

*Kean Miller Health Care Industry
Business Group*

***PHASE II OF THE FINAL
STARK REGULATIONS:
WHAT DO THEY MEAN
FOR HEALTHCARE
PROVIDERS***

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PHASE II OF THE FINAL STARK REGULATIONS: WHAT DO THEY MEAN FOR HEALTHCARE PROVIDERS

By Linda G. Rodrigue, Esq. and Clay J. Countryman, Esq.

On March 26, 2004, the Centers for Medicare and Medicaid Services (CMS) published an interim final rule with comment period (referred to as the “Phase II Regulations”) to implement the federal physician self-referral law (the “Stark Law”). *See* 69 Fed. Reg. 16054 (Mar. 26, 2004). The Stark Law is considered to be a “strict liability” law because if the Stark Law applies to a financial relationship such arrangement must meet a specific exception to the Stark Law or the parties are subject to certain penalties and sanctions regardless of the parties. This handout provides a general overview of the Stark Law and some of the new interpretations and exceptions in the Phase II Regulations.

I. Overview of the Stark Law, 42 U.S.C. § 1395nn

A. What is the Stark Law?

The Stark law is a federal civil statute that prohibits a physician from referring a Medicare (or Medicaid) patient for a “designated health service” (“DHS”) to a DHS provider if the physician (or immediate family member) has a financial relationship with the DHS provider, unless a Stark exception applies. Some exceptions are in the statute, some are in Stark regulations, and some are in both.

The Stark Law also prohibits an entity from presenting a claim to the Medicare program or to any individual or third party payer or other entity for a Designated Health Service performed pursuant to a referral prohibited by the Stark law.

B. What is a Referral?

A “referral” is defined as a request by a physician for an item or service for which Medicare Part B may pay, including a request for a consultation (including any tests ordered by the consultant), as well as a request or establishment of a plan of care, with certain exceptions for consultations by pathologists, diagnostic radiologists and radiation oncologists. A referral does not include a request for a DHS item or service that is provided or performed by the referring physician.

C. What are the Designated Health Services?

- Clinical laboratory services*
- Physical therapy, occupational therapy, speech language pathology services*
- Radiology and certain other imaging 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*
- Home health services
- Outpatient prescription drugs
- Outpatient hospital services
- Inpatient hospital services

* CMS defines these categories of DHS by CPT or HCPCS codes. The codes are updated annually. Attached is the most recent list of codes that was included with the Phase II regulations on March 26, 2004.

D. What is a Financial Relationship?

A “financial relationship” is defined by Stark as an ownership interest or a compensation arrangement. The financial relationship can be direct or indirect. Some examples are:

Direct:

- Lease of a building
- Medical director agreement

- Direct ownership in a DHS provider

Indirect:

- Physician has ownership interest in a corporation that owns a DHS provider.
- Physician has an ownership interest in a hospital, the hospital contracts for services with a clinical laboratory, and the physician refers to the laboratory. If the laboratory has “knowledge” (i.e., actual knowledge; deliberate ignorance; or reckless disregard) of the physician-hospital financial relationship, there may be an indirect compensation arrangement.

E. Is Intent an Element of a Stark Violation?

No. Additionally, the only time knowledge matters is when indirect financial relationships are being analyzed.

F. What are the Penalties for a Stark Violation?

- The DHS provider may not bill for the services, and any billing that does occur must be refunded.
- If the referral is made when the parties knew or should have known of the financial relationship, each party to the violation may be liable for up to \$15,000 per service in civil monetary penalties, and three (3) times the amount claimed may be recovered.
- Parties who participate in “circumvention schemes” [for example, a cross-referral arrangement] may be assessed a \$100,000 civil monetary penalty for each scheme.
- Parties who are assessed civil monetary penalties also face exclusion from participation in federal healthcare programs.
- Under certain circumstances, a violation of the Stark law **may** provide the predicate act for a federal False Claims Act violation. For example:
 - Physician has a financial relationship with a cost-reporting hospital that does not meet a Stark exception, and the physician refers

patients there in violation of Stark. Hospital submits a cost report that includes a written certification that the hospital is in compliance with all laws and regulations. The federal healthcare program relies on the certification in making payment. [Actual case – Texas].

- Hospital purchases physician practices and pays salaries to physicians in acquired practices, no Stark exception is met, and physicians refer patients to the hospital. [Actual case – Florida - \$22.5 million False Claims Act settlement with five (5) year Corporate Integrity Agreement].

G. What is the Status of Stark?

The 12+ year odyssey:

Stark I Statute (clinical laboratory services only)	1991
Proposed Stark I regulations	1992
Stark II Statute (adds other DHS)	1995
Final Stark One Regulations	1995
Proposed Stark II Regulations	1998
Stark II, Phase I Regulations	1/04/01–effective 1/4/02
Stark II, Phase II Regulations	3/26/04-effective 7/26/04

H. What about the Anti-Kickback Statute?

It is still alive and well. Some Stark exceptions specifically include a requirement that for the exception to apply, the arrangement must not violate the anti-kickback statute. In all instances, the anti-kickback statute is a separate law that must be separately complied with.

One material difference between Stark and the anti-kickback statute is that a Stark exception must be met or there is a violation, whereby failure to qualify for an anti-kickback exception does not automatically mean there is a violation.

II. Overview of the Phase II Regulations

A. What was actually issued by CMS?

CMS published on March 26, 2004 an Interim Final Rule with comment period (referred to as the “Phase II Regulations”). The Phase II Regulations are effective on July 26, 2004. CMS will consider comments received on Phase II issues received by CMS before June 24, 2004. Comments received by CMS will be addressed in a separate federal register notice.

The Phase I of the Stark Law Regulations issued on January 4, 2001 covered:

- The general self-referral prohibition and the exceptions applicable to both ownership and compensation arrangements;
- Certain statutory definitions;
- Additional regulatory definitions; and
- New regulatory exceptions promulgated under section 1877(b)(4) of the Act for certain arrangements involving the following:
 - Academic medical centers;
 - Implants furnished by an ambulatory surgery center;
 - EPO and certain dialysis-related outpatient prescription drugs;
 - Preventive screening tests, immunizations, and vaccines;
 - Eyeglasses and contact lenses after cataract surgery;
 - Non-monetary compensation up to \$300;
 - Fair market value compensation;
 - Medical staff incidental benefits;
 - Risk-sharing arrangements;
 - Compliance training; and

- Indirect compensation arrangements.

The Phase II Regulations for the Stark Law cover:

- The remaining provisions of section 1877 of the Act (i.e., the exceptions for ownership and investment interests and the exceptions for various compensation arrangements);
- Additional regulatory definitions; and
- Additional new regulatory exceptions promulgated under section 1877(b)(4) of the act for certain arrangements involving the following:
 - Temporary noncompliance with an applicable exception;
 - Intra-family referrals;
 - Charitable donations by a physician;
 - Referral services;
 - Obstetrical malpractice insurance subsidies;
 - Professional courtesy;
 - Retention payments in underserved areas; and
 - Community-wide health information systems.

Phase II also addresses public comments on the Phase I regulations.

B. Specific Areas in the Phase II Regulations

1. Physician Compensation

The Stark Law contains different exceptions for physician compensation depending on whether physicians are in a group practice, employees or independent contractors. The following are a summary changes made by CMS in the Phase II regulations that affect several exceptions related to physician compensation (e.g.,

employment, personal services, fair market value, and academic medical centers):

a. Percentage Compensation Arrangements

- i) CMS provided in Phase II that the “set in advance” criteria in the personal service arrangements and fair market value exceptions may be satisfied by percentage compensation arrangement if the methodology for calculating the compensation is set in advance and does not change over the course of the arrangements in any manner that reflects the volume or value of referrals or other business generated between the parties.
- ii) This change will allow independent contractor physicians and academic physicians to receive a percentage based compensation payment and meet these exceptions.

b. Productivity Bonuses

Several new interpretations by CMS in the Phase II regulations will allow all physicians to still meet certain compensation exceptions when receiving the following productivity bonuses: (1) productivity bonus based on work a physician personally performs; (2) group practices may pay independent contractor and employed physicians productivity bonuses based on “incident to” services; and (3) indirect bonuses and profit shares that may include DHS revenues provided that the distribution methodology meets certain criteria in the regulations.

c. Regulatory Safe Harbor for Hourly Physician Compensation

- Part of the regulatory definition of FMV
- For consideration in medical director agreements
- For services provided directly by a physician (not by physician’s employee or company)
- Use is voluntary
- Two methodologies for calculating what will be “deemed” to be FMV:

- Hourly payment must be less than or equal to the average hourly rate for ER physician services in the relevant market, provided there are at least three (3) hospitals providing ER services in the market.
- Averaging the 50th percentile salary for the physician's specialty of at least four (4) of six (6) identified national salary surveys and dividing the average by 2000 hours to obtain an hourly rate. If the specialty is not identified in the survey, general practice is used.
 - The surveys available for averaging are:
 - a. Sullivan, Cotter & Associates, Inc. – Physician Compensation and Productivity Survey
 - b. Hay Group – Physicians Compensation Survey
 - c. Hospital and Healthcare Compensation Services – Physician Salary Survey Report
 - d. Medical Group Management Association – Physician Compensation and Productivity Survey
 - e. ECS Watson Wyatt-Hospital and Health Care Management Compensation Report
 - f. William M. Mercer – Integrated Health Networks Compensation Survey

2. Physician Incentive Plans and Other Risk-Sharing Arrangements

The Phase II regulations permit group practice, employed, and academic medical center physicians to be paid under risk-sharing arrangements.

3. Requirement for a Physician to Refer to Certain Providers

CMS narrowed an regulatory exception for compensation arrangements that require physicians to refer to a particular provider as a

condition of payment to apply to employment, managed care, and other professional service arrangements and only if: (1) those referrals related to the physician's services that are covered by the contractual arrangement and (2) the referral requirement is reasonably necessary to effectuate the legitimate purposes of the compensation arrangement.

For example, CMS commented that an entity that employs a physician on a part-time basis to provide services that such entity cannot condition the employment (including any compensation) on referrals of the physician's private practice business (i.e. patients seen by the physician when he or she is not working for the entity).

III. Exceptions Applicable to Ownership and Compensation Arrangements

A. In-Office Ancillary Services Exception

This exception is probably one of the most utilized exceptions because it allows physicians in a group practice to refer Medicare patients to (or within) the physician's practice for DHS (e.g., ultrasounds, MRIs, CTs, physical therapy) if certain supervision, location, and billing requirements are met.

1. Supervision Requirement: The DHS must be provided personally by: (1) the referring physician; (2) a physician who is a member of the same group practice as the referring physician; or (3) individuals "directly supervised" by the physician or another physician in the group practice.

In Phase I of the Stark regulations, CMS interpreted "directly supervised" to mean that the supervision must meet the physician supervision requirements in the applicable Medicare coverage rules.

CMS commented in the Phase II regulations that a solo practitioner may refer designated health services if he or she meets the in-office ancillary services exception, including providing the necessary supervision himself or herself.

2. The Location (Building) Requirements: The DHS must be furnished to patients in the "same building" "where the referring physician provides his or her regular medical services, or for a group practice in a central building used by the group to provider DHS. A group practice may meet the "building requirement" by satisfying the "same building" criteria or by providing the DHS in a "centralized building" used by the group to furnished that particular DHS; whereas, a solo practitioner must meet the "same building" requirements.

A big change in Phase II Regulations was the new 3 alternative tests that CMS provided that a group practice or solo practitioner may satisfy to meet the “Same Building” requirement. The following is a summary of these 3 alternative tests (of which only one must be met):

(1) First Test: A designated health service is furnished in the “same building” if the building is one in which the referring physician or his or her group practice (if applicable) has an office that is normally open to their patients at least 35 hours per week, and the referring physician or one or more members of his or her group regularly practices medicine and furnishes physician services to patients in that office at least 30 hours per week. Some of the services must be physician services that are unrelated to the furnishing of DHS, whether Federal or private pay, although the unrelated physician services may lead to the ordering of DHS.

(2) Second Test: A designated health service is furnished in the “same building” if the building is one in which the referring physician or his or her group practice has an office that is normally open to their patients at least 8 hours per week, and the referring physician regularly practices medicine and furnishes physician services to his or her patients in that office at least 6 hours per week (including some physician services unrelated to the furnishing of DHS). In this test, services provided by members of the referring physician’s group practice do not count toward the 6-hour threshold. In addition, the building must be one in which the patient receiving designated health service usually sees the referring physician or other members of his or her group practice (if the physician practices in a group practice).

(3) Third New Test: A designated health service is furnished in the “same building” if the building is one in which the referring physician or his or her group practice has an office that is normally open to their patients at least 8 hours per week, and the referring physician or a member of his or her group practice (if any) regularly practices medicine and furnishes physician services to patients at least 6 hours per week in that office (including some physician services unrelated to the furnishing of DHS). In addition, the referring physician must be present and order the designated health service in connection with a patient visit during the time the office is open in the building or the referring physician or a member of his or her group practice (if any) must be present while the designated health service is furnished during the time the office is open in the building. This test requires presence in the building, but not necessarily in the same space or part of the building.

3. **The Billing Requirement:** The DHS must be billed by one of the following: (1) the physician performing or supervising the service; (2) the group practice of which that physician is a member under the that group practice’s billing number; or (3) or an

entity that is wholly owned by the referring or supervising physician or the referring or supervising physician's group practice.

B. Prepaid Plan Exception

This exception provides that services provided by certain Medicare managed care plans (e.g., Medicare HMOs) are not subject to the Stark Law.

IV. Exceptions Related Only to Ownership or Investment Interests

A. Rural Providers

1. CMS created a new exception for certain referrals from a referring physician to a DHS entity with which his or her immediate family member has a financial relationship, if the patient being referred resides in a rural area and there is no DHS entity available in a timely manner in light of the patient's condition to furnish DHS to the patient in his home (for DHS furnished in a patient's home) or within 25 miles of the patient's home.
2. CMS changed portions of the "rural provider" exception because of the Medicare Prescription Drug, Improvement, and Modernization Act to specify that for the 18-month period beginning on December 18, 2003, the rural provider may not be a specialty hospital.

B. Hospital Ownership (Applicable to Specialty and other hospitals)

Specialty Hospitals

- Under Stark, physician ownership of a hospital meets an exception if:
 - The physician is authorized to perform services there (privileges) [CMS requires the authorization to be "*bona fide*", *i.e.*, the physician uses the privileges]
 - The ownership is in the whole hospital and not in just a unit or department
- The referred DHS that are permitted under this exception are those provided by the hospital (but not by any hospital-owned entity, such as a hospital-owned home health agency]

- “Specialty hospitals” have begun to emerge (and proliferate in some states such as Louisiana). These hospitals are usually physician-owned (CMS has been “watching” this development). GAO studies have been released on the development and growth of these hospitals. They are generally defined as engaged primarily and exclusively in care and treatment of one of the following:
 - cardiac conditions
 - orthopedic conditions
 - surgical procedures
 - any specialized category of services designated by the Secretary of DHHS.
- The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the “MMA”) changed the hospital ownership exception to disqualify “specialty hospitals”, except for those grandfathered by the MMA, and created an 18-month moratorium on new ownership. Grandfathered hospitals are those in operation or “under development” (subject to a case-by-case determination by CMS) as of November 18, 2003.

V. Exceptions Related to Other Types of Compensation Arrangements

A. Rental of Office Space and Equipment

Phase II highlights:

- Subleases are permitted as long as the lessee (sublessee) does not share the space with the lessor or any person or entity related to the lessor (for example, group practice). A sublease may, however, create an indirect compensation arrangement between the sublessee and the lessor.
- Contracts may be terminated during the first year of the term, with or without cause, as long as no “replacement” contract is entered during the first year, and any new agreement meets an exception.

- A month-to-month holdover, for a maximum of six (6) months, is permitted if all other terms remain the same.
- “Per click” or “per test” rental payments are permitted if they are fair market value and do not take into account the volume or value of referrals or other business generated by the referring physician.

B. Employment Relationships

A referral restriction will not violate the volume and value of referrals standard if:

- (1) The referring physician is compensated at fair market value for services performed in an arrangement that otherwise fits within the employment (or another) exception;
- (2) The referral restriction relates solely to the physician’s services covered by the scope of the employment or contract and is reasonably necessary to effectuate the legitimate purposes of the compensation relationship; and
- (3) Referrals are not required (directly or indirectly):
 - a. When the patient expresses a different choice;
 - b. When the patient’s insurer determines the provider; or
 - c. When the referral is not in the best medical interest of the patient in the physician’s judgment.

C. Personal Services Arrangements

Phase II highlights:

- Compensation may be percentage-based
- Contract may be terminated, with or without cause, during first year as long as the parties do not enter into the same or substantially the same arrangement during the year and any subsequent agreement meets a Stark exception.

- A physician may use employees (but not independent contractors) and a wholly owned company to perform “non-physician” contracted services.
- A personal services arrangement may involve both services and equipment (to perform the services), and both may be contracted for in one agreement, but the services and equipment must be separated for purposes of determining fair market value.

D. Physician Recruitment

- Phase II makes substantive changes
 - Applies to hospitals and federally qualified health centers (“FQHC’s”)
 - Focus is on the relocation of the physician’s medical practice, not the physician’s residence
 - A hospital’s geographic area is defined by continuous zip codes corresponding to 75% of inpatients, and physician must either (1) move his practice site at least 25 miles; or (2) derive 75% of his patient revenue from services to new patients (including services to hospital’s inpatients)
 - Permits cross-town recruitment of residents and physicians in practice less than one (1) year without regard to change in practice location (they are deemed not to have an established practice)
 - In some situations, recruitment payments may be made through an existing group practice if:
 - a. The group practice signs the recruitment agreement
 - b. The payment is passed through to the recruited physician (can be minus actual costs to recruit the physician)
 - c. In the case of an income guarantee by the hospital, the costs allocated to the recruited physician are attributable to the physician

- d. Record retention for five (5) years
- e. No anti-kickback violation
- f. Remuneration from the hospital may not take into account the group's actual or expected referrals.
- g. Group may not impose practice restrictions (for example, a non-compete) other than quality of care.
- h. The physician must establish a practice in the hospital's geographic service area and must join the medical staff.
- i. The physician is not required to refer to the hospital and may obtain privileges at other hospitals.
- j. The physician is allowed to refer business to other entities (unless restricted by an employment agreement that meets a Stark exception).

VI. Regulatory Exceptions

A. Ambulatory Surgical Centers ("ASC's")

- Phase I established a new exception for implants furnished by an ASC. (Created because the items are DHS, but are not included in the ASC composite rate.)
- The implementation of brachytherapy seeds is not included.
- Applies when the ASC (not the physician) bills for the implant.
- If the physician wishes to bill for the implant, he must meet some other Stark exception.

B. Non-Monetary Compensation (Gifts)

- Now will be subject to indexing for inflation each year on January 1, based on CPI increase for the one (1)-year period ending the prior September 30.

- Current limit is \$300 annually per physician

C. Medical Staff Incidental Benefits

- Expanded beyond hospitals – if there is a *bona fide* medical staff
- Current limit is \$25 per occurrence, but subject to CPI Indexing
- Traditional items are parking, meals, lab coats
- Expanded to include technology benefits under certain circumstances
- The requirement that the benefits be of the type offered by other hospitals has been deleted

D. Compliance Training

- May be provided by hospitals, as well as other entities that furnish designated health services.
- Does not include CME
- Training may be provided to the physician, as well as to the physician's office staff
- Reminder: must be provided in the local community or service area and to those who practice there

E. Professional Courtesy

1. CMS added a new regulatory exception for professional courtesy provided to a physician or his or her immediate family members. CMS defines “professional courtesy” in § 411.351 as the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff. To qualify for the new exception, the arrangement must meet the following conditions:
 - (a) The professional courtesy is offered to all physicians on the entity's bona fide medical staff or in the entity's local community without

regard to the volume or value of referrals or other business generated between the parties;

- (b) The health care items and services provided are of a type routinely provided by the entity;
- (c) The entity's professional courtesy policy is set out in writing and approved in advance by the governing body of the health care provider;
- (d) The professional courtesy is not offered to any physician (or immediate family member) who is a Federal health care program beneficiary, unless there has been a good faith showing of financial need;
- (e) If the professional courtesy involves any whole or partial waiver of any coinsurance obligation, the insurer is informed in writing of that reduction so that the insurer is aware of the arrangement.
- (f) The professional courtesy arrangement does not violate the anti-kickback statute or any billing or claims submission laws or regulations.

F. Charitable Donations by a Physician

1. CMS interprets charitable donations from a physician to a DHS entity to constitute "remuneration" as defined in the statute.
2. CMS added a new exception for bona fide charitable donations made by a physician (or immediate family member). To qualify, donations must be made to an organization exempt from taxation under the IRS Code (or to an exempt supporting organization, such as a hospital foundation). The new exception provides that the donation may not be solicited or made in any manner that reflects the volume or value of referrals or other business generated from one party for the other.

G. Other Regulatory Exceptions

1. Retention Payments for Physicians in Underserved Areas
2. Preventive Screening Tests
3. Intrafamily Referrals
4. Exception for Certain Arrangements Involving Temporary Noncompliance with a Stark Exception