

CHAPTER 2

THE STARK LAW

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§ 2.01 INTRODUCTION

The federal physician self-referral law commonly referred to as the “Stark Law,” after the name of its chief legislative sponsor, Fortney (Pete) Stark, is premised on the government’s belief that a conflict of interest is inherent to any arrangement where a physician refers patients to a health care entity in which he or she has a financial stake. To eliminate financial incentives to self-refer, the Stark Law broadly prohibits physicians from referring their Medicare patients to health care entities with which they have a financial relationship. As originally enacted in 1989,¹ the Stark Law focused exclusively on physician referrals for clinical laboratory services. The law was expanded significantly in 1993,² however, to prohibit physician referrals for a host of other designated health services (DHS), which, in addition to clinical laboratory services, include, among other things, inpatient and outpatient hospital services, durable medical equipment, many diagnostic radiology and imaging services, and physical therapy services. Accordingly, in the absence of an exception, the Stark Law now forbids physician referrals of patients to an entity for the furnishing of DHS covered by Medicare, if the physician has a financial relationship with the entity.³ It also prohibits (again, if no exception applies) the entity that furnishes the DHS from billing for any services provided pursuant to a prohibited referral.⁴

These expansive prohibitions implicate most arrangements between physicians and a wide range of health care entities, including hospitals, clinical laboratories, independent diagnostic testing facilities and the physicians’ own practice or practice group. Indeed, nearly all hospital-physician arrangements such as medical directorships, medical office building leases, physician recruitments and relocations and medical staff benefits implicate—and potentially violate—the Stark Law. For these reasons, the Stark Law is considered to be one of the federal government’s most significant and far-reaching fraud and abuse enforcement tools. The Law’s strict prohibitions also have made it popular among “whistleblowers”—private individuals who bring causes of action on behalf of the United States under the federal civil False Claims Act.

Section 2.01 of this chapter outlines the primary policy objectives of the Stark Law, compares the Stark Law to the federal health care program anti-kickback law (Anti-Kickback Law), explains how the Stark Law affects the Medicare and Medicaid programs differently, and introduces state physician self-referral laws. **Section 2.02** discusses the Stark Law’s principal prohibitions and outlines the primary elements of the Law. **Section 2.03** covers the statutory and regulatory exceptions to the Stark Law. Finally, **Section 2.04** summarizes the law’s penalties, sanctions and collateral consequences. Reference charts and compliance checklists are contained in **Appendices 1–3**.

¹ Omnibus Budget Reconciliation Act of 1989 (Pub. L. No. 101-239) (effective Jan. 1992). ³ 42 U.S.C. § 1395nn(a)(1)(A); 42 C.F.R. § 411.353(a).

² Omnibus Budget Reconciliation Act of 1993 (Pub. L. No. 103-66) (effective 1995). ⁴ 42 U.S.C. § 1395nn(a)(1)(B); 42 C.F.R. § 411.353(b).

Throughout this chapter, both the Stark statute and implementing regulations issued by the Centers for Medicare & Medicaid Services or its predecessor agency, the Health Care Financing Administration (jointly, “CMS”), are referred to collectively as the “Stark Law,” and include citations to each authority, as applicable. However, where a distinction is warranted, the statute and regulations are referred to separately as the “Stark Statute” and “Stark Regulations.”

[A] Policy Objectives

As noted above, the prohibitions of the Stark Law were created based on the premise that a physician’s loyalties will be unavoidably divided if the physician has a financial interest in or with a health care entity to which he or she is in a position to make referrals, as the physician may be “unduly influenced by a profit motive.”⁵ The main objective of the Stark Law, therefore, is to prevent financial relationships that potentially give rise to such divided loyalties, which, in turn, ultimately could result in inappropriate utilization of Medicare funds. Not surprisingly, then, only carefully crafted arrangements that give rise to a financial relationship but include a variety of safeguards—via the full satisfaction of an exception—are protected and permissible under the Stark Law.

Further expanding upon the primary objectives of the Stark Law, CMS has explained that the law is intended to:

1. Prevent overutilization of health care items and services paid for by Medicare;
2. Prevent a diminution in patient freedom of choice among health care providers, or, stated another way, to prevent patient steering to a particular provider; and
3. Prevent unfair competition in the health care marketplace such that new providers are unable to gain business even if they offer superior quality, service, or price.⁶

[B] The Stark Law Versus the Anti-Kickback Law

The Stark Law is not the only federal authority designed to prevent inappropriate referrals and business generation within the health care industry. The Anti-Kickback Law—often considered to be the Stark Law’s primary fraud and abuse deterrence companion—also was designed (albeit almost 20 years earlier) to prevent conflicts of interest arising between and among referrals sources (e.g., physicians) and other health care providers and entities, and the concomitant risk of federal health care program abuse.⁷

In a nutshell, the Anti-Kickback Law prohibits a person or entity from “knowingly and willfully” paying (or offering to pay) remuneration to another person or entity to induce the recipient to:

1. Refer an individual to a person or entity for the furnishing of an item or service paid for by a federal health care program (“covered item or service”);

⁵ 63 Fed. Reg. 1659, 1662 (1998).

⁶ *Id.*

⁷ 42 U.S.C. § 1320a-7b(b).

2. Purchase, order or lease a covered item or service;
 3. Arrange for the purchase, order or lease of a covered item or service;
- or
4. Recommend the purchase, order or lease of a covered item or service.⁸

The Anti-Kickback Law also prohibits the solicitation or receipt of remuneration for any of the purposes set forth above.⁹

Although the Stark and Anti-Kickback Laws are similar in that they both contain broad prohibitions designed to prevent fraud and abuse related to referrals of health care patients and generation of health care business, the two laws differ in several key respects. First, the scope of the Stark Law is not coterminous with that of the Anti-Kickback Law. In particular, the Stark Law's prohibitions apply to certain items and services (i.e., DHS) that are covered by the Medicare program only; the Anti-Kickback Law applies to numerous federal health care programs, including, for example, Medicaid, TRICARE, the Public Health Service, and the Black Lung Program.¹⁰ In addition, the Stark Law only applies to physician referrals; the Anti-Kickback Law covers arrangements involving referrals between among and any type of person or entity.

Second, unlike the Anti-Kickback Law, a violation of which requires "scienter" (i.e., that a person act with the requisite state of mind—"knowingly and willfully"), the Stark Law is essentially a "strict liability" statute.¹¹ Thus, even if the parties to a particular arrangement do not intend to violate the Stark Law, and indeed have the very best motivations, the Law will nevertheless be violated if there is a prohibited referral and no exception applies.

Third, the Stark Law provides for civil and administrative sanctions.¹² The Anti-Kickback Law, in contrast, is a criminal statute (the violation of which has attendant civil and administrative sanctions).¹³ Finally, although the violation of both laws may result in exclusion from participation in federal health care programs (such as Medicare and Medicaid), such exclusion is always permissive in the context of the Stark Law, but mandatory in connection with some (criminal) Anti-Kickback Law convictions.¹⁴

[C] Medicare Versus Medicaid

The Stark Law's prohibitions are intended primarily to protect the Medicare trust fund. Its form follows this purpose by prohibiting the referral of patients for certain items or services covered by Medicare. That said, the Stark Law also protects the Medicaid program, albeit indirectly: The Stark Law prohibits the expenditure of federal funds for services furnished to Medicaid patients if the

⁸ 42 U.S.C. § 1320a-7b(b)(2).

⁹ 42 U.S.C. § 1320 a-7b(b)(1).

¹⁰ 42 U.S.C. § 1320a-7b(f).

¹¹ 42 U.S.C. § 1320a-7b(b).

¹² 42 U.S.C. § 1395nn(g)(3), cross-referencing 42 U.S.C. § 1320a-7a(a).

¹³ 42 U.S.C. §§ 1320a-7b(b)(1)-(2), 1320a-7a(a)(7), 1320a-7(b)(7).

¹⁴ 42 U.S.C. § 1395nn(g)(3), cross-referencing 42 U.S.C. § 1320a-7a(a). 42 C.F.R. § 1001.952, 1003.105(a)(1).

services are based on a referral that would be considered a prohibited referral under the Medicare program.¹⁵ In other words, the Stark Law does not prohibit the referral of Medicaid patients *per se*, but arrangements that violate the Stark Law may preclude a state Medicaid program from receiving federal matching funds for services furnished to Medicaid patients pursuant to such arrangements.

[D] State Self-Referral Laws

Although the Stark Law is certainly the most prominent legal authority regulating physician self-referrals, many states have laws that parallel, or are otherwise similar to, the Stark Law. For example, New York has a physician self-referral law that mirrors the Stark Law's general prohibitions.¹⁶ The New York law prohibits a health care practitioner from making a referral for clinical laboratory, pharmacy, radiation therapy, physical therapy, and X-ray or imaging services to a health care provider providing such services, where the practitioner has a financial relationship with such health care provider.¹⁷ In addition, under the New York law, the health care provider may not bill or submit a claim to any payor or individual for services furnished pursuant to an improper referral.¹⁸

It is important to note, however, that many state physician self-referral laws do not have the same—or as many—exceptions as the Stark Law.¹⁹ As such, a comprehensive fraud and abuse risk analysis of any arrangement involving a physician who has a financial relationship with a health care entity is not complete without an examination of applicable state laws as well. Put differently, the fact that an arrangement does not implicate or violate the Stark Law does not necessarily mean that it is consistent with corresponding state physician self-referral laws.

§ 2.02 PRINCIPAL PROHIBITIONS AND ELEMENTS

[A] General Standard

The Stark Law prohibits a “physician” from “referring” a patient “to” an “entity furnishing” designated health services (DHS) that is covered by Medicare if the physician (or an immediate family member) has a “financial relationship” with the entity and no exception applies. Accordingly, the relevant inquiries are as follows:

- Is there a physician participating in the arrangement?
- If so, is he or she making a referral?

¹⁵ 42 U.S.C. § 1396b(s); 63 Fed. Reg. 1659, 1704 (1998).

¹⁶ N.Y. C.L.S. Pub. Health §§ 238-238d (2005); 10 N.Y.C.R.R. §§ 34-1.1–34-1.7 (2006).

¹⁷ N.Y. C.L.S. Pub. Health § 238-a(1)(a).

¹⁸ N.Y. C.L.S. Pub. Health § 238-a(1)(b).

¹⁹ For example, although the Maryland physician self-referral law has an “in-office ancillary services” exception that closely tracks its federal counterpart, the Maryland exception carves out two key imaging modalities (MRI and CT) for all physicians except radiologists. Md. Code Ann., Health Occ. §§ 1-301–1-302 (2006).

- If so, is the referral being made to an entity for the furnishing of DHS?
- If so, is the DHS covered by Medicare?
- If so, do the physician (or an immediate family member) and the entity have a financial relationship with the furnishing entity?
- If so, does a statutory or regulatory exception apply?

[B] Dual Prohibitions

This general standard gives rise to two broad prohibitions: (1) a “referral” prohibition, and (2) a “billing” prohibition.

[1] Referral Prohibition

Under the referral prohibition of the Stark Law, in the absence of an exception, a physician who has a financial relationship with an entity cannot make a referral to that entity for the provision of DHS.²⁰ For example, a physician who has a medical directorship arrangement with a hospital that does not meet an exception (e.g., because the hospital pays the physician an amount that exceeds fair market value) cannot, under the Stark Law, refer Medicare patients to the hospital for the provision of inpatient or outpatient hospital services (both of which are DHS).

[2] Billing Prohibition

Under the billing prohibition of the Stark Law, an entity cannot bill *anyone* for improperly referred services.²¹ In other words, an entity that furnishes DHS pursuant to a prohibited referral cannot “present” a claim or bill, or “cause” a claim or bill to be presented for such services to the Medicare program or any other payer.²² Using the example set forth above, the hospital cannot bill Medicare, any other payors, or the patients themselves, for any services provided to patients covered by Medicare (either primarily or secondarily) pursuant to the medical director’s referrals.

[C] Principal Elements

[1] Physician (and Immediate Family Members)

Under the Stark Law, a “physician” is defined as a doctor of (1) medicine, (2) osteopathy, (3) dental surgery, (4) dental medicine, (5) podiatric medicine, or (6) optometry.²³ Chiropractors also fall within the definition of a physician.²⁴

It also is worth noting that the Stark Law’s prohibitions apply to the unaccepted financial relationships of a physician and his or her “immediate family members” (such as a spouse or parent).²⁵ As a practical matter, this means that if a

²⁰ 42 U.S.C. § 1395nn(a)(1)(A).

²¹ 42 U.S.C. § 1395nn(a)(1)(B).

²² *Id.*

²³ 42 C.F.R. § 411.351.

²⁴ *Id.*

²⁵ An “immediate family member” also includes a child or sibling; stepparent, stepchild, stepsibling; father- and mother-in-law, son- and daughter-in-law, brother- or sister-in-law; grandparent or grandchild; and the spouse of a grandparent or grandchild. 42 C.F.R. § 411.351.

physician's spouse has a financial relationship with an entity, the physician cannot refer Medicare patients to the entity for the furnishing of DHS unless an exception applies.

[2] Referral

The definition of the term "referral" is extremely broad for purposes of the Stark Law. Indeed, a physician is deemed to make a "referral" under the Stark Law any time he or she (1) requests an item or service that is payable by Medicare Part B, or (2) requests or establishes a plan of care that includes DHS.²⁶ A referral includes a request for a consultation by another physician, and may be in any form, including, written, oral, or electronic.²⁷

There are, however, two important exceptions to the definition of referral. First, there is a somewhat narrow exception for a request by certain specialists for certain specified services pursuant to a consultation.²⁸ Second, there is an exception for services "personally performed" by the referring physician.²⁹ These two exceptions are discussed below.

[a] Consultation Exception

The term "referral" does not include requests by three types of specialists—pathologists, radiologists, and radiation oncologists—for certain specified services. Specifically, a referral does not include a request by (1) a pathologist for clinical diagnostic laboratory tests or pathological examination services, (2) a radiologist for diagnostic radiology services, or (3) a radiation oncologist for radiation therapy services, provided two conditions are satisfied:

- The request is the result of a consultation initiated by another physician; and
- The tests or services are furnished by, or under the supervision of, the pathologist, radiologist, or radiation oncologist or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same physician group practice as the pathologist, radiologist, or radiation oncologist.³⁰

[b] Personally Performed Exception

The second exception is both broader and more commonplace and provides that a "referral" does not include any referrals for DHS "personally performed or provided by the referring physician."³¹ As this standard implies, the DHS at issue must actually be performed by the referring physician, and only the referring physician. A service is not considered "personally performed" if it is performed by any other person, including, for example, the physician's

²⁶ 42 U.S.C. §§ 1395nn(h)(5)(A), (B).

²⁷ 42 C.F.R. § 411.351.

²⁸ 42 U.S.C. § 1395nn(h)(5)(C); 42 C.F.R. § 411.351.

²⁹ 42 C.F.R. § 411.351.

³⁰ *Id.* Note that this exception does not extend to a request by a radiologist for interventional (as opposed to diagnostic) radiology.

³¹ 42 C.F.R. § 411.351.

employees, independent contractors, or members of the physician's group practice.³² Therefore, services performed "incident to" the physician's services do not qualify for this exception to the definition of "referral."³³

It also is critical to note that the exception for personally performed services covers only the physician's professional services, not any associated technical component of such services. For example, when a physician personally performs DHS at a hospital, the physician's claim for the professional component of the DHS will not constitute a "referral" under the Stark Law. However, the resulting claim by the hospital for the technical component of the DHS at issue (i.e., the facility fee) may reflect a referral.³⁴

[3] To

When a physician has made a referral (that does not fit within the two exceptions described above), and the physician directs the patient to a specific entity, it is clear that the physician has made a referral "to" a particular entity. Absent such specific direction by the physician, however, it may be more difficult to determine whether a physician has made a referral "to" a particular entity. That said, practical matter, CMS appears to take the (conclusory) position that all referrals are deemed to be made "to" the entity from which the patient ultimately receives services. Indeed, CMS has stated that it will presume that a physician has made a referral to an entity where the physician has referred a Medicare patient for DHS and, thereafter, the patient receives such DHS from an entity with which the physician has a financial relationship.³⁵ This presumption is rebukable, although this may be hard to do as a practical matter.

[4] Furnishing Entity

Under the Stark Law, an "entity" is defined broadly to cover any type of corporate structure, organization, or person, including:

- A physician's sole practice;
- A practice of multiple physicians;
- A sole proprietorship;
- A public or private agency or trust;
- A corporation;
- A partnership;
- A limited liability company;
- A foundation;
- A not-for-profit corporation;
- An unincorporated association; and
- Any other person.

³² *Id.*

³³ *Id.*

³⁴ 66 Fed. Reg. 856, 871 (2001).

³⁵ 63 Fed. Reg. 1659, 1711 (1998).

Under the Stark Regulations, the “furnishing” entity is the one which receives payments from CMS.³⁶ For example, if a hospital furnishes inpatient hospital services (which constitute DHS), bills Medicare for such services, and receives payment from Medicare for such services, the hospital will be considered to be “furnishing” DHS under the Stark Law. By contrast, if a physical therapy company provides physical therapy to a patient of a skilled nursing facility (SNF) on a contract basis, and pursuant to consolidated billing rules, the skilled nursing facility bills Medicare and receives payment from CMS for the physical therapy, the SNF will be considered to be the entity “furnishing” DHS for purposes of the Stark Law.

[5] Designated Health Services

There are 11 categories of Designated Health Services (DHS). The first five categories—(1) clinical laboratory services, (2) physical therapy services (3) occupational therapy services, (4) radiology and other imaging services and (5) radiation therapy services and supplies—are defined by reference to current procedural terminology (CPT) codes and health care common procedure coding system (HCPCS) codes. The DHS codes are available on CMS’s website.

The six remaining categories of DHS—(6) durable medical equipment and supplies (DME), (7) parenteral and enteral nutrients, equipment and supplies, (8) prosthetics, orthotics, and prosthetic devices and supplies, (9) home health services, (10) outpatient prescription drugs, and (11) inpatient and outpatient hospital services—are defined narratively, without reference to particular CPT or HCPCS codes.

Table 2-1 lists the 11 categories of DHS, along with a few examples.

Table 2-1

Designated Health Services		
No.	DHS	Examples
1	Clinical Laboratory Services	<ul style="list-style-type: none"> • CPT Code 80051–Electrolyte panel • CPT Code 80061–Lipid Panel
2	Physical Therapy Services	<ul style="list-style-type: none"> • CPT Code 97001–Physical therapy evaluation • CPT Code 97002–Physical therapy reevaluation
3	Radiology Services	<ul style="list-style-type: none"> • CPT Code 70250–Radiological examination, skull, less than four views • CPT Code 70360–Radiological examination, neck, soft tissue

³⁶ 42 C.F.R. § 411.351.

Table 2-1

Designated Health Services		
No.	DHS	Examples
4	Occupational Therapy	<ul style="list-style-type: none"> • CPT Code 97003–Occupational therapy evaluation • CPT Code 97004–Occupational therapy reevaluation
5	Radiation Therapy Services and Supplies	<ul style="list-style-type: none"> • CPT Code 77261–Therapeutic radiology treatment planning, simple • CPT Code 77280–Therapeutic radiology simulation-aided field setting, simple
6	Durable Medical Equipment and Supplies	<ul style="list-style-type: none"> • Iron lungs • Hospital beds • Wheelchairs • Glucose monitors, lancelets, and strips
7	Prosthetics, Orthotics and Prosthetic Devices and Supplies	<ul style="list-style-type: none"> • Artificial legs and leg braces • Colostomy bags
8	Parenteral and Enteral Nutrients Equipment, and Supplies	<ul style="list-style-type: none"> • Nutrients provided through a catheter • Nutrients provided through nasogastric, jejunostomy or gastronomy tubes
9	Home Health Services	<ul style="list-style-type: none"> • Part-time or intermittent nursing care, medical, and social services
10	Outpatient Prescription Drugs	<ul style="list-style-type: none"> • Prescription medication covered by Part B (and soon Part D)
11	Inpatient and Outpatient Hospital Services	<ul style="list-style-type: none"> • Inpatient–bed and board, nursing services, drugs, and biologicals • Outpatient–hospital services incident to physician services, and diagnostic services*

* Lithotripsy is not considered to be an outpatient hospital service. 42 C.F.R. § 411.351.

[6] Financial Relationships

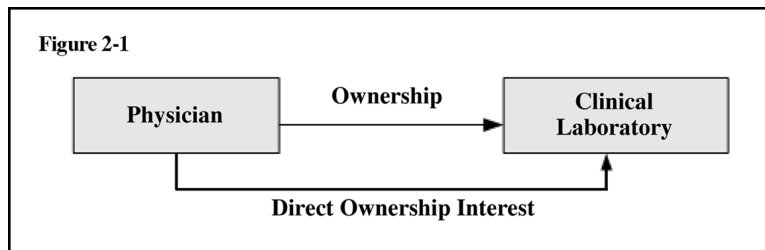
The Stark Law ultimately is predicated on the physician at issue (or an immediate family member) having a financial relationship with the DHS entity at issue. Under the Stark Law, there are two principal types of financial relationships: ownership interests and compensation arrangements. Each of these financial relationships, in turn, may take one of two forms: direct or indirect.

[a] Ownership Interests

This type of financial relationship arises when a physician has an ownership or investment interest (collectively, “ownership interest”) in a DHS entity.³⁷ An ownership interest may be through equity, debt, or other means,³⁸ and may include, among other things, stock, partnership shares, memberships, securitized loans, and/or bonds.³⁹

[i] *Direct ownership interests.*

A direct ownership interest exists when no persons or entities intervene between the physician and the DHS entity that he or she owns.⁴⁰ For example, where a physician owns stock in a company that operates a clinical laboratory, the physician will be considered to have a direct ownership interest in—and financial relationship with—the laboratory. See **Figure 2-1**.



[ii] *Indirect ownership interests.*

A physician has an indirect ownership interest in an entity if (1) there is an unbroken chain of one or more ownership interests between the physician and the DHS entity, and (2) the DHS entity either has “actual knowledge of” or acts in “reckless disregard or deliberate ignorance of” the fact that the referring physician has an ownership interest through any number of intermediary ownership interests in the DHS entity.⁴¹ For example, where a physician is an owner of a physician practice group, and the group owns an interest in a clinical laboratory company, an indirect ownership interest may be created between the physician and the clinical laboratory company. Indeed, an indirect ownership interest will be created if the laboratory meets the knowledge requirement set forth above. See **Figure 2-2**.

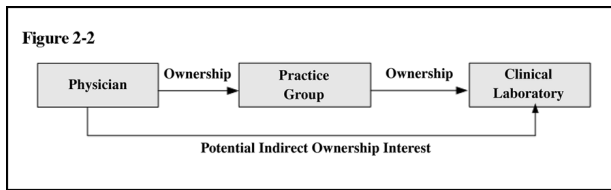
³⁷ 42 U.S.C. § 1395nn(a)(2).

³⁸ *Id.*

³⁹ 42 C.F.R. § 411.354(b)(1).

⁴⁰ 42 C.F.R. § 411.354(a)(1)(i), (a)(2), (b).

⁴¹ 42 C.F.R. § 411.354(b)(5)(i).

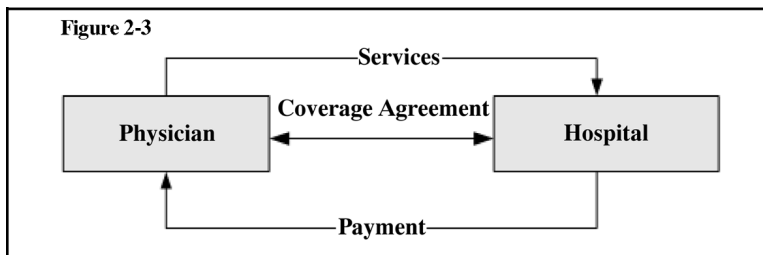


[b] Compensation Arrangements

A compensation arrangement includes any arrangement (other than an ownership interest) that involves the exchange of remuneration between a physician and a DHS entity.⁴² Remuneration includes anything of value, including both cash and in-kind items or services.⁴³ Like ownership interests, compensation arrangements may be either direct or indirect.

[i] Direct compensation arrangements.

A physician has a direct compensation arrangement with an entity (e.g., a hospital) when remuneration passes directly (i.e., without any intervening persons or entities) from the physician to the entity and vice versa. For example, where a physician has a paid contractual agreement to provide on-call coverage to a hospital, the physician will have a direct compensation arrangement with the hospital by virtue of the payments made by the hospital to the physician for such services. See **Figure 2-3**.



[ii] Indirect compensation arrangements.

An indirect compensation arrangement exists between a physician and DHS entity if three conditions are met. As explained in greater detail below, the three conditions require (1) an unbroken chain of more than one financial relationship between the physician and the DHS entity, (2) that the physician’s aggregate compensation varies in a prohibited manner, and (3) that the DHS entity has knowledge of the fact that the physician’s aggregate compensation varies in a prohibited manner.⁴⁴

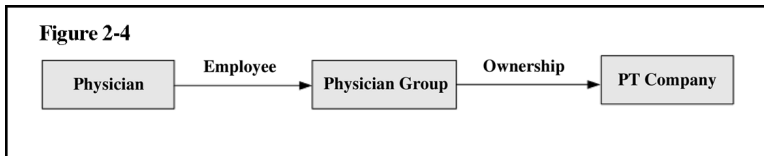
Unbroken chain. First, there must be an “unbroken chain” of two or more financial relationships between the referring physician and the entity furnishing DHS, at least

⁴² 42 U.S.C. § 1395nn(h)(1)(A), (C).

⁴⁴ 42 C.F.R. § 411.354(c)(2).

⁴³ 42 U.S.C. § 1395nn(h)(i)(B).

one of which is a compensation arrangement. It is important to note that, for purposes of determining whether an indirect compensation arrangement exists, it does not matter whether any direct financial relationship in the chain is protected by an exception. For example, if a physician is an employee of a physician group that, in turn, owns a physical therapy company (PT Company), and the employment arrangement (between the physician and the group) meets the Stark Law exception for *bona fide* employment relationships, there nevertheless exists an unbroken chain of financial relationships between the physician and the PT company.⁴⁵ See **Figure 2-4**.



Aggregate compensation. Second, the definition of an indirect compensation arrangement requires that the referring physician’s “aggregate compensation” varies with, or otherwise reflects the volume or value of referrals or other business generated by the referring physician for the DHS entity.⁴⁶ One of the more complicated aspects of this prong of the definition of indirect compensation arrangements centers around the phrase “aggregate compensation.” In 2001 CMS promulgated certain “special rules on compensation” that provided unit-based compensation methodologies did not trigger the volume or value standard if certain conditions were met.⁴⁷ However, in 2004 CMS clarified that these special rules do not apply to “aggregate compensation” determinations under the definition of indirect compensation arrangements. In other words, parties to an arrangement involving time-based or unit of service-based payments cannot cite the special rules on compensation and claim that aggregate compensation does not trigger the volume or value standard. Indeed, CMS takes the position that when considered in the aggregate, unit-based compensation arrangements *always* trigger the volume or value standard.⁴⁸ (Although CMS has stated its position on this issue very clearly, it may be somewhat of an overstatement, as noted in the example below.)

Determining whether a physician’s aggregate compensation triggers the “volume or value” standard depends on whether the closest financial relationship to the referring physician in the unbroken chain of financial relationships is a compensation or an ownership relationship. In the case of the former, it is that link—the compensation arrangement—that must be analyzed to determine whether the physician’s aggregate compensation triggers the volume or value standard. In the latter case, the analysis focuses on the direct compensation arrangement link in the chain that is closest to the physician.⁴⁹

⁴⁵ 69 Fed. Reg. 16,054, 16,059–16,060.

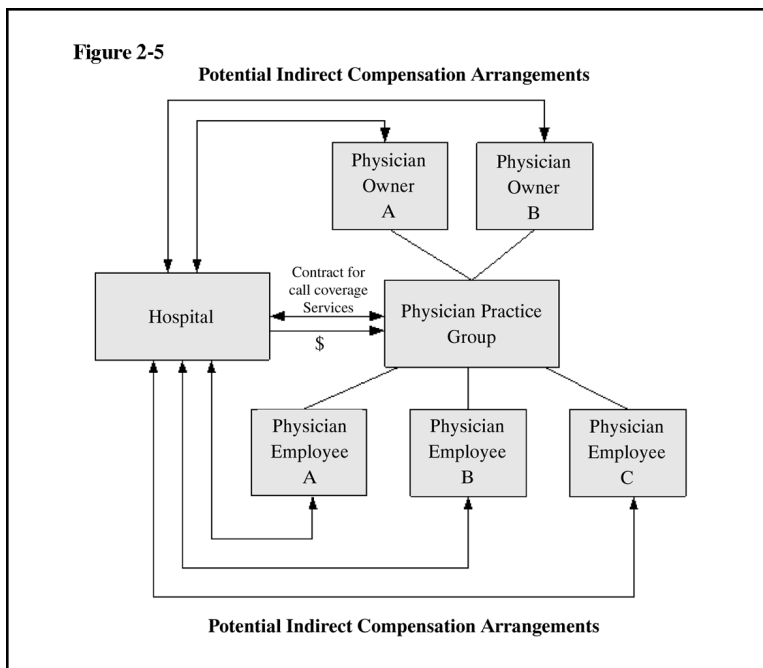
⁴⁶ 42 C.F.R. § 411.354(c)(2)(ii).

⁴⁷ 42 C.F.R. § 411.354(d)(2).

⁴⁸ 69 Fed. Reg. 16,054, 16,058–16,059 (2004).

⁴⁹ 42 C.F.R. § 411.354(c)(2)(ii).

For example, assume a hospital (Hospital) has a call coverage agreement with a physician group practice (Group) to staff its Emergency Department (ED) and the Group has two owners, Drs. A and B, and three employees, also Drs. A and B plus Dr. C (a non-owner). This arrangement potentially gives rise to two separate indirect compensation arrangements among the physicians of the Group and the Hospital. With respect to Drs. A, B, and C, as employees, the doctors have a direct compensation arrangement with the Group (via employment), and the Group has a direct compensation with the Hospital (via the ED staffing agreement) as follows: physician, Group, then Hospital. Under these circumstances, the analysis will focus on whether Drs. A, B, and C's aggregate compensation from the Group (the compensation link closest to the referring physicians) varies with or reflects their referrals to the Hospital. With respect to Drs. A and B, as owners of the Group, the doctors have a direct ownership interest in the Group, and the Group has a direct compensation arrangement with the Hospital. Because the closest compensation arrangement to Drs. A and B in this unbroken chain is the ED staffing agreement between the Group and the Hospital, the analysis focuses on whether the aggregate compensation the Group receives from the Hospital varies with or otherwise reflects the volume or value of referrals or other business generated by Drs. A or B for the Hospital. See **Figure 2-5**.



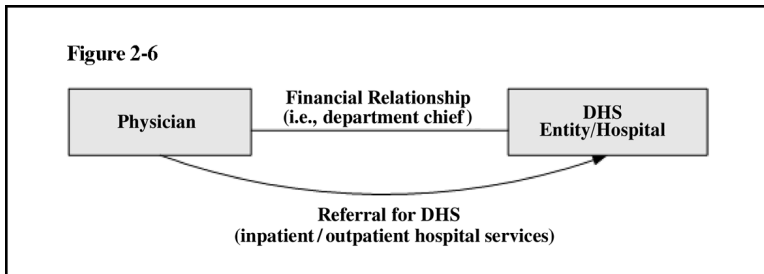
Assume that, pursuant to an agreement, the Hospital agrees to pay the Group \$1000 per month for one year, and for the Group to paint the hospital's ED each month. Drs. A and B (owners) furnish the services to the hospital. Since the

physicians have a direct ownership interest in the chain as financial relationships, the analysis would focus on whether the aggregate compensation paid by the hospital to the Group varies with the volume or value of referrals or other business generated by Drs. A and B for the hospital. CMS likely would take the position—as explained above—that this unit-based payment methodology triggers the volume or value standard. As also set forth above, however, CMS’s position seems incorrect given that the Group will be paid \$1000 per month regardless of whether the physicians make ten, five or no referrals to the hospital.

Knowledge. The third and final component of the definition of an indirect compensation arrangement is that the entity furnishing DHS must have actual knowledge (or act in reckless disregard or deliberate ignorance) of the fact that the referring physician’s aggregate compensation varies as set forth in the second requirement described above.⁵⁰ Given that this last requirement is subjective and all three conditions must be met, it is difficult to conclude with absolute certainty that an arrangement does not give rise to an indirect compensation arrangement. As such, a comprehensive analysis of an indirect compensation arrangement often includes an analysis of the indirect compensation exception as well. (the indirect compensation arrangements exception is discussed in § 2.03[E]).

[D] Summary of Stark Law Elements and Prohibitions

As explained above, the Stark Law prohibits physician referrals of Medicare patients for the provision of DHS to entities with which they have a financial relationship, unless an exception applies. Thus, for example, where a hospital and a physician have a contract for the physician to serve as the chief of the hospital’s department of orthopaedics, the hospital and the physician will have a direct compensation arrangement. The physician cannot refer Medicare patients to the hospital for inpatient or outpatient hospital services (which are DHS), and the hospital cannot bill anyone for such services, unless an exception applies. If no exception applies, the Stark Law will be violated by each referral to the hospital for DHS, and the hospital will be prohibited from billing for any services furnished pursuant to such prohibited referrals. As discussed in § 2.03, however, the Stark Law includes a number of exceptions, including an exception for personal service arrangements provided certain requirements are met. See **Figure 2-6**. See also **Appendix 2-1** for a checklist of the Stark Law elements.



⁵⁰ 42 C.F.R. § 411.354(c)(2).

§ 2.03 EXCEPTIONS

The Stark Law recognizes four categories of exceptions: (1) “all-purpose” exceptions, which apply to any type of financial arrangement; (2) ownership and investment exceptions, which apply to direct or indirect ownership or investment interests; (3) direct compensation exceptions, which protect direct compensation arrangements; and (4) indirect compensation arrangement exceptions, which protect indirect compensation arrangements. A chart detailing each exception and its statutory and regulatory citation, is set forth in **Appendix 2-2**.

Before turning to a discussion of these exceptions within each category, several key terms are defined below.

[A] Key Definitions

[1] Fair Market Value

Satisfaction of numerous exceptions to the Stark Law is predicated upon the existence of a fair market value (FMV) exchange. The basic premise of this concept is that if the compensation flowing to (or from) a referring physician constitutes FMV goods or services, there is an equal exchange of value and, as such, no additional or “excess” remuneration to induce the physician to make improper referrals of Medicare patients. The Stark Law defines FMV as the “value in arm’s-length transactions, consistent with the ‘general market value.’”⁵¹ This definition, at its core, requires that the amount of compensation paid be commercially reasonable and the result of *bona fide* bargaining between the parties. There are additional requirements for the valuation of assets, rental or lease payments, and service arrangements that are discussed below.

[a] Assets

For assets, “general market value” is defined as “the price that an asset would bring as a result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business” for one another.⁵² The definition further provides that “[u]sually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality and quantity in a particular market.”⁵³

[b] Leases

With respect to leases, FMV is the value of the rental property for general commercial purposes, not taking into account its intended use.⁵⁴ In the case of a lease for space, the FMV cannot be adjusted to reflect the additional value the prospective lessee or lessor may attribute to the proximity or convenience to the lessor when

⁵¹ 42 C.F.R. § 411.351.

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

the lessor is a potential source of patient referrals to the lessee.⁵⁵ Notably, a payment is not viewed to take into account the intended use of the space if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.⁵⁶

[c] Services

For services, “general market value” is defined as the compensation that would be included in a service agreement as a result of *bona fide* bargaining between well-informed parties who are not in a position to generate business for each other. Like assets, the FMV price for services is usually equal to the compensation included in *bona fide* services agreements with comparable terms and where the “compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.”⁵⁷

In 2004, CMS provided additional guidance for assessing the FMV of hourly payments for physician services by effectively creating two “safe harbors.” The first provides that hourly compensation will be deemed to be FMV if the hourly rate is less than or equal to the average hourly rate of emergency room physicians in the relevant physician market (based upon at least three hospitals providing emergency services in the service area).⁵⁸ The second provides that hourly compensation will be deemed to be FMV if the rate is determined by averaging the 50th percentile national compensation for physicians of the same specialty in at least four of six designated compensation surveys and dividing by 2,000 hours.⁵⁹ If the compensation falls outside of the ranges resulting from two safe harbor formulas, it does not mean that the compensation exceeds FMV; rather, the payment amount will be assessed under the facts and circumstances of the arrangement.

[2] Set In Advance

A number of Stark Law exceptions also require that compensation be “set in advance.” CMS has addressed this standard in a “special rule on compensation,” which provides that compensation will be considered “set in advance” if the “aggregate compensation, a time-based or per unit of the service based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid”.⁶⁰ Thus, “per click fee” arrangements (e.g., \$50 per unit) will be considered set in advance if the payment methodology is set in advance, notwithstanding that the aggregate compensation itself cannot be determined in advance.

⁵⁵ *Id.*

⁵⁶ 42 C.F.R. § 411.351.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ The six surveys are (1) Sullivan, Cotter & Associates; (2) Hay Group; (3) Hospital and

Healthcare Compensation Services; (4) MGMA; (5) ECS Watson Wyatt; and (6) Mercer-Integrated Health Networks. *See* 42 C.F.R. § 411.351.

⁶⁰ 42 C.F.R. § 411.354(d)(1).

[3] Volume or Value of Referrals

Many Stark Law exceptions also require that the compensation at issue not vary with, reflect or otherwise take into account the “volume or value of referrals” between the parties. Such referrals include, in particular, DHS referrals related to Medicare beneficiaries. However, non-DHS referrals, and referrals that are “required” from employed physicians to a DHS entity, generally do not implicate the “volume or value” prohibition, subject to certain restrictions.⁶¹ Additionally, as noted in the discussion regarding the definition of “referral” in § 2.02[C][2], a DHS that is personally performed by the referring physician is not considered to be a referral, so payment that varies for personally performed physician services will not run afoul of the “volume or value of referrals” standard.

Finally, pursuant to CMS’s “special rules on compensation,” certain unit-based compensation (e.g., per-use, per-procedure or percentage-based formulas) will not be deemed to trigger the “volume or value of referrals” standard if the compensation is set in advance and is consistent with fair market value—provided the per unit compensation does not vary during the course of the compensation arrangement in any manner that takes into account DHS referrals.⁶² In the rare instance when a unit-based payment methodology decreases as the volume increases (i.e., volume discounts), CMS has stated it will review such payment methodologies on a case-by-case basis.⁶³ In addition, as previously explained, CMS has made it clear that the special rules on compensation have no application with respect to aggregate compensation.

Compliance Tip: CMS’ formal review process—via advisory opinions—is not likely to yield a quick response to requests for clarification on the issue of volume discounts. As such, volume discount and click fee arrangements should be carefully analyzed prior to their adoption.

[4] Other Business Generated

Many Stark Law exceptions contain a prohibition on compensation varying with or, more commonly, “taking into account” the volume or value of “other business generated” between the parties. CMS has stated that:

Congress intended the [other business generated standard] to be a limitation on the compensation or payment formula parallel to the statutory and regulatory prohibition on taking into account referrals of DHS business. Simply stated, in the provision in which the phrase appears, affected payments cannot be based or adjusted in any way on

⁶¹ 42 C.F.R. § 411.354(d)(4).

⁶² 42 C.F.R. § 411.354(d)(2).

⁶³ 69 Fed. Reg. 16,054, 16,069 (2004).

referrals of DHS or any other business referred by the physician, including other federal and private pay business.⁶⁴

Thus, it is clear that the “other business generated” standard includes all other (i.e., non-DHS) referrals, regardless of the payor source. However, certain time-based or unit-based compensation will be deemed under the Stark Regulations to *not* implicate the “other business generated” standard so long as the compensation is FMV for items and services actually provided and does not vary during the course of the arrangement in a manner that takes into account referrals or other business generated by the referring physician, including private pay business (except for services personally performed by the referring physician).⁶⁵ Although circular, this special rule on compensation essentially follows the other special rule regarding the volume or value of referrals as applied to unit-based or time-based compensation arrangements (discussed in § 2.03[A][3] above).

[5] Group Practice

The Stark Law’s definition of a physician “group practice” is an integral component of two all-purpose exceptions: (1) in-office ancillary services; and (2) physicians’ services. Pursuant to the Stark Statute, a group practice is “legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association.”⁶⁶ The Stark Regulations provide a detailed and, in certain respects, more expansive definition of “group practice.”⁶⁷ In particular, the Stark Regulations broaden the definition by including any organizational form recognized by the state in which the practice operates, for instance, a limited liability company. It also includes group practices that provide services across state lines (in contiguous states).⁶⁸

Numerous additional requirements must be met in order for a group of physicians to qualify as a “group practice” under the Stark Law. First, the group practice must consist of a single legal entity formed primarily for the purpose of being a physician group practice, even if owned by a number of other persons or entities.⁶⁹ Second, the group practice must have at least two “members,” defined in the Regulations as (1) a physician with a direct or indirect ownership interest in the practice; (2) a full or part-time physician employee; (3) a *locum tenens* physician; or (4) an on-call physician (while providing on-call services to the group). Importantly, the regulatory definition excludes from the definition of “member” (of a group practice) any independent contractors and leased employee physicians (unless the leased employee meets the IRS common law definition of an employee).⁷⁰ Third, each member of the group must furnish “substantially the full range” of patient care services that he or she “routinely” furnishes through the joint use of shared office space, facilities, equipment and personnel. Fourth,

⁶⁴ 66 Fed. Reg. 856, 877 (2001).

⁶⁵ 42 C.F.R. § 411.354(d)(3).

⁶⁶ 42 U.S.C. § 1395nn(h)(4)(A).

⁶⁷ 42 C.F.R. § 411.352.

⁶⁸ 42 C.F.R. § 411.352(a).

⁶⁹ *Id.*

⁷⁰ 42 C.F.R. § 411.351.

subject to certain specific exceptions, the group physicians must provide “substantially all” of the patient care services (at least 75 percent of the total patient care services), and those services must be billed under a group billing number assigned to the group.⁷¹ (CMS sets out various ways to calculate and meet the “substantially all” patient care services test and provides some leeway during the “start-up” phase of a group practice and for newly recruited physicians.). Fifth, members of the practice must personally conduct no less than 75 percent of the physician-patient encounters of the practice. Sixth, there must be “unified” management of the group. Seventh, there must be a method for distributing expenses and income among members.⁷²

Other conditions related to “group practices” prohibit the compensation of a member directly or indirectly based on the volume or value of DHS referrals, except in the case of certain productivity bonuses, which may include a distribution of overall profits of the group and “incident to” service revenues.⁷³ However, in a classic exception to the exception, the Stark Regulations prohibit productivity bonuses paid to a group practice member that are *directly* related to the volume or value of DHS referrals of that particular physician (again, with further exceptions for commercial pay referrals and when compensation for DHS referrals is less than 5 percent of compensation from the group per physician). Finally, the Stark Regulations further specify that the “productivity bonus should be calculated in a reasonable and verifiable manner.”⁷⁴

[B] All-Purpose Exceptions

The Stark Statute and Regulations include a series of exceptions that apply to all types of financial relationships—whether ownership or compensation, is direct or indirect. The three most commonly utilized, and, arguably, most important, exceptions include those for (1) in-office ancillary services, (2) physician services, and (3) academic medical centers. Each of these all-purpose exceptions is discussed below. There are also six other all-purpose exceptions that are much more limited in scope. These also are summarized below.

[1] In-Office Ancillary Services Exception

The in-office ancillary services exception is designed to permit physicians to provide certain services (e.g., lab tests, X-rays, physical therapy, and other DHS) that are ancillary to the physician’s care, provided a number of conditions are met.⁷⁵ While simple in concept, CMS has placed a number of restrictions on the use of this exception. Four detailed requirements must be satisfied, relating to (1) the types of DHS being furnished, (2) who furnishes or supervises the furnishing of the DHS, (3) where the DHS is furnished, and (4) how the DHS must be billed. These restrictions have made the in-office ancillary services exception among the more complex Stark Law exceptions. However, given the broad array of physician self-referral arrangements that fall within the ambit of this exception

⁷¹ 42 C.F.R. § 411.352(c)–(d).

⁷² 42 C.F.R. § 411.352(e)–(f), (h).

⁷³ 42 C.F.R. § 411.352(i).

⁷⁴ 42 C.F.R. § 411.352(i)(3).

⁷⁵ 42 U.S.C. § 1395nn(b)(2); 42 C.F.R. § 411.355(b).

and, despite its complexity, this exception is among the most important and heavily utilized.

[a] Type of Designated Health Services

The in-office ancillary exception covers all Designated Health Services (DHS) except: (1) a broad range of durable medical equipment (with the exception of those commonly found in physicians' offices, such as canes, crutches, walkers, manual wheelchairs, and certain blood glucose monitors), and (2) parenteral and enteral nutrients, equipment, and supplies.⁷⁶ (Inpatient and outpatient hospital services and home health services are also applicable.) Thus, for example, continuous passive movement devices are not eligible for the exception, but crutches, prosthetics and orthotics are.

[b] Furnishing and Supervision

The next requirement of the in-office ancillary services exception is that the DHS must be furnished 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 who are supervised by the physician or another physician in the group practice. With respect to the latter category, CMS has explained that the requisite level of supervision is that required by Medicare billing and coverage rules.⁷⁷ Except for services performed personally by the referring physician, satisfaction of this requirement turns largely on the definition of a "group practice," discussed above.

[c] Location

The third requirement of the in-office ancillary services exception requires that the ancillary services at issue be furnished either (1) in the "same building" in which the group practice furnishes its services, or (2) in a "centralized building" used by the group for the provision of some or all of its DHS.⁷⁸ The "same building" means a single structure or several structures with a single street address, but excludes exterior spaces, such as loading docks or garages. (Thus, mobile vans or trailers do not qualify for the same building test.)⁷⁹ A "centralized building" means all or part of a building and may include a mobile van or trailer owned or leased on a full-time basis for not less than six months by a group practice and used exclusively by that group. Using either method, numerous additional qualifications apply. As such, this aspect of the in-office ancillary services exception is often the most difficult to apply and satisfy.⁸⁰

⁷⁶ 42 C.F.R. § 411.355(b)(4).

⁷⁷ 42 C.F.R. § 411.355(b)(1)(iii).

⁷⁸ 42 C.F.R. § 411.355(b)(2); CMS proposed to modify the definition of centralized building in its proposed rule dated August 24, 2006 (proposed 2007 Medicare Physician Fee Schedule). This proposed change would limit "condo" or "pod" pathology lab

arrangements as well as other shared service arrangements.

⁷⁹ 42 C.F.R. § 411.351.

⁸⁰ For example, group practices purchasing diagnostic services (such as CT tests) must still satisfy this standard if they bill globally for both the technical and professional components of such tests.

[d] Billing

The final requirement of the in-office ancillary services exception relates to who may bill for the ancillary services at issue. In a nutshell, and subject to certain qualifications, the DHS services must be billed by (1) the referring or supervising physician, (2) the group practice, or (3) a third-party billing company on behalf of the physician or group.

Compliance Tip: If a physician group practice provides and bills for any DHS in a location outside of its office suite on a full- or part-time basis, it is important to conduct a complete assessment of the “same building” or “centralized building” standards under the in-office ancillary exception.

[2] Physicians Services

The next important all-purpose exception permits a physician within a “group practice” (as described above) to make referrals to other physicians in the group practice for physician services.⁸¹ (Note, as discussed in the previous section, certain services personally performed by the referring physician do not constitute “referrals” under the Stark Law.)

Under the physicians’ services exception, DHS (in the form of physician services) may be performed by or under the supervision⁸² of another physician in the referring physician’s group practice.⁸³ Physician services include professional services performed by physicians, including surgery, consultations, and home, office and institutional visits. The exception only covers “incident to” services where such services constitute “physician services.” All other incident to services are not covered by the exception.⁸⁴

[3] Academic Medical Centers

The Stark Regulations include an all-purpose exception for DHS services furnished by an academic medical center (AMC) pursuant to referrals made by *bona fide* physician-employees of the AMC or any of its component parts.⁸⁵ The AMC exception defines an academic medical center fairly broadly to include an accredited medical school, one or more affiliated faculty practice plans, and one or more hospital components (with a medical staff composed of a majority of physicians who are faculty members and who, in turn, account for a majority of the hospital’s admissions).⁸⁶ In addition, the AMC must be *bona fide* insofar as it must

⁸¹ 42 U.S.C. § 1395nn(b)(l); 42 C.F.R. § 411.351(a).

⁸² Like the in-office ancillary services exception, discussed above, the level of supervision required to satisfy this exception is the same level of supervision required under Medicare billing and coverage provisions.

⁸³ 42 U.S.C. § 1395nn(b)(1); 42 C.F.R. § 411.355(a).

⁸⁴ 42 C.F.R. § 410.20(a).

⁸⁵ 42 C.F.R. § 411.355(e).

⁸⁶ 42 C.F.R. § 411.355(e)(2).

(1) serve the AMC mission, (2) have an approved (at Board of Trustees/Directors level) written agreement among AMC components, and (3) ensure that payments to physicians for research relate to *bona fide* research.⁸⁷

The AMC exception requires, among other things, that the referring physician (1) has a *bona fide* faculty appointment at the affiliated medical school or at one or more of the AMC's educational programs (in other words, the referrals of a community-based physician on the medical staff would not be covered); (2) provides either "substantial" academic teaching and/or clinical services (defined as 20 percent of professional time or eight hours each week); and (3) is paid compensation that in the aggregate is set in advance, does not exceed FMV, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician.⁸⁸

Compliance Tip: Teaching hospitals and other AMC components should first assess whether they meet the definition of an AMC under the Stark Law through the use of a detailed questionnaire. They should maintain the documentation showing that it meets the definition.

[4] Other All-Purpose Exceptions

The Stark Regulations include other, more limited all-purpose exceptions, including those for:

- Services furnished to enrollees of certain managed care organizations, HMOs, and prepaid health plans;⁸⁹
- Implants furnished by ambulatory surgical centers;⁹⁰
- Dialysis-related drugs furnished in dialysis centers;⁹¹
- Preventive screening tests, immunizations, and vaccines;⁹²
- Eyeglasses and contact lenses following cataract surgery; and⁹³
- In rural areas, certain intra-family referrals (from a referring physician to his or her immediate family members) or a referral to an entity furnishing DHS with which an immediate family member has a financial relationship.⁹⁴

⁸⁷ 42 C.F.R. § 411.355(e)(1)(iii).

⁸⁸ 42 C.F.R. § 411.355(e)(1).

⁸⁹ 42 U.S.C. § 1395nn(b)(3); 42 C.F.R. § 411.355(c).

⁹⁰ 42 C.F.R. § 411.355(f)

⁹¹ 42 C.F.R. § 411.355(g).

⁹² 42 C.F.R. § 411.355(h).

⁹³ 42 C.F.R. § 411.355(i).

⁹⁴ 42 C.F.R. § 411.355(j). Certain additional restrictions apply to the intra-family referral exception, including that no other physician or entity was available to furnish the services in a timely manner, and the financial relationship does not violate the Anti-Kickback Law, other state or federal law or regulation governing billing or claims submission.

[C] Ownership and Investment Exceptions**[1] Publicly Traded Securities and Mutual Funds**

The Stark Law includes two related exceptions covering investments. The first exception protects a referring physician's investment in securities (e.g., shares) in a publicly traded company that has stockholder equity exceeding \$75 million.⁹⁵ The second exception protects a referring physician's ownership of shares in mutual funds.⁹⁶

[2] Ownership in a Rural Provider

Physician ownership in certain rural health care entities is protected by a Stark Law exception for "rural providers." A rural provider is defined as an entity that furnishes at least 75 percent of DHS to residents of a rural area and that is not a specialty hospital (as of December 8, 2003). In general, rural areas are not Metropolitan Statistical Areas, as determined by the Office of Management and Budget.⁹⁷

[3] Ownership in a Hospital in Puerto Rico

Physician ownership in a hospital located in Puerto Rico also is protected by a Stark Law exception designed specifically for this purpose.⁹⁸

[4] Ownership in Whole Hospital

Physician investment in hospitals, which historically has been commonplace in the health care industry, may be protected under the Stark Law exception for a referring physician's investment in an entire or "whole" hospital.⁹⁹ This exception does not, however, protect an investment in a distinct part or subdivision of a hospital.

With interest in investing in high-profit hospital service lines and the advent of "specialty hospitals" (e.g., so-called "heart hospitals"), this exception ignited a significant policy debate regarding physician ownership in specialty hospitals. This debate caused Congress to implement an 18-month moratorium (effective December 8, 2003) on the ability of physician owners of specialty hospitals to avail themselves of the Stark Law exception for "whole" hospitals.¹⁰⁰ When the congressional moratorium expired, CMS effectively extended it by freezing its enrollment of new specialty hospitals.¹⁰¹ As of this writing, and pursuant to the Deficit Reduction Act of 2005, the moratorium on CMS approval (i.e., enrollment) of new

⁹⁵ 42 U.S.C. § 1395nn(c)(1); 42 C.F.R. § 411.356(a).

⁹⁶ 42 U.S.C. § 1395nn(c)(2); 42 C.F.R. § 411.356(b).

⁹⁷ 42 C.F.R. §§ 411.356(c)(1), 42 C.F.R. § 412.62(f)(1)(iii) (for definition of rural area).

⁹⁸ 42 U.S.C. § 1395nn(d)(1); 42 C.F.R. § 411.356(c)(2).

⁹⁹ 42 U.S.C. § 1395nn(d)(3); 42 C.F.R. § 411.356(c)(3).

¹⁰⁰ Medicare Prescription Drug, Improvement and Modernization Act of 2003, section 507.

¹⁰¹ See CMS Web site at <http://www.cms.hhs.gov/PhysicianSelfReferral/06_specialty_hospital_issues.asp#TopOfPage>.

specialty hospitals was lifted following until CMS's release of a final report on specialty hospitals.¹⁰² However, physician investment in existing specialty hospitals remains an option that is protected under the exception. Congress, CMS, General Accountability Office, many physician and hospital associations, and state regulators will continue to closely monitor physician investment in specialty hospitals and, as such, changes to the Stark Law regarding this exception, as well as to state licensing laws pertaining to specialty hospitals, are quite possible.

[D] Direct Compensation Arrangement Exceptions

As discussed above in § 2.02[C][6], the Stark Law recognizes four separate financial relationships, the most common of which are “direct compensation arrangements” (i.e., arrangements that involve a direct and uninterrupted—meaning there are no intervening or intermediate parties—exchange of remuneration between the referring physician and the DHS entity).¹⁰³

A direct compensation arrangement will trigger the Stark Law's referral and billing prohibitions unless one or more of the “all-purpose” or “direct compensation” exceptions apply. There are a total of 22 direct compensation exceptions. For purposes of this chapter, we have organized these exceptions into four broad categories: (1) the exceptions that involve a fair market value exchange (e.g., rent for office space, salary for the services of an employee); (2) the exceptions that, by definition, do not involve a FMV exchange (e.g., a gift or donation of something of value from one party to another); (3) exceptions that involve physician recruitment and retention; and (4) the three remaining exceptions that, for lack of a better classification, fall into the “other” category.

[1] Fair Market Value Exchange

[a] Space and Equipment Rental Exceptions

Given that (1) hospitals (and other DHS entities) frequently enter into leases covering space and equipment with physicians, and (2) that such arrangements typically enhance the delivery of care, both the Stark Statute and Regulations include exceptions for space¹⁰⁴ and equipment¹⁰⁵ rentals. These two exceptions remove rental payments from the ambit of the Stark Law, provided multiple conditions are met. These include, by way of example, that the rental agreement

¹⁰² CMS issued an interim report May 9, 2006 and a final report on August 8, 2006.

¹⁰³ A direct compensation arrangement is created, for example, when a hospital pays a physician for medical directorship services. If, however, the hospital pays a group practice for medical directorship services to be furnished by one or more of the group's

physicians, the arrangement is no longer a direct compensation arrangement because the group constitutes an intervening party in the stream of remuneration.

¹⁰⁴ 42 U.S.C. § 1395nn(e)(1)(A); 42 C.F.R. § 411.357(a).

¹⁰⁵ 42 U.S.C. § 1395nn(e)(1)(B); 42 C.F.R. § 411.357(b).

be set out in a writing that is signed by the parties and specifies the premises or equipment covered; that the space (or equipment) is used exclusively by the lessee when used by the lessee (and, with the exception of common space areas, is not shared with the lessor); and, that the rental charges are set in advance and are consistent with FMV without taking into account the volume or value of referrals or other business generated.

Several aspects of these two rental exceptions are noteworthy. They are as follows:

- In 2004, CMS clarified that the exclusive use requirement (referenced above) does not preclude properly structured subleases.¹⁰⁶
- Although both exceptions require a lease term of at least one year, the parties may terminate their arrangement (with or without cause) at an earlier date, provided that they do not enter into a new lease arrangement during the original first-year term.¹⁰⁷ (It is unclear whether the prohibition on entering into a new rental arrangement forecloses parties to the original rental arrangement from entering into an arrangement involving a different location or piece of equipment. CMS commentary suggests that this is permitted, provided that the new lease satisfies all of the requirements of the applicable rental exceptions.)¹⁰⁸
- Both regulatory exceptions expand upon their statutory counterparts by providing (pragmatically) that holdover tenancies leasing arrangements will not give rise to a prohibited compensation arrangement so long as the holdover (i) immediately follows the expiration of a written lease arrangement that qualified for the rental exception, (ii) is on the same terms as the original lease, and (iii) does not exceed a period of six months.¹⁰⁹
- With respect to the FMV of equipment leases, the exception permits unit-based (e.g., per-use) compensation, provided the unit-based compensation methodology (e.g., \$100 per MRI scan) is set in advance, is FMV, and does not trigger the volume or value standards.¹¹⁰
- With respect to the FMV of space leases, the Stark Law focuses on the value of the rental property for general commercial purposes without regard to the proximity of the space to the lessor when the lessor is a potential source of patient referrals (e.g., a hospital).¹¹¹
- Equipment leases may be combined with other compensation arrangements (e.g., personal services), provided that a separate FMV is allocated to each component of the combined arrangement.¹¹²

¹⁰⁶ 69 Fed. Reg. 16,054, 16,085 (2004).

¹⁰⁷ 42 C.F.R. §§ 411.357(a)(2), (b)(3).

¹⁰⁸ 63 Fed. Reg. 1659, 1713 (1998).

¹⁰⁹ 42 C.F.R. §§ 411.357(a)(7), (b)(6).

¹¹⁰ 69 Fed. Reg. 16,054, 16,058 (2004).

¹¹¹ 42 C.F.R. § 411.351 (definition of FMV).

¹¹² 69 Fed. Reg. 16,054, 16,091 (2004).

- Under certain circumstances, equipment leases may be protected under the FMV exception (discussed below).¹¹³ This is not the case with space rental arrangements, however.¹¹⁴

See **Appendix 2-3** for a Compliance Checklist when analyzing space lease arrangements.

[b] Employment

Importantly, the Stark Law includes an exception that protects payments made by an employer to a bona fide employee (including a physician), provided certain conditions are met.¹¹⁵ The most important of these conditions is that the payments to the employee are commercially reasonable and consistent with FMV without taking account (either directly or indirectly) the volume or value of referrals. That said, the exception does permit a physician-employee to earn a productivity bonus based on DHS that are “personally performed” by the physician. Such bonuses, however, may not include “incident to” services (i.e., services furnished by a physician extender such as a nurse or a physician assistant) or any services performed by anyone other than the physician (e.g., the physician’s partner). It is also worth noting that an employer may require a physician-employee to refer patients to the employer (subject to certain restrictions) without violating the volume or value standard.¹¹⁶

[c] Personal Services Arrangements

The Stark Law also has an exception for payments made by an entity to a non-employed physician (or an immediate family member).¹¹⁷ The exception is predicated on the satisfaction of six conditions, including, but not limited to, that the arrangement be set out in a signed writing, be for a term of at least one year, and provide for compensation that is set in advance and consistent with FMV for services actually rendered.¹¹⁸

Several features of the personal services arrangements exception warrant discussion. First, the word “personal” notwithstanding, a physician (or immediate family member) may delegate the performance of the services at issue to an employee, a wholly owned entity, or to a *locum tenens* physician (but not to a contractor).

Second, as is the case for space and equipment rental arrangements (discussed in § 2.03[D][1][a]), the one-year term requirement may be satisfied even if the agreement permits an earlier termination, provided that the agreement

¹¹³ 69 Fed. Reg. 16,054, 16,086 (2004).

¹¹⁴ *Id.*

¹¹⁵ 42 U.S.C. § 1395nn(e)(2); 42 C.F.R. § 411.357(c). CMS does not presume employment. Rather, the entity seeking to rely on this exception has the burden of establishing the “necessary indicia of employment” under the common law rules used by the Internal

Revenue Service. 69 Fed. Reg. 16,054, 16,086–16,087 (2004).

¹¹⁶ See 42 C.F.R. § 411.354(d)(4); 69 Fed. Reg. 16,068–16,069.

¹¹⁷ 42 U.S.C. § 1395nn(e)(3); 42 C.F.R. § 411.357(d).

¹¹⁸ *Id.*

precludes the parties from entering into a new agreement for the same (or substantially the same) services until one year after the commencement date of the agreement.¹¹⁹

Third, although the exception forbids compensation that takes into account DHS referrals or other business generated, health plans are permitted to establish and maintain physician incentive plans (e.g., withhold or bonus pools).

Fourth, the Stark Regulations provide several (fundamentally conservative) methodologies for determining FMV in the personal services context see § 2.03[A][1][c]. Hourly compensation that is established on the basis of other methodologies is not presumptively erroneous. By the same token, if the parties' alternative methodology yields a materially different result than CMS's methodologies, CMS may (or is likely) to question (and possibly reject) the alternative methodology.

Finally, and as noted above, in the discussion of equipment leases, CMS takes the position that, for purposes of this exception, the provision of services may be combined with the provision of equipment, provided that the payments for each component (i.e., services versus equipment) can be shown to separately be FMV.¹²⁰

[d] Fair Market Value

The Stark Regulations include an exception that protects payments to a physician, a group of physicians, or their immediate family members in return for the provision of items or services,¹²¹ provided that six conditions are met. As the name of the exception suggests, the most important of these conditions is that the compensation (or compensation methodology) (e.g., \$100 per hour) must be consistent with FMV. In addition, the compensation (or compensation methodology) also has to be set in advance and determined in a manner that does not take into account the volume or value of referrals or other business generated.

The FMV exception is more flexible than its "personal services arrangement" cousin (discussed immediately above) in that it protects arrangements for periods of less than one year, provided that if such short-term arrangements are renewed during a one-year period, the terms (including compensation) may not be amended. (Moreover, the FMV exception does not require that the compensation be set in advance; however, it is sufficient that the compensation methodology is set in advance.) On the other hand, the FMV exception is less flexible than the personal services arrangements exception in that it does not cover payments by physicians to DHS entities for the provision of items or services, but rather applies only to services furnished by physicians to DHS entities (and thus receiving payments *from* DHS entities).

¹¹⁹ Note that the fair market value exception (discussed below) does not require a one-year term.

¹²⁰ 69 Fed. Reg. 16,054, 16,091 (2004).

¹²¹ 42 C.F.R. 411.357(l).

[e] Isolated Transactions

The direct compensation exception for “isolated transactions” protects certain one-time financial transactions.¹²² CMS defines the term “isolated transaction” to mean a business transaction (such as a sale of a property or a medical practice) that involves a single payment or multiple integrally related payments, provided that the total aggregate payment is fixed in advance, does not take into account the volume or value of referrals or other business generated, and is negotiable, guaranteed or otherwise secured.¹²³ In order for the exception to apply, the transaction must be commercially reasonable and consistent with FMV without regard to the volume or value of referrals or other business generated.¹²⁴ In addition, the parties may not engage in additional transactions during the six months following the isolated transaction, unless such additional transactions (i) meet the terms of another exception (e.g., after selling his or her professional corporation (PC) to a group practice, the physician-owner of the PC works for the group as a physician-employee), or (ii) involve commercially reasonable post-closing adjustments.¹²⁵

[f] Payments by a Physician

Both the Stark Statute and Regulations include an exception for payments made by a physician (or an immediate family member) to a DHS entity for certain items and services.¹²⁶ Thus, if a physician’s husband is treated in a hospital’s emergency department and pays for such services, the physician could continue to refer Medicare patients to the hospital in reliance on this exception. The exception has two principal limitations. First, the payments must be consistent with the FMV of the items of services at issue.¹²⁷ Second, the payments must not be for items or services that are specifically covered by another Stark Law exception, such as the exception for space rental.¹²⁸

[g] Group Practice Arrangements with Hospitals

The Medicare program has always recognized that hospitals may furnish services directly or indirectly (i.e., under arrangements). Accordingly, both the Stark Statute and Regulations include an exception that protects remuneration paid by a hospital to a group practice for services that are furnished by the group, but are billed for by the hospital as hospital services.¹²⁹ In order to meet the exception, seven separate conditions must be met. One of these conditions—that the arrangement at issue must have begun and continued in effect without interruption since December 19, 1989—causes the exception to have decreasing relevance with the passage of time, and, ultimately, will render the exception moot.

¹²² 42 U.S.C. § 1395nn(e)(6); 42 C.F.R. § 411.357(f).

¹²³ 42 C.F.R. § 411.351 (“Transaction” defined).

¹²⁴ 42 C.F.R. § 411.357(f).

¹²⁵ *Id.*

¹²⁶ 42 U.S.C. § 1395nn(e)(8); 42 C.F.R. § 411.357(i).

¹²⁷ CMS has noted that this exception will cover “legitimate discount[s].” 69 Fed. Reg. 16,054, 16,099.

¹²⁸ *Id.*

¹²⁹ 42 U.S.C. § 1395nn(e)(7)(A); 42 C.F.R. § 411.357(h).

[2] Compensation Exceptions with No Fair Market Value Exchange

[a] Charitable Donations

In 2004, CMS established a regulatory exception for *bona fide* charitable donations by a physician (or his or her immediate family members) to a tax-exempt DHS entity.¹³⁰ This exception protects all types of charitable donations (e.g., cash, goods, services) provided that the donation is not solicited or made in a manner that takes into account the volume or value of referrals or business generated.¹³¹ It is unclear whether the exception extends to charitable donations made to a DHS entity's affiliate (e.g., the separately incorporated foundation of a hospital.)

[b] Compensation under \$300

Because it is commonplace for physicians to receive various gifts (e.g., a holiday basket) and other items of *de minimis* value (e.g., a free meal) from the entities with which they do business, CMS has created a regulatory exception for such remuneration. At bottom, this exception permits annual compensation to an individual physician, provided:

- The compensation, in the aggregate, does not exceed \$300 per annum, as adjusted to reflect CPI-U increases.¹³² (The adjusted annual amount for calendar year 2006 is \$322.)
- The compensation is not in the form of cash or a cash equivalent.
- The physician (or his or her practice) does not solicit the compensation. (Thus, a hospital administrator may give a physician a ticket to a sporting event, provided the value of the ticket is under \$300. However, when a second physician learns about this and asks the administrator for a ticket for himself, the administrator may not give a ticket to the second physician).
- The compensation may not be determined in a manner that takes into account the volume or value of referrals or other business generated, nor may it violate the Anti-Kickback Law.

Although this exception ultimately is a creature of CMS's pragmatism, it requires hospitals and other DHS entities to accurately monitor their compensation arrangements with physicians. CMS's view is that such monitoring should not be "unduly burdensome."¹³³ However, compliance with this exception is only possible if the DHS entity implements a comprehensive and methodical tracking system.

¹³⁰ 42 C.F.R. § 411.357(j).

¹³¹ *Id.*

¹³² Such increases are posted at <<http://cms.hhs.gov/PhysicianSelfReferral>>.

¹³³ 69 Fed. Reg. 16,054, 16,112 (2004).

[c] Medical Staff Incidental Benefits

Hospitals routinely furnish members of their medical staff with certain incidental benefits—such as free or discounted parking or meals—thereby creating numerous direct compensation arrangements. Because such “incidental” benefits do not pose a material risk of program or patient abuse,¹³⁴ CMS has created an exception for items and services (other than cash) furnished by a hospital (or any other DHS entity) to members of its bona fide medical staff.¹³⁵ Thus, incidental benefits do not give rise to a compensation arrangement, provided certain conditions are met. These include that (1) the benefit is provided uniformly to all physicians within a specialty without regard to the volume or value of referrals or other business generated; (2) the benefit is provided and used only on the facility’s campus; and (3) the benefit (in each instance) is valued at \$25 or less, as annually adjusted for CPI-U.¹³⁶ Note that in contrast to the exception compensation under \$300 a year annum exception (discussed above), the furnishing entity does not have to aggregate annually the value of benefits and, as such, may provide its staff with unlimited incidental benefits, provided each benefit is below \$25 (as adjusted) and the other requirements of the exception are satisfied.

[d] Compliance Training

Because the provision of compliance training by a DHS entity to a physician (or his or her immediate family or office staff) likely gives rise to a direct compensation arrangement, CMS sought to encourage such “beneficial” conduct by creating an exception for compliance training programs offered in the DHS entity’s local community or service area.¹³⁷ (Thus, if an Atlanta-based hospital sent one of its medical directors to a compliance conference in Chicago, the hospital could not rely on this exception to avoid the billing prohibitions of the Stark Law.) The exception defines the term “compliance training” broadly to include training regarding the elements of a compliance program, the requirements of particular health care laws and regulations, proper coding, and the like.¹³⁸ It expressly excludes continuing medical education (CME) on the grounds that CME is not “primarily intended to promote legal compliance.”¹³⁹ The precise scope of this exclusion is unclear. It is unlikely that CMS intended to exclude compliance training that qualifies for CME credit in general (e.g., for attorneys or compliance personnel); rather, CMS probably intended to exclude training that is so clinical in nature as to qualify for CME.

¹³⁴ 66 Fed. Reg. 856, 921.

¹³⁵ 42 U.S.C. § 1375(m).

¹³⁶ *Id.* (listing other conditions in addition to those set forth in the text). The most current

dollar limit, as adjusted for CPI-U, is \$27. See <<http://cms.hhs.gov/PhysicianSelfReferral>>.

¹³⁷ 42 C.F.R. § 411.357(o).

¹³⁸ *Id.*

¹³⁹ 69 Fed. Reg. at 16,114.

[e] Obstetrical Malpractice Insurance

In light of the growing malpractice insurance crisis in many parts of the nation and given the particularly acute impact that the crisis has had on obstetricians, in 1999, the U.S. Department of Health and Human Services, Office of Inspector General (OIG) promulgated a safe harbor to the Anti-Kickback Law for obstetrical malpractice insurance subsidies.¹⁴⁰ In 2004, CMS established a mirror Stark Law exception that protects the payment of medical malpractice premiums, provided all of the conditions of the Anti-Kickback Law safe harbor are met. The safe harbor has eight separate requirements, the most important of which essentially requires that no less than 75 percent of the physician's obstetrical patients must reside in a health professional shortage area (HPSA),¹⁴¹ reside in a medically underserved area,¹⁴² or be part of a medically underserved population.¹⁴³ Consequently, this is a narrow exception.

[f] Professional Courtesy

Given the longstanding and fairly ubiquitous practice of hospitals and other providers of offering physicians and their families certain health care items and services at a reduced (or no) charge (e.g., flu vaccines), CMS created the "professional courtesy" exception.¹⁴⁴ Under the exception, professional courtesies may be extended not only to physicians, but also to their immediate family members and office staff.¹⁴⁵ Such courtesies will not give rise to a prohibited financial relationship if six separate conditions are met. These include: (1) the courtesies at issue must be of a type routinely provided by the DHS entity (e.g., an ambulatory surgical center (ASC) may not offer the physicians on its staff free vaccines unless the ASC furnishes vaccines in the ordinary course); (2) the courtesies at issue must be extended pursuant to a written professional courtesy policy that has been approved by the entity's governing board; and (3) the courtesies must be offered to all physicians on the entity's medical staff or in its service area (or community).¹⁴⁶

[g] Community-Wide Health Information Systems

The Stark Regulations include an exception for information technology that is provided to a physician to enable the physician to participate in a community-wide health information system.¹⁴⁷ According to CMS, the exception both hardware (e.g., hand-held devices) and software (e.g., EMR programs).¹⁴⁸ The exception, however, requires, among other things, that (1) the health information system be available to all providers, practitioners, and residents in the community, and (2) the physicians at issue use the technology principally as part of the

¹⁴⁰ 42 C.F.R. § 1001.952(o).

¹⁴¹ The term "HPSA" refers to an area designated under Section 332(a)(1)(A) of the Public Health Services Act for primary medical care professionals. See 42 C.F.R. § 411.351.

¹⁴² 42 C.F.R. § 1001.952(a)(3).

¹⁴³ *Id.*

¹⁴⁴ 42 C.F.R. § 411.357(s).

¹⁴⁵ 42 C.F.R. § 411.351.

¹⁴⁶ 42 C.F.R. § 411.357(s).

¹⁴⁷ 42 C.F.R. § 411.357(u).

¹⁴⁸ 69 Fed. Reg. 16,054, 16,113.

community-wide health system.¹⁴⁹ Thus, a hospital that furnishes a certain kind of technology to all members of its medical staff could not rely on this exception, assuming there were other providers or practitioners in the community who were not on the hospital's staff. (Such an arrangement arguably could be protected under the exception for "incidental benefits" (42 C.F.R. § 411.357(m)), provided the technology was wholly dedicated for use in connection with hospital services furnished to hospital patients on the hospital campus.)¹⁵⁰

[h] Electronic Prescribing and Health Records

In an effort to promote the widespread adoption of electronic prescribing and electronic health records technologies, on August 8, 2006, CMS published two new regulatory exceptions that permit certain DHS entities to offer certain electronic items of services to certain physicians at no or a highly discounted charge.¹⁵¹ Although the two exceptions have certain commonalities, they are sufficiently different as to warrant separate discussion.

[i] *Electronic prescribing items and services*

This exception protects remuneration in the form of electronic prescribing hardware, software, and information technology and training services by three types of DHS entities to certain physicians.¹⁵² Specifically, the exception allows hospitals to provide these items and services to physicians on their medical staffs, group practices (as that term is defined at 42 C.F.R. § 411.352) to provide these items and services to physicians who are members of the group, and, prescription drug plan sponsors and Medicare Advantage organizations to provide these items and services to a prescribing physician.¹⁵³ Although the exception does not protect the exchange of money, it does not place a limit on the value of the items or services provided; nor does it require the receiving physician to pay for any portion of the associated costs. The exception contains other conditions, including that no action is taken to restrict the compatibility of the items and services at issue with other e-prescribing and e-health records systems;¹⁵⁴ that the items and services are provided pursuant to a written and signed agreement;¹⁵⁵ and, that the items and services are provided in a manner that is not conditioned upon and does not take into account the volume or value of referrals or business generated.¹⁵⁶

[ii] *Electronic health records items and services*

This exception protects remuneration in the form of software and information technology and training services that is both necessary and used predominantly to create, maintain, transmit and receive electronic health records.¹⁵⁷ Like the e-prescribing exception discussed immediately above, protected items and services must, among other things, be provided pursuant to a written and signed

¹⁴⁹ 42 C.F.R. § 411.357(u).

¹⁵⁰ 69 Fed. Reg. 16,054, 16,113.

¹⁵¹ 71 Fed. Reg. 45140 (August 8, 2006).

¹⁵² 42 C. F. R. § 411.357(v).

¹⁵³ *Id.* § 411.357(v)(1).

¹⁵⁴ *Id.* § 411.357(v)(3).

¹⁵⁵ *Id.* § 411.357(v)(7).

¹⁵⁶ *Id.* § 411.357(v)(5),(6).

¹⁵⁷ 42 C.F.R. § 411.357(w).

agreement;¹⁵⁸ be provided without restrictions on their compatibility with other with other e-prescribing and e-health records systems;¹⁵⁹ and, be provided in a manner that is not conditioned upon and does not take into account the volume or value of referrals or business generated.¹⁶⁰ The e-health records exception is more onerous than its e-prescribing counterpart in that it requires that the items and services be “interoperable”;¹⁶¹ that the physician recipient make an upfront payment equal to 15 percent of the donating entity’s costs,¹⁶² which amount cannot be financed by the donor;¹⁶³ and, that the receiving physician use the items or services primarily for purposes related to his or her medical practice.¹⁶⁴ The e-health records exception is more generous than its e-prescribing counterpart in that it applies to all DHS entities and all physicians, provided the other terms of the exception are satisfied.

[3] Physician Retention and Recruitment

There are two direct compensation arrangement exceptions that address physician recruitment and retention.

[a] Physician Recruitment

The physician recruitment exception (both in its statutory¹⁶⁵ and regulatory¹⁶⁶ form) arguably is the most complex of all of the direct compensation exceptions and, as such, warrants a more extensive discussion. Such added attention is further justified by the fact that the federal government views recruitment arrangements with particular skepticism, and has sought both criminal and civil remedies for perceived abuses, as well as the proposed exclusion of one hospital for physician recruitment activities.¹⁶⁷ Following the structure of the regulatory exception, we discuss solo recruitment separately from recruitment of physicians who will join host practices.

[i] *Solo physician recruitment*

Provided certain conditions are met, a hospital (or a federally qualified health center (FQHC))—but not other DHS entities—may provide remuneration to a physician to induce him or her to relocate his or her medical practice to the geographic service area (GSA) served by the hospital or FQHC without triggering the Stark Law’s referral and billing prohibitions. The principal elements of the exception are discussed below.

First, although the exception is called the physician “recruitment” exception, the protections of the exception extend only to remuneration that is provided to a

¹⁵⁸ *Id.* § 411.357(w)(7).

¹⁵⁹ *Id.* § 411.357(w)(3).

¹⁶⁰ *Id.* § 411.357(w)(5),(6).

¹⁶¹ *Id.* § 411.357(w)(2). CMS has both defined the term “interoperable” and established interoperability deeming standards.

¹⁶² *Id.* § 411.357(w)(4).

¹⁶³ *Id.*

¹⁶⁴ *Id.* § 411.357(w)(10).

¹⁶⁵ 42 U.S.C. § 1395nn(e)(5).

¹⁶⁶ 42 C.F.R. § 411.357(e).

¹⁶⁷ See OIG Press Release, OIG Notifies Tenet of Potential Exclusion of Alvarado Hospital (May 8, 2006), available at <<http://oig.hhs.gov/publications/docs/press/2006/Alvarado%20MW%20Press%20Release%205.8.061.pdf>>.

physician who is willing to “relocate” his or her practice from *outside* of the GSA to *inside* the GSA. CMS has clarified that the focus of the relocation is on the site of the physician’s practice as opposed to his or her residence. (Thus, a physician can relocate within the meaning of this exception without moving his or her residence.) Moreover, CMS defines the term “GSA” to mean “the area composed of the lowest number of contiguous ZIP codes from which the hospital draws at least 75% of its inpatients.”¹⁶⁸

Second, a physician will be considered to have relocated if (1) he or she moves his or her medical practice at least 25 miles or (2) he or she derives at least 75 percent of revenues from professional services furnished to new patients (i.e., patients not previously treated by the physician in the three years prior to the relocation).¹⁶⁹ Note that new physicians (i.e., residents and those who have practiced medicine for less than one year) are exempt from the “relocation” requirement; therefore, they do not have to move their practices from outside to inside the GSA.

Third, upon relocation, the physician must become a member of the recruiting hospital’s medical staff.¹⁷⁰ (At bottom, this requirement precludes a hospital from furnishing financial assistance to relocate a physician who is already a member of the hospital’s staff.)

Fourth, upon relocation, the physician must be free to establish staff privileges at, and refer patients to, other hospitals and entities.¹⁷¹

Finally, the exception is predicated on the satisfaction of three additional conditions:

1. The remuneration paid to the physician cannot take into account the volume or value of actual or anticipated referrals;
2. The arrangement cannot be conditioned on referrals; and
3. The arrangement must be set forth in a writing that is signed by both parties.¹⁷²

[ii] *Host practice recruitment*

Hospitals and FQHCs also may provide financial support to induce the relocation of a physician who, upon relocation, will join an existing (i.e., the “host”) practice. In order to qualify for exemption under the physician recruitment exception, the sponsoring hospital, recruited physician, and host practice must meet not only the conditions set forth above with respect to solo physician recruitment, but also all of those discussed below. Note that these additional requirements apply regardless of whether the financial support is made directly to the recruited physician or the host practice.

¹⁶⁸ 42 C.F.R. § 411.357(e).

¹⁶⁹ 42 C.F.R. § 411.357(e)(2).

¹⁷⁰ 42 C.F.R. § 411.357(e)(1).

¹⁷¹ 42 C.F.R. § 411.357(e)(1)(iv).

¹⁷² 42 C.F.R. § 411.357(e)(1).

- The arrangement must be set forth in a written agreement signed by the sponsoring hospital, recruited physician, and host practice.¹⁷³
- Except for “actual costs incurred” by the physician or host practice (such as headhunter fees, airfare and the like), the remuneration from the hospital must pass through to, or remain with, the recruited physician.¹⁷⁴
- In the case of income guarantees, the costs allocated to the recruited physician must not exceed the “actual additional incremental costs” attributable to the recruited physician.¹⁷⁵ (Thus, for example, a four-physician practice group that utilizes a single receptionist may not allocate one-fifth of the receptionist’s salary to the fifth (i.e., recruited) physician because the salary is a pre-existing cost as opposed to an additional incremental one.)
- With the exception of restrictions relating to quality of care, the host practice may not impose practice limitations on the recruited physician.¹⁷⁶ According to CMS, this requirement precludes the host practices from securing a covenant not to compete from the recruited physician.¹⁷⁷
- The remuneration at issue must not take into account the volume or value of actual or anticipated referrals of the recruited physician or host practice.¹⁷⁸
- Records of all costs—both actual and those passed through—must be retained for at least five years, and produced to CMS upon request.¹⁷⁹
- The recruitment must not violate the Anti-Kickback Law or any other billing or claim submission law or regulation.¹⁸⁰

[b] Physician Retention

As a general rule, the Stark Law does not permit hospitals (or any other DHS entities) to pay physicians to remain in the relevant community. There are two narrow exceptions to this rule. First, the physician recruitment exception, discussed above, exempts payments intended to induce new physicians (e.g., medical residents) to remain and to establish their medical practice in the geographic area served by the hospital. Second, CMS created an additional “physician retention” exception.¹⁸¹ Although not limited to new physicians, the exception is very narrow, as explained below.

As an initial matter, the exception applies only with respect to payments made by hospitals or FQHCs located in a GSA (1) that is a health professional shortage area (HPSA) (regardless of the physician’s clinical specialty), or (2) that has a demonstrated need for the physician’s specialty, as determined by CMS

¹⁷³ 42 C.F.R. § 411.357(e)(4)(i).

¹⁷⁴ 42 C.F.R. § 411.357(e)(4)(ii).

¹⁷⁵ 42 C.F.R. § 411.357(e)(4)(iii).

¹⁷⁶ 42 C.F.R. § 411.357(e)(4)(vi).

¹⁷⁷ 69 Fed. Reg. 16,054, 16,096–16,097 (2004).

¹⁷⁸ 42 C.F.R. § 411.357(e)(4)(v).

¹⁷⁹ 42 C.F.R. § 411.357(e)(4)(iv).

¹⁸⁰ 42 C.F.R. § 411.357(e)(4)(vii).

¹⁸¹ 42 C.F.R. § 411.357(t).

through the Stark Law advisory opinion process.¹⁸² Because the vast majority of hospitals are not in an HPSA and because obtaining a Stark Law advisory opinion is cumbersome at best, this exception is unlikely to be of much utility. Moreover, the exception is further limited by the requirement that the retention payments only be made in response to a *bona fide* competitive offer that would recruit the physician to move his or her medical practice at least 25 miles and outside of the geographic service area.¹⁸³ (CMS has the discretion to waive the latter requirement if the payment satisfies the other seven conditions of the exception.)¹⁸⁴

[4] Other Direct Compensation Arrangement Exceptions

[a] Referral Services

In recognition of the fact that the Anti-Kickback Law contains a safe harbor that immunizes payments for certain referral services, in 2004, CMS created a parallel exception under the Stark Law.¹⁸⁵ At bottom, this exception protects payments by a physician to a referral service, provided the conditions set forth in the Anti-Kickback Law safe harbor (42 C.F.R. § 1001.952(f)) are satisfied. Among other things, these conditions require the referral services to include all qualified physicians and that a series of disclosures be made to those seeking referrals, including the way it selects the physician to refer (e.g., geographic proximity, rotating basis).

[b] Unrelated Remuneration

The Stark Statute and Regulations include an exception that protects certain remuneration that is unrelated to the provision of DHS.¹⁸⁶ This exception, as promulgated in the Stark Regulations is exceedingly narrow. First, it does not apply to any DHS entities other than hospitals. Second, it protects remuneration to physicians only (not their immediate family members). Finally, CMS interprets the term “unrelated” so restrictively, that the exception is of little practical value.

[c] Risk-Sharing Arrangements

Historically, the Stark Law did not apply (due to a specific exception) to services furnished to enrollees of certain federally funded “prepaid health plans.”¹⁸⁷ In 2004, CMS supplemented the prepaid health plans exception by protecting certain compensation arrangements between managed care organizations (MCOs) that operate commercial or employer-sponsored (as opposed to federally funded) health plans and physicians. It is important to note that this exception does not cover all compensation arrangements between MCOs and physicians; rather, it is limited to “risk-sharing arrangements” (i.e., withholds, risk pools, and bonuses).¹⁸⁸

¹⁸² 42 C.F.R. § 411.357(t)(1)(ii).

¹⁸³ 42 C.F.R. § 411.357(t)(1)(iii).

¹⁸⁴ 42 C.F.R. § 411.357(t).

¹⁸⁵ 42 C.F.R. § 411.357(q); 69 Fed. Reg. 16,114.

¹⁸⁶ 42 U.S.C. § 1935nn(e)(4); 42 C.F.R.

§ 411.357(g).

¹⁸⁷ 42 C.F.R. § 411.355(c).

¹⁸⁸ 42 C.F.R. § 411.357(n).

[E] Indirect Compensation Arrangements Exception

Setting the all-purpose exceptions (discussed above) aside, indirect compensation arrangements exception is the only exception that can protect indirect compensation arrangements only.¹⁸⁹ In other words, if the financial relationship between the parties is not an indirect compensation arrangement (i.e., it is a direct compensation arrangement or a direct or indirect ownership arrangement), it is not eligible for the indirect compensation arrangements exception.

The indirect compensation arrangement exception has three prongs, all of which must be satisfied for the exception to apply. First, the exception requires that the compensation arrangement (in the unbroken chain of financial relationships that make up the indirect compensation arrangement at issue) which is closest to the referring physician: (a) be consistent with FMV for services or items actually provided, and (b) not take into account the volume or value of referrals or other business generated by the physician for the furnishing entity.¹⁹⁰ Note that in contrast to the definition of “indirect compensation arrangements” (discussed earlier in this chapter), which focuses on the *aggregate compensation* received by the referring physician, the exception drops the work “aggregate,” focusing instead on the referring physician’s *compensation*. This is important, because, as previously noted, CMS takes the position that the special rules on compensation (which provide that unit-based compensation methodologies do not violate the volume or value standard) do not apply where the focus is on *aggregate compensation* as opposed to *compensation* alone. This is a long way of saying that if the compensation closest to the referring physician involves a unit-based payment methodology, it can still satisfy this first prong of the exception pursuant to the terms of the special rules on compensation.

Second, the compensation arrangement closest to the referring physician must be set out in a writing that is signed by the parties and specifies the services covered by the arrangement.¹⁹¹ A written agreement is not required, however, in the case of a *bona fide* employment relationship between an employer and an employee.¹⁹² Under those circumstances, though, the arrangement must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.¹⁹³

Third, the compensation arrangement must not violate the Anti-Kickback Law or any federal or state law or regulation governing billing or claims submissions.¹⁹⁴

[F] Temporary Noncompliance Exception

CMS has created a regulatory exception that provides for a “grace period” of up to 90 days for arrangements that (1) fall out of compliance with a Stark Law exception due to events beyond the parties’ control, or (2) do not comply with an exception for a temporary period of time.¹⁹⁵

¹⁸⁹ 42 C.F.R. § 411.357(p).

¹⁹⁰ 42 C.F.R. § 411.357(p)(1).

¹⁹¹ 42 C.F.R. § 411.357(p)(2).

¹⁹² *Id.*

¹⁹³ *Id.*

¹⁹⁴ 42 C.F.R. § 411.357(p)(3).

¹⁹⁵ 42 C.F.R. § 411.353(f).

Pursuant to this exception for “temporary noncompliance,” a DHS entity may submit a claim to Medicare for improperly referred DHS (and payment may be made to the entity that submits the claim), provided four conditions are met:

1. The financial relationship between the referring physician and the entity must have complied with another Stark Law exception for at least 180 consecutive days immediately preceding the date on which the financial relationship became noncompliant with that exception;
2. The financial relationship must have fallen out of compliance with the exception for reasons beyond the control of the entity;
3. The entity must take prompt steps to rectify the noncompliance; and
4. The financial relationship cannot violate the Anti-Kickback Law or any other federal or state laws, rules, or regulations.

It is important to note, however, that the exception (1) may only be used by a DHS entity once every three years with respect to the same referring physician, and (2) does not apply to lapses in compliance with the exceptions for (a) compensation under \$300 per year, or (b) medical staff incidental benefits.¹⁹⁶

§ 2.04 PENALTIES, SANCTIONS AND COLLATERAL CONSEQUENCES

The consequences of violating the Stark Law can be severe. This severity is compounded by the fact that the Stark Law is essentially a “strict liability” statute, and, as such, well-intentioned parties may nevertheless be subject to harsh penalties.

If a claim is submitted for DHS in violation of the Stark Law, the following sanctions may apply:

- Medicare will not make payment;
- If Medicare does make payment, the DHS entity must refund the amounts received; and
- If there is a “knowing” violation, the U.S. Department of Health and Human Services, Office of Inspector General (OIG) may impose civil monetary penalties (CMPs), seek an assessment for up to three times the amount claimed, and commence exclusion proceedings.

Separate and apart from the sanctions that arise directly from a violation of the Stark Law, such violations can also lead to other potentially severe collateral consequences, including False Claims Act liability (which may attach to both the DHS entity and the physicians who cause the DHS entity to submit the allegedly false claim). Each of these sanctions and collateral consequences is discussed in greater detail below.

¹⁹⁶ 42 C.F.R. § 411.353(f)(ii)(4).

[A] Payment Denial

The Stark Statute states that “no [Medicare] payment may be made . . . for a designated health service which is provided” pursuant to a prohibited referral.¹⁹⁷ There is one narrow exception to this payment prohibition: The DHS entity did not know (and did not have reason to know) of the identity of the referring physician, and the claim otherwise meets applicable laws and regulations.¹⁹⁸ This exception is narrow insofar as regulators will likely assert that the DHS entity should have known the identity of the referring physician. In general, however, the denial of payment rule will, in all likelihood, be honored in the breach because the Medicare claims payment system remains a “pay and chase” system. Put another way, Medicare claims processors, such as fiscal intermediaries and carriers, process claims in reliance on certifications by providers and physicians that the claims are correct and in compliance with the law. This allows Medicare claims processors to pay claims if, on their face, they appear correct. Moreover, the Medicare carriers and fiscal intermediaries rarely possess the information to determine whether a DHS claim was presented for a service arising from a prohibited referral.

[B] Refund Obligation

Because it is likely that a Medicare claim for a DHS arising from a prohibited referral will be paid for the reasons set forth above, the sanction that will have a more direct impact on DHS entities will be the Law’s directive that a person or entity that “collects any amounts billed in violation [of the Stark Law]” has an obligation to “refund on a timely basis to the individual, any amounts so collected.”¹⁹⁹ Although this statutory language refers to refunds “to the individual” (and does not specify refunds to the Medicare program), the Stark Regulations make it clear that the refund obligation requires repayment to the Medicare program. Specifically, the Stark Regulations provide that a refund must be made on all collected amounts received pursuant to a prohibited referral.²⁰⁰ By logical extension, if amounts collected on a prohibited referral were received from Medicare, the refund would be owed to the Medicare program. A payment to any other entity would not constitute a “refund” or repayment. That said, because of the potentially onerous and punitive nature of the refund obligation, especially in connection with so-called “technical violations” (e.g., a missing signature on an otherwise appropriate and compliant lease agreement), some have suggested that the Stark Law’s refund obligation remains unclear because of the statutory reference to refunds “to the individual” and the failure of CMS in its Stark Regulations to make it explicitly clear that Medicare payments received pursuant to a prohibited referral must be refunded to Medicare.

The Stark Regulations establish that a DHS entity will meet the Stark Law’s “timely” refund obligation if it refunds amounts within 60 days from when the

¹⁹⁷ 42 U.S.C. § 1395nn(g)(1).

¹⁹⁸ 42 C.F.R. § 411.353(e).

¹⁹⁹ 42 U.S.C. § 1395nn(g)(2).

²⁰⁰ 42 C.F.R. § 411.353(d).

prohibited payments were collected.²⁰¹ In many ways, this timely refund obligation is a perfect recipe for failure, if for no other reason than a DHS entity will more often than not discover that it received a DHS payment in violation of the Stark Law long after 60 days have passed. Receipt of prohibited payments are often discovered following compliance or other reviews undertaken in good faith and not within 60 days of receipt of payment. To cure this impractical requirement, CMS noted in the preamble to the 1998 Proposed Regulations that OIG intended to change the “timely basis” timeframe to begin “when the individual or entity knew or should have known that the amount collected was related to a prohibited referral.”²⁰² OIG has not, however, amended the definition of “timely basis” as of this date, adding to the confusion regarding the applicable timeframe.

[C] Civil Monetary Penalties

For “knowing” violations, the Stark Law contains several provisions providing for the imposition of civil monetary penalties (CMPs). Specifically, any person who presents or causes to be presented a “bill or claim” for a service that the person knows or should know was provided pursuant to a prohibited referral, is subject to a CMP of not more than \$15,000 for each such service, plus up to three times the amounts claimed.²⁰³ Although the term “knows” refers to actual knowledge, the term “should know” is defined the same as under the False Claims Act—“a person, with respect to information” either “acts in deliberate ignorance of the truth or falsity of the information” or “acts in reckless disregard of the truth or falsity of the information.” In addition, “no proof of specific intent to defraud is required.”²⁰⁴ The Stark Law CMP provisions do not appear in the Stark Regulations; rather, they appear in the regulations related to the OIG’s CMP authority.²⁰⁵ (Knowing Stark Law violations also may lead to exclusion from Medicare and Medicaid.)²⁰⁶

There are three primary CMPs for Stark Law violations: (1) for the presentation of a claim (or causing to submit a claim); (2) for failure to refund amounts received from a prohibited referral; and (3) circumvention schemes. The first two types of knowing violations give rise to \$15,000 CMPs plus up to three times the amount claimed; the third type, regarding circumvention schemes, is subject to a CMP of up to \$100,000 for each such arrangement or scheme plus an assessment.²⁰⁷ Note, the Stark Law CMPs, like other OIG CMP authorities, provide for assessments based on the amounts claimed as compared to the amount of “damages” under the federal civil False Claims Act (FCA). Consequently, the OIG may look to the charged amount instead of the actual (and typically lesser) amount of Medicare payment.

²⁰¹ 42 C.F.R. § 1003.101 (CMP regulations).

²⁰² 63 Fed. Reg. 1659, 1695 (Jan. 9, 1998).

²⁰³ 42 U.S.C. §§ 1395nn(g)(3), 1320a-7a(a).

²⁰⁴ 42 U.S.C. § 1320a-7a(i)(7).

²⁰⁵ 42 C.F.R. §§ 1003.102 *et seq.*

²⁰⁶ 42 U.S.C. § 1395nn(g)(3); 42 C.F.R. § 1003.105(a)(1).

²⁰⁷ 42 U.S.C. § 1395nn(g)(4).

[D] Federal False Claims Act Stark Law Actions

A significant, collateral risk associated with Stark Law non-compliance relates to potential liability under the federal False Claims Act (FCA),²⁰⁸ and perhaps state false claims laws under the following theory: Medicare providers certify in various CMS billing forms, cost reports, enrollment applications, and elsewhere that their claims are submitted in conformity with various laws, including the Stark Law and Anti-Kickback Law. Additionally, providers may impliedly certify compliance with those laws merely by their participation in the Medicare program. If the providers submit claims to Medicare (and receive payment) for services furnished pursuant to a prohibited referral under Stark Law, and no exception applies to the underlying arrangement, the claims are ostensibly false. If the provider either knew or should have known that the claims presented were false, the provider may be liable under the FCA for up to three times the amount claimed plus between \$5,500 and \$11,000 for each false claim. Physicians or others involved in the prohibited referral may also be liable for “causing” the DHS entity to submit the false claim.

Because the FCA has a whistleblower (*qui tam*) provision that enables private individuals or entities to bring a lawsuit on behalf of the United States—and typically awards between 15 and 20 percent of any FCA settlement to the whistleblowers—there is a significant incentive to bring these types of lawsuits. Thus, it is not surprising that there have been a large number of *qui tam* lawsuits related to alleged Stark and Anti-Kickback Law violations involving illicit or improper physician financial arrangements with DHS entities, such as hospitals.

Indeed, since approximately 2000, the FCA theory specified above has been used consistently and frequently by the United States and *qui tam* relators, resulting in at least a dozen substantial FCA settlements with hospitals and corporate integrity agreements (CIAs) with the OIG. As of this writing, it is estimated that there are more than 100 Stark Law FCA investigations underway, some of which will undoubtedly result in significant civil fraud settlements.

These FCA investigations are costly and time consuming, and often create significant disruption between and among the DHS entity and staff physicians. Additionally, because the FCA and CMP risk of Stark Law non-compliance has grown, many hospitals and other DHS entities find themselves increasingly struggling with decisions regarding whether to self-report potential Stark Law non-compliance to enforcement agencies, such as the OIG and Department of Justice. Further complicating this uncertainty, on April 24, 2006, the HHS Inspector General, Daniel Levinson, issued an “Open Letter” encouraging providers to self-disclose to the OIG probable Stark Law violations as part of a new initiative.²⁰⁹ Undoubtedly, some of these disclosures will also result in new CMP and FCA settlements and physician-relationship-focused CIAs.

²⁰⁸ 31 U.S.C. §§ 3729–3733.

²⁰⁹ OIG, An Open Letter to Health Care Providers (Apr. 21, 2006), available at <[http://oig.](http://oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf)

[hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf](http://oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf).

APPENDIX 2-1

COMPLIANCE CHECKLIST FOR STARK LAW ELEMENTS

1	Is a <u>physician</u> participating in the arrangement?
2	If so, is the physician making a <u>referral</u> ?
3	If so, is the referral of a <u>Medicare patient</u> ?
4	If so, is the referral being made <u>to an entity furnishing DHS</u> ?
5	If so, do the physician and the entity have a <u>financial relationship</u> ?
6	If all of the above elements are present, does an <u>exception</u> apply? Exceptions correspond to the type of financial relationship at issue: <ul style="list-style-type: none">• Direct Compensation Arrangement = Direct Compensation Exceptions• Direct or Indirect Ownership or Investment Interest = Ownership or Investment Exceptions• Indirect Compensation Arrangement = Indirect Compensation Arrangement Exception• Any Type of Financial Arrangement = All-Purpose Exceptions

APPENDIX 2-2

STARK LAW EXCEPTIONS

All-Purpose Exceptions	Statutory Citation	Regulatory Citation
Physicians Services	42 U.S.C. § 1395nn(b)(1)	42 C.F.R. § 411.355(a)
In-Office Ancillary Services	42 U.S.C. § 1395nn(b)(2)	42 C.F.R. § 411.355(b)
Prepaid Health Plan Services	42 U.S.C. § 1395nn(b)(3)	42 C.F.R. § 411.355(c)
Academic Medical Centers	—	42 C.F.R. § 411.355(e)
Implants furnished in ASCs	—	42 C.F.R. § 411.355(f)
EPO and Other Dialysis-Related Drugs Furnished in or by an ESRD Facility	—	42 C.F.R. § 411.355(g)
Preventative Screening Tests, Immunizations, and Vaccines	—	42 C.F.R. § 411.355(h)
Eyeglasses and Contact Lenses Following Cataract Surgery	—	42 C.F.R. § 411.355(i)
Intra-Family Rural Referrals	—	42 C.F.R. § 411.355(j)
Ownership/Investment Exceptions	Statutory Citation	Regulatory Citation
Publicly Traded Securities	42 U.S.C. § 1395nn(c)(1)	42 C.F.R. § 411.356(a)
Mutual Funds	42 U.S.C. § 1395nn(c)(2)	42 C.F.R. § 411.356(b)
Rural Provider	42 U.S.C. § 1395nn(d)(2)	42 C.F.R. § 411.356(c)(1)
Puerto Rican Hospital	42 U.S.C. § 1395nn(d)(1)	42 C.F.R. § 411.356(c)(2)

Whole Hospital	42 U.S.C. § 1395nn(d)(3)	42 C.F.R. § 411.356(c)(3)
Direct Compensation Arrangements Exceptions	Statutory Citation	Regulatory Citation
Space Rental	42 U.S.C. § 1395nn(e)(1)(A)	42 C.F.R. § 411.357(a)
Equipment Rental	42 U.S.C. § 1395nn(e)(1)(B)	42 C.F.R. § 411.357(b)
Employment	42 U.S.C. § 1395nn(e)(2)	42 C.F.R. § 411.357(c)
Personal Services Arrangements	42 U.S.C. § 1395nn(e)(3)	42 C.F.R. § 411.357(d)
Physician Recruitment	42 U.S.C. § 1395nn(e)(5)	42 C.F.R. § 411.357(e)
Isolated Transactions	42 U.S.C. § 1395nn(e)(6)	42 C.F.R. § 411.357(f)
Certain Arrangements with Hospitals	42 U.S.C. § 1395nn(e)(4)	42 C.F.R. § 411.357(g)
Group Practice Arrangements with a Hospital	42 U.S.C. § 1395nn(e)(7)	42 C.F.R. § 411.357(h)
Payments by a Physician	42 U.S.C. § 1395nn(e)(8)	42 C.F.R. § 411.357(i)
Charitable Donations	—	42 C.F.R. § 411.357(j)
Compensation Under \$300	—	42 C.F.R. § 411.357(k)
Fair Market Value	—	42 C.F.R. § 411.357(l)
Medical Staff Incidental Benefits	—	42 C.F.R. § 411.357(m)
Risk-Sharing Arrangements	—	42 C.F.R. § 411.357(n)
Compliance Training	—	42 C.F.R. § 411.357(o)
Referral services	—	42 C.F.R. § 411.357(q)

Obstetrical Malpractice Insurance	—	42 C.F.R. § 411.357(r)
Professional Courtesy	—	42 C.F.R. § 411.357(s)
Physician Retention	—	42 C.F.R. § 411.357(t)
Community-Wide Health Information Systems	—	42 C.F.R. § 411.357(u)
Other Exceptions	Statutory Citation	Regulatory Citation
Indirect Compensation Arrangements	—	42 C.F.R. § 411.357(p)
Temporary Noncompliance	—	42 C.F.R. § 411.353(f)
Certain Entities	—	42 C.F.R. § 411.353(e)

APPENDIX 2-3

COMPLIANCE CHECKLIST FOR LEASE ARRANGEMENTS

Written Agreement
Is there a written lease agreement?
Is the agreement signed and dated by each party?
Is the lease currently in effect according to its specified term? If the agreement has expired, is the lessee still occupying the premises? Have more than six months passed since the expiration? Have the terms pursuant to which the lessee is occupying the premises changed?
Core Lease Terms
Does the agreement specify the leased premises (including the full address)?
Does the agreement specify the total square footage comprising the leased premises?
Does the agreement specify the term of the lease?
If the agreement term is for a period of less than one year, does it prohibit the parties from entering into another agreement covering the same premises until one year has elapsed?
If the agreement may be terminated by either party during the first year, does it prohibit the parties from entering into another agreement covering the same premises until one year has elapsed?
If the agreement is a time-share arrangement, does it set forth with specificity the lessee's scheduled use of leased the premises (i.e., exact schedule of intervals of time lessee may access the premises and their precise length) and the exact rent for such intervals?
Is the leased premises shared by the lessee and lessor during the time it is rented?
Does the agreement set in advance rental charges over the term of the agreement?

Fair Market Value (FMV)
Has a fair market value assessment been conducted in connection with agreement?
Is the FMV assessment comprehensive, accurate, and complete?
Does the agreement provide for rent abatements or periods of free rent? If so, are there indicia that such abatements/free rent are commercially reasonable?
Does the rental amount to be paid by a Hospital (as less) to a Physician/Group (as less) under the lease agreement exceed the range set forth in fair market value analysis?
Is the rental amount to be paid by a Physician/Group (as lessee) to a Hospital (as lessor) under the agreement less than range set forth in fair market value analysis?
Are there indicia that a Hospital is paying more under a master lease than the Physician/Group is paying under a sublease?
Tenant Improvements
Does the agreement provide for a tenant improvement allowance? If so, are there indicia that such allowance is commercially reasonable?
Have any tenant improvement allowances been paid inconsistent with the terms of the agreement?
Was a tenant improvement allowance paid even though the agreement did not provide for such an allowance?
Other Factors/Intent
Are there indicia that the lessor informed the lessee that rent provided for in the agreement need not be paid?
Are there indicia that the rental amount set forth in the agreement takes into account anticipated volume or value of referrals or other business generated between the parties?
Are there indicia that the agreement may have been intended to induce referrals or generate other business between the parties?
Are there indicia that the leased premises exceeds that which is reasonably necessary to accomplish the legitimate business purpose of the agreement?
Are there indicia that the lessor provided additional benefits to the lessee at no cost or below fair market value?
Are there indicia that a lessor wrote off or forgave lease amounts owed by a lessee without justification?

Is the agreement a multi-year agreement that does not provide for periodic rent increases?
Are there indicia that the lessor is not collecting periodic rent increases?
Does the agreement not require the lessee to pay its proportionate share of building operating expenses/common area maintenance costs?
Are there indicia that the lessor is not charging the lessee its proportionate share of building operating expenses/common area maintenance costs?
Does the agreement require all Physician lessees to be active members of the Hospital's/lessor's medical staff?
Does the agreement prohibit a Physician lessee (or members of his/her Group) from maintaining or exercising medical staff privileges at another hospital?
Are there indicia that rental payments made by the lessee were not consistent with the terms of the agreement?
Is the lessee in arrears on rental payments?
If the lessee is in arrears on rental payments, are there indicia that the lessor has made no or insufficient collection efforts?
If the lessee is in arrears on rental payments, are there indicia that the lessor has not assessed penalties provided for in the agreement?
If the lessee is a holdover tenant, is the lessor collecting payments as called for by the holdover provisions of the agreement?
If the agreement is between a Hospital and a Group, are there indicia the Hospital has obtained assurances from Group that compensation received by physician owners, employees or contractors of Group (a) is commercially reasonable and consistent with fair market value and (b) does not reflect or relate to the volume or value of referrals to, or business generated for, the Hospital.

