Ethics: FCA, OIG, AKS and other Scary Acronyms: A Discussion about Trends in Government Enforcement

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FCA, OIG, AKS and Other Scary Acronyms
A Discussion of Trends in Government Enforcement

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Overview

• Key Fraud and Abuse Laws
  ▪ False Claims Act
  ▪ Anti-Kickback Statute
  ▪ Ethics in Physician Referrals Act (Stark)
  ▪ Civil Monetary Penalties Law

• Enforcement Actions

• Ethical Considerations

• Action Items
Key Fraud and Abuse Laws

"Stay with me now, people, because in step C, things get a bit delicate."
False Claims Act (FCA)

Anytime a claim is submitted to a government payor that does not precisely capture the services provided.
False Claims Act (FCA)

Key Provisions

• Civil liability for:
  ▪ Knowingly presenting a **false or fraudulent** claim to the government for payment, and
  ▪ Making a **false record or statement** that is material to the false or fraudulent claim.

• If overpaid by a Federal program, must report and return overpayment within 60 days.
  ▪ Failure to do so may make the overpayment a false claim.
False Claims Act (FCA)

Penalties

• Repayment plus interest
• Civil monetary penalties of $5,500 to $11,000 per claim
• Treble damages
• Exclusion from Medicare/Medicaid/Federal Programs
Examples

• Claims for services that were not provided or were different than claimed.

• Failure to comply with quality of care.
  ▪ Express or implied certification of quality.
  ▪ Provision of "worthless" care.

• Failure to comply with conditions of payment or relevant fraud and abuse laws.
  ▪ Express or implied certification of compliance when submitting claims.
    ○ E.g., cost reports or claim forms.
False Claims Act (FCA)

*Qui Tam Suits*

• Entities (employees, patients, providers, competitors, etc.) may sue suspected FCA violators on behalf of the government.
  • Government may or may not intervene.
  • *Qui Tam* relator:
    • Receives a percentage of any recovery.
    • Recovers their costs and attorneys fees.
Anti-Kickback Statute (AKS)

Anytime a provider:
• Gives or receives anything to induce or reward referrals;
• Does any deal with a referral source.
Anti-Kickback Statute (AKS)

Key Provisions

• Cannot knowingly and willfully
  ▪ Offer
  ▪ Pay
  ▪ Solicit
  ▪ Receive

Remuneration to induce referrals for items or services covered by Federal program unless transaction fits within a regulatory safe harbor.
Anti-Kickback Statute (AKS)

Remuneration

- Money
- Free or discounted items or services
  - Perks, gifts, space, equipment, meals, insurance, trips, etc.
- Overpayments or underpayments
  - Not FMV
- Payments for items/services that are not provided
- Payments for items/services that are not necessary
- Professional courtesies
- Waivers of copays or deductibles
- Low interest loans or subsidies
- Business opportunities that are not commercially reasonable
- Anything else of value....
Anti-Kickback Statute (AKS)

One Purpose Test

• AKS applies if one purpose of the remuneration is to induce referrals, even if there are other legitimate purposes.
  ▪ Difficult to disprove.

• Ignorance of the law is no excuse.
Anti-Kickback Statute (AKS)

Penalties

• 5 years in prison
• $25,000 criminal fine
• $50,000 penalty
• 3x damages
• Exclusion from Medicare/Medicaid
Anti-Kickback Statute (AKS)

Penalties

• AKS violation = FCA violation
  ▪ Lower standard of proof
  ▪ Subject to FCA penalties
  ▪ Subject to *Qui Tam* suit

• OIG Self-Disclosure Protocol
  ▪ Minimum $50,000 settlement
Anti-Kickback Statute (AKS)

Which of the following is an AKS violation?

A. Paying a referring physician more than Fair Market Value (FMV) for medical director or other services.
B. Charging a referring physician less than FMV to use your space or equipment.
C. Hiring a referring physician to act as a consultant even though you don't really need one.
D. Sending "thank you" gifts to referring providers or their offices.
Anti-Kickback Statute (AKS)

Safe Harbors

• No liability if satisfy **ALL** the requirements of a safe harbor.
  ▪ "Squarely within"

• Examples:
  ▪ *Bona fide* employment
  ▪ Personal services contracts
  ▪ Leases for space or equipment
  ▪ Investments in group practice
  ▪ Sale of practice

  ▪ Recruitment
  ▪ Certain investment interests
  ▪ Waiver of beneficiary coinsurance and deductible amounts
Anti-Kickback Statute (AKS)

Safe Harbors

• No *de minimus* safe harbor.

• No FMV safe harbor.
  ▪ FMV payment does not legitimize a payment if there is an illegal purpose.
  ▪ But fairly safe if remuneration represents FMV for legitimate, needed services or items.

• Consider risk of federal program abuse.
  • Incorporate safeguards to protect against abuse.
Ethics in Physician Referrals Act (Stark)

There is any shared financial relationship or item of value between a physician (or their family) and an entity providing DHS.
Key Provisions

• If a physician (or their family member) has a financial relationship with an entity:
  ▪ The physician may not refer patients to that entity for designated health services (DHS), and
  ▪ The entity may not bill Medicare for services resulting from a prohibited referral

unless arrangement is structured to fit within a regulatory exception.
Ethics in Physician Referrals Act (Stark)

Physician cannot refer and DHS provider cannot bill, for DHS unless transaction fits in safe harbor.
Ethics in Physician Referrals Act (Stark)

Applies to

• Referrals to entities with which physician (or family member) has a **financial relationship**.

• Financial relationship =
  ▪ Ownership or investment
    ○ Stocks, bonds, partnership, membership shares, secured loans, securities, etc.
  ▪ Compensation:
    ○ Employment, contract, lease, payments, gifts, free or discounted items, etc.
Ethics in Physician Referrals Act (Stark)

Intent

• Violation may occur even if no intent to violate statute.
• But intent + knowledge may be a defense.
  ▪ Entity may bill for services rendered per improper referral if entity:
    1. Did not know, and
    2. Did not act in reckless disregard or deliberate indifference concerning the identity of the referring physician.
Ethics in Physician Referrals Act (Stark)

Penalties

• No payment for services provided per improper referral.
• Repayment of payments improperly received within 60 days.
• Civil penalties:
  ▪ $15,000 per claim submitted.
  ▪ $100,000 per scheme.
• May also trigger AKS & FCA violation.
Ethics in Physician Referrals Act (Stark)

 Exceptions

• No liability if comply with all the requirements of an applicable exception.
• Need only comply with one safe harbor for each financial relationship.
Civil Monetary Penalties Law (CMP)

A provider has violated the FCA, AKS, or Stark laws, or has engaged in similar prohibited conduct.
Civil Monetary Penalties Law (CMP)

Key Provisions

- Allows the OIG to punish for specific violations
  - Submitting false or fraudulent claims or misrepresenting facts relevant to services.
  - Offering inducements to program beneficiaries.
  - Offering inducements to physicians to limit services.
  - Submitting claims for services ordered by, or contracting with, an excluded entity.
  - Failing to report and repay an overpayment.
  - Failing to grant the government timely access.
Civil Monetary Penalties Law (CMP)

Sound Familiar?

• CMP violations often implicate:
  ▪ False Claims Act
  ▪ Anti-Kickback Statute
  ▪ Stark Law
Civil Monetary Penalties Law (CMP)

Penalties

- Vary based on conduct, but generally range from:
  - $2,000 to $50,000 fines
  - Denial of payment
  - Repayment of amounts improperly paid
  - Exclusion from government programs
  - Treble Damages
Enforcement Actions
Trends in Enforcement

• Federal agencies recovered over $4.7 billion in FCA settlements and judgments in 2016.
  ▪ The third-highest amount on record!

• 2016 was the seventh consecutive year the government recovered over $3 billion.
Trends in Enforcement

Number of New Enforcement Actions

![Graph showing trends in enforcement actions from 1987 to 2016, comparing QUI TAM and NON QUI TAM actions.]
Trends in Enforcement

Total Amounts Recovered
Trends in Enforcement

Recoveries by Industry

$2.5 billion from the health care industry in 2016
Trends in Enforcement

Be Aware: It is easier than ever for courts to find fraud and abuse violations

• Recent U.S. Supreme Court holding asserted the "implied false certification" theory of liability
  • A provider can violate fraud and abuse laws by failing to comply with material payment regulations but submitting claims for reimbursement as though he/she has been compliant
  • Mitigating factor: misrepresentation must be material
  • Lower courts are already using this theory to fine providers

Trends in Enforcement

Be Aware: Fraud and abuse penalties have increased

• Bipartisan Balanced Budget Act of 2015 required all federal agencies to make civil penalty inflation adjustments

  Fine Increases per Violation:
  - False Claims Act Min: $5,500 → $10,781
  - False Claims Act Max: $11,000 → $21,563
  - Anti-Kickback Statute: $5,000 → $73,588
  - Stark Law: $15,000 → $238,633

• Greater return on investment may push agencies to increase investigations and recovery efforts
Cases & Settlements

Branch Banking & Trust Co.

• Regional Bank in Southeast United States agreed to pay $9.5 million.

• Government alleged the bank knowingly originated and underwrote faulty mortgage loans issued by HUD and FHA.

• Bank admitted that it improperly certified loans, inadequately monitored its underwriting process, and failed to self-report suspected findings of fraud to HUD.
Cases & Settlements

Bechtel National, Inc., Bechtel Corp., URS AECOM Energy

- Energy Department contractors agreed to pay $125 million.
- Government alleged improper billing for services and goods to clean up a nuclear site.
- Three whistleblowers (former employees) caused the investigation.
Cases & Settlements

B&H Education, Inc.,

- Defunct cosmetology school agreed to pay $8.6 million.
- *Qui Tam* allegations: Former employees alleged that they obtained federal student loans for students that did not have high school diplomas.
- School fraudulently allowed students to "earn" high school diplomas.
Cases & Settlements

Tenet Healthcare Corp.

- U.S. hospital network and two subsidiaries to pay more than $513 million.
- Government alleged bribery and kickbacks to prenatal care clinics in exchange for patient referrals.
  - *Qui Tam* relator will receive more than $84 million.
Cases & Settlements

Life Care Centers of America Inc.

• Skilled nursing facility chain to pay $145 million.
• Government alleged submitted false claims to Medicare and TRICARE for unreasonable or unnecessary services.
  ▪ Company policies increased billing to Medicare and TRICARE. E.g., encouraging providers to request longer-than-necessary patient stays.
  ▪ *Qui Tam* relator will receive $29 million.
Cases & Settlements

Biocompatibles Inc.

• Medical device company to pay $25 million.
• Government alleged submitted false claims to government health care programs.
  ▪ The company promoted its embolization device for off-label use that was not approved by the FDA or supported by substantial clinical evidence.
  ▪ The company also to pay an additional $11 million in criminal fines and forfeitures.
Forest Laboratories LLC

• Pharmaceutical company to pay $38 million.
• Government alleged company paid kickbacks to induce physicians to prescribe its drugs.
  ▪ Kickbacks came in the form of meals and payments in connection with speaker programs.
  ▪ Provided the payments even when the programs were cancelled, when no licensed health care professionals attended the programs, or when the same physicians attended multiple programs over a short period of time.
Cases & Settlements

Mercy Hospital Springfield & Mercy Clinic Springfield Communities

• Health care providers to pay $34 million.
• Government alleged company paid kickbacks to induce physicians to refer to its infusion center.
  ▪ The company compensated oncologists based in part on a formula that took into account the value of their referrals.
  ▪ *Qui Tam* relator will receive $5.4 million.
Walgreen Co.

• Pharmacy chain to pay $50 million.

• Government alleged company gave government beneficiaries monetary incentives to induce patronage.
  ▪ Monetary incentives included enrolling government beneficiaries in prescription savings program.
  ▪ Marketed the program to government beneficiaries and paid employees bonuses for each enrollee, without verifying whether the customers were government beneficiaries.
Cases & Settlements

Future of Enforcement

• Administrative Changes? Unlikely.
• Enforcement will remain robust.
  ▪ Fraud and abuse laws permit government to recover substantial penalties
  ▪ Recall those huge recoveries
    o 2016: DOJ recovered $4.7 billion in fraud and abuse settlements & judgments
    o $2.5 billion from health care industry
Ethical Considerations

“Lately I’ve been feeling ethical. Can you prescribe something for that?”
Ethical Considerations

Model Rule 1.1 – Competence

• A lawyer shall provide competent representation to a client. Competent representation requires the legal knowledge, skill, thoroughness and preparation reasonably necessary for the representation.

  ▪ Comment 8:
    ○ To maintain the requisite knowledge and skill, a lawyer should keep abreast of changes in the law and its practice, including the benefits and risks associated with relevant technology, engage in continuing study and education and comply with all continuing legal education requirements to which the lawyer is subject.
Model Rule 1.2 – Scope of Representation

• A lawyer shall not counsel a client to engage, or assist a client, in conduct that the lawyer knows is criminal or fraudulent, but a lawyer may discuss the legal consequences of any proposed course of conduct with a client...

  ▪ Comment 9:
    o The fact that a client uses advice in a course of action that is criminal or fraudulent of itself make a lawyer a party to the course of action.
Model Rule 1.13 – Organization as Client

A lawyer employed or retained by an organization represents the organization acting through its duly authorized constituents.

Comment 3:

- When one of the constituents of an organizational client communicates with the organization's lawyer in that person's organizational capacity, the communication is protected by Rule 1.6 (confidentiality).
- E.g., if an organizational client asks its lawyer to investigate allegations of wrongdoing, interviews made in the course of that investigation between the lawyer and the client's employees or other constituents are covered by Rule 1.6.
Ethical Considerations

Model Rule 1.13 – Organization as Client

• If a lawyer knows that an officer, employee, etc. is acting or intends to act in a manner that violates a legal obligation that reasonably might be imputed to the organization, and that is likely to result in substantial injury to the organization, then the lawyer shall proceed in the best interest of the organization (likely refer the matter to a higher authority in the organization).
  • Comment 3:
    • Knowledge can be inferred from circumstances, and a lawyer cannot ignore the obvious.
Ethical Considerations

Model Rule 8.4 – Misconduct

• It is professional misconduct for a lawyer to engage in conduct involving dishonesty, fraud, deceit or misrepresentation.
Action Items

COMPLIANCE TRAINING?

BUT I'M ALREADY KOALIFIED!
Action Items

Analyze Existing Relationships

- Identify remunerations to referral sources (e.g., providers, facilities, vendors, government program patients).
  - Contracts (employment, independent contractors, etc.).
  - Group compensation structures.
  - Leases (space, equipment, etc.).
  - Subsidies or loans.
  - Joint ventures or partnerships.
  - Free or discounted items or services (e.g., use of space, equipment, personnel or resources; professional courtesies; gifts; etc.).
  - Marketing programs.
  - Financial policies.
Action Items

Analyze Existing Relationships

• Ensure:
  ▪ No intent to induce referrals for government program business.
  ▪ Written contracts are current and signed by parties.
  ▪ Compliance with terms of contract.
     o Parties providing required services, and
     o Documentation confirming that services provided.
  ▪ Compensation not based on volume or value of referrals.
  ▪ Arrangement is commercially reasonable and serves legitimate business purpose.
  ▪ Fair market value.
Action Items

Analyze Existing Relationships

• Implement method to track and monitor relationships with referral sources.
  ▪ Central repository for contracts or deals.
  ▪ Process for confirming compliance before payment.
  ▪ Require compliance officer, attorney, or other qualified individual to review:
    o Contracts,
    o Joint transactions with referral sources,
    o Benefits or perks to referral sources, and
    o Marketing or advertising.
Action Items

Create a Compliance Plan

• ACA requires providers to have compliance plan to enroll in Medicare, Medicaid, and CHIP.
• Even if not mandated, compliance plan is still a good idea.
Action Items

Create a Compliance Plan

• Facilitates compliance to avoid repayments and penalties.
  • Improves performance by:
    • Facilitating prompt claims submissions;
    • Identifying undercoding & upcoding; and
    • Improving medical record documentation.
  • May even mitigate penalties.

• Compliance plan = preventative medicine.
Create a Compliance Plan

- OIG Compliance Program Guidance
  - Not mandatory.
  - Provides a guide/outline for a compliance plan.
  - Feds will give deference to plans that address the elements and standards in the OIG guidance.
    - 7 elements are based on Federal Sentencing Guidelines.
Action Items

Create a Compliance Plan

• OIG Compliance Program Guidance
  1. Internal monitoring and auditing.
  2. Written standards, policies and procedures.
  3. Compliance officer or contacts.
  4. Education and training.
  5. Investigation of alleged violations and appropriate disclosures to government agencies.
  6. Open lines of communication, *e.g.*, open discussions at staff meetings or bulletin board notices.
  7. Enforcement of disciplinary standards.

Implementation depends on practice size & resources.
Create a Compliance Plan

• Train key personnel, including:
  ▪ Administration,
  ▪ Compliance officers and committees,
  ▪ Human resources,
  ▪ Physician relations and medical staff officers,
  ▪ Marketing / public relations,
  ▪ Governing board members, and
  ▪ Purchasing and accounts payable.

• Document that training!
Action Items

If you think you have a problem....

• Suspend payments or claims until resolved.
• Investigate problem per compliance plan.
  ▪ Consider involving attorney to maintain privilege.
• Implement appropriate corrective action.
• If repayment is due:
  ▪ Report and repayment per applicable law.
    ▪ Report to OIG if knowing violation of FCA, AKS, CMP.
    ▪ Report to CMS if violation of Stark.
Review

• Key Fraud and Abuse Laws
  ▪ False Claims Act
  ▪ Anti-Kickback Statute
  ▪ Ethics in Physician Referrals Act (Stark)
  ▪ Civil Monetary Penalties Law

• Enforcement Actions

• Ethical Considerations

• Action Items