Anti-Kickback, Stark Law, and Other Regulatory Considerations When Analyzing Neuromonitoring Arrangements

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✓ The Federal Anti-Kickback Statute (brief overview)
✓ The Federal Stark Law (brief overview)
✓ Neuromonitoring Arrangement (example considerations)
✓ Other Regulatory Considerations (brief overview)
The Federal Anti-Kickback Statute
What is AKS?

- Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate federal health care program business
- Statute: 42 U.S.C. 1320a-7b(b)
- Safe Harbor Regulations: 42 C.F.R. 1001.952
Criminal statute

- Intent must be proven (knowing and willful)

Applies to items/services under federal programs

- Includes non-clinicians
- States may limit kickbacks in cash/private plans

One purpose test

- Payment is illegal where one purpose of the payment is to unlawfully induce referrals even if other legitimate purposes exist

Voluntary safe harbors

- See HHS-OIG Advisory Opinions
Penalties

- **Criminal**
  - Fines up to $100,000 per violation
  - Up to 10 years in prison per violation

- **Civil**
  - Potential exclusion from Medicare and Medicaid programs
  - False Claims Act liability
  - Potential $100,000 CMP per violation
  - Up to 3 times amount of remuneration

*See increases in civil and criminal penalties under Bipartisan Budget Act of 2018*
Small Investment Safe Harbor

Eight elements total, but two of particular importance here:

i. no more than **forty percent** of an entity’s **investment interests** may be **held by investors that are in a position to make or influence referrals** to, or otherwise generate business for, the entity; and

ii. no more than **forty percent** of an entity’s **gross revenue** may come **from referrals or business generated from investors**.
Personal Services Safe Harbor

i. the agreement is set out in writing and signed by the parties;

ii. the agreement covers all of the services to be provided for the term of the agreement and specifies the services to be provided;

iii. if the agreement is intended to provide for the services on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals;

iv. the term of the agreement is for not less than one year;
Personal Services Safe Harbor Cont.

i. the aggregate compensation paid over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs;

ii. the services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law; and

iii. the aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.
Advisory Opinion No. 12-06

Arrangement involving an anesthesia services provider (Provider) and physician-owners (Physicians) of ambulatory surgery center (ASC)

The Provider had been providing anesthesia services to patients at the ASC

Under proposed arrangement, Physicians would establish companies to provide anesthesia services to the ASC

The Physicians would contract to Provider (a former competitor) substantially all anesthesia operations, such as billing and personnel for negotiated rate

OIG concluded risk of fraud and abuse under AKS was more than minimal
Advisory Opinion No. 12-06, cont’d.

OIG noted “long-standing concerns” about physician joint ventures especially when all or most of the business of the joint venture is derived from one or more of the physician owners.

OIG expressed concern when health care provider expands into a related health care business and “contracts out substantially the entire operation of the related line of business” to otherwise potential competitor in exchange for return on the profits of the business.

OIG concluded proposed arrangement “is designed to permit the [Physicians] to do indirectly what they cannot do directly; that is, to receive compensation, in the form of a portion of the [Provider’s] anesthesia services revenues, in return for their referrals to the [Provider]”
Advisory Opinion No. 11-15

Found arrangement where physicians invested in company that provided pathology laboratory management services to third-party lab posed risk under the AKS

Owning interest in management company does not protect arrangement: “rather than contracting with an existing provider to obtain turn-key laboratory services for which a physician-owned entity would bill Federal health care programs, the Requester, a physician-owned entity, would contract to provide such services to an entity that would, in turn, bill Federal health care programs.”
Special Fraud Alert

OIG expressed concern for arrangements that:

(i) Select investors in position to generate business for entity;

(ii) Require investors who cease practicing in service area to divest other investments;

(iii) Distribute extraordinary returns not commensurate with risk involved;

(iv) Include few physician-owners so referrals closely correlate to return on investment;

(v) Result in physician-owners altering medical practice after investing; and

(vi) Have physician-owners as sole users of the items or services.
Special Fraud Alert

OIG listed certain “suspect characteristics”:

(i) The size of investment varies with volume/value of devices used by physician;

(ii) Distributions not in proportion to ownership interest or physician-owners contribute different prices because volume/value of devices used;

(iii) Owners condition referrals on purchase of company’s devices through coercion or promises;

(iv) Owners encouraged/required to refer/recommend use or purchase of company’s devices;
Special Fraud Alert

OIG listed certain “suspect characteristics,” cont’d:

(i) Company retains right to repurchase investment shares due to failure to refer/recommend purchases;

(ii) Company is a shell entity;

(iii) Company does not maintain oversight of distribution functions; and

(iv) Failure to inform or disclose conflict of interest when requested.
The Stark Law
What is Stark?

- Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare [or Medicaid] to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies.
- Prohibits the entity from presenting or causing to be presented claims to Medicare [or Medicaid] (or billing another individual, entity, or third party payer) for those referred services.

“Referral” does not include a referral for a service the referring physician personally performs

Statute: 42 U.S.C. 1395nn

Regulations: 42 C.F.R. 411.350 et seq.
What is DHS?

- Clinical laboratory services (defined by code)
- Physical therapy services (defined by code)
- Occupational therapy services (defined by code)
- Outpatient speech-language pathology services (defined by code)
- Radiology and certain other imaging services (defined by code)
- Radiation therapy services and supplies (defined by code)
- Durable medical equipment and supplies (defined at 42 CFR 411.351)
- Parenteral and enteral nutrients, equipment, and supplies (defined at 42 CFR 411.351)
- Prosthetics, orthotics, and prosthetic devices and supplies (defined at 42 CFR 411.351)
- Home health services (defined at 42 CFR 411.351)
- Outpatient prescription drugs (defined at 42 CFR 411.351)
- Inpatient and outpatient hospital services (defined at 42 CFR 411.351)
- Generally prohibits self-referrals for Medicare/[Medicaid]
  - Must involve physician referral
  - DHS only
  - Ownership or compensation arrangement
  - State laws may limit non-Medicare business arrangements
Mandatory exceptions

- Many exceptions for direct compensation relationships similar to AKS safe harbors (e.g., personal services, employee, lease, etc.)
- Potential indirect relationships examined to determine if they meet indirect compensation arrangement definition, and then exception
- Note - limited exceptions for ownership (i.e., no “small investor safe harbor” but do have in-office ancillary services exception and some services are not DHS)
Penalties

- Strict liability statute, no intent required
- Overpayment refund obligation
- FCA liability
- Civil monetary penalty liability of up to $15,000 per service plus treble damages and/or $100,000 per circumvention scheme
- Potential exclusion from federal healthcare programs
History/Significant Stark Law Changes

Stand in the shoes rule (42 C.F.R. 411.354(c)(3)(i))

- Physician owner of a medical practice stands in the shoes of the practice itself, so that any financial relationship between the practice and another DHS entity is attributed to the individual physician owner.

- Practical effect is that arrangements (e.g., Hospital > Practice > Physician Owner) that were previously considered potential indirect arrangements could now be considered direct arrangements with the physician owner and would have to meet a direct compensation arrangement exception.
Definition of DHS entity (42 C.F.R. 411.351)

- Includes entity that performs the DHS (not just entity that submits claim)

- Practical effect is that under arrangements become problematic. For example, if a hospital contracts with a physician-owned entity to perform a service that the hospital bills for under arrangement, the physician-owned entity could be considered a DHS entity. If the physician owner makes a referral for DHS to the entity, there is potentially no applicable Stark exception (e.g., there is no small investor safe harbor under Stark).
Indirect Compensation Arrangement Definition (42 C.F.R. § 411.354(c)(2)):

- **Unbroken chain** of financial relationships;

- Referring **physician** receives aggregate compensation from the person/entity in the chain with which the physician has a **direct financial relationship** that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS; and
  
  - If the direct financial relationship is ownership/investment interest, look to nonownership/noninvestment interest closest to the referring physician.

- Entity furnishing DHS has **actual knowledge of**, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.
Indirect Compensation Arrangement Exception (additional requirements for specific types of arrangements, i.e., rental of office space/equipment) (42 C.F.R. § 411.357(p)):

- The compensation received by the referring physician is fair market value for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS;

- The compensation arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement; and

- The compensation arrangement does not violate the federal anti-kickback statute, or any federal or state law or regulation governing billing or claims submission.
**CAUTIONS** for neuromonitoring arrangements (and others):

- States may have laws similar to AKS and Stark that could be more restrictive (e.g., include all payors)
- Do not rely on excluding gov’t payors (state law, commercial bribery statutes and US Travel Act)
Neuromonitoring
Sometimes referred to as “intraoperative neuromonitoring” or “intraoperative monitoring” (IOM) or “intraoperative neurophysiological monitoring” (IONM).

Involves stimulating nerves and muscles and using electrophysiological methods (i.e., EEG, EMG, etc.) to monitor patient’s nervous system during surgery.

- Typically involves neuromonitoring equipment, technician, and neurophysiologist or neurologist (often remotely monitoring) to interpret signals.

- Surgeon often requests neuromonitoring service.
**Benefits:** Provides real-time feedback during surgery, allowing opportunity for the surgeon to intervene and potentially avoid or mitigate neurological damage.

**Potential Issues:** Could involve billing patients and insurers at higher, out-of-network charges; could have potential for overuse; typical fraud concerns (e.g., billing for services that are not provided, or billing for monitoring multiple patients at same time).
CPT Codes

- 95940 - used to report time for one-on-one patient monitoring when the provider is physically present in the operating room.

- 95941 - for simultaneous monitoring of multiple patients by a single provider in connection with non-Medicare cases in which the monitoring provider is not in the operating room or monitoring more than one case (note that this is not billable to Medicare).

- G0453 - similar to 95940, but used when IOM is provided outside the operating room (i.e., remotely).
Inpatient hospital services are DHS
  - Consider the services each entity is performing and billing for.

Physician direct or indirect financial relationship with IOM entity may implicate AKS/Stark Law.
Surgeon owns entity that provides management services to IOM entity

- Which entities perform/bill for DHS? Keep in mind limited exceptions for physician ownership in DHS entities (e.g., in-office ancillary services).

- Are any entities a “physician organization” so that a physician owner must stand in the shoes (i.e., potential direct compensation relationship if physician organization contracts with DHS entity)?

- Is there a potential indirect compensation relationship?
STATE LAW CONSIDERATIONS

- State laws applying AKS/Stark to commercial payors
- Financial Interest disclosure requirements
- Balance billing laws
- Heightened scrutiny from state licensing agencies
Surgeon’s practice owns IOM entity, no government payors

- Surgeon owner refers surgery patients to hospital
- IOM entity bills commercial payors for IOM services at hospital (including for surgeon owner’s patients)
- Considerations under state law?
General Considerations

- Contracts for services should be fair market value and commercially reasonable
- Carefully consider structure under Stark (direct/indirect financial relationships)
- How much business is generated by physician owner? Consider 40/60 AKS safe harbor if applicable
- State laws may have broader reach, but could also incorporate federal AKS safe harbors
- Disclosure requirements (potentially under state law)
QUESTIONS?

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