

Compliance with Stark II Phase II: A Hospital Perspective

By: Cheryl L. Brooks, MSA, CFAAMA
Vice President, Compliance/Managed Care
Mary Rutan Hospital
Bellefontaine, OH

Introduction

The physician self-referral laws and regulations were implemented to close loopholes in financial relationships between physicians and entities to which they referred. Representative Fortney "Pete" Stark led the movement in Congress in the late 1980s. Various studies and research conducted during this period supported a correlation between increased utilization of services to those entities to which the physician had financial ties.

The Office of Inspector General conducted a study in 1989 that found that patients of physicians that had an ownership or investment interest in independent clinical laboratories received 45% more laboratory services than Medicare patients in general, regardless of the place of service. Medicare patients whose physicians were owners or investors in independent physiological laboratories received 13% more physiological testing (OAI-12-88-01410).

Several studies examined the prevalence of joint ventures in Florida. The data was collected under a legislative mandate and supported the common practice of physician ownership of businesses that provide diagnostic and other ancillary services. At least 40% of Florida physicians had investment interests in the health care entity to which they referred their patients (Mitchell and Scott). Another study examined the effects of physician joint ventures with freestanding physical therapy and rehabilitation facilities. Patient visits were 39% to 45% higher, both gross and net revenue per patient were 30% to 40% higher, and percent operating income and percent markup were higher in these joint venture physical therapy and rehabilitation facilities (Mitchell and Scott). Although these studies were conducted in the state of Florida, it is likely that these arrangements occur elsewhere.

Health Stop, a for-profit ambulatory care chain, changed its compensation system to allow physicians to earn bonuses dependent on the gross income they generated individually. The practice patterns of fifteen physicians were compared before and after the incentive arrangement. The results revealed the number of laboratory test performed per patient increased by 23% and the number x-ray films per visit increased by 16% (Hemenway, Gillen, Cashman and Bicknell).

The U.S. General Accounting Office (GAO) issued a report on physician-owned imaging facilities and found that physician owners of Florida diagnostic imaging facilities had higher referral rates than non-owners for expensive high technology imaging services. Physician owners ordered 54% more MRI

scans, 27% more CT scans, 37% more nuclear medicine scans, 27% more echocardiograms, 22% more ultrasound services, and 22% complex x-ray (GAO Report No. B-253835).

The laws and regulations that followed the findings of these case studies became known as the Stark regulations. The regulations were designed to curb fraud and abuse and excessive spending in governmental health care programs from these types of physician referral patterns. The self-referral law prohibits some physician referral patterns but also contains exceptions that allow physicians to structure financial arrangements and business practices that comply with the law.

Stark Law History

Statutory Provisions

The Omnibus Budget Reconciliation Act of 1989 prohibited physician self-referral in section 1877 of the Act. This legislation applied only to physician referrals for clinical laboratory services. In 1990 Section 1877 was amended. Reporting requirements and definitions were clarified. The Omnibus Budget Reconciliation Act of 1990 extended the prohibited referrals to ten additional designated health services (DHS). This Act added some new and modified exceptions and extended some of this law to Medicaid. The Social Security Act Amendments of 1994 amended the list of DHS and some of the effective dates and modified the reporting requirements.

Regulatory History

The Health Care Financing Administration (HCFA) published the final rule on August 14, 1995, that incorporated the changes from the Omnibus Budget Reconciliation Act (OBRA) 1993 and the Social Security Act Amendments of 1994 relating the clinical laboratory services. On January 9, 1998, HCFA published a proposed rule that included the additional ten designated health services and the Medicaid expansion. More than 12,000 public comments were made objecting to the HCFA interpretation. Concerns were raised that the proposed rule intruded into the physicians' office practice, the rule was unclear, and some parts of the rule were administratively impractical and cost prohibitive.

Because of the issues that were raised during the comment period, the rulemaking process was separated into two phases to provide improved guidance. The January 2001 "Phase I" became effective January 2002 with the exception of home health services, which became effective in April 2001. The December 2001 notice in the Federal Register delayed the effective date regarding percentage compensation in definition of "set in advance" until January 2003. In November 2002, a further delay until July 2003 regarding percentage compensation was published in the Federal Register. A notice in the Federal Register in April 2003, again delayed the effective date regarding percentage compensation. The December 2003 notice in the Federal Register further delayed the effective date until July 2004. Finally on March 26, 2004, the interim final rule "Phase II" was published with an effective date of July 26, 2004.

Key Concepts of Stark II

The Stark II self-referral ban basically prohibits physician referrals of Medicare and Medicaid beneficiaries to entities with which they or an immediate family member have a financial relationship for designated health service. The law also prohibits an entity such as a hospital from billing for services that were provided as result of a prohibited referral. The final regulations define a physician as a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor. An immediate family member is a husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother or stepsister; father-in-law, mother-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grand child. A referral is any request, order, or certification of need (oral or written) for any Medicare reimbursable designated health service (DHS). Designated health services include any of the following:

Clinical laboratory services	Parenteral and enteral nutrients,
Physical therapy services	equipment, and supplies
Occupational therapy services	Prosthetics, orthotics, and
Certain radiology services	prosthetic devices and supplies
Radiation therapy services and supplies	Home health services
Durable medical equipment and supplies	Outpatient prescription drugs
Inpatient and outpatient hospital services	

An important key concept is the type of financial relationship that may exist. There are two types of financial relationships: ownership or investment interests and compensation arrangements. The financial relationships can be of a direct or indirect nature.

A number of exceptions are defined in the statute that fall into three categories. Those exceptions that apply to both ownership and compensation arrangements are considered general exceptions. A second group protects ownership interests. The last type of exception is designed to protect only compensation arrangements.

Some of the exceptions in Phase II are revisions made in response to public comments received on Stark

I. Others have been clarified in the final regulation. A few of the more significant exceptions are for:

Ownership in publicly traded securities	Risk sharing arrangements
Academic medical centers	Isolated transactions
Hospital ownership	Payments made by a physician
Physician recruitment	Remuneration unrelated to DHS
Personal services	Compliance training
Space and equipment leases	Non-monetary compensation up to \$300 and medical staff incidental benefits

Phase II has created some new exceptions including:

- Arrangements involving temporary noncompliance
- Retention payments in underserved areas
- Professional courtesy
- Charitable donations by a physician
- Community-wide information systems
- Referral services
- Obstetrical malpractice subsidies

Implications for the Hospital

Stark II violations will be enforced with other federal laws including the anti-kickback statute. Civil monetary penalties up to \$100,000 for each arrangement that violate the statute may be imposed. Reporting requirement penalties may be imposed on entities that fail to submit information by the deadline established by the Centers for Medicare and Medicaid (CMS). An entity that fails to submit timely information will be subjected to a civil money penalty of up to \$10,000 a day past the deadline. A financial exposure exists unless the financial relationship with a referring physician meets a statutory or regulatory exception. No intent is required and financial exposure exists even if it is a mistake. A knowing violation could also lead to liability under the False Claims Act.

Hospital Strategy

The significant financial impact of Stark II violations required a compliance strategy to be developed at the community hospital. The Chief Executive Officer, Compliance Officer, and hospital Legal Counsel met to develop a plan to meet compliance with the regulations. A thorough review of the hospital's contracting was required to avoid the potential of large fines. The analysis was initiated by responding to three important questions:

- 1) Which physicians make referrals for designated health services to the hospital?
- 2) Is there a financial relationship with the physician or immediate family and the hospital?

3) Does the financial relationship fit into a Stark II exception?

The analysis began by identifying each physician that made referrals to the hospital and the type of financial arrangement. This process was completed for the hospital and subsidiary corporations. After identifying the physicians who had financial relationships with the hospital the type of arrangement was identified. The types of financial arrangements included the following:

Employment Contracts

Lease Agreements

Service Agreements

Income Guarantees

Each of the financial arrangements was reviewed against a standard template that covered the requirements for the appropriate exception. Each type of the contract was revised as required to meet the regulations listed below.

Employment contracts

Any payments made to a physician or immediate family member when a bona fide employment relationship exists are excepted from the Stark prohibition, if certain conditions are met:

- (1) The employment is for identifiable services;
- (2) The amount of the payment is fair market value for the services and is not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals by the referring physician;
- (3) The employment agreement would be commercially reasonable even if no referral were made to the employer; and
- (4) The employment meets such other requirements as the Secretary may impose to protect against program or patient abuse. Section 1877 (e) (2) and 42 CFR 411.357 (c).

The statute also allows employers to pay productivity bonuses based on services the employee personally provides.

Lease Agreements

In order for an office space or equipment lease to meet the exceptions, the following requirements must be met:

- (1) The lease must be in writing, signed by both parties, and specifies the space or equipment covered by the lease;
- (2) The term of the agreement is at least one year;
- (3) The space or equipment rented or leased does not exceed what is reasonable and necessary for the legitimate business purposes of the lease, and is used exclusively by the lessee when being used (except that prorated payments for common areas are allowed);

- (4) The rental charges over the term of the lease are set in advance and are consistent with fair market value;
- (5) The rental charges over the term of the agreement are not determined in manner that takes into account the volume or value of any referral or other business generated between the parties'; and
- (6) The agreement would be commercially reasonable even if no referral were made between the parties. 42 CFR 411.357 (a) and 411.357 (b).

Service Agreements

The personal service exception criteria:

- (1) Agreement is set out in writing and signed by the parties and specifies the services covered by the agreement;
- (2) Agreement covers all the services to furnished by the physician (or immediate family member) to the Hospital;
- (3) Term of the agreement must be at least one year;
- (4) Compensation must be set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan, does not take into account the volume or value of referrals or other business generated between the parties; and
- (5) Does not violate the anti-kickback statute or any other state or federal law.

Physician Recruitment

An exception is available to a hospital when compensation is provided to a physician to induce the physician to relocate to the geographic area served by the hospital in order for the physician to become a member of the medical staff. The arrangement must be in writing, signed by both parties; the arrangement must not be conditional on referrals; the amount of the recruitment incentive must not be based on the volume or value of referrals; the recruited physician is allowed to establish privileges at any other hospital and refer business to other entities (permits reasonable credentialing on physicians becoming competitors with the hospital). 42 CFR 411.357(e)

Some additional requirements must be applied when a recruited physician joins a group practice. The group must sign the written agreement, if the group receives any indirect or direct payments. Costs allocated to the recruited physician must not exceed the actual additional increment costs that are attributed to the recruited physician when there is an income guarantee. Records of actual cost and pass through amounts must be kept five years and available to the U.S. Department of Health and Human Services (HHS) on request. There can be no practice restrictions such as covenant not to compete on the recruited physician. The arrangement cannot violate the anti-kickback statute.

The reporting obligation requires that all financial relationships between the hospital and a physician or any immediate family members must be tracked and maintained. A Stark II database was designed to meet this requirement for all the current contracts. The database included the following:

Physician UPIN

Physician Name

Financial Relationship: Ownership/investment or Compensation Arrangement or Both

Affiliated Group

Family Member and Name

The type of Designated Health Service (DHS)

Written Agreement

Type of Arrangement

Nature of Financial Arrangement

Several other areas were reviewed under the Stark audit. Physician incidental benefits may only be provided while the physician is on the hospital campus and engaged in services or activities that benefit the hospital. Each benefit may not exceed twenty-five dollars in value. There is no limit on the number of benefits that can be given. Transcription services, lab coats and laundry, and Internet access were a few of the incidental benefits provided to the physicians at the hospital. Non-monetary compensation not exceeding three hundred dollars is permitted if it is not determined by the volume or value of referrals. It must not exceed the cap annually. Meals off the hospital campus or with recruitment candidates, free continuing medical education, and physician attendance at board retreats with spouse were all reviewed. Professional courtesy discounts such as the free or discounted healthcare services were considered and addressed in policy.

Conclusion

The Stark II audit was an important function that provided a better understanding of the regulation. It identified the need to develop policies and procedures in obtaining and retaining information needed to comply with reporting obligations. It identified the need to document reasonable, consistent and objective fair market determinations in financial relationships with physicians.

Physicians are looking more frequently for financial assistance from the hospital in the current healthcare environment. The malpractice crisis in our state and reductions in physicians' payments have increased requests from physicians to the hospital to enter into financial relationships that fall under the Stark II regulations. The Hospital must understand and be prepared to enter into these financial relationships more frequently. At the same time, all financial relationships with physicians will be viewed with much greater scrutiny in the post Stark II environment.

References

- Federal Register, 42 CFR Part 411 and 424, Friday, March 26, 2004. Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have a Financial Relationships (Phase II); Interim Final Rule Retrieved August 4, 2004, from the World Wide Web:
<http://www.gpoaccess.gov>
- The U.S. House of Representatives. Congress Pete Stark, Stark II Regulations. Retrieved August 4, 2004, from the World Wide Web:
<http://www.house.gov/stark/stark2.html>
- The U.S. House of Representatives. Information Packet on Stark II/Physician Self-Referral Law. Retrieved August 4, 2004, from the World Wide Web:
<http://www.house.gov/stark/stark2/stark2info.html>
- The U.S. House of Representatives. Information Packet on Stark II/Physician Self-Referral Law. Self-Referral Studies. Retrieved August 4, 2004, from the World Wide Web:
<http://www.house.gov/stark/stark2/stark2info.html>
- CMS Issues Interim Final Rule Addressing Physician Self-Referrals. Retrieved August 4, 2004, from the World Wide Web:
<http://www.cms.hhs.gov/media/pres/release>.
- Amednew.com. August 2, 2004. Stark II "exceptions for physician recruitment by hospital" by Steven M. Harris. Retrieved on August 4, 2004, from the World Wide Web:
<http://www.ama-assn.org/amednews/2004/08/02>