

The Stark Reality About Shared Nuclear Medicine Imaging Equipment Leasing Arrangements After January 1, 2007

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INTRODUCTION

Are you currently involved in, or contemplating entering into, a shared equipment leasing arrangement for nuclear medicine imaging equipment? Although such arrangements have for many years been required to comply with the federal antikickback law, effective January 1, 2007, nuclear medicine imaging equipment arrangements will also be required to comply with the requirements of the federal physician self-referral law (commonly referred to as the Stark law). Therefore, serious consideration must be given to whether these types of arrangements should be entered into and, if already in existence, whether such arrangements will need to be restructured before January 1, 2007, when nuclear medicine and positron emission tomographic (PET) scans will officially be considered "designated health services" (DHS) for purposes of the Stark law.¹

Although compliance with both the Stark and antikickback laws has long been required for the leasing of other diagnostic imaging equipment, such as magnetic resonance imaging (MRI) scanners, computed tomographic (CT) scanners, and ultrasound equipment, the in-

clusion of nuclear medicine systems and PET scanners as DHS for the purposes of the Stark law will have a significant impact on existing and contemplated arrangements for such equipment. For example, physician practices leasing nuclear medicine systems and PET scanners must have offices in the same buildings in which the leased equipment is located. Additionally, if the leasing physicians are otherwise referral sources to the physician practices from which the equipment is leased, the arrangements must be structured to avoid the "suspect" characteristics of contractual joint ventures, as articulated by the US Department of Health and Human Services Office of Inspector General (OIG).

This column addresses some of the key legal issues as they relate to a case study involving a shared lease arrangement between a radiology practice and an orthopedics practice for the use of a PET scanner. We note that although the application of the Stark law to the case study does not apply until January 1, 2007, any contemplated nuclear imaging arrangements should be structured to comply with the Stark law in light of the impending applicability of the statute.

CASE STUDY

Universal Radiology is a radiology practice that owns certain diagnostic imaging equipment (eg, a CT scanner, an MRI scanner, nuclear

medicine systems, PET scanners, ultrasound equipment). Central Orthopedics, an orthopedic practice, has approached Universal Radiology to lease its PET scanner during certain hours when it is not otherwise being used. Central Orthopedics also wishes to lease (1) the office space in which the PET scanner is located and (2) Universal Radiology's technicians to administer the scans. Central Orthopedics will furnish the PET scans to its own patients and will bill for such services under its own billing number.²

APPLICATION OF THE LEGAL REQUIREMENTS TO THE CASE STUDY

Can Universal Radiology enter into these lease arrangements with Central Orthopedics without violating the Stark or antikickback laws?³ As

² We note that the discussion of the applicability of the Stark and antikickback laws applies not only in leasing arrangements but also in ownership arrangements. We further note that although this case study is limited to the use of a leased PET scanner, the Stark and antikickback laws may also be implicated if Central Orthopedics refers patients to Universal Radiology for other diagnostic imaging procedures, such as MRIs, CT scans, or ultrasounds, and therefore, such referrals must independently satisfy the Stark law exceptions or the antikickback safe harbors. An analysis of these situations, however, is beyond the scope of this column.

³ We note that state laws also govern these types of arrangements but are outside of the scope of this column. To the extent that you are involved in the type of arrangements discussed in this article, you should seek advice from your local counsel as to the implications of your state's laws.

¹ In light of the 9% increase in the utilization of nuclear medicine and PET scans between 1993 and 2004, Congress added nuclear medicine and PET scans to the list of DHS because of its concern that physicians investing in imaging centers may be ordering unnecessary scans to enhance their own reimbursement.

discussed below, the answer depends on how the arrangement is structured.

The Stark Law

The Stark law generally prohibits a physician from making referrals to an entity for the furnishing of certain DHS reimbursable by Medicare if the physician (or an immediate family member of the physician) has a direct or indirect financial relationship with that entity, unless an exception to the law is satisfied [1]. If the referral is prohibited, so too is the submission of a claim for payment by the entity that receives the prohibited referral. These prohibitions extend to referrals made to outside physician practices as well as to physicians within the same practice. The penalties for violating the Stark law include (1) the denial or the required refund of any payments for services that resulted from an unlawful referral, (2) civil monetary penalties, and (3) exclusion from federal health care programs.

Under the Stark law, there are many different categories of DHS, including, but not limited to, certain radiology services, such as MRIs, CT scans, and ultrasound services, as well as nuclear medicine and PET scans as of January 1, 2007 [2]. Given that these radiology services qualify as DHS under the Stark law, a prohibited referral may occur if a physician from Central Orthopedics refers a Medicare patient for one of these radiology services to either (1) Universal Radiology or (2) another physician who is a member of Central Orthopedics. Because there exists a financial relationship between the referring physician and Universal Radiology (created by the shared equipment lease arrangement) or another physician within Central Orthopedics (created by the com-

pensation arrangement between the physicians or the practice), and a referral has been made for DHS (the radiology services), the Stark law will be violated unless an exception is satisfied.

With respect to the case study, the most obvious reason for Universal Radiology and Central Orthopedics to enter into a lease arrangement for a PET scanner is to permit Central Orthopedics to perform and bill for the PET scans it orders on its own patients. This internal referral within Central Orthopedics will violate the Stark law when a scan is performed on a Medicare patient unless Central Orthopedics complies with the requirements of Stark's "in-office ancillary services" exception [3]. This exception is designed to allow physicians in a group practice to furnish DHS that are ancillary to the physicians' core medical practice as long as such services are provided in a location where the core medical services are routinely delivered [4]. To qualify for this exception, however, Central Orthopedics must meet numerous requirements, including the supervision, location, and billing requirements of the exception.

Although a detailed analysis of each of the requirements of the in-office ancillary services exception is outside of the scope of this column, one of its key requirements, as applied to the case study, is whether the PET scanner is located either in a "centralized location" or in the "same building" in which Central Orthopedics maintains an office. The arrangement between Universal Radiology and Central Orthopedics does not qualify for the centralized location requirement, because Central Orthopedics does not exclusively own or operate (on a 24/7 basis) the part of the building in which the PET scanner is lo-

cated. The space is owned by Universal Radiology and leased part-time by Central Orthopedics, leaving neither party with exclusive ownership of the space. Central Orthopedics may, however, satisfy the same building requirement, provided the practice has an office in the same building in which the PET scanner is located. There are 3 separate tests, any one of which may be met, to satisfy the same-building requirement [5]. For example, under one of these tests, Central Orthopedics would need to maintain an office (in the same building in which the PET scanner is located) that is normally open at least 8 hours a week, and a member of the group practice must regularly practice medicine and furnish services to patients (some of which must be unrelated to the use of the PET scanner) in the office at least 6 hours per week.

Assuming that the same building and all other requirements of the in-office ancillary services exception are satisfied, a shared equipment leasing arrangement is, as a threshold matter, at least a possibility under Stark. In addition, however, if Central Orthopedics makes other referrals to Universal Radiology, then other applicable Stark law exceptions must be met relating to all aspects of the financial relationship between the parties (ie, the actual leasing of the equipment, space, and personnel). The applicable Stark exceptions for each of these leasing arrangements require, for instance, that the lease be in writing, that the term be at least 1 year, and that the price be set in advance at fair market value in a manner that does not take into account the value or volume of any referrals between the parties.

If the Stark law requirements are not satisfied under either the in-office ancillary services exception,

with its same building requirement, or the other applicable exceptions, the shared leasing arrangement will violate the law. In such a case, both parties, Universal Radiology and Central Orthopedics, could be subject to sanctions and penalties.

The Antikickback Law

As if complying with the Stark law were not enough, physicians involved in shared equipment leasing arrangements must also comply with the federal antikickback law or fit within all applicable safe harbors. The antikickback law prohibits the offering, payment, solicitation, or receipt of any remuneration (including kickbacks, bribes, or rebates, whether in cash or in kind) in return for the referral of patients for the purchasing or leasing (or the ordering, recommending, or arranging) of items or services for which payment may be paid in whole or in part by “a federal healthcare program,” including Medicare and Medicaid [6]. Violation of this law is a criminal offense that could result in significant fines or imprisonment for both sides of an illegal kickback arrangement. In addition, substantial civil monetary penalties and administrative penalties, including exclusion from federal and state health care programs, may also result from violations of the antikickback law.

Applying the antikickback law to the facts of our case study, if Central Orthopedics is in a referral relationship with Universal Radiology, the leasing arrangement could potentially violate the antikickback law because the lease payments may constitute remuneration for the referrals. For example, if Central Orthopedics refers Medicare or Medicaid patients to Universal Radiology for other radiology services, such as CT scans or ultrasounds, the lease payments could constitute

remuneration and could be seen as potential kickbacks for such referrals if, for example, the payments were for less than fair market value. Therefore, to the extent that a referral relationship exists, the arrangement should be structured to satisfy all of the applicable antikickback safe harbors, which include those for space rentals, equipment rentals, and personal services and management contracts [7].

In general, these safe harbors require the same provisions as those required by the Stark law exceptions for equipment and space leases, as discussed above. The most important requirement, however, is that the prices paid for the space, equipment, and personnel must be set in advance and consistent with fair market value. These safe harbors serve to protect against the risk that the arrangement will be viewed by the OIG as a disguised kickback.

Assuming that all aspects of the arrangement in the case study comply with all of the requirements of the applicable antikickback safe harbors, there is still a risk that the OIG may nonetheless find the arrangement to violate the antikickback law because Central Orthopedics, the referral source, is being given the opportunity to bill for a service that could have otherwise been billed by Universal Radiology. The OIG has taken the position that the transfer of a revenue stream to a referral source constitutes remuneration in certain arrangements often referred to as “contractual” joint ventures.⁴

Of particular concern to the OIG are “turnkey” type arrangements, in which referring physicians (Central Orthopedics) expand into a new line of business

(PET scanning services) to service their existing patient population by contracting with an existing provider or potential competitor (Universal Radiology). This is particularly suspect to the OIG when the referring physicians contract out the entire operation (ie, space, equipment, and personnel) to their potential competitor in return for the ability to retain the profits from the radiology referrals they would otherwise be unable to retain. In this situation, the OIG may view Central Orthopedics as doing virtually nothing except profiting from the arrangement. Also of concern to the OIG is the fact that the referring physicians assume little or no risk when entering into this new line of business. This is highlighted by the fact that the referring physicians commit virtually nothing in the way of financial, capital, or human resources. Under the OIG’s rationale, paying a set rental fee does not constitute financial risk because the referring physicians can increase the amount of business they do (ie, referring more patients for PET scans) and thus obtain a windfall in return for their PET scan referrals.

In essence, the OIG views these types of arrangements as nothing more than a way for the provider of a Medicare service, such as Universal Radiology, to indirectly pay its referral source, Central Orthopedics, a share of the profits from Central Orthopedics’ PET scan referrals, something that clearly is impermissible under the antikickback law. In short, the OIG has stated that these types of “contractual” joint ventures may be problematic if structured in such a way that permits the parties to do indirectly what they cannot do directly (ie, paying for referrals).

Thus, if Central Orthopedics provides referrals to Universal Ra-

⁴ The OIG addressed the issue of contractual joint ventures in an April 2003 special advisory bulletin and Advisory Opinion 04-17.

diology for services reimbursable through federal health care programs, such as Medicare and Medicaid, precautions must be taken when structuring the leasing arrangement to avoid the concerns articulated by the OIG. This requires careful analysis of the factors the OIG considers suspect, including (1) whether Central Orthopedics is entering into a new line of business (ie, providing PET scanning services); (2) whether Central Orthopedics is assuming any real risk by contributing something to the venture other than referrals (ie, financial, capital, staff); (3) whether Universal Radiology, the would-be competitor, is providing or performing many or all of the day-to-day operations necessary for the new line of business (ie, by provid-

ing equipment, office space, and personnel); and (4) whether the PET scanning services permit Central Orthopedics to collect revenue for tests that otherwise would have been provided by Universal Radiology.

CONCLUSION

If you are considering entering into a shared equipment leasing arrangement for diagnostic imaging equipment, careful consideration must be taken to ensure that the arrangement complies with all applicable Stark law exceptions and antikickback safe harbors and is not structured in a way that the OIG could view as suspect. This is nothing new for physicians involved in the leasing or sharing of MRI equipment, CT scanners, and ul-

trasound equipment. However, for physicians currently involved in, or contemplating entering into, equipment leasing arrangements for nuclear medicine systems and PET scanners, this a new requirement that carries with it hefty fines for failing to comply.

REFERENCES

1. 42 USC § 1395nn.
2. 42 USC § 1395nn(h)(6); 42 CFR § 411.351.
3. 42 CFR § 411.355(b).
4. Stark II Phase I Regulations (Preamble), 66 Federal Register 856, 888 (Jan. 4, 2001) (Preamble to the Stark II Phase I Regulations).
5. 42 CFR § 411.355(b)(2). *See also* Stark II, Phase II Regulations (Preamble), 69 FR 16,054, 16,073 (Mar. 26, 2004).
6. 42 USC § 1320a-7b(b).
7. 42 CFR §§ 1001.952(b)-(d).

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