PUBLICATION

SIGNIFICANT CHANGES MADE TO STARK REGULATIONS

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The Centers for Medicare and Medicaid Services (CMS) released the FY 2009 Inpatient Prospective Payment System Rule on July 31, 2008, which included significant changes to the Stark Law rules on physician self-referral. These rules will be published in the August 19, 2008 issue of the *Federal Register*.

The Stark Law (1) prohibits a physician from making referrals for "designated health services" (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation) unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those DHS rendered as a result of a prohibited referral.

Key changes in these new Stark rules include (1) the expansion of the definition of DHS "entity"; (2) prohibition of percentage-based payments and per-click arrangements for space and equipment leases and (3) clarification of the concept of when a physician is deemed to "stand in the shoes" of his or her physician organization. Many legitimate business arrangements, including office space and equipment leases and physician ownership in joint ventures which provide services "under arrangements" with hospitals and other providers, have been entered into in compliance with and in reliance upon the exceptions provided in the Stark Law and rules. Under these new rules, many of these arrangements must be restructured.

Although certain provisions of the rules are effective October 1, 2008, the effective date is October 1, 2009, for the provisions which will require restructuring of current compliant arrangements, such as the change in the definition of DHS "entity" and revisions to the exceptions for space leases, equipment leases, fair market value compensation arrangements and indirect compensation arrangements to place limitations on the payment methodologies allowed under these exceptions.

The final rules are even broader than the key changes noted above. A brief summary of the rule changes is as follows:

Burden of Proof. The ultimate burden of proof at each level of appeal is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral.

Period of Disallowance. The period during which referrals are prohibited is the period of disallowance. The period of disallowance begins at the time the financial relationship fails to satisfy the requirements of an applicable exception and ends no later than:

(i) where noncompliance is unrelated to compensation, the date that the financial relationship satisfies all of the requirements of an applicable exception;

(ii) where noncompliance is due to payment of excess compensation, the date on which all excess compensation is returned and the financial relationship satisfies all requirements of an applicable exception; and

(iii) where noncompliance is due to payment of compensation that is of an amount insufficient to satisfy the requirements of an applicable exception, the date on which all additional required compensation is paid and the financial relationship satisfies all requirements of an applicable exception.

Alternative Method for Compliance. If the compensation arrangement fully complied with an applicable exception, except with respect to the signature requirement, the parties may obtain the required signature and still satisfy the exception:

(i) for inadvertent failure to comply, within 90 consecutive calendar days immediately following the date on which the compensation arrangement becomes noncompliant; or

(ii) for failure which was not inadvertent, within 30 consecutive calendar days immediately following the date on which the compensation arrangement becomes noncompliant.

Physician "Stand in the Shoes" Provisions. A physician is deemed to "stand in the shoes" of his or her physician organization if the physician has an ownership or investment interest in the physician organization. Physicians who are not owners are not deemed to "stand in the shoes" of their employers, but may elect to do so.

Percentage-based Compensation Formulae and Unit of Service ("Per Click") Payment Prohibitions. Changes were made to the exceptions for office space and equipment lease arrangements, fair market value compensation, and indirect compensation arrangements to prohibit rental charges over the term of the agreement from being determined using a formula:

i) 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 by the use of the equipment leased; or

(ii) based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred between the parties.

Revision of Definition of DHS "Entity." This definition was expanded to include the person or entity that has performed services that are billed as DHS, whether or not that person or entity presents a claim to Medicare for the DHS. This change was made to address service companies which do not bill or submit claims, but provide "services under arrangement" with hospitals or other providers.

Revision to Exception for Obstetrical Malpractice Insurance Subsidies. This exception had previously imported the requirements for the Anti-kickback Safe Harbor for Obstetrical Malpractice Insurance Subsidies into the physician self-referral law exception. The rule retains the provisions of the current exception and provides an alternative set of requirements under which hospitals, federally qualified health centers and rural health clinics (but not other entities) may provide obstetrical malpractice insurance subsidies.

Ownership or Investment Interests in Retirement Plans. The definition of ownership previously did not include an "interest in a retirement plan." The rule amends this exclusion from the ownership definition to cover "an interest in an entity that arises from a retirement plan offered by that entity to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that entity."

Finally, the regulations address the Disclosure of Financial Relationships Report (DFRR), and CMS states that it is proceeding with its proposal to send the DFRR to 500 hospitals.