Strategies for Handling Medical Directorships

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Who Am I?

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Agenda

- Overview of the Federal Stark Law and Personal Services Exception
- Overview of Federal Anti-Kickback Statute and Personal Services Safe Harbor
- Medical Directorships—Stark Law Compliance Hot Buttons and Audit Opportunities
- Q&A

Context

- Medical Directors are physicians with experience and expertise to improve patient care in particular providers, departments, or units.
- Not patient care focused; rather, oversight of clinical care; medical staff leadership; training & education; quality control
- Medical Directors often receive supplemental compensation or consideration for the provision of their services—often as an independent contractor, sometimes as an employee.
- Because compensation paid to a physician (who likely is a source of referrals) there are health care regulatory concerns. CMS and OIG want to ensure the legitimacy of these arrangements.
Anti-Kickback Statute & Stark Law: Highlights and Key Comparisons

<table>
<thead>
<tr>
<th>Anti-Kickback Statute (AKS)</th>
<th>Stark Law (STARK)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criminal/Civil</td>
<td>Civil only</td>
</tr>
<tr>
<td>Any Federal Healthcare Program</td>
<td>Medicare only</td>
</tr>
<tr>
<td>Requires proof of improper intent</td>
<td>Strict liability</td>
</tr>
<tr>
<td>Applies to any referral source</td>
<td>Must be a physician and an entity in the mix</td>
</tr>
<tr>
<td>Safe Harbors</td>
<td>Exceptions</td>
</tr>
<tr>
<td>OIG Advisory Opinions</td>
<td>CMS Advisory Opinions</td>
</tr>
</tbody>
</table>

The Stark Law

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The Stark Law

Stark Law:
- Statute: 42 USC § 1395nn
- Regulations: 42 CFR § 411.350, et seq.

Enforcement:
- Centers for Medicare & Medicaid Services (CMS)
- HHS-Office of Inspector General (FCA)
- Department of Justice (FCA)

Stark Law (42 USC § 1395nn)

- Civil law
- Its own penalties and those connected to False Claims Act (see Tuomey, Halifax)
- Prohibits certain referrals
- Prohibits billing Medicare for items and services that are the result of certain services
- **Strict liability law** – Stark Law relationship must fit into one of enumerated exceptions
  - If financial relationship meets one of the exceptions, then referrals and billing Medicare is allowed
- Non-compliance period is “disallowance period”
  - No billing Medicare or patient during disallowance period/non-compliance period
Stark Prohibits:

- A physician
- From making a referral
- Of a Medicare patient
- To an entity that furnishes “designated health services” (DHS) [DHS entity]
- If the physician has a financial relationship with the DHS entity
- Unless an exception applies.

Stark Law—Three Step Analysis

1. Is there a referral from a physician for a DHS?
   - If no, STOP. No Stark Law concern.
   - If yes, then . . .

2. Does the physician (or an immediate family member) have a financial relationship with the DHS entity?
   - If no, STOP. No Stark Law concern.
   - If yes, then . . .

3. Does the financial relationship satisfy an exception?
   - If no, STOP. Stark Law concern.
   - If yes, then . . .
Sanctions & Remedies

- **Denial.** CMS will **not pay** claims for improperly referred DHS.
- **Refund.** Entity has duty to **refund**.
- **Civil Monetary Penalties.**
  - $15,000 for knowingly presenting or causing another to present improper claim.
  - $100,000 for “scheme” to circumvent.
- **Exclusion potential.**
- **Potential False Claims Act liability.**

Period of Disallowance

- **Begins** when financial relationship fails to satisfy applicable exception.
- **Ends** no later than:
  - Date financial relationship satisfies exception (where not related to compensation); or
  - Date excess compensation is returned by party that received it, or if additional compensation is owed, on the date additional compensation is paid by party owing it, and all other requirements of exception are met.
Financial Relationship

- May be ownership/investment interest or compensation arrangement.

- May be direct or indirect.

The Stark Exceptions
A Note on Exceptions

- All exceptions have detailed criteria.

- All criteria in an exception must be met in order to use an exception.

- If any criterion is not met, then arrangement does not meet the exception. Substantial compliance is not enough.

- Note that some exceptions have special definitions within the exception
Personal Service Arrangements Exception

42 CFR § 411.357(d)

(1) General - Remuneration from an entity under an arrangement or multiple arrangements to a physician or his or her immediate family member, or to a group practice, including remuneration for specific physician services furnished to a nonprofit blood center, if the following conditions are met:

(i) Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) The arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity. This requirement is met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of contracts. A physician or family member can “furnish” services through employees whom they have hired for the purpose of performing the services; through a wholly-owned entity; or through locum tenens physicians (as defined at § 411.351, except that the regular physician need not be a member of a group practice).

(iii) The aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).

(iv) The duration of each arrangement is at least 1 year. To meet this requirement, if an arrangement is terminated with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original arrangement.

(v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined at § 411.351 of this subpart), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(vi) The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.

(vii) If the arrangement expires after a term of at least 1 year, a holdover arrangement immediately following the expiration of the arrangement satisfies the requirements of paragraph (d) of this section if the following conditions are met:

(A) The arrangement met the conditions of paragraphs (d)(1)(i) through (vi) of this section when the arrangement expired;

(B) The holdover arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(C) The holdover arrangement continues to satisfy the conditions of paragraphs (d)(1)(i) through (vi) of this section.
Personal Service Arrangement Exception—Key Components

- Written agreement, signed by both parties
- Reasonable and necessary
- Term of at least 1 year
- Compensation set in advance, FMV, no accounting for volume or referrals
- Holdover allowed after 1-year on same terms and conditions.

Also consider the employment exception (42 CFR 411.357(c))
The Federal Anti-Kickback Statute (AKS)

- Core of AKS – Prohibits anyone from purposefully offering, soliciting, or receiving anything of value to generate referrals for items or services payable by any Federal health care program.
- 42 states and D.C. have enacted their own anti-kickback statutes

Elements

- Remuneration;
- Offered, paid, solicited, or received;
- Knowingly and willfully;
- To induce or in exchange for Federal program referrals.
Remuneration

- **Anything** of value
- “In-cash or in-kind”
- Paid directly or indirectly
- Examples:
  - Cash, free goods or services, discounts, below market rent, relief of financial obligations (e.g., forgiveness of loans)

To Induce Federal Program Referrals

- Any Federal health care program (e.g., Medicare, Medicaid, Tricare)
- A nexus between payments and referrals
- Covers any act that is intended to influence and cause referrals to a Federal health care program
- **One purpose test** and culpability can be established without a showing of specific intent to violate the statutory prohibitions
Fines and Penalties

The Government may elect to proceed:

**Criminal:**
- Felony, imprisonment up to 5 years and a fine up to $25,000 or both
- Mandatory exclusion from participating in Federal health care programs
- Brought by the DOJ

**Civil:**
- CMPs
- A violation of the federal AKS also constitutes a false or fraudulent claim under the civil False Claims Act

Fines and Penalties (cont’d)

**Administratively:**
- Monetary penalty of $50,000 per violation and assessment of up to three times the remuneration involved
- Discretionary exclusion from participating in Federal health care programs
- Brought by the OIG
Safe Harbors

- Many harmless business arrangements may be subject to the AKS
- 25 exceptions ("Safe Harbors") have been created by the OIG
- Compliance with a Safe Harbor is voluntary
- Must meet all conditions to qualify for Safe Harbor protection
- But is substantial compliance enough?

AKS Safe Harbors

- Investment Interests
- Space Rental
- Equipment Rental
- Personal Services and Management Contracts
- Sale of Practice
- Referral Services
- Warranties
- Discounts
- Employees
  - Group Purchasing
  - Waiver of Beneficiary Coinsurance and Deductible Amounts
  - Increased Coverage, Reduced Cost-Sharing Amounts or Reduced Premium Amounts Offered by Health Plans
  - EMR
- Price Reductions Offered to Health Plans
- Practitioner Recruitment
- Obstetrical Malpractice Insurance Subsidies
- Investments in Group Practices
- Cooperative Hospital Service Organizations
- Ambulatory Surgical Centers
- Referral Agreements for Specialty Services
- Price Reductions Offered to Eligible Managed Care Organizations
- Price Reductions Offered by Contractors with Substantial Financial Risk to Managed Care Organizations.
As used in section 1128B of the Act, “remuneration” does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met:

(1) The agency agreement is set out in writing and signed by the parties.
(2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
(3) If the agency agreement is intended to provide for the services of the agent 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.
(4) The term of the agreement is for not less than one year.

(5) The aggregate compensation paid to the agent 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.

(6) The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.

(7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

For purposes of paragraph (d) of this section, an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.
Personal Service Arrangement Exception—Key Components

- Written agreement, signed by both parties
- Intervals specified
- Term of at least 1 year
- AGGREGATE compensation set in advance, FMV, arms-length, no accounting for volume or referrals
- No provision for holdovers

Also consider employment safe harbor 42 CFR 1001.952(i).
Medical Directorship Compliance Hot Buttons (and Audit Opportunities)

- Written agreement signed by both parties
  - AP does not pay a physician or group for medical director services unless it has a signed written agreement
Medical Directorship Compliance Hot Buttons (and Audit Opportunities)

- Services are specified
  - What services is medical director expected to provide? Are Medical Director services specified? Is there a detailed Job Description?

Medical Directorship Compliance Hot Buttons (and Audit Opportunities)

- Evaluation
  - Is performance measurable?
    - By task? By outcome? By hours?
  - Is performance evaluated?
    - How often?
Medical Directorship Compliance Hot Buttons (and Audit Opportunities)

• How long is term of Medical Director Agreement?
  ✓ Evergreen?
  ✓ Holdover language?

• Is the Medical Director Agreement commercially reasonable (i.e., legitimate)?
  ✓ Why is the agreement necessary? Driven by licensure/accreditation/certification requirements?
  ✓ Driven by need/desire for patient referrals?
  ✓ One of many similar (duplicate) agreements?
Medical Directorship Compliance Hot Buttons (and Audit Opportunities)

- How is compensation tracked?
  - Activity/hours log? Who reviews and approves?
    Detailed service description or cursory description?
  - Physician attestation? Manager attestation?
  - Evidence of (routine) duplication?
  - Evidence of (routinely) reaching/exceeding hours cap?

Medical Director Compliance Checklist

- Medical Director is in good standing at the institution or healthcare system.
- The Medical Director is not excluded from participating in
  federally funded health care programs.
- The MDA is intended to obtain or provide an item or service that is
  reasonable and necessary for a legitimate business purpose.
- MDA is in writing.
- MDA has a description of services.
- Term of MDA is at least one year.
- The total compensation to be paid to the Medical Director is set in advance.
- Fair market valuation is on file.
- (Total) Compensation does not exceed fair market value.
- Compensation is not determined in a manner that will take into account the volume or
  value of any referrals or other generated business.
- The aggregate contracted services do not exceed those that are reasonable and
  necessary for the business purposes of the arrangement.
- Time and effort requirements should be outlined in the MDA with the requirement for
  tracking such information.
- Monthly time attestation requirement.
Questions?