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CMS Continues to Change the “Stark” Rules for the Health Care Industry

On July 31, 2008, the Centers for Medicare and Medicaid Services (“CMS”) published the final FY 2009 Inpatient Prospective Payment Systems and FY 2009 Rates (“Final IPPS Rule”). As foreshadowed in the proposed IPPS rules published earlier this year and the proposed CY 2008 Physician Fee Schedule (the “2008 PFS”), the Final IPPS Rule contains a number of changes to the Ethics in Patient Referral Act (the “Stark Law”). Although the Stark Law II, Phase III regulations (the “Phase III Regulations”) published on September 5, 2007 purported to be the final installment of the Stark Law, CMS continues to modify, substantially at times, its regulation of financial relationships between health care entities and physicians that make referrals for designated health services (“DHS”) to such entities. This Client Alert highlights significant changes to the Stark Law set forth in the Final IPPS Rule and discusses disclosure requirements that will be imposed upon certain hospitals. Clients affected by these Stark Law changes or disclosure requirements should seek specific legal guidance.

CHANGES TO THE STARK LAW

A Revision to the Stand in the Shoes Provisions

The Stark statute, as enacted by Congress, only addressed direct financial relationships between physicians and health care entities to which they make referrals for DHS. Following the enactment of the statute, CMS expressed concern about indirect financial relationships where the financial relationship between a health care entity and the referring physician runs through intervening entities such as the physician’s medical practice or a joint venture. In the Stark Law II, Phase I regulations, CMS used its regulatory authority to define an “indirect compensation relationship” and to create a regulatory exception for a certain subset of permissible “indirect compensation relationships.” Following the creation of the exception for indirect compensation relationships, CMS was concerned that many indirect relationships were still outside the reach of the Stark Law and that the requirements for the exception were less stringent than those for direct compensation exceptions. Consequently, in the Phase III Regulations, CMS adopted the concept whereby physicians were deemed to “stand in the shoes” of their physician organizations; accordingly, compensation relationships that were previously indirect compensation relationships under the Stark Law were deemed direct, and the parties were required to meet an exception for direct compensation relationships (e.g., the personal services exception).

Many academic medical centers (“AMCs”) expressed concern over the application of the physician stand in the shoes provisions to compensation arrangements involving mission support and similar payments. As a result, CMS delayed the effective date of the physician stand in the shoes provisions to certain compensation arrangements involving (1) AMCs and (2) physician organizations owned by and integrated with non-profit hospitals. CMS later proposed to revisit the physician stand in the shoes provisions and also proposed a corollary provision pursuant to which a DHS entity, such as a hospital, would stand in the shoes of other health care entities.

Physician Stand in the Shoes Provisions

In the Final IPPS Rule, CMS finalizes revisions to the physician stand in the shoes provisions. Effective October 1, 2008, a physician who has an ownership or investment interest in a physician organization stands in the shoes of that physician organization. Physicians who have only a titular interest in the physician organization – that is, physicians who have no ability or right to receive the financial benefits of ownership or investment such as dividends, the distribution of profits, or sale proceeds – are not required to stand in the shoes of their physician organizations. Non-owner physicians, such as non-owner employees, and titular owners may, but are not required to, stand in the shoes of their physician organizations; this allows the physicians and physician organizations to avail themselves of the indirect compensation arrangement exception or any applicable direct compensation relationship exception. In addition, the physician stand in the shoes provisions do not apply when an arrangement complies with the requirements of the exception for AMCs at 42 C.F.R. § 411.355(e).

CMS notes that, as a result of the physician stand in the shoes provisions, some arrangements between DHS entities and physician organizations may require modification during the term of the arrangement. Therefore, CMS interprets the “set in advance” requirement present in many Stark Law exceptions to permit amendments during the term of an agreement provided that (1) all of the requirements of an applicable exception are satisfied, (2) the amended charge or compensation is determined before the amendment is implemented and the formula permits objective verification, (3) the formula does not take into account the volume or value of referrals or other business generated by the referring physician, and (4) the amended charge or compensation remains in place for at least one year from the date of the amendment. This rule regarding the amendment of arrangements applies to all Stark Law compensation exceptions that include a one-year term requirement (e.g., the exceptions for space rental, equipment rental, and personal service arrangements).

DHS Entity Stand in the Shoes Provisions

CMS previously proposed to require a DHS entity to stand in the shoes of an organization that it owns or controls, then revised its proposal to require a DHS entity to stand in the shoes of an organization in which it has a 100% ownership interest. However, in the Final IPPS Rule, CMS decided not to finalize a DHS entity stand in the shoes provision.

Percentage-Based Compensation Formulas

CMS and the health care industry have had a running dialogue over whether percentage-based payments would be permissible under the Stark Law for certain compensation arrangements where, among other requirements, the compensation must be “set in advance” and “not vary based on the value or volume of referrals or other business generated between the parties.” In the commentary to the Phase III Regulations, CMS refused to give blanket approval to compensation calculated using a percentage-based formula even though it is common in many compensation arrangements in the health care industry including personal services contracts, management and billing contracts, and space and equipment leases. The Final IPPS Rule prohibits the use of percentage-based compensation formulas in determining rental charges for the lease of office space or equipment. Furthermore, to ensure that parties will not evade the prohibition by using the fair market value exception (with respect to equipment leases) or the indirect compensation exception (with respect to space or equipment rentals), CMS has included language in each of these exceptions to prohibit the determination of rental charges using a percentage-based compensation formula. Parties are prohibited from calculating rent based upon a percentage of revenue raised, earned, billed, collected or otherwise attributable to the services performed or business generated through the use of the office space or equipment. Existing lease agreements where the rental rate is determined using a percentage-based compensation formula must be restructured to comply with the new language by October 1, 2009.

CMS makes it clear that *at this time* it is not extending the prohibition on the use of percentage-based compensation formulas to arrangements for non-professional services (such as management or billing services) but will continue to monitor these arrangements. Therefore, parties should be cautious when entering into an agreement for non-professional services if the agreement provides for compensation to be determined based upon a percentage of revenue.

Unit-of-Service (“Per Click”) Payments in Lease Arrangements

In the 2008 PFS, CMS stated that arrangements in which a lessor comprised of physician investors leases equipment such as a MRI or CT to an entity such as a hospital and receives “per click” rental payments are susceptible to abuse and proposed that such arrangements would not qualify for the exceptions for space and equipment leases. In the Final IPPS Rule, CMS has revised the space and equipment lease exceptions, as well as the fair market value exception (as it pertains to equipment leases), and the exception for indirect compensation arrangements (as it pertains to space and equipment leases), to provide that per click rental charges are not permitted to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. Because of the physician stand in the shoes provisions, the prohibition on per click payments applies regardless of whether the lessor is an individual physician or an organization in which the referring physician has an ownership or investment interest. The prohibition also applies when an entity, such as a hospital, leases equipment or space to a physician or physician organization on a per click basis. CMS is delaying the effective date of the amendments until October 1, 2009, in order to allow parties adequate time to restructure existing lease arrangements. Please note that although not specifically included in the revised language, CMS is also prohibiting “on demand” rental agreements (where the rental times are not set in advance but the rented space or equipment is available on the demand of the lessee), which CMS considers to be essentially a per-use or per click type of arrangement.

CMS is not, at this time, prohibiting parties from leasing space and equipment on a time-based rental basis, such as a block lease. CMS believes that block time leases, depending upon how they are structured, may meet the requirements of the space and equipment lease exceptions. However, CMS indicates that it is continuing to study the ramifications of block time leasing arrangements and may address these arrangements in the future.

Services Provided “Under Arrangement”

The Stark Law prohibits a physician from making a referral for DHS to an “entity” with which the physician has a financial relationship, unless an exception applies. “Entity” is not defined by the Stark statute enacted by Congress, but prior Stark Law regulations have applied the term almost exclusively to an “entity” that bills Medicare for DHS. As a result, physicians have been able to refer patients to joint ventures in which they had a financial relationship if that joint venture merely furnishes DHS to another provider that bills for the services. These joint ventures were commonly formed to provide DHS “under arrangements” to hospitals. CMS identified this development as an area of potential abuse and expressed its longstanding concern about overutilization of services provided “under arrangement.”

In the Final IPPS Rule, CMS amends the definition of “entity” to provide that a person or entity is an “entity” under the Stark Law if it performs the DHS or presents a claim for Medicare benefits for the DHS. If one entity performs a service that is billed by another entity, both are DHS entities under the Stark Law. CMS does not go so far as to define the term “performs” but states that an entity that leases or sells space or equipment, furnishes supplies, or provides management, billing services, or personnel to the entity performing the service is not itself performing DHS. Because there are few Stark Law exceptions applicable to ownership interests, a physician investor in a provider that is providing services to patients “under arrangement” with a

hospital will most likely be prohibited from making referrals to that provider. In order to provide ample time to restructure arrangements impacted by the new definition of “entity,” CMS delayed the effective date of the amended definition until October 1, 2009.

Revisions to the Exception for Obstetrical Malpractice Insurance Subsidies

In the Stark Law II, Phase II regulations, CMS created a new exception for obstetrical malpractice insurance subsidies that complied with the Anti-Kickback Statute safe harbor for such arrangements. In the 2008 PFS, CMS expressed concern that the current exception for obstetrical malpractice insurance subsidies may be too narrow. In the Final IPPS Rule, CMS revises the exception to (1) retain the provisions of the current exception, which permits a hospital or other entity (such as a group practice) to provide the obstetrical malpractice insurance subsidy; and (2) provide an alternative set of requirements under which hospitals, federally qualified health centers, and rural health clinics (but not other entities such as group practices) may provide obstetrical malpractice insurance subsidies. The new language permits hospitals, federally qualified health centers, and rural health clinics to provide the subsidy to a physician who regularly engages in obstetrical practice as a routine part of a medical practice that is (1) located in a primary care health professional shortage area, rural area, or an area with a demonstrated need, as determined in an advisory opinion by the Secretary of the United States Department of Health and Human Services; or (2) is comprised of patients at least 75% of whom reside in a medically underserved area or are part of a medically underserved population.

Ownership or Investment Interest in Retirement Plans

The Stark Law prohibits a physician from making referrals for DHS to an entity with which the physician has a financial relationship, whether it is a compensation relationship or an ownership or investment interest. However, the Stark Law specifically excludes from the definition of “ownership or investment interest” an interest in a retirement plan. In the Final IPPS Rule, CMS clarifies that when a retirement plan offered by the physician’s employer purchases or invests in a second DHS entity, the interest in the second DHS entity is not automatically excluded from the definition of “ownership or investment interest.”

Period of Disallowance

The “period of disallowance” refers to the period of time when a financial relationship between an entity, such as a hospital, and a physician (or physician organization) fails to satisfy all of the requirements of a Stark Law exception. During the period of disallowance, a physician may not refer DHS to the entity and the entity may not bill Medicare for any DHS referred to it by the physician. CMS has historically interpreted the period of disallowance as beginning on the date the arrangement first fell out of compliance and ending on the date the arrangement came into compliance or ended. In the Final IPPS Rule, CMS provides that where noncompliance with an exception exists because one party is paying for items or services in excess of fair market value, the period of disallowance will continue until all of the excess compensation is returned to the party that paid it and the relationship satisfies all other requirements of the applicable exception. Similarly, where one party is paying for items or services at a price that is below fair market value, the period of disallowance will continue until the party pays all additional required compensation and the relationship satisfies all other requirements of the applicable exception. CMS stresses that it is not sufficient for the parties to address a noncompliant situation on a going forward basis or for some partial period. Rather, the parties must fully rectify the situation or the period of disallowance will continue.

Where the noncompliance is unrelated to compensation (e.g., the parties do not have a written agreement as required by the applicable exception), the period of disallowance ends no later than the date on which the financial relationship satisfies all requirements of an applicable exception. It is important to note that the Final IPPS Rule *does not* define when a financial relationship begins or ends. The Final IPPS Rule merely prescribes

the outer boundaries of a period of disallowance – the parties may argue that a period of disallowance ended earlier (perhaps because the physician relocated to another state) than the prescribed outer boundary.

Alternative Methods of Compliance with Signature Requirements in Certain Exceptions

Many exceptions to the Stark Law – such as the exceptions for the rental of office space, rental of equipment, personal service arrangements and recruitment agreements – require the parties to sign a written agreement. The 2008 PFS considered whether CMS should provide an alternate method for satisfying exceptions when the parties have failed to comply with a procedural requirement set forth in the exception, such as failing to obtain the signatures of all parties to a written agreement. The Final IPPS Rule adopts these considerations by providing that payment may be made to a health care entity that submits a claim for DHS if the financial relationship between the referring physician and the health care entity complies in all respects with an applicable Stark exception, except that the parties failed to sign the required written agreement. The Final IPPS Rule requires the parties to obtain the missing signature within a defined period of time (ninety days from the beginning of the financial relationship if the failure to obtain the signature was inadvertent or thirty days from the beginning of the financial relationship if the failure to obtain the missing signature was intentional or knowing). It is important to note that this provision may only be used by a health care entity once every three years with respect to the same referring physician.

Where a financial relationship fails to meet the signature requirement of an applicable Stark Law exception, and where the parties to the relationship fail to obtain the missing signature within the applicable time period, a period of disallowance will arise dating back to the beginning of the financial relationship. During this period, a referring physician may not refer DHS to a health care entity with which is has a noncompliant financial relationship, and the health care entity may not bill Medicare for any DHS referred to it by the physician. See the “Period of Disallowance” discussion set forth above.

Burden of Proof

In the Final IPPS Rule, CMS clarifies that in any appeal of a denial of payment for DHS that was made on the basis that the DHS was furnished in violation of the Stark Law, the claimant (that is, the entity appealing the denial) bears the burden of proof in the claims appeal process. CMS notes that it believes it is appropriate to place the burden on providers and suppliers to show that they are in fact entitled to government funds.

CMS also notes that the burden of production is initially borne by the claimant but may shift to the government during the course of the appeal proceeding. For example, all of the Stark Law exceptions for financial relationships require that the relationship not violate the Anti-Kickback Statute. Therefore, in an appeal proceeding, the claimant must initially show that it did not violate the Anti-Kickback Statute. When the claimant has offered evidence on such issue, the burden of production may then shift to the government to show that the relationship did in fact violate the Anti-Kickback Statute.

DISCLOSURE REQUIREMENTS

CMS has never engaged in a comprehensive effort to examine financial relationships between hospitals and physicians but previously proposed to send an information collection instrument, the Disclosure of Financial Relationships Report (“DFRR”), to 500 hospitals to identify financial relationships that may not be compliant with the Stark Law and to identify practices that may assist in future rulemaking. In the Final IPPS Rule, CMS states that it will proceed with its plan to send the DFRR to a total of 500 hospitals, both acute care and specialty hospitals but may, on further review, decide to send the DFRR to fewer (but not more) hospitals. CMS estimates that a hospital will spend an average of 100 hours completing the DFRR at an average cost of \$4,080. CMS adopted a 60 day limit for completing the DFRR but noted that a hospital may receive an

extension upon a showing of good cause. Furthermore, prior to imposing any monetary penalty, CMS will contact a hospital that does not return the completed DFRR within the required time frame concerning the reason for the delay.

CMS is careful to point out that its failure to identify a Stark Law violation based on a hospital's completion of the DFRR is not assurance that all the reported financial relationships are in compliance. CMS may still determine that a financial relationship violates the Stark Law based on further review of the DFRR or on additional information provided. Finally, at this time, the DFRR is a one-time collection effort; no regular reporting or disclosure process is established by the Final IPPS Rule.

The Final IPPS Rule substantially revises many of the regulations that govern hospitals and physician practices. Click [here](#) for a copy of the Final IPPS Rule.

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