The Federal Stark Law and Anti-Kickback Statute: Keeping Up With Recent Trends

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- We have no financial relationships with commercial interests to disclose.

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Overview of the Anti-Kickback Statute and the Stark Law

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ANTI-KICKBACK STATUTE (AKS)

- Generally prohibits the knowing and willful solicitation, offering or receipt of any type of gift or remuneration in exchange for rewarding referrals for federal healthcare program business.

- Penalties:
  - Criminal penalties, including fines up to $25,000 and a 5-year prison term per kickback.
  - Civil penalties can cost as much as $50,000 per kickback, in addition to 3 times the amount of damages sustained by the government, and possible exclusion from federal healthcare programs.
ANTI-KICKBACK STATUTE (AKS)

- **9 Statutory Exceptions:**
  1. Discounts
  2. Employer-Employee
  3. Group Purchasing
  4. Waivers of Part B Coinsurance
  5. Managed Care Plans
  6. Pharmacy Waivers/Part D Cost-Sharing
  7. Federally Qualified Health Centers (“FQHCs”) and Medicare Advantage Organizations
  8. FQHCs and Donor
  9. E-Prescribing

- **25 Regulatory Safe Harbors:** Payment and business practices are protected under Safe Harbor Regulations if various elements are satisfied:
  a. Investment Interests
  b. Space Rental
  c. Equipment Rental
  d. Personal Services and Management Contracts
  e. Sale of Practice
  f. Referral Services
  g. Warranties
  h. Discounts
  i. Employees
  j. Group Purchasing Organizations
  k. Waiver of Beneficiary Coinsurance and Deductible Amounts
  l. Increased coverage, Reduced Cost-Sharing Amounts, or Reduced Premium Amounts Offered by Health Plans
  m. Price Reductions Offered to Health Plans
  n. Practitioner Recruitment
  o. Obstetrical Malpractice Insurance Subsidies
  p. Investments in Group Practices
  q. Cooperative Hospital Service Organizations
  r. Ambulatory Surgical Centers
  s. Referral Arrangements for Specialty Services
  t. Price Reductions Offered to Eligible Managed Care Organizations
  u. Price Reductions Offered by Contractors with Substantial Financial Risk to Managed Care Organizations
  v. Ambulance Replenishing
  w. Federally Qualified Health Centers
  x. ePrescribing Items and Services
  y. Electronic Health Records Items and Services
DO WE STILL NEED THE AKS?

- The AKS was enacted to protect patients and federally-funded healthcare programs from fraud and abuse by ending “the corrupting influence of money on health care decisions,” according to the Office of Inspector General (OIG).
  - Headlines and *qui tam* actions act as a deterrent and health care providers are on heightened alert due to increasing liability.
- AKS compliance is a significant expense for small providers.
- Uncertainty of the government’s interpretation of the AKS and the expansive application of the AKS diminishes willingness of entrepreneurs to take any risk in an industry that needs innovation and integrated relationships.
- AKS’s broad reach means providers and suppliers are vulnerable to harsh penalties unless their conduct satisfies one of the statutory exceptions or regulatory “safe harbors.” Many common business practices do not fit squarely within an exception or “safe harbor.”
WHAT’S NEW WITH THE AKS?

• Patient Protection and Affordable Care Act’s (PPACA) Impact on the AKS:
  ➢ Clarification that violation of the AKS is a “false or fraudulent claim” under the False Claims Act (FCA).
  ➢ Government uses the AKS and the FCA together to impose liability.

• Combination of statutes allows government to use civil liability—with its lesser standard of proof—to reach settlements that had previously required criminal prosecutions.

• Settlements show the government uses the AKS to target a wide variety of alleged activities in the health care setting.

• Proposed Expansion of AKS Safe Harbors: Proposed changes include:
  ➢ Making a technical correction to “referral services” safe harbor;
  ➢ Adding a new provisions in the “waiver of beneficiary coinsurance and deductible amounts” safe harbor for cost-sharing waivers by pharmacies under Medicare Part D and for certain emergency ambulance services;
  ➢ Codifying a safe harbor for Medicare Advantage payments to Federally Qualified Health Centers;
  ➢ Codifying a safe harbor for discounts in the price of certain drugs under the Medicare Coverage Gap Discount Program; and
  ➢ Adding a safe harbor for free or discounted local transportation.
    • Comments were due March 2, 2015. See https://www.federalregister.gov/articles/2014/10/03/2014-23182/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the
UNITED STATES V. PATEL

- **United States v. Patel**, (Case No. 14-2607), 7th Circuit Court of Appeals.
  - **Facts**: Dr. Patel made an initial determination that the patient required home healthcare services. Once the determination was made, Dr. Patel did not personally discuss the selection of providers with the patients or family members. The patients discussed home healthcare options with Dr. Patel’s medical assistant who provided an array of 10 to 20 brochures from various providers. However, Dr. Patel received payments from Grand Home Care, if the patients choose Grand as its provider.
  - **Court’s Ruling**: When a physician makes a certification and re-certification for Medicare-reimbursed home health services – even without playing a role in the patient’s selection of the provider – this is a referral within the meaning of the AKS.
    - See, the February 10, 2015, 7th Circuit Court of Appeals ruling.
  - This case could give broad leeway to prosecutors and make it more difficult for counsel to advise clients on the scope of the Anti-Kickback Statute.
The court found it did not matter who identified the home care provider. What matters is “whether the doctor facilitated or authorized that choice... the doctor acted as a gatekeeper-without his approval, the patient could not receive treatment from the provider the patient had selected.” Patel, in signing Form 485, “chose whether his patients could go to Grand.”

The court sought to limit the ruling to Medicare certifications and re-certifications. The court stated that a provider cannot be prosecuted for receiving payments for legitimate services, such as giving a speech. An illegal referral, according to the court, “requires a doctor to do something that either directs a patient to a particular provider or allows a patient to receive care from that provider.”

This ruling broadens the Anti-Kickback Statute in very troubling ways. Counsel must be aware of this case when advising clients on the meaning of referrals under the Anti-Kickback Statute.

Referrals are not defined in the Anti-Kickback Statute or related regulations.
STARK LAW

• Stark (42 U.S.C. 1395nn) generally prohibits a physician from referring Medicare healthcare program patients for a designated health service (DHS) to an entity with which the referring physician or an immediate family member has a financial relationship, and prohibits the entity performing the DHS from billing Medicare for any such referred DHS.

• Stark is a strict liability law – intent not required.
**STARK LAW**

**Penalties:**

- Denial of payment from Medicare, Medicaid, patient or third-party.
- Repayment of any payment received.
- Civil monetary penalties of up to $15,000 per service may be imposed upon entity submitted claims in violation of the law and those that have failed to make required refunds.
- Penalties of up to $100,000 may also be imposed for circumvention schemes where physicians or entities enter into arrangements that have the principal purpose of ensuring referrals to an entity in violation of the law.
- Physicians and entities that violate Stark can also be excluded from participating in Medicare and Medicaid programs.
Existing Stark exceptions are helpful.

In 2013, H.R. 2914, the Promoting Integrity in Medicare Act, provided that the IOAS exception should not be available for "specified non-ancillary services," which include advanced diagnostic imaging services (currently diagnostic MRI, CT and nuclear medicine, including PET, services), anatomic pathology services, radiation therapy services and supplies, and physical therapy services.

- Has not passed but expect similar actions in future due to strong lobbying.
Application to Medicaid:

- Medicaid Physician Self-Referral Act of 2015: Introduced by congressman Jim McDermott (D-WA) to clarify the application of the Stark Law to Medicaid designated health services in the same way that it applies to Medicare designated health services.
- Private whistle-blowers have been pressing for clarity on the issue because of a 1993 law applying Stark to Medicaid, which remains on the books but has not been applied by CMS.
- The 1993 law directed CMS to withhold from state Medicaid programs the federal matching portion of any claim that violates Stark, but those rules were only proposed in the 1998 Federal Register and were never finalized or implemented.
- In *US v. All Children’s Health System* (2013), a case that settled for $7 million, the US District Court for the Middle District of Florida issued an opinion containing statements regarding the applicability of the Stark Law to Medicaid. In its decision, the Court appeared to take the position that the Stark Law applies to Medicaid.
60-DAY RULE

- The Patient Protection and Affordable Care Act (PPACA)
  - Section 6402(a), codified at Section 1128j(d) of the Social Security Act, requires all Medicare and Medicaid participating providers and suppliers to report and refund known overpayments by the later of 60 days from the date the overpayment is “identified” or the date the corresponding cost report is due.

- This law was enacted in 2010 and created numerous issues, including:
  - Short window to respond; and
  - Lack of regulatory guidance on critical definitions, such as when an overpayment is actually “identified” and when the 60-day clock starts to run.

- Providers who fail to meet this deadline can suffer a variety of hardships, including damages and penalties under the False Claims Act and civil monetary penalties up to and including exclusion from participation in federal healthcare programs.
### 60-DAY RULE

- On February 13, 2012, CMS issued a proposed rule for the 60-day rule.
- Proposed rule parallels the statutory language of the 60-day rule in many ways.
- Introduced a “reasonable inquiry” principle to offer greater flexibility for when the 60-day clock starts to run.
- Proposed a 10 year look-back period for retrospective overpayment reviews that significantly expanded the potential liability of providers when refunding overpayments.
- The proposed rule has not been finalized.
- Some states have implemented local policies addressing Medicaid overpayments.
- First case: Kane v. Health First
May 12, 2014, OIG published proposed rule authorizing civil monetary penalties for failure to report and return the overpayments within the 60-day window.

- OIG proposed penalties of up to $10,000 “per day” for each day after the 60-day window has expired.
- Penalty could grow considerably in the case of an overpayment that goes unreturned for an extended period of time.
- PPACA did not mandate this “per day” penalty, so the OIG recognizes this approach is potentially subject to challenge.
- Deadline to submit comments was July 11, 2014.
60-DAY RULE

• February, 2015, CMS announced that it is not quite ready to finalize details on implementation of the 60-day rule.
• Providers still being held to full compliance with the law whether they understand it or not.
• Whistleblowers assisting in finding cases for the government.
• In 2014 there were 700 whistleblower filings and more than $2.3 billion generated from FCA health care litigation alone. (www.justice.gov/opa/pr/justice-department-recovers-nearly-6-billion-false-claims-act-cases-fiscal-year-2014)
• Bigger enforcement budget in 2015.
PRACTICAL EXAMPLES OF RISK AREAS
AND RECENT ENFORCEMENT TRENDS

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Physician-Lab Industry Relationships

• OIG focusing on physician-lab industry relationships.
  
  
  
  
  ➢ Suspect Physician-Lab Arrangements.
  
  ➢ Recent Enforcement Actions.
OIG Questionable Billing Report

- OIG Report: **Questionable Billing for Medicare Part B Clinical Laboratory Services** (August 2014)

- The study found (“RED FLAGS”):
  - Unusually high average number of claims per ordering physician. Some of the labs had a small number of physicians ordering all of their lab tests.
  - Unusually high percentage of claims for patients with no associated Part B services with the ordering physician.
  - Unusually high percentages of claims for patients who reside more than 150 miles from the ordering physician.
Physician-Lab Industry Relationships

OIG Special Fraud Alert

- **Laboratory Payments to Referring Physicians** (6/25/14)

- Risk areas raised by OIG:
  - **Remuneration to physicians (directly or indirectly) for blood-specimen collection, processing, and packaging arrangements.**
    - Probability of unlawful intent increases if payment exceeds FMV or physician is already compensated for the service by Medicare or another payor (i.e., double payment).
      - E.g., venipuncture collection fee
      - E.g., bundled payment
  - **Registry payments to physicians for data collection and reporting.**
    - Evidence of unlawful purpose:
      - Paid on a per patient basis (takes into account referrals);
      - Not FMV;
      - Must perform tests a set # of times per year; and
      - Duplicative testing.
    - Payments to physicians for legitimate research activities are OK, as long as there is no intent to induce referrals.

- Lab’s proposal to enter into agreements with physician practices to provide all laboratory services for the practices’ patients and to waive fees for those patients whose insurance plans require them to use a different laboratory.

- The proposed arrangement involves referrals and federally payable services, and the main purpose is to secure all referrals, including services that would be rendered to federal health care program beneficiaries, from participating practices.

- OIG found that the proposed arrangement could generate unlawful remuneration under the Anti-Kickback Statute because it would “reduce administrative and possibly financial burdens associated with using multiple laboratories” because:

  1. The physicians would gain the benefit of “receiving all test results with consistent reference ranges and the efficiency of maintaining a single interface with a single laboratory”; and

  2. It could relieve physician practices of the monthly maintenance fee “for any interface that the physician practice no longer would maintain.”

- OIG also found that the proposed arrangement may justify use of the “substantially in excess” provision of the permissive exclusion authority, which authorizes a permissive exclusion where a provider or supplier charges the Medicare/Medicaid programs “substantially in excess of” their “usual charges to other payors for the same items or services.”
Carve-Out Lab Model:

• Involves physician direct investment in a lab entity that does not participate in Medicare/Medicaid (non-Medicare lab).

• The Medicare referrals are often sent to an “affiliated lab.” Where do Medicare referrals go?

• Capital investment is nominal, but returns are significant.

• Considerations:
  ➢ Is there an “affiliated lab” that accepts the Medicare specimens?
  ➢ Do State fraud and abuse laws apply to non-federal sources of payment?
  ➢ 60%/40% investment distribution structure present?
  ➢ Is the investment interest withdrawn if physician stops referring/referrals decline?
  ➢ OIG considers carve-outs to be highly suspect.
“Shell” Entity Lab Investments:

- Physician investment in a “shell” entity – not direct investment in an operating lab.

- The “shell” entity contracts directly with an “affiliated lab” to provide “marketing” or other “administrative” services. The “shell” entity’s sole purpose is to arrange for lab specimens to be sent to the “affiliated lab,” and is paid a “per test” fee (sometimes only for non-Medicare specimens).

- “Shell” entity often does not provide any legitimate service.

- Capital investment is nominal, but returns are significant.

- Considerations:
  - Does the “shell” entity provide any legitimate services?
  - Are the services needed?
  - How are investors selected?
  - 60%/40% investment distribution structure present?
  - Is the investment interest withdrawn if physician stops referring/referrals decline?
**Physician-Lab Industry Relationships**

**Suspect Physician-Lab Arrangements**

**Turn-Key Lab Management Arrangements:**

- Lab establishes a management entity that contracts with physicians to help set up in-office labs.
- Physician in-office lab sometimes only tests non-Medicare specimens, but the Medicare specimens are sent to the lab that owns the management entity.
- Compensation is often a percentage or “per specimen” fee.
- **Other Considerations:**
  - Do Stark Law restrictions and exceptions (e.g., building/location requirements, exclusivity requirements, etc.) apply?
  - Are the fees for the turn-key services (e.g., set-up fees, ongoing fees, etc.) FMV?
  - Turn-key laboratory models can be properly structured and compliant. However, when they are being sold by a lab (especially with a Medicare/Medicaid carve-out component), generally, they *are not* properly structured and *are not* legally compliant.
  - OIG warns that these improperly structured turn-key arrangements are highly suspect.
Physician-Lab Industry Relationships

Suspect Physician-Lab Arrangements

Research and Other Service Arrangements:

- Labs offering various compensation arrangements designed to incentivize physicians to switch to or continue to use the lab’s services.

- “Incentive payments” structured as an administrative, consulting, or research arrangement, but it is questionable whether the physician’s contracted services are needed, performed, and/or reflect fair market value without regard to referrals.
Other Physician-Industry Relationships That Are Highly Scrutinized

• The same principles that apply to physician-lab relationships apply to other physician-industry relationships, including physician relationships with:
  - Mobile certified IDTF arrangements
  - Pharmacies and Compounding Pharmacies
  - DME
  - Pharmaceutical and Medical Device Companies
  - Home Health Agencies
Physician-Lab Industry Relationships

Ameritox, Ltd. v. Millennium Lab, Inc.

- Pending appeal, Case No. 14-14281 (11th Circuit).
- DOJ took unusually step of filing an amicus brief in the civil suit. The DOJ took the position that Millennium’s provision of free POCT cups to physicians = remuneration.
  - The free POCT cups did not fall under the “free items, devises, or supplies” exception to remuneration because they were not used solely to collect, transport, process, or store the specimens or communicate the results of the tests for the entity providing the POCT cups (i.e., Millennium). Rather, the POCT cups were for the sole benefit of the physicians.
  - The provision of free POCT cups (i.e., containing the immunoassay testing strip) “is no different from taping a five dollar bill to the inside of an ordinary specimen cup.”
- Applies to non-laboratory issues. Physicians should closely scrutinize any free items or services offered to them to ensure it falls within the exception to what is considered “remuneration.”
  - One example is in the radiology realm. See, CMS-AO-2008-01 (http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/downloads/cms-ao-2008-01.pdf) (Free computer interfaces used to transmit results if used solely to communicate the results of tests for the entity.)
  - See also OIG Advisory Opinion 12-20 (https://oig.hhs.gov/fraud/docs/advisoryopinions/2012/AdvOpn12-20.pdf) (Free access to hospital interface used only for ordering laboratory and other diagnostic tests and reporting test results provided no independent value to physicians.)
Family Dermatology, P.C., owns a dermatopathology lab and a number of dermatology practices. The practice employs dermatologists as independent contractors and requires them to use the in-house dermatopathology lab.

The government alleged False Claims Act violations because the practice’s financial relationships with some of these physicians did not comply with Stark requirements, and it improperly billed Medicare for dermatopathology analyses for specimens sent by the employed physicians.

3 qui tam lawsuits filed resulting in a settlement of over $3.2 million plus interest.

DOJ Press Release (April 21, 2015):
Recent **Qui Tam** Actions

- Biodiagnostic Laboratory Services, LLC, allegedly paid bribes (including payments ranging from $2,000 to $5,000 per month) to multiple physicians in exchange for referrals.

- One physician sentenced to 37 months in prison and ordered to pay a $5,000 fine. Two other physicians sentenced to 14 months and 24 months in prison, and ordered to pay $10,000 each in fines. Another physician awaiting sentencing.

- DOJ Press Releases:
Physician-Lab Industry Relationships

**Corporate Integrity Agreements – Focused Arrangement Procedures**

- Health Diagnostics Laboratory, Inc., and Singulex, Inc., two cardiovascular testing disease labs, to pay $48.5 million to settle claims they violated the False Claims Act by paying remuneration to physicians (processing and handling fees between $10 and $17 per referral) in exchange for patient referrals and, as a result, the physicians allegedly referred patients for medically unnecessary tests billed to Medicare.

- The labs entered into Corporate Integrity Agreements (CIA) with the OIG.
  - CIAs are less common with labs than with pharma and device companies, for example. This may be an indication that the government will negotiate CIAs as part of future lab settlements and the CIAs will **include information about physician-lab relationships**.
  - CIAs include management certifications, mandatory compliance training, independent review organization oversight, etc.
  - These CIAs include a **new** provision which scrutinizes all payments between labs and physicians called **“Focus Arrangement Procedures”**.
  - In this case, the OIG defined a “Focus Arrangement” as every arrangement:
    1. between the lab and any actual source of health care business or referrals to the lab and involves, directly or indirectly, the offer payment, or provision of anything of value; or
    2. between the lab and any physician (or a physician’s immediate family member) who makes a referral to the lab for designated health services.

Within 120 days, the lab must create procedures reasonably designed to ensure that each Focus Arrangement does not violate the Anti-Kickback Statute and/or Stark Law.

- Procedures must include:
  - Compliance training for all parties to the Focus Arrangement (e.g., the physician);
  - Centralized tracking system for Focus Arrangements;
  - Tracking system for remuneration to and from all parties (e.g., the physician);
  - Tracking/activity logs to ensure physicians (or other parties) are performing the services required by the Focus Arrangement;
  - Monitoring use of leased space, supplies, equipment, etc.;
  - Written review/approval process for Focus Arrangements, including at least:
    - (i) a review by legal counsel with expertise in AKS and Stark;
    - (ii) a process for specifying a business need/rational for the Focus Arrangement; and
    - (iii) a process for determining/documenting FMV of remuneration;
  - Compliance Officer review on at least an annual basis; and
  - Effective response procedures when suspected AKS and Stark violations are discovered.

The Focus Arrangement Procedures requirement evidences the government’s continued scrutiny into physician-lab arrangements with a focus on eliminating under-the-table physician-lab arrangements (i.e., the Focus Arrangements must be in writing and the CIA requires a comprehensive tracking system for lab payments to physicians).
Physician-Lab Industry Relationships

Recent Enforcement
Detroit U.S. Attorney

• U.S. Attorney Barbara McQuade raised concerns about healthcare fraud in the lab industry, especially in Detroit.

➢ “A key risk is physicians sending samples for analysis as a panel that labs instead unbundle and bill for separately to boost reimbursement. With physicians mainly interested in the results, that sort of unbundling can go overlooked.”

➢ “It is difficult for the physicians to keep track of what the labs are billing for. It’s kind of an easy fraud to get away with if the physician doesn’t know what’s going on.”
April 2014, CMS released data on utilization and payments for procedures/services provided to Medicare fee-for-service beneficiaries by hospitals, physicians, and other suppliers.

Associated Press analyzed the “data dump”:

- Out of 800,000+ physicians, only 344 received $3 million+ in payments.
- Data is incomplete. Revenue doesn’t = profit (overhead and other factors not accounted for). Medicare billing for multiple providers often processed through a single name/entity. Doesn’t provide insight into quality.

Top paid docs (Medicare reimbursement) will be scrutinized.

- Highest paid docs = ophthalmologists.
- FL Cardiologist paid $20 million+; MI Oncologist paid $10 million+ (indicted for fraud); RI Anesthesiologist paid $3 million (indicted for fraud).
- OIG has said they will automatically scrutinize providers paid $3 million+, but threshold could be lower.

Additional Resources

- **OIG website**
  - [http://oig.hhs.gov/](http://oig.hhs.gov/)

- **ABA Health Law Section**
  - [http://www.americanbar.org/groups/health_law.html](http://www.americanbar.org/groups/health_law.html)

- **ABA Fraud & Abuse Toolkit**
  - [http://www.americanbar.org/groups/health_law/publications/starktoolkit.html](http://www.americanbar.org/groups/health_law/publications/starktoolkit.html)

- **ABA Publications:**
  - *What Is...Stark Law?*
  - *What Is...The Anti-Kickback Statute?*
Questions?

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