



## CMS Issues the 2009 Inpatient Prospective Payment Systems Final Rule and Makes More Changes to the Stark Law Regulations

On August 19, 2008, the Centers for Medicare & Medicaid Services ("CMS") issued the Hospital Inpatient Prospective Payment Systems final rule for discharges in Fiscal Year (FY) 2009 ("2009 Final Rule"). While technically speaking, it may not be called the Stark II, Phase IV regulations, what it lacks in name it undoubtedly makes up for in substance. CMS has used the 2009 Final Rule to adopt a number of important changes and clarifications to the Stark Law regulations based on proposals in the Hospital Inpatient Prospective Payment Systems proposed rule for discharges in FY 2009 ("2009 IPPS Proposed Rule") as well as proposals in the 2008 Medicare Physician Fee Schedule proposed rule ("2008 MPFS Proposed Rule") that were not addressed in the 2008 Medicare Physician Fee Schedule final rule. This newest round of changes is by far more reaching than any of the changes implemented by CMS in the Stark II, Phase III regulations issued last year.

The Stark-related changes and clarifications contained in the 2009 Final Rule are, generally speaking, effective October 1, 2008. Certain of the changes, however, such as the provisions prohibiting common "under arrangements" transactions, percentage-based lease payments and per-unit leases, are not effective until October 1, 2009, in an effort to give providers time to restructure or unwind existing arrangements that currently do not comply with the new changes. This executive summary will review these Stark-related changes and clarifications, beginning first with the changes that are effective October 1, 2009, as these are the changes that potentially will have the greatest impact on providers' current arrangements.

### I. Changes effective October 1, 2009

#### A. "Under Arrangements"

An "under arrangement" transaction is one in which a hospital contracts with a physician or practice to provide a hospital service or item through an arrangement with the physician or practice, but the hospital, instead of the physician or practice providing services, submits the claim for payment. Under the Stark Law, physicians are prohibited from making referrals for designated health services ("DHS") to an entity with which the physician (or an immediate family member) has a financial relationship, and entities are prohibited from billing Medicare for DHS unless an exception applies.

Previously, the definition of "entity" included only the billing person or entity, and not the person or entity that performed the DHS where the person or entity performing the DHS is not the person or entity billing for it. The prior definition had effectively allowed referring physicians to circumvent the intent of the rule, which was to curb the risk of over utilization of services by physicians who stood to benefit financially from making referrals to entities in which they had an ownership or investment interest. Before the Final Rule change, only the billing entity, and not the service provider (provided they were different), was deemed to be furnishing DHS. Effective October 1, 2009, CMS will amend the definition of "entity" such that any person or entity will be deemed to be "furnishing" DHS if it is the person or entity that performed DHS, even if another person or entity submitted a claim to Medicare for DHS.

In practice, the change means that physicians will no longer be able to own or invest in an entity that provides DHS "under arrangements" absent compliance with a Stark exception. Referrals made by physicians

*continued...*

who do not have an ownership or investment interest in the entity providing services to the entity that bills for DHS may be protected under the direct compensation exception, but few other exceptions will be available.

Note that the definition of "entity" will not include a physician organization that bills for the professional component of a diagnostic test where the anti-markup provisions of §414.50 are applicable to the professional component, and the physician organization bills in accordance with the anti-markup provisions.

## **B. Prohibition on Percentage-Based Compensation for Rental of Office Space and Equipment**

If a physician has a financial relationship with an entity that provides DHS, Stark requires that the compensation arrangement between the parties be "set in advance," meaning that the aggregate compensation (*i.e.*, a time-based or per-unit amount, or a specific formula for calculating the compensation) be set forth in an agreement between the parties before the furnishing of items or services for which compensation is to be paid. In Phase I, percentage-based compensation arrangements did not meet the "set in advance" standard. In Phase II, on the theory that its original position was overly restrictive in certain instances, CMS made an exception for physicians who earned percentage-based compensation for services they personally performed. Under the 2009 Final Rule, CMS will continue to allow physicians to earn percentage-based compensation for services they personally perform, but will expressly prohibit all percentage-based compensation arrangements that pay for items and services, such as medical equipment and office space, on a percentage of revenues realized by the equipment or space.

CMS believes that lease payments based on a percentage of revenues earned by the lessee provide an incentive for the lessor to increase DHS referrals to the lessee, potentially resulting in increased rental payments under the lease. In addition, fluctuating rental payments determined by a percentage-based formula may not result in fair market value payments (even if the formula itself is arguably reasonable), which also poses an increased risk of program or patient abuse. For example, under the indirect compensation exception, which requires that the compensation received by the referring physician (or immediate family member) be fair market value for the services and items provided, a compensation arrangement based on a percentage of collections may not, depending on how actual collections progress, result in fair market value by the referring physician (or immediate family member). Likewise, with respect to an indirect compensation arrangement involving, for example, the rental of equipment between a physician lessor and a DHS entity lessee, compensation based on a percentage of collections for the services performed on the equipment may not result in fair market value, depending on how the collections actually materialize.

Specifically, the 2009 Final Rule amends the current Stark exceptions for the rental of office space (§411.357[a]), the rental of equipment (§411.357[b]), fair market value compensation arrangements (§411.357[1]), and indirect compensation arrangements (§411.357[p]) to prohibit the use of compensation formulae for space or equipment leases based on a percentage of the revenue raised, earned, billed, collected or otherwise attributable to the services performed or business generated in the leased office space or to the services performed on or business generated by the use of leased equipment. Although the prohibition does not extend to the use of percentage-based compensation formulae to arrangements for any non-professional service (such as management or billing services), CMS reiterated its intention to continue to monitor arrangements for non-professional services that are based on a percentage of revenue raised, earned, billed, collected or otherwise attributable to a physician's (or physician organization's) professional services.

Note that under the Final Rule, all percentage-based arrangements for the lease of space or equipment will be prohibited, whether structured as direct or indirect financial arrangements. All such arrangements must be restructured no later than October 1, 2009, when the rule becomes effective.

## **C. Prohibition on Unit of Service (Per-Click) Arrangements**

One of the most important changes in the 2009 Final Rule addresses "per-click" space and equipment leases. In the 2008 Proposed Rule, CMS stated that per-click payments made to a physician lessor by an entity lessee for services rendered to a patient referred by the physician lessor are inherently susceptible to abuse, due to the profit incentive for referring a higher volume of patients to the lessee. Accordingly, effective October 1, 2009 the Final Rule will prohibit per-click payments from physician lessors to DHS entity lessees for services rendered to patients referred by such physician lessors (and vice versa, if the entity is a DHS entity that refers patients to the physician lessee). In other words, such arrangements will not qualify under the exceptions for space and equipment leases, nor can they be used to rent equipment under the fair market

*continued...*

value or indirect compensation exceptions. The prohibition on per-click payments for space or equipment used in the treatment of a patient referred to the lessee by a physician lessor applies regardless of whether the physician himself or herself is the lessor, or the entity in which the referring physician has an ownership or investment interest is the lessor.

Given the prohibition on percentage-based compensation and per-click payments, the Final Rule changes will necessitate the restructuring of joint ventures between entities and referring physicians who invest in a joint venture, where the joint venture entity leases space or equipment to a hospital or other DHS entity, to the extent that the lease payments to the joint venture entity are based on (i) a percentage of revenue raised, earned, billed, collected or otherwise attributable to the services performed or business generated in the space or through use of the equipment, or (ii) per-click rental charges, to the extent that such charges reflect services provided to patients referred between the parties.

For parties to per-click leasing arrangements, CMS reiterated that the existing exceptions include the requirements that the leasing agreement be at fair market value (§§411.357[a][4] and 411.357[b][4]) and that it be commercially reasonable even if no referrals were made between the parties (§§411.357[a][6] and 411.357[b][5]). As an example, CMS stated that it would not consider an agreement to be at fair market value if the lessee is paying a physician substantially more for a lithotripter or other equipment and a technologist than it would have to pay a non-physician-owned company for the same or similar equipment and service. CMS also stated that it would have a serious question as to whether an agreement is commercially reasonable if the lessee is performing a sufficiently high volume of procedures, such that it would be economically feasible to purchase the equipment rather than continuing to lease it from a physician or physician entity that refers patients to the lessee for DHS. Such agreements raise the issue of whether the lessee is paying the lessor more than it would have to pay another lessor, or is leasing equipment rather than purchasing it, because the lessee wishes to reward the lessor for referrals and/or because it is concerned that, absent such a leasing arrangement, referrals from the lessor would stop. CMS added that in some cases, depending on the circumstances, such arrangements may also implicate the anti-kickback statute.

Note that CMS did not prohibit “time-based” lease deals, including “block leases” on the theory that time-based leases can meet applicable Stark exceptions, but it will monitor them and may issue future rules.

## **II. Changes effective October 1, 2008**

### **A. “Stand in the Shoes” Provisions**

Originally added in the Stark II, Phase III regulations, the “stand in the shoes” (“SITS”) rules provided that a physician was deemed to have a direct – rather than indirect – compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her “physician organization” (defined as a physician, including a professional corporation of which the physician is the sole owner, a physician practice, or a group practice that complies with the Stark regulations’ requirements for group practices). As a practical matter, the SITS rules deemed that physician members, employees, and independent contractors of a physician organization will have the identical compensation arrangement (with the same parties and under the same terms) as the physician organization itself. Where applicable, SITS converts what traditionally has been considered an indirect compensation arrangement into a direct compensation arrangement, and necessitates that the exceptions applicable to direct (rather than indirect) compensation arrangements be satisfied.

In an attempt to simplify the analysis of many financial arrangements and make it easier to apply in practice, CMS has limited its SITS rules to apply only to physicians who have ownership or investment interests in a physician organization. Under the 2009 Final Rule, the SITS rules do not apply to physicians who have only a compensation arrangement with, or a “titular” ownership interest in, a physician organization. Stated differently, physicians who have no ownership/investment interest in a physician organization (e.g., physician employees and independent contractors), and physicians with only a “titular” ownership/investment interest in a physician organization (e.g., where the physician does not have the ability or right to receive the financial benefits of ownership or investment, which is common in a captive PC arrangement), are permitted, but not required, to stand in the shoes of their physician organization.

In amending its SITS rules, CMS sought to address the concerns raised by academic medical centers (“AMC”) and integrated, tax-exempt health care delivery systems after publication of the Stark II, Phase III

*continued...*

regulations. Specifically, CMS clarified that SITS does not apply to arrangements that satisfy the requirements of the AMC exception. In addition, AMC and integrated, tax-exempt health care delivery systems' physicians may continue to rely on the indirect compensation arrangement definition and exception because they will not be required to stand in the shoes of their faculty practice plan or other physician organization. While CMS declined to extend the SITS moratorium applicable to AMCs and integrated health care delivery systems beyond its December 4, 2008 deadline, the revisions to the SITS rule contained in the 2009 Final Rule, which are effective October 1, 2008, should allow such entities to continue utilizing an indirect compensation analysis.

## **B. Period of Disallowance**

In the 2009 IPPS Proposed Rule, CMS proposed to clarify the period of time during which (1) a physician cannot refer a Medicare beneficiary for DHS to an entity, and (2) the entity cannot bill Medicare for DHS furnished to such patient because the financial relationship between the referring physician and the entity failed to satisfy all of the requirements of an exception to the Stark Law. CMS referred to this time period as the "period of disallowance." CMS has finalized these clarifications in the 2009 Final Rule, thus creating a bright-line rule for determining the outer limit of the period of disallowance.

Specifically, the 2009 Final Rule provides that if the cause for the non-compliance is unrelated to compensation (i.e., an agreement lacks a physician's signature), then the period of disallowance ends no later than the date that the financial relationship satisfies all of the requirements of an applicable exception. If the cause for the non-compliance is related to the parties' incorrect valuation of compensation (i.e., excessive or inadequate remuneration), the disallowance period ends no later than the date on which all excess compensation is returned to the party that paid it, or all additional required compensation is paid to the party to which it is owed.

CMS provided some practical illustrations of how the period of disallowance is applied. For example, for arrangements that are non-compliant for reasons wholly unrelated to compensation, CMS offered the following: On January 1, 2009, a referring physician and a DHS entity enter into a lease of office space (thus creating a financial relationship), but the physician failed to sign the lease agreement, then subsequently did so. If the physician signed the agreement more than 90 days after January 1, 2009, the arrangement would be non-compliant with the lease exception, and there would be a period of disallowance beginning as of January 1, 2009. Under the new rule, the period of disallowance would run until no later than the date the physician signed the agreement. However, in providing such example, CMS noted that taking action that fixes the non-compliance and ends the period of disallowance does not vitiate a DHS entity's overpayment for any claims submitted during the period of disallowance as a result of the prohibited referrals.

CMS offered the following example of an arrangement that is not compliant because the compensation does not comport with fair market value: A referring physician and a DHS entity enter into a personal services arrangement on January 1, 2009 and the physician is unknowingly paid excess compensation for the first six months of the agreement. The parties discover the error at the end of month six, and on July 1, 2009, fix it going forward. Such action would not end the period of disallowance simply because the arrangement is brought into compliance with an exception going forward. Rather, the parties would have to fix the arrangement going forward and the physician would have to repay the excess compensation due to the DHS entity for the first six months of the arrangement. In discussing this example, CMS noted that even though the period of disallowance would end on July 1, 2009, claims submitted for referrals for DHS made during the period of disallowance are not payable. In addition, CMS cautioned that civil monetary penalties, assessments and exclusion could also be assessed, irrespective of whether harm is caused to the Medicare program, and liability under the False Claims Act could be imposed. Further, the parties could also potentially be found guilty, depending on the facts, of violating the anti-kickback statute or other criminal or civil law.

In the commentary, CMS was careful to its position that the Stark Law does not contemplate that parties may resolve technical violations of the statute by simply back-dating arrangements, returning compensation, or otherwise attempting to turn back the clock so as to bring an arrangement into compliance retrospectively. Under the Stark Law, all requirements of an applicable exception must be met at the time the referral is made; thus, a technical violation is a violation. CMS believes that allowing parties to retroactively "cure" a non-compliant relationship by having one party repay another party excess compensation, would pose a risk of program abuse. But, such action would end the period of disallowance, thus permitting a physician to refer a Medicare beneficiary for DHS to an entity, and such entity to bill Medicare for DHS furnished to such patient going forward.

*continued...*

### **C. Alternative Compliance Provision for Signature Requirements in Certain Exceptions**

CMS modified its original proposal to amend certain of the Stark Law exceptions for violations in which a financial relationship fails to satisfy a procedural or “form” requirement of an exception, which it referred to as the “alternative method for compliance.”

The proposed rule had a number of requirements, including self-disclosure of the non-compliance, in order to be able to take advantage of the alternative method for compliance. In the 2009 Final Rule, however, CMS did not adopt many of its proposals. Instead, it simplified the terms for the alternative method for compliance and made it applicable only to written arrangements that failed to comply with the signature requirement. Thus, under the 2009 Final Rule, payment may be made to an entity that submits a claim or bill for DHS if the financial relationship between the entity and the referring physician fully complied with an applicable Stark Law exception but for the signature requirement; provided, however, that where the lack of signature was inadvertent, it is rectified within 90 days after the commencement of the financial relationship, or, where there was a knowing lack of signature, it is rectified within 30 days of the start of the financial relationship.

There are a number of Stark Law exceptions for compensation arrangements that require, as an element of the exception, that the arrangement be in writing and be signed by both parties. The alternative method for compliance provisions will provide hospitals and physicians a limited grace period in which to bring their written agreements into compliance. However, in order to take advantage of the protection these provisions provide, the underlying financial relationship at issue must, at the commencement of the financial relationship, satisfy all of the other requirements of an applicable exception. CMS was quick to note that it did not intend for the alternative method for compliance to be used as a default method by which parties comply with the conditions of a certain exception. Accordingly, CMS limited the ability to remedy signature deficiencies with respect to an individual referring physician to only once every three years.

### **D. Obstetrical Malpractice Subsidies**

The 2009 Final Rule maintains the current exception for obstetrical malpractice subsidies provided by a hospital or other entity (which requires that the subsidies meet the anti-kickback safe harbor for such subsidies), but added additional language to expand the exception to cover a broader range of geographies for subsidies only provided by a hospital, federally qualified health center or rural health clinic.

Under the revised exception, a physician who engages in obstetrical practice as a routine part of his or her medical practice will be eligible for receipt of an obstetrical malpractice subsidy if his or her medical practice is: (1) located in a primary care Health Professional Shortage Area (“HPSA”), a rural area, or an area with demonstrated need for the physician’s obstetrical services (as determined by CMS in an advisory opinion); or (2) comprised of patients, at least 75 percent of whom reside in a medically underserved area (“MUA”) or are members of a medically underserved population (“MUP”). Of significance, the revised exception permits the inclusion of patients who reside in a rural area when calculating whether at least 75 percent of the patients treated reside in an underserved (i.e., HPSA or MUA) area, or are part of a MUP.

### **E. Ownership/Investment in Retirement Plans**

The existence of a financial relationship – which is the factual predicate for triggering the application of the Stark Law – may arise from an ownership or investment interest or a compensation arrangement. Under the current regulations, ownership and investment interests do not include an interest in a retirement plan.

In the 2009 Final Rule, CMS adopted its proposal to clarify that only interests in a retirement plan offered to physicians (or their immediate family members) by virtue of the physician’s (or immediate family member’s) employment with that entity would be excluded from the definition of “ownership or investment interest” for purposes of determining whether a financial relationship exists. In so doing, CMS made clear that it did not exclude from the definition of “ownership or investment interests” any interest the physician may have had in another entity through the retirement plan’s purchase of an interest in that other entity. Otherwise, physicians may be able to circumvent the self-referral prohibition by allowing physicians to do indirectly what they would not be able to do directly.

*continued...*

To illustrate, assume a hospital offers its employed physicians participation in its retirement plan. The assets of the retirement plan are used to invest in an imaging facility that furnishes DHS and to which the hospital's employed physicians refer. Under the revised regulations, the physician's interest in the hospital's retirement plan would not constitute an ownership or investment interest. But, the physician's interest in the imaging facility, through the assets of the retirement plan, would require compliance with an applicable exception, just as if the physician had directly purchased or invested in the imaging facility.

#### **F. Burden of Proof**

CMS, in a new regulatory provision, has clarified that any appeal of a denied claim for payment for DHS that resulted because the service was furnished pursuant to a prohibited referral requires the entity submitting the claim (not CMS or its Medicare contractors) to prove that the services was not furnished pursuant to a prohibited referral. That is, the burden of proof (which CMS refers to as the "burden of persuasion") is on the entity submitting the claim throughout the course of the appellate proceeding and at each level of the appeal. However, the burden of proof, while initially on the entity, may shift to CMS or its contractors during the course of the appeal.

\* \* \*

To the extent that you have any questions, please contact your regular GWT attorney.

### About Garfunkel, Wild & Travis, P.C.

Garfunkel, Wild & Travis, P.C. was founded in 1980 with a single purpose in mind: to become a preeminent health care law firm attending to the unique business and legal needs of its clients. Since then, the firm has grown to 80 attorneys devoted to addressing the complex legal, regulatory, business and financial needs of its diverse clients.

If you would like to receive Legal Alert mailing from Garfunkel, Wild & Travis, P.C. electronically in the future, or if you would like to be removed from the mailing list, please contact us at (516) 393-2258 or [subscriptions@gwtlaw.com](mailto:subscriptions@gwtlaw.com). You may also visit the Firm's website at [www.gwtlaw.com](http://www.gwtlaw.com).

THIS MATERIAL IS INTENDED AS INFORMATIONAL ONLY AND THE CONTENT SHOULD NOT BE CONSTRUED AS LEGAL ADVICE. READERS SHOULD NOT ACT UPON INFORMATION IN THIS MATERIAL WITHOUT FIRST SEEKING PROFESSIONAL ADVICE.

111 Great Neck Road  
Great Neck, NY 11021  
(516) 393-2200 ● fax (516) 466-5964

411 Hackensack Avenue  
Hackensack, NJ 07601  
(201) 883-1030 ● fax (201) 883-1031

350 Bedford Street  
Stamford, CT 06901  
(203) 316-0483 ● fax (203) 316-0493