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STARK AND ANTI-KICKBACK

A Basic Overview

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The Stark Law

- ❑ Stark Law prohibits a physician from making referrals for “designated health services” to entities with which the physician or immediate family member has direct or indirect financial relationship.
- ❑ Only applies to Medicare DHS services.

What Is DHS?

“Designated Health Services” (or DHS) are defined as the following:

- ❑ Clinical laboratory services;
- ❑ Physical therapy, occupational therapy, and speech-language pathology services;
- ❑ Radiology and certain other imaging services;
- ❑ Radiation therapy services and supplies;
- ❑ Durable medical equipment and supplies;

DHS cont'd

- Parenteral and enteral nutrients, equipment and supplies;
- Prosthetics, orthotics, and prosthetic devices and supplies;
- Home health services;
- Outpatient prescription drugs; and
- Inpatient and outpatient hospital services.
- BUT NOT ambulatory surgical centers.

What Is A Financial Relationship?

- ❑ Financial relationship is defined broadly to include any direct or indirect ownership or investment in an entity furnishing DHS;
- ❑ *Or* compensation arrangement with an entity furnishing DHS.

How Do You Protect Yourself?

- ❑ The Stark Law imposes strict liability – meaning that any violation of the statute, even if unintentional, will result in liability.
- ❑ If activity is within a recognized “exception” the financial arrangement is protected.

Stark Exceptions

- Rental of office space or equipment;
- Bona fide* employment relationships;
- Personal service arrangements;
- Physician recruitment;
- Isolated transactions;
- Whole hospital ownership;
- Group practice in-office ancillary services;
- Payments or charitable donations by a physician;
- Non-monetary comp up to \$300;
- Fair market value compensation;
- Medical staff incidental benefits;

Stark Exceptions cont'd

- Risk sharing arrangements;
- Compliance training;
- Indirect comp arrangements;
- Referral services;
- Obstetrical malpractice ins. subsidies;
- Professional courtesy;
- Retention payments in underserved areas;
- Community-wide health info systems;
- Electronic prescribing items and services.; and
- Electronic health records items & services.

The Stark Law

□ Stark II, Phase III Regulations:

- Issued by CMS on September 5, 2007.
- Made significant changes:
 - ✗ “Stand in the Shoes” provision – physician stands in the shoes of its physician organization;
 - ✗ Changes regarding physician recruitment arrangements – clarified service area, practice restrictions and allocation of practice costs;
 - ✗ Fair market value exception clarified (payments to and from DHS entity); and
 - ✗ Group practice compensation – when distributing income, can base productivity bonuses on “incident to” services (except radiology).

Consequences

- ❑ CMS and OIG can require reporting on financial information.
- ❑ Staff physicians may be required to provide information.
- ❑ See also N.H. R.S.A. 125:25a-c.

Physician Fee Schedule and Anti-Markup Rule

- ❑ Cannot purchase technical or professional service from other providers and mark it up from Medicare unless you meet certain exceptions.
- ❑ Physicians can't mark-up unless provide radiology in own offices.
- ❑ Challenging percentage compensation, per-click arrangements between physicians and entities to which they refer in-office ancillary services and “under arrangement” ventures.

The Anti-Kickback Statute

- ❑ 42 U.S.C. § 1320a-7b(b) and implementing regulations at 42 C.F.R. § 1001.952.
- ❑ Makes it illegal for any person to knowingly and willfully pay or receive any compensation in return for:
 - a referral for any item or services paid for by a federal health care program; or
 - purchasing, leasing or ordering any good, facility, service or item paid for by a federal health care program.

The Anti-Kickback Statute cont'd

- ❑ Applies to all federal health care programs, not just Medicare.
- ❑ Applies to any good, service or item under such programs.
- ❑ Unlike Stark, it is a knowledge-based statute (no strict liability).
- ❑ “Safe harbor” exceptions (some overlap with Stark Law exceptions).

Safe Harbors

- Investment interests;
- Rental of space or equipment;
- Personal services and management contracts;
- Sale of practice;
- Referral services;
- Warranties;
- Discounts;
- Amounts paid by employers to employees with bona fide employment relationships;
- Group purchasing organizations;
- Waiver of beneficiary coinsurance and deductible amounts;
- Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans;

Safe Harbors cont'd

- Price reductions offered by health plans;
- Practitioner recruitment;
- Obstetrical malpractice insurance subsidies;
- Cooperative hospital service organizations;
- Ambulatory surgical centers;
- Referral arrangements for specialty services;
- Price reductions offered to eligible managed care organizations;
and
- Ambulance replenishing.

Common Safe Harbors/Exceptions

□ In-office ancillary services/Group practice exception:

- In-office ancillary services are excluded if they meet the following requirements:
 - ✘ **Physician Supervision:** They are personally furnished by the referring physician, a member of the referring physician's group practice, or an individual supervised by the referring physician or member of the group practice;
 - ✘ **Same Building:** The services are provided in the building where the physician or group practice conducts their practice; and
 - ✘ **Billing:** The services are billed by: (i) the physician performing or supervising the service; (ii) the group practice of which the performing or supervising physician is a member; (iii) an entity wholly-owned by the physician or group practice; or (iv) a third-party as billing agent.

Personal Services Arrangements

- Remuneration from an entity to a physician, an immediate family member or a group practice are excluded from the prohibition if the following requirements are met:
 - The agreement is in writing, signed and specifies the services covered;
 - The arrangement includes all services provided by the physician (can be multiple agreements if they all reference one another);
 - Services must be reasonable and necessary;
 - The term of the agreement is at least 1 year;
 - The comp is set in advance, doesn't exceed FMV, and, except for physician incentive agreements, doesn't take into account volume or value of referrals; and
 - Services don't involve recommending or promoting of a business arrangement.

Leases

- Payments for office space or equipment if there is a lease that meets the following requirements:
 - The agreement is in writing, signed and specifies the space or equipment to be leased;
 - The term of the agreement is at least 1 year;
 - The space or equipment leased is reasonable and necessary;
 - The rent is set in advance and consistent with FMV;
 - Rent payment doesn't take into account volume or value of referrals; and
 - The lease would be commercially reasonable in absence of referrals.

OIG Compliance Program Guidance For Group Practice

[http://oig.hhs.gov/authorities/docs/
physician.pdf](http://oig.hhs.gov/authorities/docs/physician.pdf)