

New Stark rules: Yet more arrangements to be restructured

On Aug. 19, 2008, the Centers for Medicare and Medicaid Services (CMS) published final Stark rules in its 2009 Final Hospital Inpatient Prospective Payment Systems rule (Final Rule). The Final Rule contains several important revisions to the Stark regulations, some of which will require physicians, hospitals, or other health care providers, to unwind or restructure their arrangements.

Some of the new Stark rules are not effective until Oct. 1, 2009, to give parties with arrangements that are impacted by the new rules time to unwind or restructure, but other provisions are effective Oct. 1, 2008.

In addition to these new Stark changes, health care providers must stay tuned for additional significant Stark and Medicare payment regulatory changes, which are expected to be published in November 2008 as part of the 2009 Medicare Final Physician Fee Schedule, and in future regulations.

With all of the recent regulatory changes, health care providers should have their arrangements reviewed to ensure that they continue to be in compliance with the Stark law.

A synopsis of the Final Rule Stark changes is as follows:

- **“Stand in the shoes” provisions** Effective Oct. 1, 2008, only physicians who have an ownership or investment interest in their physician organizations (e.g., group practice) will be required to stand in the shoes (SITS) of those organizations. The SITS doctrine no longer applies to non-owner physicians. CMS also carves out an exception for physicians participating in financial arrangements that satisfy the Stark exception for academic medical centers.

The SITS concept is used for purposes of determining whether a physician has a direct or indirect financial relationship with a DHS entity.

- **“Set in advance” and amendments to agreements:** CMS now states that it is reversing its prior position and permitting multi-year agreements to be amended after the first year without violating Stark’s “set in advance” requirement.

- **Period of disallowance:** Effective Oct. 1, 2008, CMS establishes a rule that sets the outer limit of the time period during which referrals are prohibited as a result of a financial relationship that fails to satisfy a Stark exception. Disallowance begins when the relationship fails to satisfy an exception and ends no later than the date that it satisfies an exception and the parties have returned any overpayments or paid any underpayments.

- **Alternative method for compliance:** Effective Oct. 1, 2008, if a financial relationship complied with an applicable Stark exception, except for meeting the signature requirement, Medicare payments to the entity will be permitted if the signature requirement is complied with within 30 days (for knowing failures) or 90 days (for inadvertent failures) after the commencement of the relationship.

- **“Per-click” leasing arrangements:** Effective Oct. 1, 2009, CMS eliminates the use of “per-click” fee payments

- **Ownership or investment interest in retirement plans:** Effective Oct. 1, 2008, CMS narrows the so-called “retirement plan exception” to ensure that referring physicians cannot use it to evade Stark’s self-referral prohibition by investing in a DHS entity via their employer’s retirement plan. Under the Final Rule, only a physician’s ownership or investment interest in their employer-sponsored retirement plan is protected.

- **Burden of proof:** Under the Final Rule, CMS revises the regulations to place the burden of proof in appeals of Stark-based payment denials on the entity appealing the denial. This burden is consistent with the burden of proof on Medicare providers and suppliers appealing payment denials based upon other reasons, such as a failure to meet a condition of coverage.

- **Disclosure of Financial Relationships Report (DFRR):** The Final Rule announces that CMS is proceeding with its proposal to send the DFRR to 500 hospitals. The DFRR is designed to collect information regarding the ownership and investment interests and compensation arrangements between hospitals and physicians.

- **Medicare Stark payment denial code:** Although not part of the Final Rule, it is significant for health care providers to note that Medicare carriers and intermediaries have now been given a specific code to deny payment to providers due to violations of Stark.



in space and/or equipment leases when the payments reflect services provided to patients referred between the parties. This “per-click” fee prohibition applies to both direct leasing arrangements and indirect leasing arrangements (e.g., leases between physician-owned leasing companies and hospitals).

- **Percentage-based leasing arrangements:** Effective Oct. 1, 2009, CMS eliminates percentage-based compensation in space and equipment leases, paralleling its treatment of “per-click” payments in space and equipment leases. Under the Final Rule, compensation for the rental of office space or equipment that is 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 the services performed or business generated through the use of equipment is prohibited.

- **Services provided “under arrangements”:** Effective Oct. 1, 2009, both the hospital that bills for services provided “under arrangements” and the entity that provides the services to the hospital will be considered to be furnishing “designated health services” (DHS) under Stark. This change will effectively eliminate a referring physician’s ability to own interests in such service providers.

- **Exception for obstetrical malpractice insurance subsidies:** Effective Oct. 1, 2008, CMS adds an alternative exception for subsidies of malpractice insurance premiums provided by hospitals, federally qualified health centers and rural health clinics.

Stand in the shoes (SITS)

Under the Final Rule, a physician who has an ownership or investment interest in a physician organization (e.g., group practice) is deemed to stand in the shoes of his or her physician organization, but a physician who has only a compensation arrangement (or one with only titular ownership interest) need not be treated as standing in the shoes of such organization.

A titular ownership interest is an ownership interest in which the physician is not able or entitled to receive any of the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale or similar return on investment (e.g., captive PC). For physicians who are not required to be treated as “standing in the shoes,” an entity may elect to apply “stand in the shoes” on a case-by-case basis.

The new SITS rule does not apply to arrangements that satisfy the requirements of the academic medical center (AMC) exception, but CMS declined to finalize a separate exception for compensation arrangements involving mission support payments or similar payments in the context of AMCs or integrated delivery systems.

CMS also declined to extend the current SITS moratorium applicable to AMCs and integrated health care delivery systems beyond its Dec. 4, 2008, deadline. However, the new revisions to the SITS rule should allow an indirect compensation analysis of many arrangements to be preserved.

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Last, CMS did not finalize its earlier proposal to apply SITS to owners of DHS entities beyond physician organizations.

'Set in advance' and amendments to agreements

In response to a comment in the preamble discussion of the Final Rule, CMS indicates that it has reconsidered and changed its earlier Stark II Phase III Final Rule position, that a multi-year agreement for rental of office space or a personal service arrangement may not be amended during its term without violating the Stark exceptions' requirement that the compensation under the arrangement be "set in advance" for the term of the agreement.

This position was widely criticized as imposing additional transaction costs on the parties to these agreements by requiring them to terminate an existing agreement and enter into a new agreement on modified terms rather than simply amending the agreement.

CMS now states that in light of the new final revisions with respect to percentage-based and "per-click" compensation formulae, an agreement is permitted to be amended as long as the following criteria are met:

- All of the requirements of an applicable exception are satisfied;
- The amended rental charges or compensation (or the compensation formula) is determined before the amendment is implemented, and the formula is sufficiently detailed so it can be verified objectively;
- The formula for amended rental charges does not take into account the volume or value of referrals or other business generated by the referring physician;
- The amended rental charges or compensation (or the compensation formula) remains in place for at least one year from the date of the amendment.

Period of disallowance for non-compliant relationships

In the Final Rule, CMS finalizes its earlier proposal to provide that from the time that a financial relationship fails to satisfy a Stark exception to a period no later than the date that the financial relationship satisfies all of the requirements of a Stark exception (including returning any overpayments or paying any underpayments), a physician may not refer DHS to the entity and the entity may not bill Medicare.

These new rules create an outside limit for the period of disallowance and are not intended to prevent parties from arguing that the period of disallowance ended sooner on the theory that the financial relationship ended earlier.

CMS cautions, however, that the beginning and end dates of a financial relationship for purposes of the disallowance period do not necessarily correspond with the term of the parties' written agreement.

Alternative method for compliance

A host of Stark compensation exceptions include a signature requirement. The Final Rule adopts a provision which permits payments to an entity that fully complied with an applicable Stark exception, except with respect to a signature requirement, if:

- the failure to comply with the signature requirement was inadvertent and the entity rectifies the failure to comply within 90 days after the commencement of the financial relationship (without regard to whether referrals have occurred or compensation paid); or
- the failure to comply with the signature requirement was not inadvertent (knowing) and the entity rectifies the failure within 30 days after the commencement of the financial relationship.

This new exception may only be used once every three years with respect to the same referring physician.

Prohibition on 'per-click' space, equipment lease arrangements

Under the Final Rule, CMS prohibits the use of "per-click" payments for space and equipment leasing arrangements. CMS makes clear that the prohibition on "per-click" payments applies regardless of whether the physician is personally the lessor or whether the lessor is an entity in which the referring physician has an ownership or investment interest.

This limitation applies where the lessor is a DHS entity that refers patients to a physician or physician organization lessee.

This new "per-click" prohibition, combined with the prohibition on percentage-based compensation formulae, will have a significant effect on current leasing joint venture arrangements whereby referring physicians and hospitals or others have formed a joint venture entity for the purpose of leasing space or equipment to a hospital or other DHS entity on a variable fee basis.

The Final Rule now requires that to the extent there are any physician investors in the joint venture leasing entity that refer to the lessee entity, the lease payments between the lessee and the joint venture may not be based on either:

- 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
- per-unit rental charges, to the extent that such charges reflect services provided to patients referred between the parties.

Percentage-based leasing arrangements

In an earlier proposal, CMS planned on eliminating percentage-based compensation arrangements except in the context of personally performed service agreements. CMS now modifies its earlier position, and finalizes a rule that eliminates all percentage-based compensation only in the context of 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 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.

In implementing this rule, CMS effectively ends all percentage-based arrangements for the lease of space or equipment, whether structured as direct or indirect financial arrangements. Current percentage lease arrangements that run afoul of this new prohibition will need to be re-structured prior to Oct. 1, 2009.

'Under arrangements' under attack

Under current Stark law, only entities that bill Medicare for DHS are considered DHS entities. The Final Rule significantly expands the definition of "entity" to include entities that perform services that are in turn billed as DHS by another entity. As a practical matter, this change means that referring physicians likely will not be able to have an ownership or investment interest in "under arrangements" service providers.

Because this change will require the unwinding or restructuring of many "under arrangements" transactions (e.g., physician-owned entities that provide services to hospitals "under arrangements"), CMS delayed the effective date until Oct. 1, 2009.

Under the current Stark regulations, because the "under arrangements" service provider is not considered a DHS entity, the Stark analysis focuses on the relationship between the hospital and the referring physicians associated with the service provider.

These arrangements are analyzed as either direct financial arrangements (if a referring physician stands in the shoes of the service provider) or indirect financial arrangements (if "stand in the shoes" does

not apply) and generally can be structured to fit within a direct or indirect compensation exception.

Under the Final Rule, any financial relationship between the service provider and the physicians who refer patients to it for services that the hospital bills "under arrangements" will need to comply with a Stark exception.

Direct compensation exceptions should be available to protect referrals from the service provider's non-owner physicians, but very few exceptions are available for referring physicians who own an interest in the service provider. In most cases, the only exception that could apply is the exception for rural providers.

CMS makes clear that even if a service provider, such as a cardiac-catheterization lab, performs services that would not otherwise be DHS if the services were provided and billed by the service provider in a freestanding setting, the services become DHS and the service provider becomes a DHS entity when a hospital bills for those services pursuant to an "under arrangements" contract as the services are considered inpatient or outpatient hospital services.

CMS did not define when an entity is considered to be "performing" DHS. CMS states that the common meaning of the term should apply. CMS states in preamble commentary that it considers a physician or physician organization to have performed DHS "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."

However, CMS states that it would not consider a lessor of equipment or space, a provider of management, billing services, or personnel, or an entity that furnishes supplies that are not separately billable but are used in the performance of medical services to be performing DHS.

Left unclear is whether an entity that does some, but not substantially all, of the "medical work" for the service (such as a turn-key management service provider) will be considered

to be performing DHS.

Additionally, because of the new "per-click" and percentage-based compensation prohibitions discussed above, even if not deemed to be a DHS entity, many of these arrangements will no longer meet a Stark exception.

Alternative exception for obstetrical malpractice insurance subsidies

The Stark regulations currently include an exception for obstetrical malpractice insurance premium subsidies that meet the federal anti-kickback safe harbor. The Final Rule includes a new alternative exception that protects subsidies paid by a hospital, federally qualified health care center or rural health clinic if 10 specific requirements are met.

Under the new alternative, among others, the physician's practice must be located in a primary care Health Professional Shortage Area, rural area, or area with a demonstrated need for obstetrical services; or at least 75 percent of the physician's obstetrical patients must live in a medically underserved area or are part of a medically underserved population.

Ownership or investment interests in retirement plans

Under current Stark regulations, ownership and investment interests do not include an interest in a retirement plan. The Final Rule modifies this exception to address concerns regarding potential circumvention of the self-referral prohibition by referring physicians investing through retirement plans in a DHS entity

that he or she would be prohibited from investing in directly.

CMS revises the retirement plan exception to except only ownership or investment interests in an entity "that arises from a retirement plan offered by that entity to physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that entity."

Accordingly, under the Final Rule, a referring physician, for example, that is employed by a practice that furnishes in-office ancillary services (practice) and, through his employment with practice, has an interest in the practice's retirement plan, and the practice's retirement plan then invests in a home health agency (HHA), will need to rely upon an ownership exception for his investment in the HHA, just as if he or she invested in the HHA directly. As a practical matter, unless the rural provider exception applies, there likely is no applicable ownership exception.

'Burden of proof'

In the Final Rule, CMS clarifies that when a DHS entity appeals a claim for payment that was denied on the basis that it was furnished pursuant to a prohibited referral, the DHS entity has the burden of proof at each level of the appeals process to establish that the service was not furnished pursuant to a prohibited referral.

The burden of production on each issue at each level of appeal is initially on the DHS entity, but may shift to CMS or its contractors depending on the evidence the DHS entity presents. CMS notes that this approach is consistent with the current Medicare claims appeals process.

Given the far reach of Medicare's Recovery Audit Contractors (RACs) and CMS's new Stark payment denial code, in the near future, providers may be faced with RAC auditors (who are paid on a contingency basis) denying services based on Stark violations. Although this raises several issues not addressed in this article, it certainly should change one's perspective on the fairness of requiring the claimant to establish the burden of proof at each level of the appeals process.

The Disclosure of Financial Relationships Report

The Final Rule announces that CMS is proceeding with its proposal to send the Disclosure of Financial Relationships Report (DFRR) to 500 hospitals (general acute care and specialty).

The DFRR is designed to collect information concerning the ownership/investment interests and compensation arrangements between hospitals and physicians. Hospitals that receive the DFRR will have 60 days to respond. CMS may decide to decrease (but not increase) the number of hospitals that will receive the DFRR.

CMS notes that although it has authority to impose civil monetary penalties of up to \$10,000 per day for late submissions, it is using the Final Rule to inform the public that it will issue a letter to any hospital that does not return a completed DFRR, inquiring as to why the hospital failed to do so, before imposing such penalties.

Also, CMS reiterated that it will give hospitals extensions of time to complete the DFRR submission "upon a demonstration of good cause."

What's next?

Clearly, many of the Stark changes in the Final Rule will require modification, restructuring, or unwinding of existing arrangements. CMS has given providers a year to comply with many of the significant changes. However, CMS is not done yet, as many additional Stark and Medicare payment rules are expected to be published this year as part of the 2009 Medicare Final Physician Fee Schedule.

These expected changes relate to Medicare's anti-markup prohibition, new IDTF requirements for physician's furnishing imaging services in the office, and a new Stark gainsharing exception. Further, CMS has also promised future proposals which may narrow the in-office ancillary services exception, an exception that is crucial to many group practices providing ancillary services (e.g., imaging, lab, PT) through their offices.

Health care providers should consult with a qualified health care attorney to assist in interpreting the voluminous existing rules, new rules, and future proposals and how these rules and changes may apply to existing or future arrangements.

