

TOP 10 LESSONS LEARNED FROM THE PHYSICIAN PRACTICE ACQUISITION WARS

STARK AND ANTI-KICKBACK ISSUES IN PHYSICIAN COMPENSATION

By
Robert G. Homchick
Davis Wright Tremaine LLP

This presentation focuses on the reasons why hospital acquisitions of physician practices fail. Many of the reasons are operational or cultural but a misunderstanding of the regulatory requirements can also lead to significant disruption of the relationship between a hospital and a newly acquired physician practice. This paper is intended to provide background on two specific laws that are directly implicated in virtually all hospital-physician relationships: (1) the federal physician self referral or “Stark Law,” 42 U.S.C. § 1395nn, and (2) the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b).

I. STARK LAW

The Stark Law prohibits a physician from referring a Medicare patient for certain “designated health services” (DHS) to an entity with which the physician, or an immediate family member, has a financial relationship unless an exception applies.¹ The Stark Law also prohibits the entity from billing for services provided pursuant to a prohibited referral. A “financial relationship” is defined to include direct and indirect ownership or investment interests in the entity or any compensation arrangement between the entity and the physician. The Stark Law includes exceptions for a myriad of financial relationships, including exceptions for *bona fide* employment relationships and personal service arrangements.

Penalties for violating the Stark Law include denial of payment, repayment of amounts paid in violation of the law, exclusion from the Medicare program, and substantial civil monetary penalties (up to \$15,000 per service, \$100,000 for each arrangement or scheme intended to circumvent or violate the statute, or \$10,000 per day for false reporting or failure to report certain information required under the law). Violation of the Stark Law may also provide the basis for liability under the federal False Claims Act.

The Stark Law is exceedingly complex in part because of its broad application and strict liability structure. The Centers for Medicare and Medicaid Services (CMS) has exacerbated the confusion surrounding this law by issuing several sets of regulations. With each set of Stark regulations, CMS’ interpretation of the statute has evolved.

¹ Stark Law applies to Medicaid only indirectly. The Law does not prohibit the referral of Medicaid patients but rather authorizes the federal government to deny state programs the federal matching funds (federal financial participation) for any Medicaid services provided pursuant to a referral which would have been prohibited if the patient had been a Medicare beneficiary. Medicaid referrals that fall within this prohibition are subject to whatever sanctions the state has adopted.

A. Physician Compensation: Group Practice and Employment

The Stark Law imposes different limitations on physician compensation depending on whether the physician is a member of a group practice or an employee of an entity that does not qualify as a group practice. This paper summarizes both the statutory language in the Stark Law and the commentary from the Stark regulations addressing compensation under either the group practice or employee relationship exceptions. The cited sources include the Proposed Stark II regulations, 63 Fed. Reg. 1659 (Jan. 9, 1998), Stark II Phase I Interim Final Regulations, 66 Fed. Reg. 856 (Jan. 4, 2001), Stark II Phase II Interim Final Regulations, 69 Fed. Reg. 16054 (Mar. 26, 2004), and Stark II Phase III Final Regulations, 72 Fed. Reg. 51012 (Sept. 5, 2007).

1. Group Practice Compensation Rules

a. Generally

- i)** Physicians who belong to a Stark “group practice” are permitted to receive either a share of overall profits of the group or a productivity bonus based on services personally performed or services “incident to” such personally performed services, provided that the share or bonus is not determined in a manner that is directly related to the volume or value of referrals by the physician.
§ 1395nn(h)(4)(B)(i).
- ii)** By way of example, CMS has indicated that physician groups are permitted to distribute profits arising from designated health services based upon: “an even split, a physician’s investment in the group, the number of hours a physician in general devotes to the group, or the difficulty of a physician’s work.” Furthermore, a physician may receive a portion of the group’s overall profits, as long as that physician’s compensation does not include “payments based directly on the number or value of the referrals he or she has made.” Proposed Stark II regulations, 63 Fed. Reg. at 1690- 1691.

b. Productivity bonuses

- i)** Group practices may pay productivity bonuses to the physicians in the group as long as they are based on services personally performed or “incident to” such personally performed services. The productivity payments, however, may only be indirectly related to the volume or value of the physician’s referrals. In Stark II Phase I, CMS identified methodologies they deemed to be “indirectly” related to the volume or value of DHS referrals:

- (1) Productivity bonus based on physician's total patient encounters or relative value units ("RVUs");
- (2) Productivity bonus based on the allocation of a physician's compensation that is attributable to services that are not DHS payable by government or private payers; and
- (3) Productivity bonus that includes DHS revenues if the group practice's DHS revenues are less than 5 percent of the group practice's total revenues and no physician's allocated portion of those revenues is more than 5 percent of the physician's total compensation from the group.

c. Per-capita bonuses

- i) Under Stark, group practices may divide overall profits per physician, or "per capita." Stark II Phase I, 66 Fed. Reg. at 908.
- ii) In Stark II Phase I, CMS lent some flexibility to the definition of "share of overall profits" by permitting group practices to establish subgroups of at least five physicians. Overall profits may be calculated and divided among the physicians in the subgroup. Stark II Phase I, 66 Fed. Reg. at 909.

d. Other permissible income distribution methods

- i) Group practices are also permitted to divide overall profits based on revenues derived from non-DHS services. Likewise, overall profits for group practices may be divided where DHS revenues are less than 5 percent of the group practice's total revenues and no physician's allocated portion of those revenues is more than 5 percent of the physician's total compensation from the group practice. Stark II Phase I, 66 Fed. Reg. at 908.

2. Bona Fide Employment Relationship Exception

a. Generally

- i) The Stark Law includes an exception for remuneration made by an employer to a physician (or immediate family member of the physician) who has a bona fide employment relationship with the employer for the provision of services, provided that: (1) the employment is for identifiable

services; (2) the amount of the remuneration under the employment is consistent with fair market value, and is not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals by the referring physician; and (3) the remuneration is pursuant to an agreement that is commercially reasonable.

§1395nn(e)(2)(A)- (C). The exception explicitly permits productivity bonuses based on services that are personally performed by the physician (or an immediate family member of the physician). 42 U.S.C. § 1395nn(e)(2).

- ii) CMS has indicated that it expects employees of group practices to rely on the group practice, not the employee exception. If a group practice relies upon the employment exception, productivity bonuses may only be based on personally performed services and physician-employees may not be paid a share of the overall profits. Stark II Phase II, 69 Fed. Reg. at 16088.
- iii) Stark regulations define fair market value (FMV) as “the value in arm’s length transactions, consistent with the general market value. ‘General market value’ means the price that an asset would bring as the result of *bona fide* bargaining between well informed buyers and sellers who are not otherwise in a position to generate business with each other” 42 C.F.R. § 411.351. This definition is often not that helpful in practice. In response to questions or comments during rulemaking, CMS has not provided a lot of additional guidance. In Stark II, Phase III, CMS stated that there is no single, correct methodology to determine FMV – “[n]othing precludes parties from calculating [FMV] using any commercially reasonable methodology that is appropriate under the circumstances and otherwise fits” the definition of FMV. 72 Fed. Reg. at 51015. The agency concluded that FMV is determined based on facts and circumstances – “because the statute covers a broad range of transactions, we cannot comment definitively on particular valuation methodologies.” 72 Fed. Reg. at 51016.

b. Productivity bonuses for Physician Employees

- i) Under the employment exception, productivity payments are permitted for “personally performed” services.
- ii) The employment exception does not permit productivity payments for indirect or “incident to” services.

c. Per Capita Bonuses

- i) The employment exception is silent on per capita bonus compensation. If the per capita payment is a means of distributing the overall profits of the group it would probably not be permitted under the employment exception. However, the fundamental prohibition as articulated in the exception is that the remuneration must not be determined in a manner that takes into account the volume or value of “referrals.” A physician does not make a “referral” when he or she personally performs a service. 42 C.F.R. § 411.351. Assuming that the bonus funds are derived from payments for services personally performed by the physicians, a good argument can be made that the revenues that flow into the bonus funds are not tied to the volume or value of “referrals.” Per capita distribution of these incentive funds would likewise not be based on the physician-employees’ referrals.

If the revenues are not derived from DHS referrals, paying physicians their per capita share of a bonus fund should be permissible under the employment exception because the payment would not take into account the volume or value of referrals.

B. Direct and Indirect Financial Arrangements And Physician “Stand in the Shoes” Rules

Hospital-Physician integration models often result in organizational structures where the physicians may be employed by an entity affiliated with the hospital rather than the hospital itself. Given these structural options, it is important to understand the Stark Law distinctions between direct and indirect financial relationships and the physician “stand in the shoes” rules.

1. **Direct financial relationship:** An arrangement between the entity furnishing DHS and a referring physician or an immediate family member with no person or entity interposed between them (i.e., between a physician and a hospital).
2. **Indirect ownership exists when:**
 - a. There is an unbroken chain of any number (more than one) of persons or entities between the referring physician (or immediate family member) and the entity furnishing DHS, *and*
 - b. The entity providing DHS has actual knowledge or acts in deliberate ignorance that the referring physician (or family member) has such an interest.

- i) In Stark II Phase II CMS clarified that the entity need not know the precise composition of the chain or the specific terms of the investments in the chain, for an indirect ownership interest to exist.

3. Definition of *indirect compensation arrangement* has three elements:

- a. There must exist between the referring physician and the entity providing DHS an unbroken chain of persons or entities that have financial relationships between them (that is, each link in the chain has either an ownership or investment interest or compensation arrangement with the preceding link).
- b. The aggregate compensation received by the referring physician from the person or entity in the chain with which the physician has a direct financial relationship varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.
 - i) If the financial arrangement between the physician and the person or entity in the chain with which the physician has the direct financial relationship is an ownership or investment interest, the government will look to the relationship between the owned entity and the next person or entity in the chain with which the owned entity has a direct financial relationship until it reaches a compensation arrangement with a non-owned entity (i.e., the government looks for the first compensation relationship in the unbroken chain of financial relationships).
 - ii) Any “per-service” or “per-use” payment arrangement between the owned entity and the entity furnishing the DHS that is based, in whole or in part, on the referrals or other business generated by the referring physician for the entity furnishing DHS would be considered to be based on the volume or value.
 - Stark exceptions containing a requirement that compensation not take into account “the volume or value of referrals” permit time-based or unit-of-service payments (i.e., per-use payments) so long as the payment per unit is at fair market value and does not vary over the term of the agreement.
 - For purposes of determining whether a compensation arrangement is indirect, if the total compensation varies or reflects the number or value

of referrals or other business generated by the physician, the second element of the definition of the indirect compensation arrangement would be met.

- c. The entity furnishing DHS must have actual knowledge that the aggregate compensation received by the referring physician from the entity with which the physician has a financial relationship varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS, or has acted in reckless disregard or deliberate ignorance of the existence of such relationship.

C. Indirect Compensation Exception

1. The indirect compensation arrangement exception has three requirements:

- a. Compensation received by the referring physician from the person or entity in the chain with which the referring physician has the direct financial relationship is fair market value for the items or services provided under the arrangement and does not take into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS.
- b. The compensation arrangement between the referring physician and the person or entity in the chain with which the physician has the direct financial relationship is set out in writing, signed by the parties, and specifies the services covered by the arrangement.
- c. The compensation arrangement does not violate the anti-kickback statute or any laws or regulations governing billing or claims submission.

2. When the financial relationship between a physician and a person or entity with whom the physician has a direct financial relationship is an ownership or investment interest, the requirements of the exception are applied to the first compensation arrangement in the chain of relationships between the physician and entity furnishing DHS.

3. Unlike the definition of indirect compensation arrangement, the indirect exception incorporates the special rule on compensation that deems per service payments not to be based on the volume or value of referrals.

D. Physician Stand in the Shoes (SITS)

1. Basic Rule for Physician SITS

In 2007 and 2008, CMS created considerable confusion by promulgating a series of proposed and final regulations defining the circumstances under which a physician would be deemed to “stand in the shoes” of his or her physician organization. When a physician stands in the shoes of his/her organization, it has the effect of transforming indirect financial relationship in direct financial relationship. In the 2009 IPPS Final Rule, CMS put the issue to rest by amending the Stark compensation arrangement provisions to provide that effective October 1, 2008, a physician is deemed to stand in the shoes of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS when:

- the only intervening entity between the physician and the DHS entity is his or her physician organization, and
- the physician has an ownership or investment interest in the physician organization.

42 C.F.R. §411.354(c)(1)(ii)(A) & (B).

Similarly, CMS amended the definition of an indirect compensation arrangement to provide that, for the purpose of analyzing an unbroken chain of financial relationships, a physician is deemed to stand in the shoes of his or her physician organization if the physician has an ownership interest in the physician organization. 42 C.F.R. §411.354(c)(2)(iv)(A).

The SITS rules also incorporate the following exceptions:

- **AMCs.** The physician SITS rule does not apply to an arrangement that satisfies the AMC exception requirements under §411.355(e). This exception applies even if a faculty practice plan within an AMC includes physician owners or investors whose interests are not titular.
- **Titular Ownership.** Physicians who may technically be considered owners (titular owners) but who do not have the ability or right to receive the financial benefits of ownership, such as the distribution of profits, dividends, proceeds of sale, or similar returns on investment—are not required to stand in the shoes of their physician organizations.

This titular interest exception to the SITS rule addresses “captive” professional corporations formed in states with corporate practice of medicine prohibitions. Such organizations may have nominal physician ownership for purposes of control and decision-making, but do not provide profits or economic distributions based upon ownership.

II. THE FEDERAL ANTI-KICKBACK STATUTE

A. The Prohibition

The federal anti-kickback statute prohibits the knowing and willful solicitation, offer, payment or acceptance of any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind: (1) for referring an individual for a service or item covered by a federal health care program or (2) for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, service, or item reimbursable under a federal health care program. 42 U.S.C. § 1320a-7b(b). The statute applies only to remuneration offered or paid to influence the referral of items or services to be paid for by a “federal health care program,”² which includes Medicare, Medicaid and Tricare. “Remuneration” under the statute has been defined broadly to include virtually anything of value. Violations of the statute are punishable as a felony with a maximum fine of \$25,000 and five years imprisonment. Violation of the anti-kickback statute is also grounds for substantial civil monetary penalties and/or exclusion from the Medicare program.³

B. Intent

The courts have struggled to define the correct standard for intent under the anti-kickback statute. The statute itself requires that payments be made “knowingly and willfully.” There are two important issues here. The first is to what extent payments must be intended to induce referrals. Some courts have adopted a “primary purpose” test or an even more restrictive “one purpose” test. If either the “primary purpose” or “one purpose” of a payment is to induce an illegal referral, the payment is criminal, even if the payment was also made for legitimate purposes. *See United States v. Katz*, 871 F.2d 105 (9th Cir. 1989); *United States v. Bay State Ambulance & Hospital Rental Service, Inc.*, 874 F.2d 20, 29-30 (1st Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.), *cert. denied* 474 U.S. 988 (1985). The Ninth Circuit, which includes much of the West coast, has adopted the “one purpose” test. The second issue is whether the anti-kickback statute requires a specific intent to violate the law. Again the case law is mixed. In the Ninth Circuit, to violate the anti-kickback statute, the defendants must have (1) knowledge that the statute prohibits offering or paying remuneration to induce referrals, and (2) entered into the arrangement with the specific intent to violate the law. *See Hanlester Network v. Shalala*, 51 F.3d 1390, 400 (9th Cir. 1995). Other courts have adopted intent standards that are less stringent and the government has repeatedly objected to the Ninth Circuit’s position.

² Thus, the definition of a federal health care program delineates the parameters of the anti-kickback statute. A federal health care program is: (1) any plan or program that provides health benefits which is funded directly, in whole or in part, by the United States government (other than federal employees health insurance benefit programs) or (2) any state health care program funded in whole or in part by the federal government. 42 USC 1320-7b(h).

³ It is not clear to what extent a violation of the anti-kickback statute could provide a basis for liability under the Federal False Claims Act (“FCA”). *See United States ex. rel. Thompson vs. Columbia/HCA Healthcare Corporation*, 125 F.3d 899 (5th Cir. 1997). Several FCA claims premised on anti-kickback violations have been filed.

C. Exceptions and Safe Harbors

1. The Employment Exception and Safe Harbor

The anti-kickback statute includes a statutory exception for payments made to bona fide employees. 42 U.S.C. § 1320a-7b(b)(3)(B). The language of the statutory exception is broad but the OIG suggested that there are limits on how it should be applied.

The Medicare and Medicaid Patient and Program Protection Act of 1987 authorized the government to promulgate “safe harbor” regulations that specify arrangements that do not violate the anti-kickback statute. Compliance with the safe harbors is optional. On the one hand, strict compliance with a safe harbor provides comfort that an arrangement does not violate the law. On the other hand, failure to fit within a safe harbor does not mean that an arrangement is illegal. On the contrary, failure to fit within a safe harbor merely means that all facts and circumstances must be reviewed to determine whether the parties had the requisite intent to violate the anti-kickback statute. The parties’ intent to comply with a safe harbor can be relevant to showing that they did not intend to violate the law. *See* 64 Fed. Reg. 63,518, 63,521 (Nov. 19, 1999).

The U.S. Department of Health and Human Services (DHHS) has promulgated a number of safe harbors, including one for bona fide employees. 42 C.F.R. § 1001.952(i). More specifically, the safe harbor regulations specify that the term “remuneration” as used in the anti-kickback statute, does not include:

[A]ny amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs. For purposes of paragraph (i) of this section, the term employee has the same meaning as it does for purposes of 26 U.S.C. 3121(d)(2).

42 C.F.R. § 1001.952(i). In its commentary to the safe harbor regulations, the OIG has further clarified that this employee safe harbor does not apply to independent contractors. *See* 56 Fed. Reg. 35952. The OIG explains that the independent contractor relationship does not afford appropriate supervision and control, whereas the employer-employee relationship “is unlikely to be abusive, in part because the employer is generally fully liable for the actions of its employees and is therefore motivated to supervise and control them.” *See Id.* On the other hand, part-time employees paid on a commission –only basis will be included in the employee safe harbor, provided that a bona-fide employer-employee relationship is maintained. *See Id.* Recently, the OIG issued Advisory Opinion 09-02, concluding that a contract for the employment of a mental health practitioner entered into concurrently with a contract for the employer to purchase real estate from the employee satisfied the anti-kickback statutory employment exception and the employment safe harbor and, therefore, would not generate prohibited remuneration under the anti-kickback statute. The OIG based its decision on the employer’s certifications of the practitioner’s status as a bona fide employee and the terms of the compensation.

The OIG has suggested that the employment safe harbor will not protect payments to an employee in excess of fair market value. The theory is that to the extent compensation is above

fair market value the payments are not in exchange for the legitimate services provided by the employee and, therefore, not protected. Some critics have rejected the OIG's position, noting that the agency does not have the power to narrow the statutory employment exception through its interpretation of the employment safe harbor.

2. Group Practice Safe Harbor

The OIG has also created a safe harbor for investments in group practices. This safe harbor protects physicians' investments in their own practices, provided that the practice meets the definition of a group practice under the Stark Law. Additionally, this safe harbor applies to investments in solo practices where the practice is conducted through the solo practitioner's professional corporation or other separate legal entity. The safe harbor does not, however, extend to investments by group practices or members of group practices in ancillary services joint ventures. It is possible, however, that such joint ventures may qualify for protection under other anti-kickback safe harbors.