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**CMS POSTS FINAL RULE CONTAINING
SIGNIFICANT CHANGE TO STARK LAW
REGULATIONS, INCLUDING RESTRICTIONS ON
“UNDER ARRANGEMENTS” CONTRACTS AND
“PER-CLICK” AND PERCENTAGE-BASED LEASES**

August 12, 2008



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CMS POSTS FINAL RULE CONTAINING SIGNIFICANT CHANGES TO STARK LAW REGULATIONS, INCLUDING RESTRICTIONS ON “UNDER ARRANGEMENTS” CONTRACTS AND “PER-CLICK” AND PERCENTAGE-BASED LEASES

August 12, 2008

On July 31, 2008, the Centers for Medicare & Medicaid Services (“CMS”) posted for public viewing the 2009 Inpatient PPS Final Rule (the “Final Rule”). The Final Rule contains a number of changes to the regulations promulgated under the Stark Law, as discussed below, and also finalizes CMS’ plans to send an information collection instrument, known as the Disclosure of Financial Relationships Report (“DFRR”), to approximately 500 hospitals. The Final Rule is scheduled to be published in the August 19 Federal Register.

The changes in the Final Rule include restrictions on “per-click” and percentage-based leases and on “under arrangements” contracts, effective October 1, 2009, that will require a number of existing arrangements to be restructured or terminated. Other provisions of the Final Rule, including changes to the hospital inpatient prospective payment systems and fiscal year 2009 rates, are beyond the scope of this memorandum. This memorandum is not a legal opinion and may not be relied upon as legal advice.

Summary

The Final Rule changes a number of Stark Law regulatory provisions, including the following:

Effective October 1, 2008, the Final Rule:

- Revises the physician “stand in the shoes” provisions to require owners (other than titular owners) and permit non-owner physicians (and titular owners) to stand in the shoes of their physician organizations and addresses the application of the rules to the academic medical center exception (however, the delay of application of this rule to tax-exempt systems and academic medical centers will remain in effect until December 4, 2008);
- Permits correction of missing signatures in cases of otherwise compliant arrangements if corrected within 30 days if advertent and within 90 days if inadvertent (but no more than once every three years for any physician);

- Finalizes proposals to: (1) limit the exception for ownership or investment interests in retirement plans, (2) clarify that the entity submitting the claim for payment has the burden of proof in Stark Law disputes with CMS, and (3) specify the maximum period of disallowance once a non-excepted financial relationship has been created; and
- Expands the exception for obstetrical malpractice insurance subsidies.

Effective October 1, 2009, the Final Rule:

- Excludes office space and equipment lease arrangements with percentage-based compensation, or with unit-of-service (“per-click”) compensation that reflects services provided to patients referred between the parties, from qualifying for the office space, equipment, fair market value, or indirect compensation exceptions; and
- Revises the definition of “entity” to cover both the entity that provides a designated health service (“DHS”) and the entity that bills for the DHS. This change will, among other things, prevent entities that provide services “under arrangements” from having physician owners who refer the services provided “under arrangements,” unless an ownership exception applies.

Percentage-based Compensation and Per-Click Changes

Effective October 1, 2009, the office space lease exception, equipment rental exception, fair market value compensation exception and indirect compensation arrangements exception will require that the rental charges over the term of the agreement not be determined using a formula based on a “percentage of the revenue raised, earned, billed, collected, or otherwise attributable” to the services performed or business generated in the office space or to the services performed or business generated through the use of the equipment, as applicable, or based on “[p]er-unit of service rental charges, to the extent that such charges reflect services provided to patients referred between the parties.” CMS states in the commentary to the Final Rule that “on-demand” leases are “essentially a per-use or per-click type of arrangement . . . covered by our revisions in this final rule.”

These Final Rule provisions specifically address office space leases and equipment leases. CMS previously proposed restricting any percentage-based arrangements other than those for physician services.

A distinction should be noted between the percentage-based and “per-click” limitations. The Final Rule will prohibit any percentage-of-revenue-based office space or equipment rental, regardless of whether the revenue results from referrals between the parties, if the lessor or lessee (or an immediate family member) refers DHS to the other party to the lease. In contrast, the “per-click” limitation will prohibit unit-of-service-based rental only to the extent it reflects services provided to patients referred between the parties. Thus, for example, a hospital’s lease of a piece of equipment from a physician-owned leasing company could provide for fixed rental

for services rendered to patients referred by physician owners and “per-click” rental for services rendered to patients referred by other physicians. This would be the case even if there is a financial relationship between the owner physicians and the referring physicians, as long as that financial relationship does not create an indirect compensation arrangement.

It is unclear whether “patients referred between the parties” is limited to patients referred for DHS (as would be consistent with the regulatory definition of referral) or whether CMS intended “referred” to include non-DHS referrals. The preamble to the Final Rule contains statements that support both readings and appear mutually contradictory.

The Stark Law definition of “referral” excludes a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy, if the request results from a consultation initiated by another physician and the tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in his or her group practice. Therefore, an “under arrangements” contract limited to services resulting from such requests would not be prohibited under the Final Rule; similarly, a “per-click” lease limited to equipment used to provide such services would not be prohibited if utilization does not vary due to other referrals between the parties (such as referrals from a hospital to the specialist); it is unclear whether such a per-use lease would result in a non-expected financial relationship in this context if utilization does vary due to such other referrals. However, a percentage-based lease with a pathologist, radiologist, or radiation oncologist would prevent referrals from the specialist not fitting within this exception (e.g., referrals of interventional radiology) and would prevent referrals from his or her immediate family members.

In its commentary to the Final Rule, CMS makes clear that a lessee can be assessed for expenses related to the space leased by the lessee, stating that it does “not consider a percentage of expenses imposed or levied by a third party, such as property taxes or utilities, to be prohibited percentage compensation” and does not consider the changes to prohibit a lessor from charging a lessee a pro rata share of expenses attributable to the lessee’s portion of the leased space or equipment.

Revised Definition of “Entity”

The Stark Law prohibits a physician from making referrals for DHS to an entity with which the physician (or an immediate family member) has a financial relationship, and prohibits the entity from billing Medicare for the DHS, unless an exception applies. Effective October 1, 2009, the definition of “entity” for Stark Law purposes will be revised to provide that a person or entity is considered to be furnishing DHS if it “has performed services that are billed as DHS” or has presented a claim to Medicare for the DHS.

The commentary makes it clear that CMS considers an entity that provides a service “under arrangements” to be performing the service. The commentary contains the following discussion of who “performs” a service:

We decline to provide a specific definition of “perform,” but rather intend that it should have its common meaning. . . . Physicians and other suppliers and providers generally know when they have performed a service and when they are entitled to bill for it. By way of example only, we consider a service to have been “performed” by a physician or physician organization service if the physician or physician organization does the medical work for the service and could bill for the service, but the physician or physician organization has contracted with a hospital and the hospital bills for the service instead. We do not mean to imply that a physician service provider can escape the reach of the physician self-referral statute by doing substantially all of the necessary medical work for a service, and arranging for the billing entity or some other entity to complete the service. We do not consider an entity that leases or sells space or equipment used for the performance of the service, or furnishes supplies that are not separately billable but used in the performance of the medical service, or that provides management, billing services, or personnel to the entity performing the service, to perform DHS.

Thus, an entity with referring physician ownership that currently provides services “under arrangements” will be able to continue to provide a portion of the services it currently provides as long as that portion does not rise to the level of “providing” the service. It might, for example, be able to provide equipment (subject to the limitations on percentage-based and “per-click” rentals noted above), provide management or billing services, or provide staff. However, combining components may cause the arrangement to rise to the level of “providing” the service, triggering the referral prohibition.

The revised definition of entity will prevent a physician from referring DHS that will be provided “under arrangements” by the entity, but will not affect the ability of the “under arrangements” contract itself to qualify for a Stark Law exception. Thus, a physician-owned entity will be able to provide services to a hospital “under arrangements” as long as the services are referred by physicians who do not have an ownership interest in the “under arrangements” provider. (However, an arrangement whereby a hospital has contracts with two groups, each of which provides services “under arrangements” that are referred by members of the other group, would probably be challenged as a prohibited circumvention scheme and would also present a substantial risk under the Anti-kickback Statute.)

The Final Rule does not distinguish between services based on whether they are inpatient or outpatient services or based on whether they are inherently DHS (such as most imaging services) or only become DHS when billed by a hospital (such as cardiac catheterization services).

The Final Rule will not prevent continued referring physician ownership of an “under arrangements” provider if a Stark Law ownership exception applies. Thus, a physician generally will be able to own an interest in an entity that provides services referred by the physician to a hospital “under arrangements” if the “under arrangements” provider qualifies for the rural exception, is a hospital, or meets the requirements of the publicly traded security exception.

Although the new definition of “entity” was apparently designed primarily to address concerns with “under arrangements” contracts, it is not limited to those contracts. For example, the new definition would apparently apply to a non-physician-owned entity that provides turnkey DHS services to a physician group; since the physicians would be viewed as referring to that entity, the contract between the parties would need to be structured to meet the requirements of a Stark Law exception. The 2008 Physician Fee Schedule revises the Stark Law definition of “entity” to exclude a physician’s practice when it bills Medicare for the technical component or professional component of a diagnostic test for which the anti-markup rule under 42 C.F.R. Section 414.50 applies. However, it is unclear how this would apply to the entity providing the service.

Unwinding Existing Arrangements

Existing arrangements that do not meet the new requirements will need to be restructured or unwound to be brought into compliance. Thus, parties to existing “under arrangements” contracts or percentage-based or “per-click” leases should review those arrangements in order to: (1) determine whether the arrangement will be noncompliant under the Final Rule; (2) identify any contractual provisions relevant to the renegotiation process, such as legal jeopardy provisions, mediation or arbitration clauses, termination rights and put/call rights; and (3) determine what alternatives are permissible and to what extent they will address the needs of the parties.

Depending on the circumstances, various alternatives may be available to the parties to an arrangement that will become noncompliant. Alternatives for percentage-based or “per-click” leases may include:

- Restructuring the rental methodology to either a fixed rental or a bifurcated arrangement (i.e., fixed rental for use with patients referred by lessor physicians and, perhaps, lessor physicians’ employees, and “per-click” rental for use with other patients).
- Entering into a block lease arrangement under which a lessor physician group retains the leased space and equipment for use with its own patients but leases the space and equipment to the hospital during blocks that the hospital can use to provide services to patients referred by other physicians. However, this alternative may be impacted by several existing and potential limitations on block lease arrangements, as detailed below.

For “under arrangements” contracts, alternatives to consider, depending on the nature of the service, may include:

- Arranging for the hospital to provide the service directly. This approach does not preclude a continuing role for the physicians in the provision of the service, as the arrangement could be restructured so that the physician entity provides only a component of the services previously provided that does not rise to the level of “providing” the

service. For example, the physician group could provide equipment for a fixed rental or, alternatively, could manage the service provided by the hospital.¹

- Arranging for one or more physician practices to provide the service directly. If the service in question is a DHS whether or not provided by a hospital, then the parties will need to structure the arrangement to meet the requirements of the in-office ancillary exception. (However, CMS indicated in 2007 that it is considering whether to limit the services that may be provided under the in-office ancillary exception.) If provided by more than one physician practice, the existing and potential limitations on block lease arrangements should be considered.
- Restructuring the service so that it is provided by both the hospital and one or more physician practices. This would involve a block lease raising the issues discussed below.

Block Leases

In considering restructuring alternatives that involve use of office space or equipment by more than one entity, limitations on block leases must be considered. These limitations include the following:

- In order to rely on the in-office ancillary services exception, a physician practice that uses a facility on a part-time basis must have an office in the same building as the facility that meets one of three alternative use tests.
- In the 2009 Proposed Medicare Physician Fee Schedule, CMS proposed requiring that a physician office providing diagnostic services (other than, possibly, some specified tests such as x-rays, ultrasound and fluoroscopy) to enroll as an independent diagnostic testing facility (“IDTF”) by September 30, 2009 and to meet a portion of the IDTF requirements, including (but not limited to) requirements not to lease or sublease its operations or its practice location to another Medicare-enrolled individual or organization or to share diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization. If this proposal is adopted, it would prevent time-share leases of diagnostic equipment with physician lessees.
- The 2009 Proposed Medicare Physician Fee Schedule also contained several alternative approaches proposed by CMS to expand the “anti-markup rule” applicable to diagnostic tests. Under the first proposal, the anti-markup rule would apply in all cases where the professional component or technical component of a diagnostic testing service is either purchased from an outside supplier or performed or supervised by a physician who does not share a practice with the billing physician or physician organization. This would limit the shared use of facilities to groups that provide their own supervision and interpretation or that contract with another physician who does not provide interpretations or supervision for other practices (currently, it is common for multiple groups to contract with a radiologist to supervise or interpret tests).

¹ In structuring arrangements for the provision of management or other services, a hospital would need to consider the impact of the provider-based regulations at 42 C.F.R. Section 413.65.

Under the second alternative, the anti-markup rule would apply if the test is purchased from an outside supplier or ordered by a physician who does not provide substantially the full range of his or her patient care services in the same building. This would cause the anti-markup rule to apply if a physician member of a group with multiple offices orders a test that is performed at an office in a different building from where the ordering physician practices.

The commentary to the Final Rule affirms that block lease arrangements may meet the requirements of the space and equipment lease exceptions, but states:

We believe that the same concerns we identified . . . with respect to certain per-click lease arrangements can exist with certain time-based leasing arrangements, particularly those in which the lessee is leasing the space or equipment in small blocks of time (for example, once a week for 4 hours), or for a very extended time (which may indicate the lessee is leasing space or equipment that it does not need or cannot use in order to compensate the lessor for referrals). We will continue to study the ramifications of “block time” leasing arrangements and may propose rulemaking in the future. Parties entering into block leases should structure them carefully, taking into account the antikickback statute.

The above discussion does not address whether the schedule of a block lease can be amended more frequently than annually and, if so, how much more frequently. While adjustments that reflect utilization may be permissible more frequently than annually, at least if the adjustments are due to changes in referrals to a lessee hospital from non-lessor physicians, frequent adjustment may be viewed as raising the same concerns as “on demand” leases and as resulting in a “per-click” lease for Stark Law purposes.

“Stand in the Shoes”

Physician “Stand in the Shoes”

Background. In its September 2007 Phase III Stark Law regulations (the “Phase III Rules”), CMS implemented a “stand in the shoes” rule that applied to physician organizations (i.e., a physician, a wholly owned professional corporation, a group practice or other physician practice).² Under this rule, a financial relationship between an entity providing DHS and a physician organization is attributed to the physician owners, physician employees and physician contractors of the organization. In other words, the physician “stands in the shoes” of the physician organization and is treated as having the same compensation arrangements (with the same parties and on the same terms) as the physician organization in whose shoes the referring physician stands.

² In addition to the other revisions to the physician “stand in the shoes” rules discussed herein, in the Final Rule, CMS also finalized proposals contained in the 2009 IPPS Proposed Rule clarifying that (1) a physician and the professional corporation of which he or she is the sole owner are always treated the same for purposes of applying the physician “stand in the shoes” rules, and (2) a physician who “stands in the shoes” of his or her wholly-owned professional corporation also “stands in the shoes” of his or her physician organization.

On November 15, 2007, CMS issued a final rule (the “2007 Delay Rule”) delaying until December 4, 2008 the application of the physician “stand in the shoes” rule to compensation arrangements between a faculty practice plan and another component of the same academic medical center (“AMC”) and between a DHS entity and an affiliated physician practice in the same integrated section 501(c)(3) health care system, recognizing that application of the new rule could prevent certain “support” payments common in those settings. After issuance of the 2007 Delay Rule, industry stakeholders advised CMS that similar support payments were also made in non-section 501(c)(3) integrated health care delivery systems and raised similar concerns about application of the physician “stand in the shoes” rule to such payments in those settings as well.

Noting these concerns in the 2009 inpatient prospective payment system proposed rule (the “2009 IPPS Proposed Rule”), CMS proposed two alternative methods to address the issue of “mission support” payments and to simplify application of the physician “stand in the shoes” rule. The Final Rule amends the physician “stand in the shoes” rules through finalizing certain of the proposals contained in the 2009 IPPS Proposed Rule.

Revised Physician “Stand in the Shoes” Rule. The revised physician “stand in the shoes” rule adopts a relatively simple approach that should resolve many of the concerns raised by the original “stand in the shoes” approach. Under the revised physician “stand in the shoes” rule, a physician “stands in the shoes” of a physician organization if the physician has an ownership or investment interest in the physician organization. Physicians who are “titular owners” do not automatically stand in the shoes of the organizations they own. CMS considers “titular owners” to be physicians who are not able or entitled to receive *any* of the financial benefits of ownership or investment in the physician organization (including, without limitation, the distribution of profits, dividends, proceeds of sale or similar returns on investment).

Additionally, under the revised rule, CMS permits, but does not require, physicians who are not owners or investors in their physician organizations (including titular owners) to “stand in the shoes” of the physician organization for purposes of analyzing compensation arrangements between DHS entities and physicians. If the non-owner physicians were treated as “standing in the shoes” of the organization, they would have to meet one of the direct compensation arrangement exceptions, which are typically stricter than the indirect compensation arrangement exception. If the non-owner physicians were not treated as “standing in the shoes” of the organization, the compensation arrangement would be analyzed under the rules applying to indirect compensation arrangements.

CMS also clarified that the physician “stand in the shoes” rule does not apply to an arrangement that satisfies the AMC exception found in § 411.355(e). CMS did not, however, finalize a proposal contained in the 2009 Proposed IPPS Rule that would have excepted certain graduate medical education (“GME”) compensation arrangements between a physician organization and an AMC from the physician “stand in the shoes” rules. CMS also declined to finalize a separate exception for compensation arrangements involving “mission support” or similar payments, confirming that typical “mission support” payments to a physician organization with no physician owners would be viewed as an indirect compensation arrangement, but noting:

[W]e are aware of situations where non-owner physician employees and contractors have compensation arrangements that are not based on fair market value and benefit from payments made to their physician organization from entities to which the physician employees and contractors refer patients for DHS. We remain concerned about such compensation arrangements. . . . In addition, depending on the circumstances, non-fair market value compensation arrangements potentially implicate the Federal anti-kickback statute . . . and False Claims Act.”

Effective Date. The amendments to the physician “stand in the shoes” rules set forth above will be effective October 1, 2008, with two exceptions. First, as specified in the 2007 Delay Rule, application of the physician “stand in the shoes” rules to compensation arrangements between a faculty practice plan and another component of the same AMC and between a DHS entity and an affiliated physician practice in the same integrated section 501(c)(3) health care system will not be effective until December 4, 2008. Second, arrangements that either did not constitute indirect compensation arrangements or that fell into the indirect compensation arrangement exception prior to the Phase III Rules and that have been restructured to comply with a direct compensation arrangement as required under the Phase III Rules do not need to be restructured to comply with the revised physician “stand in the shoes” rules finalized in the 2009 IPPS Final Rule.

Entity “Stand in the Shoes”

The Final Rule does not include an entity “stand in the shoes” rule, although CMS has previously proposed such a rule. However, CMS cautions parties against attempting to evade restrictions on payments for referrals by using shell organizations interposed between the DHS entity and referring physicians, noting that such arrangements could be viewed as a violation of the Stark Law (by creating a nonexcepted indirect compensation arrangement or as an unlawful circumvention scheme) or as a violation of the Anti-kickback Statute. CMS notes that such an arrangement could be evidence of unlawful intent.

Reconsideration of “Set in Advance” Position

In the preamble to the Phase III Rules, CMS asserted that the “one year” and “set in advance” requirements in many of the direct compensation arrangements generally prohibited the parties to a contract from amending the compensation provisions in the contract in any respect during the initial year of the term of the contract and that, while parties could change the compensation provisions after the initial year, they could only do so by terminating the contract and entering into a new agreement. CMS retreated from this position in the Final Rule and now takes the position that amendments to an agreement between a DHS entity and a physician (or physician organization) are permitted provided certain conditions are met. The commentary to the Final Rule suggests (although it is unclear whether this is what CMS intended) that parties may amend the compensation provisions during the first year of an agreement, provided that the amended provisions remain in place for at least one year. Specifically, CMS stated:

[I]n light of the revisions we are finalizing with respect to the use of percentage-based and per-click compensation formulae for determining rental charges for

office space and equipment leases . . . , we believe that an interpretation that permits amendments to an agreement between a DHS entity and a physician (or physician organization) during the term of the agreement is consistent with our mandate to safeguard against program or patient abuse and is consistent with our rules regarding compensation that is “set in advance,” provided that: (1) all of the requirements of an applicable exception are satisfied; (2) the amended rental charges or other compensation (or the formula for the amended rental charges or other compensation) is determined before the amendment is implemented and the formula is sufficiently detailed so that it can be verified objectively; (3) the formula for the amended rental charges does not take into account the volume or value of referrals or other business generated by the referring physician; and (4) the amended rental charges or compensation (or the formula for the new rental charges or compensation) remain in place for at least 1 year from the date of the amendment. We are taking the opportunity here to clarify that the rule regarding the amendment of arrangements between DHS entities and physicians (or physician organizations) applies to all of the exceptions for compensation arrangements in 42 CFR, Subpart J that include a 1-year term requirement for satisfying the exception.

Although CMS stated that the amended terms must stay in place for at least one year, we suspect that it meant, instead, that the agreement cannot be amended during the following year (but could be terminated entirely).

Alternative Method for Compliance with Signature Requirements

The Final Rule includes an alternative method for compliance with signature requirements in certain circumstances, effective October 1, 2008. This alternative method applies to the following exceptions: (i) rental of office space; (ii) rental of equipment; (iii) personal service arrangements; (iv) physician recruitment; (v) fair market value; (vi) indirect compensation arrangements; (vii) referral services; (viii) obstetrical malpractice insurance subsidies; (ix) retention payments to physicians in underserved areas; (x) electronic prescriptions; and (xi) electronic health records. The alternative method is applicable only if all requirements of an exception other than the signature requirement are met and the following conditions are met:

(1) if the failure to comply with the signature requirement was inadvertent, the entity obtains the missing signature(s) within 90 days after the commencement of the financial relationship without regard to whether any referrals have occurred or compensation has been paid during such 90-day period; or

(2) if the failure to comply with the signature requirement was not inadvertent (i.e., knowing), the entity obtains the missing signature(s) within 30 days after the commencement of the financial relationship without regard to whether any referrals have occurred or compensation has been paid during such 30-day period.

The exception can only be used once every three years with respect to the same referring physician. DHS entities relying on this exception with respect to contracts with multi-physician

entities will need to be careful to ensure that the exception has not been used in the past three years with any of the affected physicians.

Period of Disallowance

The Final Rule provides for a maximum period of disallowance (*i.e.*, the period during which a physician cannot refer DHS to an entity and during which the entity cannot bill Medicare) for noncompliant financial relationships. The Final Rule places an outside limit on this period of disallowance, which ends no later than:

- (1) where the noncompliance is unrelated to compensation, the date that the financial relationship satisfies all of the requirements of an applicable exception;
- (2) where the noncompliance is due to the payment of excess compensation, the date on which all excess compensation is returned and the financial relationship satisfies all of the requirements of an applicable exception; and
- (3) where the noncompliance is due to the payment of insufficient compensation, the date on which all additional required compensation is paid and the financial relationship satisfies all of the requirements of an applicable exception.

The Final Rule does not define when a financial relationship begins or ends. The conduct of the parties and the specific facts of the case determine when a financial relationship begins and ends, and parties are expressly permitted by the Final Rule to argue that the period of disallowance ends earlier than the outside limit prescribed by the Final Rule. CMS stated that the Stark Law does not permit parties to back-date arrangements, return compensation, or otherwise attempt to “turn back the clock” so as to bring financial arrangements into compliance retroactively.

The Final Rule does not restrict the source of funds that the physician may use to repay excess compensation or to make up a shortfall in compensation. Thus, the physician may pay the funds out-of-pocket, may obtain a loan from a commercial lender, or may obtain a loan from the entity itself in order to repay excess compensation or to make up a shortfall in compensation. However, CMS questioned whether a loan offered by an entity to a physician to repay the entity is a sham transaction, questioned the commercial reasonableness of such loan transactions, and noted that such loans would be highly suspect under the Anti-kickback Statute and must themselves meet the requirements of an applicable exception.

Burden of Proof

Consistent with a change proposed by CMS in July, 2007, the Final Rule will place the ultimate burden of proof—the burden of persuasion—on the entity submitting the claim for payment, rather than on CMS or its contractors, in any appeal of a denial of payment for a DHS based on a Stark Law violation. Thus, entities appealing such a denial must establish that the service in question was furnished in compliance with the Stark Law and not pursuant to a prohibited referral. Although the burden of production also lies initially on the claimant, it may shift to CMS or a CMS contractor during the course of a proceeding as evidence is put forth. However, CMS declined to prescribe by regulation the type or quantity of evidence sufficient to

shift the burden of production from the claimant to CMS. CMS also clarified that the rule relates only to administrative appeals of claims denials and does not affect the appeals processes surrounding civil monetary penalties, exclusions or other remedies imposed from a determination that a DHS entity or a physician knowingly violated the Stark Law.

Many Stark Law exceptions include a requirement that the financial relationship not violate the Anti-kickback Statute, or any Federal or State law or regulation governing billing or claims submission. Thus, CMS is shifting to the claimant the burden to prove that it is not violating criminal statutes, even though the government would have the burden of proving a violation for purposes of the criminal statute itself.

Obstetrical Malpractice Insurance Subsidies

CMS finalized a new exception that allows hospitals, federally qualified health centers, and rural health clinics to provide obstetrical malpractice insurance subsidies to physicians who regularly engage in obstetrical practice as a routine part of a medical practice that is: (1) located in a primary care Health Professional Shortage Area (“HPSA”), rural area, or area with a demonstrated need as determined by the Secretary in an advisory opinion; or (2) comprised of patients at least 75 percent of whom reside in a medically underserved area (“MUA”) or are part of a medically underserved population (“MUP”). CMS also retained the existing exception for obstetrical malpractice insurance subsidies meeting the requirements of the Anti-kickback Statute safe harbor. CMS declined to expand the exception to cover malpractice insurance subsidies to physicians practicing in other medical specialties.

Disclosure of Financial Relationships

CMS is finalizing its plans to send the DFRR to approximately 500 hospitals (both general acute care hospitals and specialty hospitals), though CMS may possibly decrease this number. CMS notes that the purposes of the DFRR are to identify (a) arrangements that potentially may not be in compliance with the Stark Law and (b) practices that may assist CMS in future rulemaking regarding the reporting requirements and other Stark Law provisions. While CMS originally proposed to require completion and submission of the DFRR on a regular basis, CMS has retreated from this proposal for the time being, noting that it may in the future propose rulemaking to use the DFRR or some other information collection instrument on a periodic basis.

The DFRR requires hospitals to provide detailed information concerning both physicians’ ownership and investment interests in the hospital and physicians’ compensation arrangements with the hospital. Specifically, the DFRR requires hospitals to indicate whether they are physician-owned and, if so, to report, among other things, the following information: the class and amount of stock, and the direct or indirect ownership percentage, held by each physician investor; payments made by each physician-investor based on his or her direct or indirect ownership interest (e.g., initial investments, assessments, capital calls and loan guarantees); physician-investor distributions; and whether the physician-investor’s risk of loss or liability is limited or eliminated by an agreement or other understanding (e.g., a stop-loss agreement, a back-up guarantee, or disproportionate guarantee by a physician investor). The DFRR also requires hospitals to report certain information concerning the following compensation

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arrangements with physicians: office space rental arrangements; equipment rental arrangements; personal service arrangements; physician recruitment arrangements; isolated transactions (e.g., one-time sale of property or sale of a practice); non-DHS related compensation arrangements; payment-by-physician arrangements; physician-hospital charitable donation arrangements; and non-monetary compensation arrangements and/or medical staff incident benefits granted to a physician that exceed published limits.

Parties receiving the DFRR will have 60 days to complete and return the DFRR to CMS.

Questions regarding this memorandum may be directed to any of the following, or to the member of the firm who handles your health care matters:

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