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

This Session Uses Polling

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Agenda

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

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

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
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

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

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- Advisory Opinions address industry concerns, not precedential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
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

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

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

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
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

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)

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

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

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
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

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)

Trends in Healthcare Enforcement
1. Continued FCA Activity (cont.)

**Qui Tam actions under FCA**

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


**Relators’ Share of Qui Tam Settlements & Judgments**

- **Qui Tam Settlements & Judgments**
- **Relators’ Share**
1. Continued FCA Activity (cont.)

2017 FCA Settlements & Judgments

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

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 XIX (Medicare) or XX (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"
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

3. New Legislation

  - 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.
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 Sol., Inc., 880 F.3d 89, 100 (3d Cir. 2018)

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

- United States ex rel. Greenfield v. Medco Health Sol., 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.”

- 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

6. Private Payor Enforcement (cont.)

- Commercial payors suing providers to recoup/avoid tainted payments
  1. In-Network Litigation (Sharkey-Issaquena Cnty. 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
     - $109K 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

Conclusion & Questions