

MEDICARE FRAUD AND ABUSE PHYSICIAN SELF-REFERRAL PROHIBITION ("STARK LAW") AND ANTI-KICKBACK LAW

I. STARK LAW

A. Physician "Self-Referrals" Prohibited.

The "Stark law," named after Congressman Fortney "Pete" Stark (D-CA) who sponsored the law (Social Security Act § 1877; 42 U.S.C. § 1395nn) prohibits a physician from referring Medicare patients for the furnishing of certain types of health care services (called "designated health services" or "DHS") to an entity with which the physician or a member of the physician's immediate family has a financial relationship. In addition, the physician is prohibited from filing a Medicare claim for services arising from a prohibited referral.

B. Penalties.

Civil penalties may be imposed for violation of the Stark law. Penalties include (1) denial of payment, (2) refunds of amounts collected in violation of the law, (3) up to \$15,000 in civil monetary penalties for each claim submitted in violation of the law, (4) up to \$100,000 in civil monetary penalties for each arrangement or "scheme" that violates the law, (5) a civil monetary penalty of three times the amount claimed, and (6) exclusion from participation in the Medicare program or other government health programs. There are currently no criminal penalties for violations of the Stark Law. No proof of intent is required for there to be a violation.

C. "Designated Health Services." DHS include the following:

- Clinical laboratory services
- Radiology and certain other imaging services
- Inpatient and outpatient hospital services
- Outpatient prescription drugs
- Physical therapy, occupational therapy, and speech-language pathology services
- Radiation therapy services and supplies
- Durable medical equipment
- Home health services
- Prosthetics, orthotics, and prosthetic devices and supplies
- Parenteral and enteral nutrients, equipment, and supplies

Stark regulations establish a “bright-line” definition for clinical laboratory, physical and occupational therapy, radiology, and radiation therapy services through publication of a list of CPT and HCPCS codes.

D. "Financial Relationship." Defined as one of the following:

1. An Ownership or Investment Interest in the Entity. An equity, debt, or similar ownership or investment interest in an entity that provides DHS.

2. A Compensation Arrangement. Any arrangement involving remuneration between a physician (or immediate family member) and an entity that provides DHS.

3. An Indirect Financial Relationship. A relationship between an entity with which the physician has an ownership or compensation arrangement and another entity which furnishes DHS. The physician must have actual knowledge of the indirect financial relationship or act in reckless disregard or deliberate ignorance of the existence of the relationship.

E. “Referral.” Defined as follows:

A referral includes a request by a physician for an item or service for which payment may be made under Medicare Part B, including the request for a consultation with another physician and the request or establishment of a plan of care by a physician that includes a DHS. Excluded from the definition are DHS that a physician both orders and personally performs, as well as requests by pathologists, radiologists, and radiation oncologists for services furnished as the result of a consultation by another physician.

F. Exceptions.

The following is a list of exceptions to the Stark law:

1. Exceptions to Both Ownership and Compensation Arrangements.

- Physicians' Services
- In-Office Ancillary Services
- Prepaid Plans
- Academic Medical Centers
- Implants in ASC
- EPO furnished in or by ESRD facility
- Preventative Screening Tests
- Eyeglasses and Contacts following Cataract Surgery
- Intra-family referrals

2. Exceptions to Ownership Arrangements.

Ownership in Publicly Traded Securities and Mutual Funds

Ownership Interests in Hospitals in Puerto Rico

Ownership in Hospitals

Ownership in Rural Providers

3. Exceptions to Compensation Arrangements.

Rental of Office Space and Equipment

Bona Fide Employment

Personal Services Arrangements

Remuneration Unrelated to DHS

Physician Recruitment

Group Practice Arrangements with a Hospital

Physician Payments

Isolated Transactions

Fair Market Value Compensation

Non-Monetary Compensation

Medical Staff Incidental Benefits

Risk Sharing Arrangements

Compliance Training

Indirect Compensation Arrangements

Charitable Donations by Physicians

Referral Services

Obstetrical Malpractice Insurance

Professional Courtesy

Retention Payments in Underserved Areas

Community-Wide Health Information Systems

G. Stark Law Advisory Opinions.

An advisory opinion process is available under the Stark law. (42 U.S.C. § 1395nn; 63 Fed. Reg. 1,646 (January 9, 1998)). An advisory opinion is an opinion by the government as to whether a physician referral arrangement is prohibited by the Stark law. Such opinions are very fact specific and are binding only on the Secretary of the DHHS and the requesting party.

H. Moratorium on New Specialty Hospitals.

The Medicare Prescription Drug, Improvement and Modernization Act (MMA) imposed an 18-month moratorium on the Stark law "whole hospital" exception for "new" specialty hospitals. The specialties affected are cardiac, orthopedic, surgery and other hospitals specified by the Secretary of the DHHS. Existing hospitals and hospitals under development as of November 18, 2003 are grandfathered under the moratorium. The current moratorium on physician ownership of specialty hospitals expired on June 8, 2005; however, Congress is expected to extend the moratorium until January 1, 2007.

On February 28, 2005, the Federation of American Hospitals ("FAH") petitioned the Secretary of the DHHS to revise the Stark law exception for physician ownership in hospitals. The FAH seeks to amend the regulation to apply the hospital ownership exception only to physician investment in "full-service acute care hospitals that provide substantial and varied services." The FAH opposes physician ownership in specialty hospitals because it believes such arrangements allow physicians to "cherry pick" the most profitable services, leaving full-service hospitals with only the less profitable share of the market.

I. Physician Recruitment.

As of July 26, 2004, physician recruits who have joined existing groups cannot be subject to a non-competition restriction in any employment agreement. In addition, expense reimbursement components of income guarantees must be limited to actual additional incremental expenses incurred by the group to support the recruit. Prior to July 26th, hospitals must have complied with a "reasonable interpretation of the statute" since regulations had not yet been published. CMS states that, as long as this was the case, past payments under an income guarantee need not be recalculated.

J. Inclusion of Nuclear Medicine Services and Supplies as DHS Under Stark.

On December 13, 2004 CMS announced notice of a proposed rule to include diagnostic and therapeutic nuclear medicine services and supplies as DHS. According to the announcement, the proposed rule was to be published in September 2005, but no announcement has yet been made. The announcement does not indicate which nuclear medicine services and supplies would be included as DHS.

II. FEDERAL ANTI-KICKBACK LAW

A. Kickbacks.

The federal anti-kickback law (Social Security Act § 1128B(b); 42 U.S.C. § 1320a-7b(b)) prohibits the willful and knowing offer, solicitation, payment, or receipt of any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind (1) for referring an individual for a government health program (e.g., Medicare and Medicaid) covered service or item or arranging for such a referral; or (2) for purchasing, leasing, ordering, arranging for, or recommending the purchase, lease, or order of any good, facility, service, or item covered under a government health program.

B. Penalties for Violation.

Violation of the law is a felony punishable by not more than five years in prison and/or a \$25,000 fine. Violators are also subject to a civil money penalty of \$50,000 per act plus three times the remuneration offered, and exclusion from the Medicare program (or other government health program).

C. The Intent Element.

A person must act "knowingly and willfully" in order for a violation of the law to occur. The intent standard is met if a person knowingly and willfully makes a payment or offer of payment or solicits or receives a payment as an inducement to the payee to refer an individual for the furnishing of an item or service that could be paid for under a government health program.

D. Safe Harbors.

Safe harbors are provided for specific kinds of arrangements which are deemed not subject to criminal or civil prosecution under the law. Safe harbors include the following arrangements:

Certain investment interests
Space rental
Equipment rental
Personal services and management contracts
Sale of practice
Referral services
Warranties
Discounts
Employees
Group purchasing organizations
Price reductions offered to health plans
Waiver of beneficiary co-insurance/deductibles
Increased coverage, reduced cost sharing amounts, or reduced premium amounts offered by health plans
Investments in underserved areas
Practitioner recruitment in underserved areas
OB malpractice insurance subsidies for underserved areas
Sales of practices to hospitals in underserved areas
Investments in ambulatory surgical centers
Investments in group practices
Referral arrangements for specialty services
Cooperative hospital service organizations
Price reductions offered to eligible managed care organizations
Price reductions offered by contractors with substantial risk to managed care organizations
Ambulance replenishing

Each safe harbor contains specific elements, all of which must be satisfied in order to qualify for safe harbor treatment.

E. OIG Advisory Opinions.

Advisory opinions may be sought from the Office of Inspector General of the DHHS (“OIG”) as to whether a specific arrangement complies with the anti-kickback law. Advisory opinions only address specific fact situations and are binding only on the Secretary of the DHHS and the party requesting the opinion.

F. Special Fraud Alerts.

The OIG has issued various Special Fraud Alerts that describe certain business arrangements that may violate the anti-kickback law. Special Fraud Alerts have been issued concerning the following arrangements:

- Joint ventures
- Routine waivers of coinsurance and deductibles
- Hospital incentives to physicians
- Prescription drug marketing practices
- Arrangements for the statute of clinical laboratory services
- Home health agencies
- Nursing home suppliers
- The provision of services in nursing facilities
- Fraud and abuse in nursing home arrangements with hospices
- Physician liability for certification of medical equipment and home health services
- Physician office space rental arrangements
- Telemarketing by durable medical equipment suppliers

III. TEXAS LEGISLATIVE ACTIVITY.

The Texas legislature introduced the following notable bills affecting physicians in its most recent session affecting physicians:

A. H.B. 3281. Like the Stark law, this bill would prohibit a health care provider from referring a patient for the provision of designated health services or supplies to a person in which the health care provider is directly or indirectly an investor. Claims may not be submitted for services arising from a prohibited referral. The list of designated health services and supplies is much broader than those specified in the Stark law.

B. S.B. 872. This bill seeks to amend the Texas Occupations Code to include as unprofessional conduct a physician's referral of a patient to a specialty hospital in which the physician or immediate family member has a financial interest unless the patient is furnished with written disclosure of the interest and notified that the patient has the option to use an alternative facility. Specialty hospitals are defined as those in which the Medicare patients or, if data is available, all patients, fall into no more than two major DRGs or in specialty DRGs, or those that specialize in cardiac, orthopedics, surgery, or women's health.

C. S.B. 1622/H.B. 3316. These bills require disclosure to patients, the Texas Medical Board, and the Texas Department of State Health Services of physician ownership in specialty hospitals, ambulatory surgery centers and imaging centers. Specialty hospitals are defined as those that limit admissions according to one or more medical or surgical specialties, types of disease, or medical conditions or limits hospital services to specified surgical, diagnostic or treatment procedures. The bills impose a temporary moratorium on physician referrals to specialty hospitals, ambulatory surgery centers and imaging centers not providing services as of September 1, 2005. The moratorium would expire on September 1, 2007.