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Change to Stark In-Office Ancillary Services Exception

The recent health care reform legislation included one somewhat significant change to the Stark In-Office Ancillary Services Exception. As you will recall, this exception permits the referral source physicians who are members of a physician group practice to refer a patient for imaging services (or other Designated Health Services - DHS) to be provided within the group practice without violating Stark. This exception is basically what permits physician group practices to own and operate and receive compensation for imaging services and other DHS provided within their group practice.

Effective immediately upon the legislation being signed by Obama (March 23, 2010), a physician within a group practice referring his/her patient for MRI, CT or PET to be provided within the group practice must provide the patient, at the time of the referral, written notice that the patient may obtain these imaging services from a supplier other than the group practice. The written notice must provide the patient with a list of such alternative suppliers in the area where the patient resides.

At the present time, this new requirement only applies to DHS in the form of MRI, CT and PET. And it only applies to physician group practices composed of physician referral sources."

Stark law, actually three separate provisions, governs physician self-referral for Medicare and Medicaid patients. The law is named for United States Congressman Pete Stark, who sponsored the initial bill. Here is a list of Stark Guidelines and their ramifications.

Stark and physician referrals to facilities in which there is a financial interest.

Physician self-referral is the practice of a physician referring a patient to a medical facility in which he has a financial interest, be it ownership, investment, or a structured compensation arrangement. Critics of the practice allege an inherent conflict of interest, given the physician's position to benefit from the referral. They suggest that such arrangements may encourage over-utilization of services, in turn driving up health care costs. In addition, they believe that it would create a captive referral system, which limits competition by other providers.

Others respond to these concerns by stating that while problems exist, they are not widespread. Further, these observers contend that, in many cases, physician investors are responding to a demonstrated need which would otherwise not be met, particularly in a medically underserved area.

Stark Legislation

Congress included a provision in the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989) which barred self-referrals for clinical laboratory services under the Medicare program, effective January 1, 1992. This provision is known as "Stark I". The law included a series of exceptions to the ban in order to accommodate legitimate business arrangements. A number of observers recommended extending the ban to other services and programs. The Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) expanded the restriction to a range of additional health services and applied it to both Medicare and Medicaid; this legislation, known as "Stark II," also contained clarifications and modifications to the exceptions in the original law. Minor technical corrections to these provisions were included in the Social Security Amendments of 1994.

Passage of Stark II raised a series of concerns on the part of many provider groups. While Stark I and II were intended to remove potential conflicts of interest from physician decision making, a number of persons have argued that the legislation, particularly parts of Stark II, represents an unwarranted intrusion into the practice of medicine. They have stated that the legislation, particularly the provisions relating to compensation arrangements, is too complex and may, in fact, impede physicians' ability to participate in managed care networks.

On November 20, 1995, Congress gave final approval to the conference report on the Balanced Budget Act (BBA) of 1995. President Clinton vetoed the measure on December 6, 1995. BBA included several amendments to the physician self-referral provisions. The two major changes were the repeal of the prohibitions based on compensation arrangements and the reduction in the list of services subject to the ban.

The Federal Register announced that publication of Stark III has been extended until March 26, 2008, and Phase II will remain in effect through that date.

The Phase III final rule was published on September 5, 2007, at 72 FR 51012, and became effective December 4, 2007.

The Stark Law is related to, but not the same as, the federal anti-kickback law.

Lawyers and laypersons can find Stark at [42 U.S.C.S. ï¿½1395nn] which is ï¿½1877 of the Social Security Act. Additionally, the regulations are at [42 C.F.R. ï¿½411.350 through ï¿½411.389].

STARK II PHASE III FINAL RULE

On September 5, 2007, the Center for Medicare and Medicaid Services ("CMS") completed the long-awaited third and final installment in its rulemaking process under the federal physician self-referral prohibition commonly known as

the "Stark law." The new final rule, referred to as "Phase III," responds to public comments regarding the Phase II interim final rule with comment period published on March 26, 2004, and addresses the entire Stark law regulatory scheme. As in Phases I and II, CMS has continued its efforts in Phase III to reduce the regulatory burden on the healthcare industry through its interpretation and modification of previously promulgated exceptions to the Stark law's general prohibition on referrals. The new regulations will be effective December 4, 2007.

Laws

42 U.S.C. ï¿½ 1395nn.

The October 1st Stark Law Changes: Implications for Diagnostic Imaging Arrangements

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Last year, on August 19, 2008, the Centers for Medicare and Medicaid Services (ï¿½CMSï¿½) published final Stark rules in its 2009 Final Hospital Inpatient Prospective Payment Systems Rule (the ï¿½Final Ruleï¿½). The Final Rule contains three (3) significant modifications to the Stark regulations which become effective this year on October 1, 2009. This article addresses these modifications and their implications for common diagnostic imaging arrangements.

ï¿½Per-Clickï¿½ Space and Equipment Leasing Arrangements Generally Prohibited

Effective October 1, 2009, CMS prohibits the use of unit-of-service (ï¿½per-clickï¿½) fee payments in space and/or equipment leases when the payments reflect services provided to patients referred between the parties. Under the Final Rule, for example, a diagnostic equipment leasing company owned (directly or indirectly) by referring physicians may not lease equipment to a hospital on a per-click basis if the physician owners will be referring to the hospital. Although in the past, per-click payments were generally permitted under the Stark law, reflecting concerns that this type of compensation methodology was inherently susceptible to abuse, the Final Rule prohibits the use of per-click payment methodologies for leasing arrangements under the space and equipment lease exceptions, fair market value exception, and the exception for indirect compensation arrangements to the extent that these charges reflect services provided to patients referred between the parties. It is noteworthy that, although properly structured per-click space and equipment leases were permissible under Stark, even when the lessor was generating the ï¿½clicksï¿½ through his or her referrals, there always was a measure of uncertainty as to the level of risk these arrangements engendered under the Federal Medicare and Medicaid Anti-kickback Statute (the ï¿½AKSï¿½). The Final Rule does not, however, prohibit per-click compensation arrangements involving non-physician-owned lessors to the extent that such lessors are not referring patients for designated health services (ï¿½DHSï¿½), nor does it prohibit per-click payments to physician lessors for services rendered to patients who were not referred to the lessee by the physician lessors.

In addition to the per-click payment restrictions, ï¿½on-demandï¿½ rental agreements will be considered per-click or per-use arrangements, and are also prohibited under the Final Rule. Thus, time-based leasing arrangements whose minimum requirements are so limited and/or flexible (i.e., as to the usage level and/or schedule of use) will, in effect, convert the arrangement into a prohibited per-click rental. CMS views such arrangements as ï¿½on-demandï¿½ leases. The Final Rule, however, will not prohibit all time-based leasing arrangements (e.g., block time leases), as CMS believes that they may meet the requirements of the space and equipment lease exceptions. However, CMS specifically cautions that certain time-based leasing, such as leasing space or equipment in small blocks of time (e.g., once a week for 4 hours), raise significant concern and parties entering into block leases should carefully structure such arrangements taking into account the AKS.

Diagnostic imaging providers should consider the following when applying the new per-click leasing prohibition:

- Arrangements involving entities owned solely by radiologists who are able to qualify for the so-called ï¿½radiologist consultation exceptionï¿½ generally will not be restricted by the per-click leasing prohibition, as they are not considered referring physicians under Stark.
- The ï¿½per-clickï¿½ leasing prohibition applies regardless of whether the DHS entity (e.g., hospital, IDTF, physician practice) is the lessor or lessee.
- On-demand equipment and/or space leases (e.g., leases in which usage is not set in advance) are covered by the prohibition.
- Block schedule leases for equipment and/or space are still permissible so long as the blocks of time are not set with such minimal requirements that they cause the lease to be re-characterized as a prohibited ï¿½on-demandï¿½ per-click arrangement.
- The per-click prohibition only applies to space and equipment leasing arrangements and does not apply to personal service or other employment arrangements.

Percentage-Based Compensation Space and Equipment Leasing Arrangements Generally Prohibited

Effective October 1, 2009, CMS prohibits percentage-based compensation in space and equipment leases, paralleling its new treatment of per-click payments in space and equipment leases. Specifically, the Final Rule amends the current Stark exceptions for the rental of office space, the rental of equipment, fair market value compensation arrangements, and indirect compensation arrangements to prohibit the use of compensation formulae for space and equipment leases based upon a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space lease or to the services performed on or business generated by the use of leased equipment. Effectively, by implementing these changes, CMS precludes the use of most percentage-based arrangements for the lease of space or equipment (direct or indirect) between DHS entities (e.g., hospitals, IDTFs, physician practices) and referring physicians.

Diagnostic imaging providers should consider the following when applying the new percentage-based compensation space and equipment leasing prohibition:

- As with the per-click prohibition, radiologists (and radiologist-owned entities) who are able to qualify for the so-called ï¿½radiologist consultation exceptionï¿½ generally will not be restricted by the percentage-based compensation prohibition, as they are not considered referring physicians under Stark.
- As with the per-click prohibition, the percentage-based compensation prohibition also applies whether or not the DHS entity (e.g., hospital, IDTF, physician practice) is the lessor or lessee.
- The prohibition applies whether or not the leasing arrangement with the referring physician(s) is direct or indirect. Thus, referring physicians that own a diagnostic imaging leasing company that, in turn, leases diagnostic imaging equipment to a hospital are prohibited from charging the hospital percentage-based compensation under the lease.
- The prohibition does not extend outside of the space and equipment lease context (e.g., management services), but CMS cautioned that it intends to continue to monitor compensation formulae in arrangements between DHS entities and referring physicians and, if appropriate, may further restrict percentage-based formulae in a future rulemaking.

ï¿½Under-Arrangementsï¿½ Transactions with Referring Physicians Are Prohibited

Effective October 1, 2009, both the hospital that bills for services provided ï¿½under arrangementsï¿½ and the entity that performs the services to the hospital will be considered to be furnishing DHS under Stark. This change effectively eliminates a referring physicianï¿½s ability to maintain an ownership interest in such ï¿½under arrangementsï¿½ service providers.

Specifically, under the Final Rule, an ï¿½entityï¿½ for purposes of Stark will include the person or organization that: (1) bills for the DHS; or (2) performs the DHS. Under these new rules, where one entity performs a service that is billed by another entity, both entities are considered DHS entities with respect to that service. Under the Final Rule, for example, referring physicians of a physician-hospital joint venture entity that furnish CT angiography to a hospital pursuant to an ï¿½under arrangementsï¿½ contract are prohibited from referring patients to the hospital for such CT angiography services unless the arrangement satisfies the rural provider exception. Pursuant to the Final Rule, any financial relationship between the service provider and the physicians who refer to it for services that the hospital bills ï¿½under arrangementsï¿½ will need to comply with a Stark exception. In practice, there are limited, if any, exceptions available to protect referrals for the service providerï¿½s physicians.

CMS does not define what it means to ï¿½performï¿½ a service, but does indicate that an organization is not performing DHS if it merely leases or sells space or equipment, furnishes supplies that are not separately billable, or provides management, billing services or personnel to the entity performing the service. One issue for which it remains uncertain is whether an entity that performs some, but not substantially all, of the clinical aspect for the service (e.g., turnkey management service provider) will be considered to be performing DHS.

Diagnostic imaging providers should consider the following when applying the new definition of DHS entity:

- Unlike referring physicians (e.g., cardiologists), radiologists will generally be permitted to have an ownership in such ï¿½under arrangementsï¿½ joint ventures because they typically are not considered referring physicians under Stark. Thus, under the above CT ï¿½under arrangementsï¿½ example, if the CT service

provider is owned by non-radiologists, then the arrangement will not be viable under the Final Rule if the physician owners refer to the hospital for CT services. By contrast, however, if the entity were owned by radiologists, this arrangement could remain in effect in compliance with Stark.

- In practice, the only available ownership exception (for referring physicians) that will protect an ï¿½under arrangementsï¿½ service provider is the rural provider exception. Therefore, unless substantially all of the patients reside in a rural area, ï¿½under arrangementsï¿½ service agreements with referring physicians will be prohibited.
- Although an arrangement limited solely to discrete components of the service (e.g., equipment, supplies, non-physician personnel), by itself, will not rise to the level of ï¿½performingï¿½ the service, it is not clear, whether an entity that performs some, but not substantially all, of the clinical aspects of the service (e.g., turnkey management service provider) will be considered to be performing DHS.

Before the October 1, 2009 effective date, diagnostic imaging providers should review their current leasing and or service arrangements to ensure compliance with the new Stark rules.
