

The Stark Law and Your Medical Practice

Navigating the complexities of the Stark Law

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Firm Mission: Reduce Risk/Increase Bottom Line For Those Who Place Their Trust In Us.

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This presentation is for general educational
and informational purposes only.

Consult with an attorney concerning your
specific circumstances.

Stark Attack



The Stark Law is the physician
self-referral law.

Distinguished from the Federal
Anti-Kick back Statute.

Penalties / Sanctions

- 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 claims
 - \$100,000 for “scheme” to circumvent
- Exclusion
- Potential False Claims Liability

Who Can Initiate Sanctions?

Anyone can initiate sanctions against you

- Office manager
- Billing staff
- Receptionist or any other office staff person
- Co-conspirator
 - Associate
 - Employee/Partner

How Can Sanctions Be Initiated?

- Disgruntled individual or a former colleague can denounce you to United States Attorneys Office, FBI, OIG, MFCU, CMS
- Disgruntled individual or a former colleague can hire a hungry attorney and file a False Claims Act suit against you on behalf of the government and as a reward obtain a percentage of what the judgment/settlement is against you.

No Criminal Intent Needed for Civil False Claims Act Suit For Violating Stark

Incentives

- Big financial rewards for Relator/Plaintiff
- Significant psychological rewards
- There is little or no defense if a violation occurred

The Stark Attack Can Come From Anyone
Even Those Whom You Trust

What is the Stark Law?

(1) Prohibits a physician from making referrals for certain "designated health services" (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and

(2) Prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services.

Key Definitions

Designated Health Services (DHS)

- Clinical laboratory services
- Physical therapy services
- Occupational therapy services
- Outpatient speech-language pathology services
- Radiology and certain other imaging services, which include MRI, CT, and ultrasound services (also includes nuclear medicine services)

Designated Health 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

Designated Health Services

- Home health services and supplies
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

Key Definitions

Immediate family member of the physician includes

- Spouse
- Natural or Adoptive Parents, Children,
- Siblings
- Step-siblings
- In-laws
- Grandparents/grandchildren

Key Definitions

Entity

- A physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS.
- Does not include a referring physician, but does include his or her medical practice.
- Does not include a physician's practice when it bills Medicare for a purchased diagnostic test.

Key Definitions

Referral

- Requesting/ordering services or certifying medical necessity (including test ordered pursuant to consult)
 - **Does not** include personally performed services
 - **Does** include “incident to” services
- Referral is imputed to physician if he or she “directs” or “controls” the person making the referral
 - Preamble includes NPs and Pas in this category

Key Definitions

Financial Relationship

- May be ownership/investment interest or compensation arrangement
- May be direct or indirect

Direct Financial Relationship

- Exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the DHS entity without any intervening persons or entities between them.

Ownership or Investment Interest

- Includes equity, debt, and other means
- Does not include:
 - Interest in a retirement plan offered through employment
 - Stock options earned as compensation until exercised
 - Unsecured loans
 - “Under arrangements” contracts
 - Security interest held by a physician in equipment sold by the physician to a hospital (when financed through a loan to the hospital)

Compensation Arrangement

- Any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity
- Includes contracts between hospitals and entities providing DHS “under arrangements” to the hospital

Questions You May Be Asking Yourself?

- Who Can I have a Business Relationship With and Under What Circumstances?
- What Is A Legal Self-Referral?

EXCEPTIONS

- Exceptions are relationships specifically defined by statute or regulation that permit referrals that can be compensated for under government healthcare programs.
- Often require written documentation such as contracts setting out specific terms and conditions that define the permissible relationship.

EXCEPTIONS

Three broad categories of Statutory or Regulatory Exceptions:

- (1) Exceptions that apply to all financial relationships
- (2) Exceptions that apply only to ownership/investment interests
- (3) Exceptions that apply only to compensation interests

There are also, a number of definitional exceptions

Exceptions

Applicable to All Financial Relationships

- A. Physician Services
- B. In-office ancillary services
- C. Services furnished to prepaid plan enrollees
- D. Eyeglasses, contact lenses, following cataract surgery
- E. Academic medical centers
- F. Implants by an ASC
- G. EPO and other dialysis-related drugs
- H. Preventive screening tests; immunizations and vaccines
- I. Intra-family rural referrals

Exceptions

Applicable only to ownership interests

- A. Publicly traded securities
- B. Mutual funds
- C. Rural providers
- D. Puerto Rican hospitals
- E. Whole-hospital exception

Exceptions

Applicable only to Compensation arrangements

- A. Rental office space or equipment
- B. Employment
- C. Personal service arrangements
- D. Physician recruitment
- E. Isolated transactions
- F. Unrelated hospital remuneration
- G. Physician fair market value or payments
- H. Non-monetary compensation up to \$300
- I. Compliance program
- J. Professional courtesy
- K. Physician retention arrangements
- L. Obstetrical malpractice premium subsidies

Applicable only to Compensation arrangements cont.

M. Fair market value compensation

N. Medical staff incidental benefits

O. Temporary non-compliance

P. Community-wide HIS/EMR/E-prescribing

Q. Indirect compensation arrangements

Five selected exceptions for discussion

- 1) In-office ancillary services
- 2) Physician services
- 3) Rental office space / equipment
- 4) Academic medical centers
- 5) Personal services arrangements

In-office ancillary services

- This exception is arguably the most important single exception in the Stark Law. It applies to services that are truly ancillary to the medical services being performed by physicians' practices.
- It covers nearly all DHS except durable medical equipment (with a few carve-outs for infusion pumps, blood glucose monitors, and certain other devices that provide assistance to patients when leaving the physician's office), and parenteral and enteral nutrients, equipment and supplies.

Physician services

- This exception applies to the narrow class of physician services that are included in the definition of DHS (e.g., the professional component of radiology services)
- This exception enables physicians in a group practice to refer services to each other

Rental office space or equipment

- Lease must be in writing
- Lease at least one year
- Space or equipment leased does not exceed business purposes
- FMV
- Commercially reasonable

Academic medical centers

In order for an organization to qualify as an academic medical center, it must include the following:

- a) An accredited medical school (including a university, when appropriate), or an accredited academic hospital;
- b) One or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and
- c) One or more affiliated hospital(s) in which a majority of the physicians on the medical staff consists of physicians who are faculty members and a majority of all hospital admissions are made by physicians who are faculty members

Personal services arrangements

- 1) The arrangement must be set out in writing, signed by the parties, and specifies the services covered;
- 2) The arrangement must cover all of the services to be provided by the physician (or immediate family member) and the entity;
- 3) The aggregate services contracted for must not exceed those that are reasonable and necessary for a legitimate business purpose;

Personal services arrangements

- 4) The term must be at least one year (if the parties terminate during the term they may not enter into the same or substantially similar agreement during the first year of the original agreement);
- 5) The compensation must be set in advance, and except for physician incentive plans, must not take into account the volume or value of referrals or other business generated between the parties; and
- 6) The services to be furnished must not involve the counseling or promotion of an unlawful business arrangement or other activity that violates any law

Conclusion:

- Three Step Analysis:
 1. Is there a referral from a physician for a Designated Health Service (“DHS”)?
 2. If so, does the physician (or an immediate family member) have a financial relationship with the entity providing the DHS?
 3. If so, does the financial relationship satisfy an exception?

- Compliance program

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