cash payments or waivers of cash payments
 - Free or below FMV services or items (e.g., supplies, standalone services)
 - Discounts and rebates
 - Warranties
 - Credit arrangements
 - Profits or dividends
- "Carve out" of federal business does not eliminate AKS risk

15



AKS, enforcement

- Several statutory exceptions and regulatory safe harbors
- 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 and patient freedom of choice
 - Patient safety and quality of care concerns
 - Unfair competition

16



AKS, safe harbors

- There are several statutory exceptions and regulatory safe harbors that protect certain arrangements, including:
 - Bona fide employees
 - Personal services and management contracts
 - Small investment interests
 - Space and equipment rentals
 - Discounts

17



Texas Anti-Solicitation (Tex. Occ. Code § 102.001)

- Prohibits (1) knowingly offering or agreeing to accept any remuneration (2) for securing or soliciting a patient or patronage (3) for or from a person licensed, certified, or registered by a state health care regulatory agency
- Incorporates AKS safe harbors plus unique exceptions
- Even permissible relationships require disclosure at time of initial contact
- Unlike AKS, applies to all payors
- Misdemeanor/felony, board actions, civil penalties ≤ 10K per day

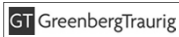
18



Texas Commercial Bribery (Tex. Penal Code § 32.43)

- Prohibits fiduciaries (including physicians) from accepting soliciting, accepting, or agreeing to accept any benefit that will influence the conduct of the fiduciary in relation to the affairs of his beneficiary
- Beneficiary consent is an exception
- Felony, fines (up to double the benefit)

19



Texas Medicaid Administrative Penalties Statute (Tex. Hum. Res. Code § 32.039)

- Liability for false claims, kickbacks, and failure to maintain documentation to support claim for payment
- Administrative action, damages, penalties up to \$15K

20



Stark Law (42 U.S.C. §1395)

- Prohibits physician self-referrals
 - Must involve *physician referral*
 - Ownership interest or compensation arrangement (*direct or indirect*)
 - *Designated health services* (e.g., outpatient drugs, DME)
 - Medicare and Medicaid (indirectly)
- 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

21



Stark Law, continued

- Stark exceptions include:
 - In-office ancillary services (group practices)
 - Publicly traded securities and mutual funds (not small entities like AKS)
 - Bona fide employment relationships
 - Personal service arrangements
 - Rental of office space and equipment
 - FMV compensation
 - Indirect compensation arrangements
- Must meet every requirement of a Stark exception
- Many exceptions require FMV and commercial reasonableness

22



Stark Law, Designated Health Services

- Clinical laboratory services
- Physical/occupational therapy, and outpatient speech-language pathology services
- Radiology and certain other imaging services
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs (including drugs administered in office)
- Inpatient and outpatient hospital services

23



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

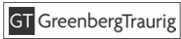
24



Texas OIG Regs

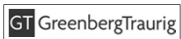
- Authorizes HHSC-OIG to take administrative action based on a number of Medicaid program violations including:
- False claims (1 Tex. Admin. Code § 371.1653)
- Failure to repay “within 60 calendar days of self-identifying or discovering an overpayment” (1 Tex. Admin. Code § 371.1655)
- Kickbacks or self-dealing (1 Tex. Admin. Code § 371.1669)

25



Trends in Healthcare Enforcement

26



1. Continued FCA Activity

Approximately what percentage of whistleblower suits in 2017 were filed by current or former employees?

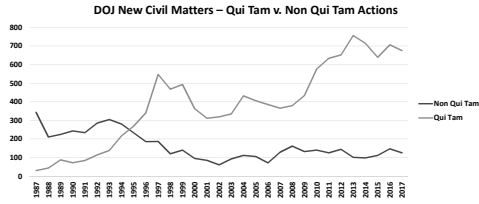
- A. 10%
- B. 25%
- C. 50%
- D. 65%

27

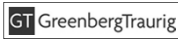


1. Continued FCA Activity (cont.)

Qui tam actions under FCA



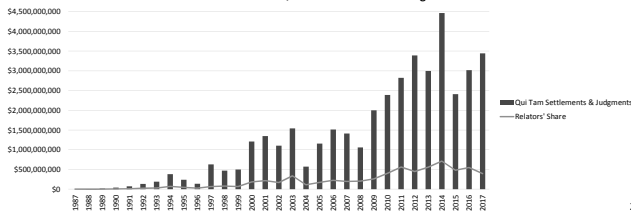
28



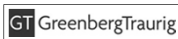
Law Office of Sean McKenna

1. Continued FCA Activity (cont.)

Relators' Share of Qui Tam Settlements & Judgments



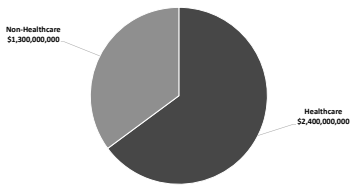
29



Law Office of Sean McKenna

1. Continued FCA Activity (cont.)

2017 FCA Settlements & Judgments



30



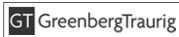
Law Office of Sean McKenna

2. Uncertainty About 60-Day Rule

A children's hospital learns facts today that put it on notice of a potential overpayment from Medicare Advantage and a Medicaid program. When does its 60-day "report and return" obligation begin?

- A. Never because the 60-day regulations do not apply to Medicare Advantage or Medicaid
- B. Once the hospital quantifies the amount of overpayment
- C. After a 6-month investigation
- D. Now because it has notice of a potential overpayment
- E. None of the above

31



2. Uncertainty About 60-Day Rule (cont.)

- Withholding "obligation" to government can form basis of FCA claim
 - "Overpayment" includes "any funds that a person receives or retains under subchapter XVIII [Medicare] or XIX [Medicaid] to which the person, after applicable reconciliation, is not entitled under such subchapter"
- An "overpayment" must be reported and returned by the later of "(A) the date which is 60 days after the date on which the overpayment was *identified*; or (B) the date any corresponding cost report is due, if applicable"

32



2. Uncertainty About 60-Day Rule (cont.)

- When does 60-day clock start?
 - Upon notice of a potential overpayment – *Kane*
 - When overpayment is quantified or provider fails to exercise reasonable diligence – CMS Part A & B regulations
 - After up to 6 months of investigation – CMS regulatory preamble

33



3. New Legislation

- Eliminating Kickbacks in Recovery Act of 2018
 - Part of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115-271)
 - New federal kickback prohibition
 - Only applies to recovery homes, clinical treatment facilities, and laboratories
 - Applies to “any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual.”
 - Exceptions for discounts, bona fide employees, independent contractors, etc.
 - New employment exception is narrower than its AKS counterpart; does not protect compensation that varies based on (1) the number of individuals referred, (2) the number of tests or procedures performed, or (3) the amount billed to or received from a public or private payor from the individuals referred. Appears to make certain productivity compensation arrangements impermissible for addiction recovery employees.

34



4. AKS Causation Questions

A pharmacy donated to specific charities in order to receive exclusive patient referrals. The pharmacy submitted claims for reimbursement for services to government beneficiaries along with certifications of compliance with the AKS. Why would that be enough to show violation of the FCA?

- A. Violations of the AKS are false claims under the FCA
- B. AKS violations “taint” all claims
- C. The claims would not have been submitted “but for” the AKS violation
- D. There is evidence “linking” the AKS violations to the claims

35



4. Causation Questions AKS-Based FCA Actions (cont.)

- “[A] claim that includes items or services *resulting from* a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]” 42 U.S.C. § 1320a-7b(g)
- What does it mean for a claim to include items or services “resulting from” an AKS violation?
 - Courts have rejected the idea that showing an AKS violation “taints” all claims
 - At a minimum, need some link between the violations and the claims
 - *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 100 (3d Cir. 2018)

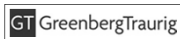
36



4. Causation Questions AKS-Based FCA Actions (cont.)

- *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 100 (3d Cir. 2018)
 - "A kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient . . . we must have some record evidence that shows a link between the alleged kickbacks and the medical care received by at least one [of a defendant's] federally insured patients"
- *United States ex rel King v. Solvay Pharm., Inc.*, 871 F.3d 318, 328–29 (5th Cir. 2017)
 - "At best, Relators' circumstantial evidence suggests only the potential for a causal link between Solvay's alleged off-label marketing and off-label prescriptions but says nothing about whether the marketing scheme *actually caused* off-label prescriptions to Medicaid patients. Without evidence indicating that off-label marketing actually caused off-label prescriptions to Medicaid patients resulting in false claims to the government, Relators' off-label marketing theory of FCA liability cannot survive summary judgment."

37

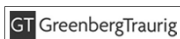


5. Use of the Federal Travel Act (18 U.S.C. § 1952)

A physician-owned, out-of-network hospital compensates physicians and other people for patient referrals. The hospital does not accept Medicare or Medicaid patients. Is this arrangement risky?

- A. Yes because it is never okay to compensate for patient referrals
- B. Yes because it is almost impossible to ensure no government reimbursement
- C. Not really, as long as the arrangement complies with the Private Payor Safe Harbor
- D. No because it does not involve Medicare or Medicaid

38



5. Use of the Federal Travel Act (cont.)

- 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 crime (commercial bribery) that is seldom prosecuted separately in state court into a federal felony
- Penalties include imprisonment up to 5 years, fines, or both

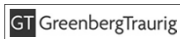
39



6. Private Payor Enforcement

- A small rural hospital pays 30% of facility fees collected on out-of-network claim to physician-owned shell companies under a billing services arrangement. No billing services are actually performed by the shell companies. However, no government reimbursement is involved, and enforcement of the state's kickback prohibition is almost non-existent. Is this still risky?
 - No because only state and federal governmental entities have jurisdiction to enforce applicable law
 - Yes because private payors have used common law causes of action to address alleged abuse of out-of-network billing and related kickback arrangements

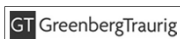
40



6. Private Payor Enforcement (cont.)

- Commercial payors suing providers to recoup/avoid tainted payments
 1. Out-of-Network Litigation (e.g., *Bay Area Surgical, Humble Surgical Hosp., Sky Toxicology*)
 - Fraud, conspiracy, unjust enrichment, intentional interference with contractual relations, etc.
 - Focus on both out-of-network claims and alleged kickback arrangements
 - \$100K for ear wax removal; \$139K to repair crooked toe
 - Alleged kickbacks include payments to physicians and copay waivers/fee forgiveness
 2. In-Network Litigation (*Sharkey-Issaquena Cmty. Hosp., The People's Choice Hosp.*)
 - Fraud, civil conspiracy/RICO, negligent misrepresentation, unjust enrichment, tortious interference, etc.
 - Focus on increased utilization/reimbursement (e.g., increase from 85 urine drug test claims over a 6-month period, to more than 37K claims over a 6-month period)

41



7. Corporate Practice of Medicine Doctrine

- Generally, physicians are prohibited from entering into partnerships, employment relationships, fee splitting or other arrangements with non-physicians where the professional practice is directed or controlled by a non-physician. Similar prohibition for dentists.
- Exceptions for employment by certain nonprofit health organizations, rural hospitals, and organizations that provide medical and/or dental care to underserved populations
- Derived from Tex. Occ. Code §§ 155.001, 155.003, 157.001, 164.052(8), 165.156.
- Management arrangements involving "captive" or "friendly" physician practices may run afoul of CPOM
- Although there is some risk of enforcement, CPOM has come up more frequently in breach of contract litigation, often with the defendant arguing that the arrangement is illegal and therefore unenforceable.

42



Conclusion & Questions

43



Law Office of
Sean McKenna
