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Client Alert

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CMS Publishes Final Rule Making Stark Law Applicable to Nuclear Medicine

In a final rule published in the November 21, 2005 Federal Register, the Centers for Medicare & Medicaid Services ("CMS") expanded the reach of the Stark Law to cover diagnostic and therapeutic nuclear medicine services. The following article explores the impact of this new development and examines the choices available to practitioners who now may need to restructure their investments before the rule takes effect on January 1, 2007.

Stark Law Generally

Unless an exception applies, the Stark Law prohibits a physician from referring Medicare and Medicaid patients to an entity for "designated health services" ("DHS"), which are categories of items and services enumerated in the statute, if the physician has a financial relationship with the entity. A physician has a financial relationship with a health care provider if the physician has either an "ownership or an investment interest" in the provider, or if the physician has a "compensation arrangement" with the provider, including any arrangement involving any kind of remuneration, "directly, indirectly...in cash or in kind." The Stark Law also prohibits an entity from submitting claims to Medicare or billing the beneficiary or any other entity for items or services that are furnished as a result of a prohibited referral.

Penalties for violating the Stark Law include fines of up to $15,000 for each prohibited service, and exclusion from participation in the Medicare and Medicaid programs. In addition, violation of the Stark Law can serve as a predicate for a violation of the False Claims Act which allows private parties to bring actions under the qui tam provisions and provides for catastrophic damages.

Changes to Stark Law

Presently, neither therapeutic nor diagnostic nuclear medicine are DHS. Thus, referrals for nuclear medicine services are not subject to the Stark Law. However, beginning January 1, 2007, under the new rule, both diagnostic and therapeutic nuclear medicine will be DHS. Consequently, beginning on January 1, 2007 physicians who refer a Medicare or Medicaid patient for nuclear medicine services, including nuclear cardiology, to an entity with which they have a financial relationship will violate the Stark Law. Moreover, because CMS declined to grandfather existing relationships, the new rule effects not only financial relationships formed after the effective date of the rule, but also financial relationships that predate the new rule. Accordingly, every physician with a financial relationship with an entity that provides nuclear medicine services will have to ensure that any referral to the entity for nuclear medicine services after January 1, 2007 complies with an exception to the Stark Law.

Relevant Exceptions to Stark Law

The key exception in the context of referrals for nuclear medicine services is likely to be the "in-office ancillary services" exception. To qualify for the ancillary services exception, a referral for a DHS must meet three tests: (i) the supervision, (ii) location, and (iii) billing tests.

Under the supervision test, the DHS must be furnished personally by the referring physician, a physician who is a member of the same group practice as the referring physician, or by another physician in the group practice.

To meet the location test, the DHS must be furnished in the same building as the offices of the practice,[1] or in the case of a group practice, in another building, provided the space is owned or leased (for at least six months) by the group on a full-time basis and used exclusively by the group.[2]

To satisfy the billing test, the DHS must be billed by the physician performing or supervising the services, by a group practice of which the supervising physician is a member, or by an entity that is wholly owned by the physician or the group practice.

Notably, in comments published together with the rule, CMS observed that nuclear medicine services such as PET furnished in mobile coaches will not satisfy "in-office ancillary services exception" because the same building requirement would not be satisfied. Therefore, providers with a financial relationship with an entity that furnishes nuclear medicine services in a mobile coach who wish to continue their financial relationship with the entity must look to another Stark Law exception.

The "rural providers" exception may be useful for some such providers. Under the "rural providers" exception, a physician with an ownership interest in an entity does not violate the Stark Law by referring a Medicare or Medicaid patient to the entity for DHS if the entity furnishes at least 75 percent of its total DHS to residents of a rural area. A rural area is defined as an area outside of a Metropolitan Statistical Area. Thus, referrals to an entity furnishing mobile services will not violate the Stark Law if the entity furnishes at least 75 percent of all its DHS to residents of a rural area.

Finally, practices that receive referrals from physicians who have a compensation arrangement with the practice can look to the "bona fide employment relationships" and "personal services arrangement" exceptions to the Stark Law. Under the "bona fide employment relationships" exception, a physician employed by a practice does not have a financial relationship with the practice if: (i) the practice employs the physician to perform identifiable services; (ii) the physician's salary is set at fair market value and is not determined in a manner that takes the volume of referrals into account; and (iii) the employment agreement is commercially reasonable even assuming that the physician will not make referrals to the practice. Practices that structure their employment relationships with physicians to meet these three requirements can receive referrals from their employed physicians without violating the Stark Law.

Similarly, under the "personal services arrangement" exception, a contract with a practitioner is not a financial relationship for the purposes of the Stark Law if: (i) the contract with the practitioner is in writing, signed by the parties, and specifies the services covered by the contract; (ii) the arrangement covers all of the services to be provided by the physician to the practice; (iii) the aggregate services to be provided under the contract do not exceed the services that are reasonable and necessary for a legitimate business purpose of the arrangement; (iv) the term of the contract is for at least one year; (v) the compensation paid over the term of the contract is set in advance, does not exceed fair market value, and, with the exception of certain physician incentive plans, does not take the volume of referrals or business generated between the parties into account; and (vi) the services do not involve the counseling or promotion of an unlawful business arrangement or other activity. Accordingly, referrals for nuclear medicine services from a physician who receives compensation from the practice will not violate the Stark Law if the contract of the practitioner meets the criteria listed above.

Restructuring Current Investment Interests

Of course, the changes required to comply with the Stark Law may lead some practitioners to choose to sell their investment interest in a group practice furnishing nuclear medicine services. However, practitioners considering divesting their interest must exercise caution because under some circumstances, such as where the sale price is above fair market value or where payment will be made in installments, referrals to the entity after the sale may still violate the Stark Law. To protect themselves from liability for violating the Stark Law, practitioners selling their interest in an entity can structure the sale so that it qualifies for the "isolated transaction" exemption from the Stark Law. To qualify for the "isolated transaction" exemption, the sale of an ownership interest must meet the following requirements: (i) the sale price must be consistent with fair market value and cannot reflect the volume or value of referrals; (ii) the contract of sale must be commercially reasonable, even if the seller does not refer to the buyer; and (iii) the buyer and seller cannot enter into any other transaction with one another for six months following the isolated transaction.

Installment payments, a common feature in contracts for the sale of an interest in a practice group, are permissible under the "isolated transaction" exemption, but only under certain conditions. First, the total payment amount must be set before the first payment is made. Second, the payment

[1] The criteria for what constitutes the same building for the purposes of the exception are technical and are beyond the scope of this alert.

[2] A physician group must satisfy the Stark Law definition of a "group practice" to be treated as such under the "in-office ancillary services" exception. The definition of a group practice under the Stark Law is detailed and highly technical. A group of physicians that is genuinely integrated financially, practices through a single legal entity, and shares responsibility for space and equipment typically can satisfy the definition without making significant changes to the structure of the group.

amount cannot take referrals into account. Third, the outstanding balance must be guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to assure payment in the event of default.

Finally, post-closing adjustments, which are commonly made after the sale of a group practice, are permitted, but only if the adjustments are commercially reasonable, the adjustments are not dependent on referrals or other business generated by the referring physician, and the adjustments are made within six months of the date of the transaction.

Conclusion

By making nuclear medicine DHS, CMS has expanded the reach of the Stark Law to include referrals for nuclear medicine. As a result of this legal change, many nuclear medicine providers will have to restructure their practices by January 1, 2007 to comply with an exception to the Stark Law. In addition, some practitioners will want to sell their interest in a group practice that furnishes nuclear medicine services. Providers interested in either option should consult qualified counsel to assist them in complying with the technical requirements attendant to both choices.

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