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Information published in the ***Special Alert*** is not intended to be, nor should it be considered, legal advice. Readers should consult an attorney to discuss specific situations in further detail.

Lynn Shapiro Snyder, Esq.
EDITOR

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Physicians Have Limited Time to Restructure or Divest Financial Interests in Nuclear Medicine Service and Supply Entities Before Stark Law Changes Take Effect in 2007

In 2005, the Centers for Medicare and Medicaid Services (CMS) issued a final rule that revised the Medicare Part B Fee Schedule for 2007. 70 Fed. Reg. 70330 (Nov. 21, 2005) (Final Rule). Among its revisions, the Final Rule expanded the scope of the physician self-referral provisions of Section 1877 of the Social Security Act, commonly known as the Stark Law, to include nuclear medicine services, including positron emission tomography (PET) scans. As a result of the modifications, effective on January 1, 2007, certain physician referrals for nuclear medicine may be prohibited unless the arrangements are restructured to meet an exception to the Stark Law or be terminated.

The Stark Law

Briefly, the Stark Law prohibits payment of Medicare (and to some extent Medicaid) claims submitted by a physician or on that physician's behalf if: (1) the physician has made a patient referral; (2) the patient referral was made to an entity for the purpose of furnishing a Designated Health Service as defined in the Stark Law and in CMS regulations; (3) the physician or a member of the physician's immediate family has a financial relationship with the entity to which the patient has been referred, which may be either an ownership interest or a compensation arrangement; and (4) the financial relationship does not fall into one of the exceptions set out in the Stark Law. If a patient referral is made by a physician to an entity for a Designated Health Service ("DHS") and that physician has a financial relationship with the entity receiving the patient referral and that the financial relationship is not permitted under the Stark Law, then a range of administrative sanctions are available to the Secretary.

The possible penalties under the Stark Law include (1) denial of payment and an obligation to refund payments made as a result of a tainted patient referral; (2) civil monetary penalties of up to $15,000 for each service that a person knows or should know violates the Stark Law; (3) civil monetary penalties of up to $100,000 for schemes to circumvent the Stark Law; (4) possible exclusion from the Medicare and Medicaid programs; (5) imposition of up to three times to amount for each item wrongfully claimed and/or (6) potential liability under the False Claims Act.

cont.

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The Final Rule Changes

Though radiology and radiation services have been treated as a DHS since the early 1990s, nuclear medicine was not among the list of Part B CPT/HCPCS codes that have historically been included in the list of DHS covered by the Stark Law. In the 2005 regulation, CMS changed its position based on several studies suggesting that a physician's referral patterns and use of nuclear medicine and services and supplies "closely correlates to whether the physician has a financial interest in the entity providing the service and supplies."[1] The modified definition of DHS that includes nuclear medicine will become effective January 1, 2007.

In the 2005 Final Rule, CMS expressly refused to grandfather existing financial relationships between physicians and nuclear medicine facilities based on its conclusion that grandfathering relationships would pose a risk of abuse. Despite the concerns raised by the American Medical Association, CMS also stated that the January 2007 deadline should provide sufficient time for divestment or restructuring. Additionally, CMS stated that it did not believe that patient care and beneficiary access would suffer under the new rule, reasoning that physicians could restructure many arrangements or sell their interests to a class of non-physician operators.[2]

Divest, Restructure or End Referrals

Prior to the January 1, 2007 deadline, physicians with an interest in a nuclear medicine entity can chose to (1) divest their interests; (2) restructure the business arrangement to meet a statutory exception to the Stark Law; or, (3) continue to maintain the interest and refer all of their patients to an entity in which the physician does not have a financial interest.

Physicians opting to divest their interest in nuclear medicine entities must do so by December 31, 2006, and ensure that the sale satisfies an applicable Stark Law exception, such as the isolated transaction exception.[3]

Alternatively, physicians who want to maintain their interest in nuclear medicine service and supply entities can opt to restructure the arrangement to meet the in-office ancillary service exception. In general, the in-office ancillary service exception allows a solo practitioner or a physician in a group practice to *internally* refer patients for diagnostic and treatment services that are ancillary, or integral, to the medical services customarily provided by the practice. Although a detailed analysis of the complex in-office ancillary exception is beyond the scope of this Special Alert, arrangements must meet a number of tests to comply with the Stark in-office ancillary service exception:

- **Performance:** the DHS must be furnished by the referring physician, a member of his group, or an individual who is supervised by a physician in the group;

[1] *See* Proposed Rule 70 Fed Reg. at 70286 (2005).

[2] *See* 70 Fed. Reg. at 70287.

[3] Briefly, the isolated transaction exception is met if the amount of remuneration under the sale is: (1) for fair market value; (2) does not take into account value or volume of referrals; and (3) the remuneration agreement itself is commercially reasonable. In addition CMS prohibits the parties from entering into a similar transaction for 6 months. *See* 42 C.F.R. 411.357.

cont.

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- **Location**: the DHS must be furnished to patients (1) in a central building that functions to house the medical group's ancillary services (*centralized building test*) or (2) in the same building where referring physician's provide their services (*same building test*);
- **Billing:** the DHS must be billed by one of the following (1) the physician providing or supervising the DHS; (2) the group practice in which the physician providing the DHS is a member -or- the group practice if the supervising physician is physician in the group practice; or (3) an entity that is wholly owned by the performing or supervising physician or group practice; -or- (4) a billing company functioning solely as an agent the performing or supervising physician or by the physician's group practice.

Significantly, freestanding joint ventures in which the nuclear medicine services are furnished in a location that is not in the same building will find it difficult to satisfy the in-office ancilliary services exception.[4] The geographic, structural, and compensation requirements under the in-office ancillary service exception and group practice definition will require the joint venture partners to potentially merge their medical practices. Consequently, significant restructuring would be required.

Another significant exception that may apply is a joint venture located in certain rural areas. The rural provider exception permits physicians to have an ownership and investment interest in an entity that furnishes at least 75% of its DHS to residents of a rural area without violating the Stark Law. In the preamble to the Final Rule, CMS discussed the availability of the rural provider exception to support its assertion that the January 1, 2007 changes would not affect beneficiary access in non-urban areas.

Finally, physicians have the option to maintain their financial interests in nuclear medicine entities without qualifying for a Stark Law exception as long as they do not self-refer Medicare patients to the entity. The Stark Law prohibits a physician who has a direct or indirect financial relationship with an entity from referring Medicare patients for DHS to that entity. However, the Stark Law does not prohibit ownership in an entity to which the physician does not refer any patients. For example, a physician may continue to lawfully own an entity that furnishes PET scans as long as the physician (or the physician's group) does not refer patients to that entity.

If they have not already done so, physicians who have a financial interest in an entity that furnishes nuclear medicine services or supplies must consider their options prior to the January 1, 2007 effective date.

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If you would like additional information regarding this topic, please contact Jason Christ at 202/861-1828 or jchrist@ebglaw or Robert E. Wanerman at 202/861-1885 or rwanerman@ebglaw.com in the firm's Washington, DC office or the Epstein Becker & Green attorney who regularly handles your legal matters. For further information about Epstein Becker & Green's Health Care & Life Sciences Practice, or to see back issues of Special Alerts, please visit our website at www.ebglaw.com.

[4] The Stark Law regulations define a "group," as a single legal entity composed of at least two non-contractual physicians formed for the primary purpose of being a medical practice that meets a number of billing, compensation, and range of care requirements. Additionally, the group must be sufficiently unified, meaning that it has: a centralized decision-making body which maintains control over the group practice's assets and liabilities; consolidated billing, accounting and financial reporting; and, centralized utilization review.

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Amy Simmons
Marketing & Recruitment Manager
Health Care & Life Sciences Practice
Epstein Becker & Green, P.C.
1227 25th St., NW, Suite 700
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