

Outpatient therapy clinics and their referring physicians: Fraud and abuse risks

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In the November 2007 issue of *Compliance Today*, in an article titled, "Therapy provided "incident to": Developing a framework for compliance by identifying risk," Nancy J. Beckley aptly identified compliance risks for physicians who offer physical or occupational therapy in their offices, including risks under the Stark Law¹ and the Anti-kickback Statute.² The risks for the physician practice under these two laws are amplified when the physician practice has a compensation arrangement with a therapy clinic or its owner.³ To complicate matters, these parties may have more than one compensation arrangement with one another, further increasing the risks. This article explores the types of relationships that arise between physician practices and therapy clinics and the Stark and Anti-kickback risks implicated.

The development of compensation arrangements between the physician and therapist can be a very natural outgrowth of establishing a prior relationship with one another. The relationship may begin when the physician refers patients to the therapy clinic. If patient feedback to the physician is positive, the physician likely will refer more patients to the clinic with confidence that the therapy clinic will provide prompt, quality care for the patients. The therapy clinic, in turn, may further gain the physician's trust and confidence by keeping the

physician informed about the patient's care, or providing information about the clinic's expertise with certain therapy techniques.

The Medicare coverage rules ensure dependence of outpatient therapy clinics on physician involvement for their continued existence and profitability. Medicare and most third-party payers will not cover physical therapy unless a physician orders the therapy and certifies continued therapy every 30 days. Because of this dependent relationship, it behooves the clinic to ensure that it maintains a good relationship with referring physicians.

Good relationships can lead to compensation arrangements. Types of compensation arrangements that may arise after establishing an initial physician referral relationship might include a consulting or medical director agreement, a lease agreement, or even a management agreement for a therapy program in the physician's office. Each one of these relationships must comply with the Stark Law and the Anti-kickback Statute.

Stark Law

The Stark Law generally prohibits referrals for certain designated health services (DHS) by a physician to an entity with whom the physician has a "financial relationship." Stark specifically includes physical therapy (PT) and occupational therapy (OT) services on the list of DHS. Physician groups and therapy clinics should not bill for any services provided to a patient referred by either party to the other, where the parties have a compensation ar-

angement in addition to a referral relationship, unless the compensation arrangement complies with the Stark Law.

Stark carves out some compensation arrangements that do not pose a substantial risk of fraud and abuse. These carve-outs are called "exceptions." The exceptions protect certain compensation arrangements from violating the law, but only if the arrangement meets every requirement of an exception. To violate Stark does not require any "intent" – rather, Stark is a strict liability law.

Anti-kickback Statute

The Anti-kickback Statute makes it a criminal offense to intentionally offer, pay, solicit, or receive any remuneration, with a purpose of inducing or rewarding referrals of items or services reimbursable by a federal health care program. The Act is violated when an entity pays remuneration to a referring physician, *knowingly and willfully*, to induce or reward referrals of items or services payable by Medicare or Medicaid. For purposes of the Anti-kickback Statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. By its terms, the statute attributes criminal liability to parties on both sides of an impermissible "kickback" transaction.

Similar to Stark, the Anti-kickback Statute sets forth "safe harbors" for relationships that are deemed not to pose a substantial risk of fraud and abuse. Failure to meet every element of a safe harbor alone will not mean the relationship violates the statute, but the relationship remains "suspect." Unlike Stark, the Anti-kickback Statute is not one of strict liability because it requires intent.

Stark vs. Anti-kickback. The fact that a relationship meets a Stark exception does not

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automatically protect it against a finding that it complies with the Anti-kickback Statute, and vice versa. So, it is important to ensure arrangements comply with both laws. The Stark Law and the Anti-kickback Statute are different in other ways besides the element of intent. Importantly, the Anti-kickback Statute is a criminal liability law that includes prison sentences and fines. Stark is a civil statute that prescribes civil monetary penalties and fines for violations.

Leases

Lease arrangements invoking the Stark Law and Anti-kickback Statute arise when a referring physician (or that physician's practice group) leases space to a therapy clinic. These laws are also invoked when the therapy clinic leases space to a referring physician or the physician's practice group. For purposes of Stark, such arrangements constitute either direct or indirect compensation, depending on the facts. For purposes of the Anti-kickback Statute, such arrangements would involve remuneration "in cash or in kind."

The applicable Stark exception would be the "lease of space and equipment" exception. A space lease will receive protection under Stark only if each of the following six criteria is met:

1. The lease must be in writing, signed by the parties, and specify the premises and any equipment that it covers.

Here, parties must ensure that the lease agreement names, and is signed by, *all* physicians who have a financial interest in the property being leased and who are referring patients to the therapy clinic. In specifying the premises, the agreement should state the address, square footage and, preferably, attach a space plan.

2. The rented space or equipment must not exceed that which is reasonable and necessary for the legitimate purposes of the lease and must be used exclusively by the

lessee when being used by the lessee (and in the case of space rental, the lessee may pay for its use of common areas based on its pro rata share of these areas).

The requirement that the lease not exceed what is reasonable and necessary reduces the risks of abuse. For example, if a referring physician leases space to a therapy clinic in excess of the amount needed and collects rental on all of the space, this may be seen as a reward or further inducement to the referring physicians to continue the referrals. The resulting abuse to the government program occurs when, due to such induced referrals, services that are not medically necessary result in overutilization of government funded services.

3. The lease must be for a term of at least one year.

A month-to-month lease would not meet this requirement. If the lease agreement is terminated before the end of a year, the parties may not enter into a new agreement before the expiration of the original lease. A six-month holdover at the end of a term of at least a year is permissible if its terms are identical to those of the base agreement.

4. The rental charges over the term of the lease must be set in advance and must be consistent with fair market value (FMV).

To meet this requirement, it is advisable that the parties obtain a FMV assessment of the space to be leased. Additionally, the lease must specify the actual rent or the method by which the parties will calculate the rent. Merely stating in the lease that the rent shall be FMV, without specifying the method or amount, places the parties at risk of failing to meet this requirement. In addition, this requirement also makes it essential to determine the square footage being leased, or the equivalent, in order to demonstrate FMV. If a referring physician is using space within the therapy clinic to see patients on certain days of the week, then the

agreement should specify precisely what space is being used and determine the physician's pro rata share of the total space in the clinic. (See Sample Sublease in box.)

Sample Sublease to Physician

A written sublease of space in a therapy clinic specifies the following space is being leased: "The Lessee [the physician] shall have exclusive use of one private office (100 sq. ft.), two exam rooms (100 sq. ft. each) and a filing and x-ray viewing area (50 sq. ft.) while he is present at the clinic. In addition, Lessee shall share the Lessor's [therapy clinic's] foyer (50 sq. ft.), a common reception area (200 sq. ft.), and a common hallway leading to Lessee's office and exam rooms (200 sq. ft.). To the extent physician needs staff, the physician shall provide such staff (Physician Staff) who shall be present only during the hours set forth in this Agreement. Physician Staff shall utilize two work stations in the Lessor's business office area for the purpose of registering and managing the financial matters of Lessee's patients. The Physician shall use the designated space on Tuesdays and Thursdays from 8:00 a.m. to 2:00 p.m." (An exhibit to the Agreement shows total clinic space of 5,000 sq. ft.)

Note that the sublease specifies which space is being used exclusively by the physician and which space is part of a common area. It also is advisable to attach an exhibit to the sublease that shows how the parties allocated the square footage of the physician's space compared with the total square footage in each area and compared with the total square footage of the clinic. The exhibit should reflect the total square footage calculated and ultimately allocated to the physician, which should be used to determine the FMV of the rental payments.

5. The rental charges cannot take into account the volume or value of referrals or other business generated between the parties.

For example, if the therapy clinic established a rental amount by using a formula that adjusts that amount based on the number of patient referrals from the physician, the lease agreement would not meet this requirement.

6. The lease must be commercially reasonable, even if no referrals were made between the parties.

For example, if a therapy clinic rents space from a physician group for the purposes of providing PT and OT services and the *only* patients treated by the therapy clinic are Medicare and Medicaid patients referred by the physician group, the lease is not likely to be seen as “commercially reasonable.” This is because the therapy clinic would have no business if you take away the referrals.

With the exception of Stark’s requirement for “commercial reasonableness,” the elements of the Anti-kickback Statute’s safe harbor for space and equipment leases are essentially the same as the Stark requirements above. Even though there is not room in this article to address each of the Anti-kickback’s safe harbor requirements, it is vital to analyze the proposed lease under Anti-kickback rules before it is executed.

Medical director agreements

Therapy clinics often retain the services of a referring physician to act as medical director who will review the clinic’s services for quality-of-care issues, help develop standard-of-care policies, and otherwise consult with the clinic’s therapists regarding application of new therapy techniques. A clinic that is enrolled in Medicare as a Part A rehabilitation agency may want to engage a medical director to help ensure that the clinic is meeting Medicare’s conditions of participation.⁴

Obtaining such direction from a referring physician usually involves a “compensation arrangement” that triggers Stark Law scrutiny and remuneration “in cash or in kind” and that triggers Anti-kickback Statute scrutiny. The most applicable Stark exception would be the “personal services arrangements” exception, and the most applicable Anti-kickback safe harbor would be the “personal services and management contracts” safe harbor. The requirements of the exception and the safe harbor are very similar, except for a nuance regarding compensation noted below.

To comply with Stark, the arrangement must meet each one of the following six requirements:

1. Be in writing, be signed by the parties to the agreement, and specify the services covered by the agreement.

For medical director agreements with a medical group, the therapy clinic should ensure that all doctors who have or may refer services to the clinic are named as parties to the agreement and sign it.

2. Cover all of the services to be furnished by the physician (or an immediate family member) to the therapy clinic.

This condition requires either a cross-reference in the agreement to other compensation arrangements or maintenance of a master list by the parties of such other arrangements. This can be done by including an exhibit to the agreement that lists all compensation arrangements that the therapy clinic has with the physician (or an immediate family member). One risk is that the parties may fail to list another compensation arrangement, because they simply were not aware of it. For example, the therapy clinic could have a lease with ABC Realty, LLC for its clinic space. Because many physicians are owners or investors in buildings used for medical services, the parties should determine whether one or more owners of ABC Realty, LLC in-

cludes a referring physician. (To reduce the risk of the unknown, before entering any space lease agreement, the parties should fully disclose all owners of the space.)

3. The aggregate services must not exceed those that are reasonable and necessary for the legitimate purposes of the arrangement.

Types of services that would certainly be reasonable and necessary for a therapy clinic would include assisting in ensuring the quality of the therapy services being provided. The medical director could participate in reviewing patient charts, plans of care, the progress of treatment and the patient’s compliance with treatment. The medical director could review policies and procedures related to the delivery of care at the clinic and provide clinical education on topics germane to the practice at the clinic. Allowing the medical director to advertise or promote his medical services to patients of the therapy clinic, however, would not be deemed reasonable and necessary to the legitimate purposes of the arrangement.

4. The term must be at least one year.

Again, if terminated during the initial year, the parties may not enter into the same or substantially the same arrangement before the end of the initial term.

5. The compensation must be determined in advance, not exceed FMV, and not be determined by the volume or value of any referrals or other business generated between the parties.

As with rental payments discussed earlier, the compensation should be documented in a way that can be objectively and readily ascertained from the face of the agreement. The parties should specify the aggregate compensation, or a time-based or per unit of service-based amount, or a specific formula

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for calculating the compensation in a way that can be objectively verified to be in line with FMV. FMV assessments often require the expertise of an appraiser with experience in valuing physician compensation arrangements, so it is advisable to consult with one.⁵ If the therapy clinic has subleased space to the medical director, as in the example discussed above, make certain that the invoiced services do not include dates and times when the physician was providing services in his own practice in the subleased clinic space.

The Anti-Kickback safe harbor differs from the Stark exception in that the safe harbor requires that the “aggregate” compensation paid over the term of the agreement be set in advance. The safe harbor further requires that the agreement specify an exact schedule for services that are periodic, sporadic, or part-time, and that the precise length of time and exact charge for each interval be stated. If the medical director’s services are to be paid on an hourly basis, as many are, and invoiced monthly according to the hours worked to perform the services, the parties will not be able to “aggregate” or total these services, because the services have not even been provided yet! However, the inability to meet this safe harbor requirement does not mean that the agreement is illegal; rather, it’s simply not “safe.” Even if the parties decide to establish an annual compensation rate for the medical director’s services, it is advisable to require the medical director to document the services he has provided each month and to retain this documentation so that his or her services can be quantified in case of a future audit.

6. The services do not counsel or promote a business arrangement or other activity that violates any state or federal law, such as the federal Anti-kickback Statute.

For example, if the medical director agreement is designed to financially benefit the physician’s

existing practice by inducing and increasing referrals, there may be problems in paradise.

Management agreements

We have covered personal services from the referring physician to the therapy clinic. What about services from the therapy clinic to the referring physician? The Stark and Anti-Kickback laws have implications for a therapy company that provides therapy program management services in the office of the physician. This is an area where the Stark and Anti-kickback laws part ways in terms of the elements that must be present to be protected or “safe.” The applicable Stark exception is the “in-office ancillary services” exception. Under Stark, designated health services, such as PT and OT, must be furnished “personally” by the physician in the physician’s offices or a “centralized building” used by the “group practice” for the provision of some or all of the practice’s DHS services. The applicable Anti-kickback safe harbor is the “personal services and management contracts” safe harbor, the same safe harbor (discussed above) applicable to medical director agreements.

Several basic terms should be considered when formulating the therapy services management agreement between the therapy clinic and the physician practice. Getting the terms right could make the road smoother for both parties and defend the legality of the arrangement. Note: These pointers should not be viewed as a recitation of specific Stark Law and Anti-kickback Statute requirements, but rather, for the sake of brevity only, are intended to reduce the most salient requirements of the complex in-office ancillary services exception into contract terms. These contract term pointers are as follows:

1. Require claims be filed under the Medicare provider number of the physician practice (not the therapy clinic);
2. Require the physician practice to retain

the exclusive authority and ultimate responsibility over the billing and collection of services provided in the therapy program, including repayment of any overpayments by Medicare, Medicaid, and other third-party payers;⁶

3. Set the aggregate compensation for the therapy company’s management services in advance;
4. Require the physician practice to retain ownership and exclusive control over the therapy program;
5. Require that the physician practice ensure therapy staff are properly licensed and compliant with HIPAA;⁷
6. Require the physician practice to assume the duty and responsibility of ensuring continuing compliance with Stark, particularly the “in-office ancillary services” exception, including:
 - a. That the physician practice constitutes a “group practice”;
 - b. That a physician who is a member of the physician practice directly supervises the individuals who provide services as part of the therapy program and otherwise meets all applicable Medicare payment and coverage rules (i.e., “incident to”);
 - c. That the physician practice will ensure that the therapy services are provided in a building that meets the Stark Law exception’s “centralized building” requirement.

Why place the onus of Stark compliance on the physician practice? Because if this arrangement is to go forward, the physician must comply with Stark’s “in-office ancillary services” exception; and this is an exception with elements over which the therapy practice may have little or no control. Why not go for another, less onerous exception under Stark? Because the Stark Law requires that compensation

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arrangements comply with the most applicable exception and, in the majority of situations, this is the most applicable exception. The personal services exception that applied to medical director services does not apply to the therapy management services because, among other reasons, the remuneration under this arrangement is running from the physician practice to the therapy clinic rather than vice versa, as was the case with the medical director agreement above. It would be nice if we could apply a less complex exception, if only to make the analysis easier – but Stark is neither nice nor easy.

In structuring the management services arrangement, keep in mind that this is a situation where the physician group desires to provide ancillary services for which it can be reimbursed. As a result, instead of referring patients to a third-party DHS entity, the physicians in this arrangement are referring patients to themselves, (i.e., the true essence of “self-referrals”). The therapy clinic is being engaged to manage those services in exchange for a pre-established fee. Even though the greatest risk under Stark would appear to be with the physician practice, because of the prohibition on physician self-referrals billed to Medicare that do not fit within a Stark exception, Stark imposes liability on both parties to a prohibited self-referral arrangement. Accordingly, the therapy clinic cannot rest easy simply by placing the onus on the physician practice to ensure Stark compliance.

A final caution

On September 5, 2007, the Centers for Medicare and Medicaid Services (CMS) released the Stark II Phase III regulations,⁸ effective November 5, 2007.⁹ Contracts that were in compliance with Stark as of September 5, 2007, were grandfathered in, until the date of their expiration or renewal. Otherwise, financial arrangements with physicians should have been in compliance with the new

regulations as of November 5, 2007.

Of particular relevance to the scope of this article is Stark’s revised “direct compensation” definition that now utilizes a “stand in the shoes” test. In essence, physicians who are members, employees, or independent contractors of a physician organization now stand in the shoes of their physician organization. As a result, each individual physician of that organization is now deemed to have the same compensation arrangement with other DHS entities that their physician organization has.

Accordingly, existing compensation arrangements between therapy clinics and physician practices should be immediately reviewed to ensure they comply in light of the new rules. For example, if the therapy clinic had a compensation arrangement with a physician organization as a whole, that arrangement is now with every physician individually. To bring such an agreement into compliance, the parties should ensure that all individual physicians who refer (or are likely to refer) patients to the therapy clinic are named as parties to, and have signed, the medical director agreement.

- 1 Ethics in Patient Referrals Act, colloquially known as “Stark,” 42 U.S.C. §1395nn.
- 2 Anti-kickback Statute, 42 U.S.C. § 1320a-7b.
- 3 Under Medicare, outpatient therapy can be provided in one of two forms: Rehabilitation Agency under Part A or Physical or Occupational Therapy Group (or Individual) in Private Practice under Part B. For convenience, I use “Therapy Clinic” to refer to both forms.
- 4 Conditions of Participation for Outpatient Rehabilitation Agencies can be found at 42 CFR 485.701 et. seq.
- 5 The Stark II Phase III regulations released on September 5, 2007, eliminated the FMV “exception” in the prior Stark II Phase II regulation that set forth two methodologies for determining the FMV of an hourly payment. Nevertheless, Phase III noted that it would still recommend using multiple, objective, independently published salary surveys to determine FMV of the hourly rate.
- 6 The therapy program manager could, however, agree to act as the billing agent of the physician under the number assigned to the physician or physician practice.
- 7 Whether the physician practice can actually employ the therapist may be controlled by state law. In South Carolina, a physical therapist is statutorily prohibited from working as an employee of a physician who refers patients to the physical therapist. See *Sloan v. S.C. Bd. of Physical Therapy Exams*, 370 S.C. 452 (S.C. 2006). The Delaware Attorney General similarly interpreted the Delaware State Physical Therapy Practice Act. See AG 02-1B25 (10/10/02).
- 8 42 CFR Parts 411 and 424, published in the Fed. Reg., Vol. 72 No. 171, Wednesday, September 5, 2007.
- 9 Although CMS suspended the effective date of the revised direct compensation definition for certain providers, such suspension does not include outpatient therapy clinics.

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