

A message from

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More Changes to the Stark Law that Affect Certain Existing Agreements and Business Arrangements

On August 19, 2008, the Centers for Medicare and Medicaid Services ("CMS") published the 2009 Final Rule regarding the Hospital Inpatient Prospective Payment System ("IPPS"). The 2009 IPPS Final Rule adopts, as final, numerous changes to the Stark Law regulations that were proposed in the 2009 IPPS Proposed Rule, including changes that were proposed in the 2008 Medicare Physician Fee Schedule and adopted as final in the Stark II, Phase III Final Rule. Those affected should have terminated or modified existing agreements or business arrangements before October 1, 2008, while others have until October 1, 2009. The following are key changes that significantly affect certain agreements and joint venture arrangements that are subject to the Stark Law:

Regulatory Changes Effective As Of October 1, 2008

"Stand-in-the Shoes" Rule. In the 2008 Medicare Physician Fee Schedule and the Stark III Final Rule, CMS added the "stand in the shoes" rule under which a referring physician is deemed to have a direct financial relationship with a designated health services ("DHS") entity when an organization owned or controlled by the physician is all that stands between the physician and the DHS entity. In these cases, any compensation arrangement between the parties would have to satisfy a direct compensation arrangements exception under the Stark Law.

Through the 2009 IPPS Final Rule, CMS amended the "stand in the shoes" rule under the Stark III Final Rule and adopted it as final. As adopted, the "stand in the shoes" rule applies only to physicians who have an ownership or investment interest in a physician organization, except in cases where such interest is merely titular and the physicians do not receive financial benefits such as profit shares, sale proceeds or dividends. Physicians employed by, or independent contractors to, a physician organization may continue to refer patients to a DHS entity without meeting a direct compensation arrangements exception. Such referrals may be analyzed under either the direct or indirect compensation arrangements exceptions. However, physicians who hold an ownership or investment interest in a physician organization and refer patients to a DHS entity must meet a direct compensation arrangements exception. The exceptions under the direct compensation arrangements category are extremely limited. In most cases, the rural provider exception may be the only exception available. Physician practices already should have examined existing contracts and business arrangements to ensure they are compliant with this change since it became effective on October 1, 2008.

Period of Disallowance for Noncompliant Financial Relationships. Under the Stark Law, CMS considered the "period of disallowance" to apply beginning from the date of noncompliance to the date the relationship or arrangement became compliant or was terminated. As of October 1, 2008, the period of disallowance begins from the date of noncompliance, but ends no later than the date on which all excess compensation is returned to the party that paid it or to whom it is owed. For example, a physician who leases space at a below market rate may not bill Medicare until the physician pays all monies required to bring the rental payments to fair market value.

Alternative Compliance Provision. Where an arrangement does not meet an exception due to the parties' inadvertent failure to secure a signature to an agreement, the parties will be allowed 90 days within which to obtain the missing signature. However, if the failure to obtain the signature was deliberate, the parties have only 30 days to obtain the signature.

Burden of Proof. If a claim for reimbursement is denied or challenged by CMS or its contractors because it covers improperly referred DHS, the burden of proof will be on the provider of services to establish that the referral in question did not violate the Stark Law.

Ownership or Investment Interest in Retirement Plans. Due to CMS' concern regarding physicians who use their ownership of or investment in retirement plans to purchase or invest in unrelated entities to which they refer patients for DHS, only retirement plans sponsored by a physician's employer qualify for the Stark Law exemption. Ownership or investment interest in retirement plans established by an entity other than the employer must be terminated as of October 1, 2008.

Regulatory Changes Effective On October 1, 2009

Under Arrangements/Entity Defined. CMS has significantly limited many "under arrangements" ventures in which physicians refer patients for the provision of DHS to entities owned by the physicians. Specifically, the 2009 IPPS Final Rule amends the Stark Law definition of the term "entity" to include a person or entity performing or furnishing the DHS. Prior to the change, only entities that billed for the DHS were considered a DHS entity. This allowed physicians to form an entity with a hospital to provide DHS. The hospital would bill for the services.

In the Preamble, CMS explains that a physician should not be allowed to circumvent the law by setting up a joint venture with a hospital under which the physician has an ownership interest and to which the physician makes referrals for DHS. CMS expressed concern regarding the increase in utilization of cath lab services and certain diagnostic imaging testing services, particularly those relating to cardiology services.

As a result of the change, effective October 1, 2009, physicians and hospitals will no longer be able to provide DHS "under arrangements", unless they meet a direct compensation exception under the Stark Law. In most cases, the exceptions are limited to those entities that meet the "rural provider" exception.

Set in Advance Compensation/Percentage-Based Compensation. The Stark Law requires that compensation between physicians and DHS entities in which the referring physicians have a financial relationship be "set in advance." At the request of contractors and hospital-based physicians with limited percentage-based compensation, CMS agreed to modify the restriction under the Stark II, Phase II regulations to allow physician to earn percentage-based compensation in the form of a productivity bonus for services they personally perform. Since the publication of the Stark II, Phase II regulations, CMS has learned of arrangements that pay for services and items from the use of equipment and space leases, for example, on a percentage of revenues realized. As a result, CMS has banned the use of percentage-based compensation formulae in space and rental arrangements. The prohibition also applies to indirect compensation and fair market value exceptions. Those affected have until October 1, 2009 to make changes to existing agreements or business arrangements.

"Per-Unit" or "Per-Click" Payments in Space and Equipment Leases. Beginning on October 1, 2009, "per unit" of service and "per click" payment methodologies will no longer be deemed to satisfy the requirements of either the space or equipment lease exceptions to the Stark Law, regardless of whether the physician or physician owned organization is the lessor or the lessee. This prohibition also applies to the fair market value and indirect compensation arrangement exceptions. CMS will not grandfather existing per-click or per service deals that otherwise would violate this final rule.

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