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

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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

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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

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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

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Agenda

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

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Key Fraud & Abuse Laws

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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/conspire a scheme/artifice in connection with delivery or payment of health care benefits:
  - Defraud *any* health care benefit program; or
  - Obtain by false or fraudulent pretenses property under custody/control of such program
- Up to 10-years imprisonment, restitution, and fine

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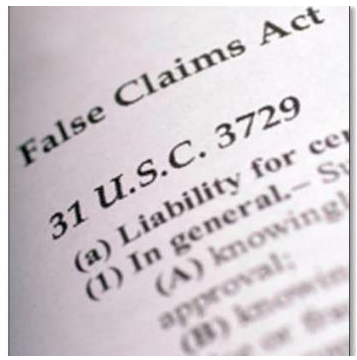
False Claims Act (31 U.S.C. § 3729)

- 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



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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

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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* (including goods and facilities) paid for by a *federal health care program*
- *Remuneration* is anything of value
- Substance not form of arrangement matters
- One purpose test; no specific intent required
- Includes non-clinicians

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AKS, penalties

- Advisory Opinions address industry concerns, not precedential
- Violation is a felony, punishable by:
  - Criminal fines of up to $100,000
  - Imprisonment for up to 10 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

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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

AKS, items or services

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

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AKS, federal healthcare program

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

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

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AKS, risk analysis

- Several statutory exceptions and regulatory safe harbors
- If no safe harbor, the totality of the facts and circumstances are analyzed
- 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
- FMV / commercial reasonableness generally means less risk

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AKS, safe harbors

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

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Texas Anti-Solicitation Statute (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

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Texas Commercial Bribery Statute (Tex. Penal Code § 32.43)

- Prohibits fiduciaries (including physicians) from 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
- Applies to the offeror of the benefit as well
- Felony, fines (up to double the benefit)

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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, administrative penalties (up to twice the amount paid, plus up to $15K per violation)

Stark Law (42 U.S.C. § 1395nn)

- 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

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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

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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

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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
  - Knowingly submit claims for pattern of items/services that lack medical necessity
  - Failure to report and report known overpayment
  - 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

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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)

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Trends in Healthcare Enforcement

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Approximately what percentage of whistle-blower suits in 2017 were filed by current or former employees?

10%

25%

50%

65%

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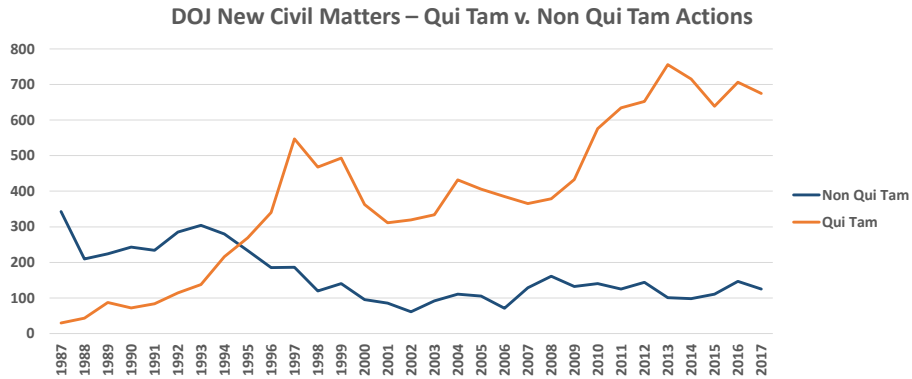
1. Continued FCA Activity (cont.)

***Qui tam* actions under FCA**



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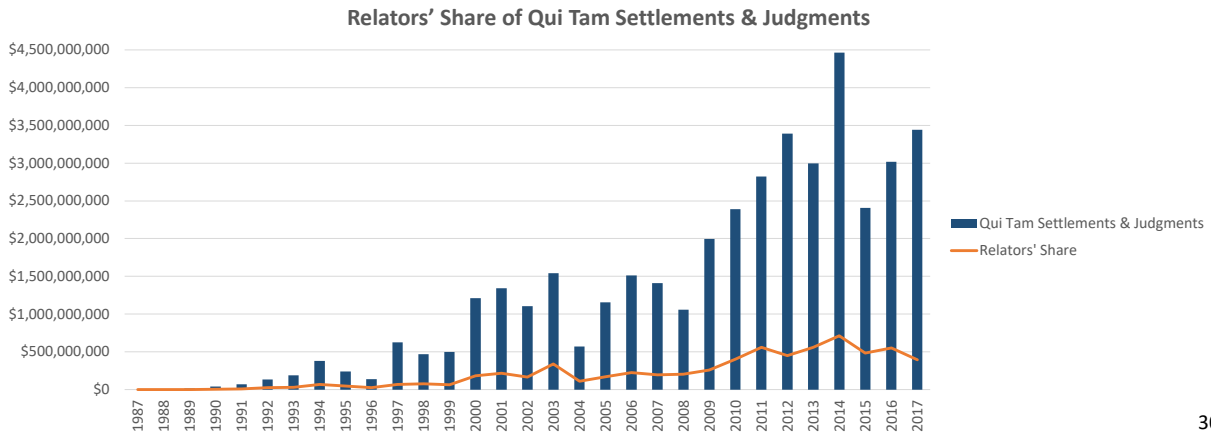

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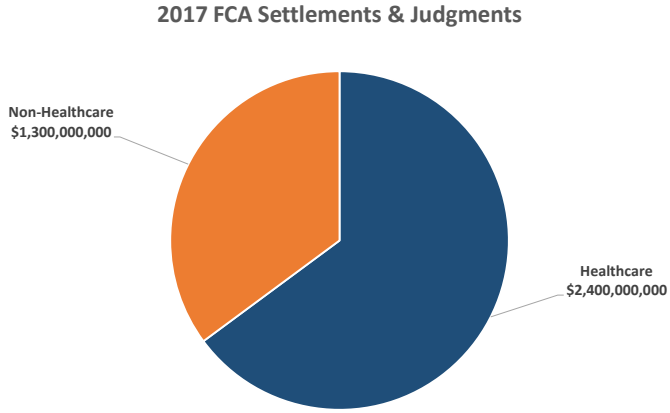

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A hospital learns facts today that put it on notice of a potential over-payment from Medicare Advantage and a Medicaid program. When does its 60-day "report and return" obligation begin?

- Never because the 60-day regulations do not apply to Medicare Advantage or Medicaid
- Once the hospital quantifies the amount of over-payment
- After a 6-month investigation
- Now because it has notice of a potential over-payment
- None of the above

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2. Uncertainty About 60-Day Rule

- 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"

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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

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3. New Legislation

- Eliminating Kickbacks in Recovery Act of 2018 (to be codified at 18 U.S.C. § 220)
  - 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 applies to payments to induce referrals 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.
  - Employment exception narrower than AKS; comp cannot vary based on (1) number of individuals referred, (2) number of tests/procedures performed, or (3) amount billed to or received from a public or private payor.

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

- Yes, violations of the AKS are false claims under the FCA
- Yes, AKS violations "taint" all claims
- No, unless the claims would not have been submitted "but for" the AKS violation
- No, unless there is evidence "linking" the AKS violations to the claims

4. Causation Questions AKS-Based FCA Actions

- "[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)

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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."

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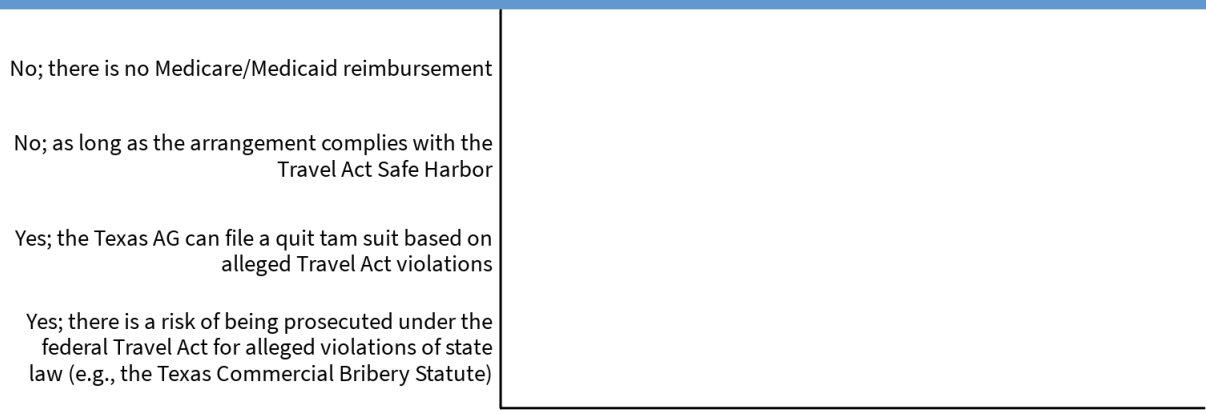
A physician-owned, out-of-network Texas hospital pays per-patient fees to physicians and others for patient referrals. The hospital does not accept Medicare or Medicaid patients. A potential investor becomes aware of these payments, but is told there is no risk and "everyone else is doing this." Should the potential investor be concerned?



5. Use of 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 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

In-network community hospital enters lab management, billing, and services arrangement with out-of-network lab and affiliated companies. Lab performs tests and submits claims to private payors under hospital's name/number, and reimbursement is split among the parties. Although previously on the brink of closure, the hospital soon sees increased revenue from testing performed on samples submitted from all over the country. Is there anything to worry about?

No; there's nothing illegal about using a reference lab

No; enforcement would put the hospital out of business and harm the community

Yes; private payors can use their influence to "inspire" government enforcement

Yes; especially if payors see a dramatic increase in lab claims and reimbursement

6. Private Payor Enforcement (cont.)

- Commercial payors suing providers to recoup/avoid tainted payments
  1. 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)
  2. 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 amount billed and alleged kickbacks
       - $100K for ear wax removal; $139K to repair crooked toe
       - Alleged kickbacks include payments to physicians *and* copay waivers/fee forgiveness

7. Texas Corporate Practice of Medicine Doctrine

- Prohibits physicians from entering into partnerships, employment relationships, fee splitting or other arrangements with non-physicians who direct or control the professional practice. 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.
- Captive practice (or "friendly" physician) model can raise CPOM concerns
- CPOM varies by state, as does CPOM enforcement
- Private parties have used CPOM as a shield in breach of contract litigation

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Conclusion & Questions

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