

Federal Self-Referral and Anti-Kickback Laws: A Primer for the General Business Lawyer



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At five o'clock one Friday afternoon, your telephone rings. At the other end of the line is your client, the president of a small business corporation in which he is also a shareholder. He has been offered the opportunity to lease a piece of equipment that is useful in his business for a rate that appears to be substantially below market. The equipment is sound and neither of you can spot a "catch" in the deal. Should he sign the lease? Now suppose your client is a physician, and the

neys who represent them are at substantial risk if they fail to consider such regulations in the day-to-day conduct of the providers' business.

This article discusses two of the principal federal laws that affect health-care providers, the Physician Self-Referral Law and the Medicare/Medicaid Anti-Kickback Statute, in the context of some common health care transactions.¹ Business attorneys who represent health-care providers,

- An office space lease between a hospital, as lessor, and a physician group, as lessee;
- An independent-contractor relationship between a physician group and a physician; and
- The joint ownership of a magnetic resonance imaging unit ("MRI") by a hospital and a physician practice.

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The Physician Self-Referral Law

The Physician Self-Referral Law, 42 U.S.C. 1395nn, is commonly referred to as "Stark" in honor of its legislative sponsor, Congressman Fortney "Pete" Stark. Under Stark, a physician may not make a referral to an entity for the furnishing of a "designated health service" if payment will be made by a federal health-care program, and the physician has a direct or indirect financial relationship with the entity. In furtherance of this statutory prohibition, health-care entities are prohibited from presenting a claim for Medicare reimbursement of services provided pursuant

potential lessor is a local hospital. Does that change your answer?

If it doesn't, it should. Health-care providers are subject to an array of state and federal regulations that can often alter radically what otherwise appear to be simple business decisions. Small health-care providers and the general-business attor-

but do not specialize in health law, should be able to identify issues requiring more extensive analysis to ensure compliance with federal law. The remainder of this article examines the application of the Physician Self-Referral Law and the Medicare/Medicaid Anti-Kickback Statute, and their exceptions, in the context of three common business arrangements:

to an unlawful referral.² Designated health services (DHS) include, among other services, clinical laboratory services, radiology services, inpatient and outpatient hospital services, durable medical equipment and supplies and outpatient prescription drugs.³ Direct and indirect financial relationships may include both investment interests and compensation arrangements.⁴ Moreover, an “indirect financial relationship” may be found to exist between a physician and the entity furnishing DHS if there is an unbroken chain of any number of persons or entities having financial relationships between them.⁵ This “linking” of physicians and entities through any number of intermediary financial relationships has a profound effect on the scope of the Stark law. The financial relationship between a physician’s practice or other corporate entity in which the physician owns an interest, on the one hand, and an entity providing DHS, on the other, will be imputed to the physician himself for Stark purposes.

Violations of Stark are subject to sanctions. Entities that furnish DHS pursuant to a prohibited referral may not claim reimbursement for such services from Medicare.⁶ Physicians who make unlawful referrals are subject to fines of fifteen thousand dollars per referral and exclusion from Medicare.⁷ Over the past decade, Stark compliance was relegated to the back-burner as the Department of Health and Human Services struggled to issue comprehensive regulations. With the issuance of final regulations on March 26, 2004, however, Stark compliance should be at the forefront of every physician’s compliance efforts.

The Stark statute and regulations establish a number of exceptions that describe situations in which referrals between a physician and an entity are not prohibited, despite the existence of a direct or indirect financial relationship between them. Exceptions exist for employment and “personal services” relationships, referrals for certain in-office ancillary services, equipment and space leases and other circumstances.⁸ The exceptions to Stark are critical: No intent is required for a violation

of Stark sufficient, at a minimum, to render all services provided under referral from a physician ineligible for reimbursement from Medicare. In the absence of an applicable exception, the mere existence of a prohibited referral is generally sufficient to implicate the statute.

Space Lease

In analyzing any physician-entity relationship for Stark purposes, it is important to first identify the existence of referrals made from a physician to an entity for DHS—for which payment may be made by Medicare. In the absence of any of these characteristics, the relationship does not implicate Stark. In their presence, however, any financial relationship between the physician and the entity to which he or she refers must qualify for one of several available exceptions to Stark. A physician and entity may have more than one financial relationship, each of which must qualify for an exception. For example, a physician who is employed by a professional corporation and also owns shares in the corporation has both an investment interest in and a compensation arrangement with the entity.

The lease of office space between a hospital and a physician practice whose members make referrals to the hospital constitutes a compensation relationship that could, in the absence of an exception, generally render such referrals unlawful. The Stark statute and regulations except from the definition of “financial relationship” space leases that meet certain requirements. To qualify for the exception, a lease must, among other requirements, be in writing and for a term of not less than one year; describe the premises, which may not exceed those which are reasonable for the legitimate business purposes of the lessee; provide for the exclusive use of the space by the lessee during the lessee’s period(s) of occupancy; and set out rental charges in advance over the lease term at rates that are consistent with fair market value and do not take into account the volume or value of referrals or other business between the parties.⁹

The limited scope of this article does not permit us to explore fully these requirements, other than to observe that terms such as the “volume or value of referrals” and “set in advance” are terms of art requiring careful review for compliance with the Stark regulations. As a single example, until recently it was not clear that a “triple net” lease, in which costs and expenses are passed through to the lessee on a periodic basis, would qualify as a lease in which rent is “set in advance.”¹⁰

Independent Contractor Relationships

An independent contractor relationship between a physician practice and an individual physician raises a pair of issues that differ substantially in their complexity. The first issue involves the relationship between the physician and the practice. For Stark purposes, a physician is deemed to make a “referral” to his or her practice any time the physician refers a patient for DHS that are provided by other employees or contractors of the practice.¹¹ For example, an employee physician who orders laboratory screenings that are performed by technicians at the practice’s in-house lab has made a referral that is, absent an applicable exception, prohibited by Stark. Stark and the regulations set out exceptions for both personal services (i.e., independent contractor) arrangements and employment agreements that except such referrals from the statute’s ambit in a relatively straightforward manner.¹²

Of greater concern, however, is the fact that independent contractor arrangements may threaten a physician practice’s ability to qualify as a “group practice” within the meaning of the Stark law and regulations. Again, a full explication of the importance of the “group practice” concept for Stark purposes is beyond the scope of this article. Stark makes available a number of exceptions that permit referrals for DHS among members of a physician “group practice.” Among these are exceptions for referrals between physician members of a group and referrals from a physician to an

in-office laboratory or imaging center.¹³ If the practice fails to qualify as a “group,” then the existence of an investment relationship between a physician shareholder and his or her practice entity may invalidate all referrals from the physician to the practice entity or to the other physicians employed by the practice.

The definition of group practice is set out at 42 C.F.R. §411.352. Among a number of other requirements, a group practice is limited in its ability to provide services through independent contractor physicians. As a result, each independent contractor relationship requires careful analysis to ensure that both referrals from the contractor to the practice qualify for the personal services exception and the relationship between the contractor and the practice does not cause the practice to fail to qualify as a “group practice” for Stark purposes.

Physician Group-Hospital Joint Venture

As with the definition of “group practice” discussed above, we simply lack the space to explore fully the potential Stark implications of a venture in which a hospital and a physician practice jointly own and operate an entity providing DHS in the form of MRI services. The example is useful, nonetheless, as an illustration of the sheer number of financial relationships for which an exception must be found under Stark. As noted above, physician members of the group practice will have one or more direct financial relationships with the practice entity, which may include investment and employment relationships. In addition, the physicians are likely to have indirect financial relationships with the joint venture entity itself. Finally, and perhaps most important, the physician members of the group practice may, by virtue of the hospital’s joint ownership of the joint venture, have an indirect financial relationship with the hospital. Each of these relationships requires careful analysis under Stark if referrals from the physicians to the remaining entities (group practice, joint venture and hospital) are to be protected.

Medicare/Medicaid Anti-Kickback Statute

Like Stark, the applicability of the Anti-Kickback Statute impacts many transactions involving health care providers and, thus, it is important to understand the basic elements of the statute. In general, the statute makes it illegal to knowingly and willfully offer, solicit, pay or receive remuneration in return for the referral of an individual for any item or service which may be paid for under Medicare/Medicaid.¹⁴

The Anti-Kickback Statute is a criminal statute and violations are punishable as felonies. Potential penalties include fines of up to twenty-five thousand dollars per violation, imprisonment for up to five years, or both. Persons convicted for violating the statute may be excluded from participation in Medicare/Medicaid.¹⁵

Similar to Stark, there are several statutory exemptions and related regulatory safe harbors which protect arrangements that might otherwise be illegal.¹⁶ An arrangement that satisfies all of the elements of a regulatory safe harbor is not illegal regardless of the parties’ intent. Unfortunately, many of the safe harbors are narrow in scope and it is very difficult to satisfy all of their elements. Unlike the Stark exceptions, however, the failure to satisfy a regulatory safe harbor does not mean an arrangement violates the Anti-Kickback

to consider the impact of the Anti-Kickback Statute because getting (or giving) too good of a deal may be illegal. For example, assume that a hospital affiliate offers to lease office space to a large surgical group in a building located on the hospital campus. If the lease rates are below fair market value, the federal government may assert that the below-market lease is illegal because it is an inducement to the physician group to refer patients to the hospital. There is, however, a regulatory safe harbor for space leases that protects arrangements which satisfy all six of its elements.¹⁸ Significantly, such safe harbor is similar to the Stark space lease exception discussed above, and arrangements that meet the Stark exception will generally be very close to satisfying all of the elements of the anti-kickback safe harbor, as well.

One common element that can be difficult to satisfy is the fair market value element. Like the Stark exception, the Anti-Kickback safe harbor requires the rental rate to be set in advance, be consistent with fair market value and not take into account the volume or value of referrals.¹⁹ Whether the rental rate is consistent with fair market value is a factual question and the parties should consider performing some basic market research to support the rental rate. Some lease arrangements may warrant a complete appraisal by a third party, others may warrant a much simpler survey.

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Statute on a per se basis. The arrangement must involve “willful and knowing” conduct to be illegal under the Anti-Kickback Statute.¹⁷ Accordingly, the legality of the arrangement must be analyzed on a facts and circumstances basis.

Space Lease

In structuring a space lease between a hospital and a physician group it is critical

One difference between the Stark exception and the Anti-Kickback safe harbor is the treatment of part-time leases. The Stark exception does not specifically address part-time leases. However, the Anti-Kickback safe harbor provides that part-time leases must specify exactly the schedule when the space will be leased, the precise length of each use and the exact rent for such use.²⁰ This element can be hard to satisfy if a physician group

wants to lease space on a part-time basis based on the group's needs. For example, some specialists located in cities have referral relationships with general practitioners located in rural areas. It is not uncommon for the specialist to accommodate the patients of such general practitioner by renting space in the general practitioner's office on a part-time basis so that the patients do not have to travel. The parties may want to structure the lease based on scheduling needs, and it may be difficult to specify in advance the exact schedule and length of use. Such an arrangement would not satisfy the Anti-Kickback safe harbor and, thus, would be subject to a facts and circumstances analysis.

Independent Contractor Relationship

The Anti-Kickback Statute also needs to be considered when structuring an independent contractor arrangement with a physician group. In many of such arrangements, the independent contractor will refer patients for other items or services that are provided by the physician group and reimbursable by Medicare/Medicaid. If the arrangement is not structured carefully, it could violate the Anti-Kickback Statute. For example, an arrangement whereby an independent contractor's compensation adjusts based on the number of diagnostic tests he refers within the physician group will, in most cases, violate the statute.

Once again, there is symmetry between the Anti-Kickback safe harbors and Stark exceptions and as a result the arrangement may be protected. The Anti-Kickback safe harbors include a regulatory safe harbor for personal service arrangements that is similar to the Stark exception for personal services, and arrangements that satisfy the Stark exception discussed above will usually satisfy the Anti-Kickback safe harbor.²¹ Similar to the Stark exception, the Anti-Kickback safe harbor requires that the compensation be consistent with fair market value and not be determined based on the volume or value of referrals. One major difference is that the Anti-Kickback

safe harbor provides that if the services are to be provided on a periodic or part time basis, then the agreement must specify "exactly the schedule of such intervals, their precise length and the exact charge for such intervals."²² This can be difficult to satisfy if the independent contractor's schedule varies depending on need or availability. In such instances the arrangement must be analyzed on a facts and circumstances basis.

Physician Group-Hospital Joint Venture

Joint ventures such as an MRI joint venture between a hospital and physician group raise a host of issues, including Anti-Kickback issues. The federal government is particularly concerned about arrangements between physicians and those who provide items or services which are paid for by Medicare/Medicaid because of the perception that the arrangement may be intended "to lock up a stream of referrals from the physician investors and compensate them indirectly for these referrals."²³ Many joint ventures are legitimate, however given the federal government's inter-

est all joint ventures should be structured to comply with the Anti-Kickback Statute.

The first step in structuring a joint venture is to identify all of the separate economic arrangements between the parties. This is critical because each separate arrangement must independently withstand Anti-Kickback scrutiny for the joint venture to be legal. For example, an MRI joint venture may involve joint ownership of an operating entity plus a management arrangement whereby the physician group manages the facility. In that case there are two separate economic arrangements which warrant Anti-Kickback scrutiny: the ownership interest in the joint venture and the management agreement.

The one arrangement that is common to most joint ventures is ownership of an interest by a physician group or other referral source. Significantly, the "small business" regulatory safe harbor provides protection for ownership interests in some joint ventures.²⁴ Unfortunately, very few joint ventures satisfy all eight elements of such Anti-Kickback safe harbor. For example, the safe harbor requires that one or

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more “investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity” may hold no more than forty percent of the ownership interests.²⁵ Many joint ventures involve a number of physicians, physician groups and other providers (including hospitals), which collectively own more than forty percent of the entity. Thus, the small business safe harbor does not apply.

Joint ventures that do not satisfy a regulatory safe harbor must be analyzed on a

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fact and circumstances basis, which analysis typically focuses on whether the parties are engaged in “willful and knowing conduct.” Features that require particular scrutiny include the manner in which investors are selected and retained, the nature of the business structure, and the manner in which the joint venture is financed and distributes profits.²⁶ Joint ventures which may be at risk include those: (a) which offer larger ownership interests to physicians who refer more patients to the joint venture, (b) in which a party that already provides certain services or goods enters into an arrangement with a referral source to provide the same services or goods through the referral source, or (c) which make distributions based on referrals and not actual ownership interests. ☞

Endnotes:

- 1 Practitioners should note also the existence of state law analogs to both the Self-Referral Statute and the Anti-Kickback Statute (including statutes at *Va. Code Ann.* § 54.1-2410 et seq. and *Va. Code Ann.* § 18.2-502). Analysis of state law is beyond the scope of this article but will be an important part of any legal analysis of these issues.
- 2 42 *C.F.R.* §411.353(b) (69 Fed. Reg. 16054, 16133 (March 26, 2004)). Final Stark regulations were published on March 26, 2004 and will become effective July 26, 2004, subject to comments accepted during a comment period ending June 24, 2004. Unless otherwise noted, all references to the Code of Federal Regulations are to regulations published at 69 Fed. Reg. 16054 – 16146.
- 3 42 *C.F.R.* 411.351 (2004).

- 4 See generally 42 *C.F.R.* §411.354 (2004). “Compensation arrangement” is a catch-all category that includes virtually any relationship in which compensation changes hands and includes employment agreements, leases, and independent contractor relationships.
- 5 *Id.* at (c)(2).
- 6 42 *U.S.C.* §1395nn(g)(1) (2004).
- 7 *Id.* at (g)(3). Although it is beyond the scope of this article, it should also be noted that Stark violations may be actionable under the federal False Claims Act, 31 *U.S.C.* §§3729-3733.
- 8 See generally 42 *C.F.R.* §§411.355-357 (2004).
- 9 42 *C.F.R.* §411.357(a) (2004). Note that an indirect financial relationship between the physicians and the hospital may also exist, notwithstanding the availability of an exception for the lease. See 42 *C.F.R.* Section 411.354(a)(3) (2004).
- 10 42 *C.F.R.* §411.354(d) (2004).
- 11 See definition of “referral” at 42 *C.F.R.* §411.351 (2004).
- 12 42 *C.F.R.* §411.357(c) and (d) (2004).
- 13 42 *C.F.R.* §411.355(a) and (b) (2004).
- 14 See 42 *U.S.C.* §1320a-7b(b).
- 15 The Anti-Kickback Statute applies solely to referrals for services or goods which may be paid for, in whole or in part, by a federal health care program. For the sake of brevity, in this section II we will use the term “Medicare/Medicaid” to refer to all federal health care programs.
- 16 See 42 *U.S.C.* §1320a-7b(b)(3) and 42 *C.F.R.* §1001.952.
- 17 This is a critical element of the statute and it is significant to note that Federal courts are still wrestling with what constitutes “willful and knowing” conduct. See *Bryan v. United States*, 118 S.Ct. 1939 (1998); *United States v. Davis*, 132 F.3d 1092 (5th Cir. 1998); *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995)). It is also important to be aware that some courts have interpreted the statute to mean that an arrangement is illegal if any one purpose is to induce referrals, notwithstanding any other bona fide purposes. (See *United States v. Greber*, 760 F.2d 68 (3rd Cir.), cert. denied 474 U.S. 988 (1985)).
- 18 See 42 *C.F.R.* §1001.952(b).
- 19 42 *C.F.R.* §1001.952(b)(5).
- 20 See 42 *C.F.R.* §1001.952(b)(3).
- 21 See 42 *C.F.R.* §1001.952(d).
- 22 See 42 *C.F.R.* §1001.952(d)(3).
- 23 See “Special Fraud Alert: Joint Venture Arrangements,” 59 *Fed. Reg.* 65372 (December 19, 1994).
- 24 See 42 *C.F.R.* §1001.952(a).
- 25 42 *C.F.R.* §1001.952(a)(2)(i)
- 26 See “Special Fraud Alert: Joint Venture Arrangements,” 59 *Fed. Reg.* 65372 (December 19, 1994); Office of Inspector General, *Special Advisory Bulletin Contractual Joint Ventures*, <http://oig.hhs.gov/fraud/docs/alertsandbulletins/042303JointVentures.pdf> (April 23, 2003).

Mergers *continued from page 37*

the acquired business is merged into the purchasing one. A reverse merger occurs when the purchasing business is merged into the acquired business; this form of transaction is often used if the selling business has contracts or permits prohibiting assignment without the consent of the contracting party or relevant agency. A “triangular merger” occurs when the purchasing business forms a subsidiary that is merged with the selling business; this type of transaction is often used to provide the purchaser with a layer of limited liability protection.

- 19 See, e.g., *Va. Code* § 13.1-721.A.3; *Va. Code* § 13.1-1073.1.
- 20 For example, there is no requirement that solely voting stock be used for a particular percentage of the selling corporation’s assets or stock. See generally, *IRC* § 368(a)(1)(A).
- 21 The value shown on the business’ financial records, taking into account all depreciation, and with no adjustment for actual fair market value.
- 22 See Section D below.
- 23 See *United States v. Anderson*, 85 F. Supp. 2d 1047 (D. Kan. 1999), in which two attorneys were indicted under the fraud and abuse law for their role in allegedly preparing contracts for the purpose of disguising kick-back payments from their hospital clients to physicians.
- 24 42 *U.S.C.* § 1320a-7a.
- 25 See, e.g., *OIG Advisory Opinion No. 04-02* (March 1, 2004). See also *U.S. v. Greber*, 760 F.2d 68 (3d Cir. 1985).
- 26 42 *U.S.C.* § 1395nn.
- 27 *OIG* for the fraud and abuse law and the U. S. Centers for Medicare and Medicaid Services (CMS) for the Stark law.
- 28 For example, the fraud and abuse law safe harbor for sale of a medical practice allows installment payments to be made to the seller over a number of years, while the Stark law safe harbor allows installment payments only if the obligation is guaranteed or secured. Compare 42 *C.F.R.* § 1001.952(e) with 69 Fed. Reg. 16,098 (March 26, 2004).
- 29 The purchaser of a medical practice is not prohibited from purchasing the Medicare accounts receivable of the selling practice by the Medicare rules against physician reassigning their right to bill Medicare. See letter of Kathleen Butto, Sale of Medical Practice, Bureau of Eligibility, Reimbursement and Coverage (CMS) dated September 22, 1998.
- 30 PL 104-191, 104th Congress (August 21, 1996); 110 Stat. 1936 et seq.
- 31 65 *Fed. Reg.* 82,799 (December 28, 2000).
- 32 *Va. Code* § 54.1-2410 et seq.
- 33 *Va. Code* § 54.1-2412.
- 34 *Va. Code* § 54.1-2405. Sending such a notice would also appear to provide a defense against patient abandonment.
- 35 *Id.*
- 36 See *Va. Code* §§ 13.1-547, -550.
- 37 1992 *Va. Op. Atty. Gen.* 147.
- 38 For example, Sections 4(1) and 4(2) of the Securities Act of 1933, as amended, will exempt most medical practice sales from registration with the U. S. Securities and Exchange Commission.