POWERS
PYLES
SUTTER &
VERVILLE PC
ATTORNEYS AT LAW

M E M O R A N D U M

TO: Clients and Friends

FROM: Christina A. Hughes and Mark R. Fitzgerald

DATE: August 8, 2008

RE: More Changes to Stark II Rules Finalized

On July 31, 2008, CMS issued more changes to its regulations interpreting the Stark law's prohibition on physician self-referrals. These changes are final and result from a number of proposals published in various Federal Register notices, including the FY 2008 Physician Fee Schedule proposed rule and the FY 2009 Inpatient Prospective Payment System proposed rule.[1]

We have summarized below what we believe are the key points to the changes with respect to three main issues addressed in the rule: 1) the "stand in the shoes" provision, 2) an alternative method of compliance with signature requirements, and 3) percentage-based compensation formulae. In addition, in its treatment of the "stand in the shoes" provision, CMS also outlined a new interpretation of the "set in advance" requirement included in several of the direct compensation exception, which is also discussed below.

We will address the remaining provisions of the changes made in a subsequent memo. We welcome any questions that you may have regarding the application of the rule to your particular arrangements.

1. The "Stand in the Shoes" Provision

In finalizing its Phase III changes to the Stark regulations, CMS added a "stand in the shoes" provision to the definition of an "indirect compensation arrangement." Under this

---

[1] *See* 72 Fed. Reg. 38,122 (July 12, 2007) ("FY 2008 PFS proposed rule") and 73 Fed. Reg. 23,528 (Apr. 30, 2008) ("FY 2009 IPPS proposed rule").

provision, for purposes of determining whether a physician has a direct or indirect compensation relationship with a designated health services (DHS) provider, a physician was deemed to "stand in the shoes" of his or her "physician organization," as defined to include professional corporations, physician practices, and group practices. CMS adopted this change to close what it described as an "unintended loophole" that caused arrangements between DHS entities and group practices to be considered outside the statute.

On November 15, 2007, however, CMS issued a final rule delaying the effective date of the provision until December 4, 2008, but only with respect to compensation arrangements involving physician organizations and academic medical centers (AMCs) or integrated section 501(c)(3) healthcare systems. With respect to all other arrangements attempting to fall under the indirect compensation exception, the "stand in the shoes" provisions became effective on December 4, 2007. In April 2008, as part of the FY 2009 IPPS proposed rules, CMS proposed changes to the "stand in the shoes" provision that would either (1) exempt certain arrangements from its application if one of three independent Stark rule exceptions were met (e.g., *bona fide* employment, personal service arrangement, or fair market value) or (2) create a new, separate exception for so-called "mission support" payments.[2]

The final rule now issued by CMS significantly revises the "stand in the shoes" provision, but not in the way originally proposed. Instead, the final rule applies the "stand in the shoes" provision only to those arrangements where a physician has an ownership or investment interest in the physician organization.[3] In such cases, the physician will be deemed to "stand in the shoes" of the physician organization when that organization is the only "intervening entity" between the physician and the entity furnishing designated health services (DHS).

This final change results in substantial improvement over the original "stand in the shoes" provision, as well as the revisions set out in the FY 2009 IPPS proposed rule. The original "stand in the shoes" provision had the unfortunate effect of making physicians with no control over the decision making and contractual arrangements of their practices (i.e., employees, members of faculty practice plans) ultimately responsible for potential violations of the Stark law by placing them in the "shoes" of the physician practice. Meanwhile, the proposed revisions, as set out in the FY 2009 IPPS proposed rule, created a somewhat complicated scenario. One proposal led to the creation of a circuitous method of determining whether a physician was required to "stand in the shoes" of his or her physician organization. The other proposal would have opened many new issues regarding what constitutes "mission support" payments, and likely would have left many physicians still in the position of being responsible for actions taken by their physician organization that were not within their control. The final change issued on July 31 is very straightforward in its language, clearly delineating which physicians are required to

---

[2] *See* 73 Fed. Reg. 23,528, 23,686-88 (Apr. 30, 2008).
[3] Included in this change are revisions to the definitions of "physician" and "physician organization" at 42 C.F.R. §§ 411.354(c)(1)(ii) and (c)(2)(iv) to clarify that a physician who is a sole owner of a professional corporation is treated the same as that professional corporation with respect to any physician organization to which the professional corporation is a member.

"stand in the shoes" of their physician organization without need for in-depth analysis and without regard for the type of physician organization involved (i.e., AMCs, tax-exempt integrated health care systems) to determine the applicability of the provision.

Thus, under the new regulations, a compensation arrangement between a DHS provider and a physician organization is deemed to create a direct compensation arrangement (with the same terms) with the referring physician, if the only intervening entity is the physician organization, and the referring physician has an ownership or investment interest in the physician organization. This type of arrangement, which was previously considered indirect, must now comply with an exception for direct compensation arrangements. Thus, for example, a compensation arrangement between a hospital and a physician-owned group practice, which previously appeared to create only an indirect compensation arrangement between the hospital and the physician-owners in the group, is now considered to constitute a direct compensation relationship between the hospital and each individual physician-owner (but not any physicians who are merely employees of the group).

For those entities that have not done so already (e.g., AMCs and tax-exempt integrated health care systems), the "stand in the shoes" rule will require hospitals and other DHS providers to revise agreements with physician-owned organizations that were structured to comply with the indirect compensation arrangements exception under Phase II of the Stark regulations. The final rule continues to exempt existing indirect compensation arrangements that were entered into prior to the publication date of Phase III (September 5, 2007) and that satisfied earlier criteria for such arrangements (commonly referred to as the "grandfather" provision). Such an exempted arrangement may continue to use the indirect compensation arrangement exception during the current term of the agreement, after which time the arrangement must be compliant under the application of the "stand in the shoes" provisions.

The new final rule also exempts any arrangement that satisfies the AMC exception (§ 411.355(e)) and those arrangements where the physician-owner's ownership interest is merely "titular." An ownership or investment interest is "titular," or nominal, when the interest excludes the ability or right to receive the traditional financial benefits of such interest (i.e., distribution of profits, dividends, proceeds of sale). Thus, those physicians who are given nominal ownership in physician organizations to comply with state laws prohibiting the corporate practice of medicine, such as hospital-owned captive practice organizations or faculty practice entities nominally owned by the dean or department chair, will not fall under the "stand in the shoes" provision.

The final issue addressed in the new final rule with respect to the "stand in the shoes" provisions was CMS' decision to <u>not</u> finalize the provision relating to DHS entities. This proposal would have required DHS entities to "stand in the shoes" of any organization in which it had 100 percent ownership interest or of which it had "control," if physicians referred Medicare patients to that organization for DHS, with respect to all arrangements analyzed under the Stark rules.

CMS indicated that the "stand in the shoes" provision applicable to physicians was sufficient to simplify the analysis of relationships between such entities and physicians. It appears that CMS may table this aspect of the proposed rules permanently, unless such a provision is felt to be required in the future to protect against improper financial relationships between DHS entities and referring physicians.

Affected regulations: 42 C.F.R. §§ 411.354(c)(1)(ii), (c)(2)(iv), and (c)(3)(ii) and (iii)
Effective date: October 1, 2008

2. Permitting Amendments to Arrangements that Must Be "Set in Advance" for Minimum One-Year Terms

In the midst of discussing the comments submitted regarding the "stand in the shoes" provision, CMS indicated that it would allow amendments to arrangements between DHS entities and physicians to meet the requirements of exceptions requiring that compensation be "set in advance" and for a minimum one-year term (e.g., space rental, equipment rental, personal service arrangements). In doing so, CMS was responding to comments submitted about the stricter requirements under the direct compensation exceptions compared to the indirect compensation exception, and the application of these requirements (e.g., "set in advance" compensation, minimum one-year terms) under the proposed "stand in the shoes" provision to arrangements that had previously fallen under the more flexible indirect compensation exception.

One commenter stated that it was "unworkable" to apply the "set in advance" requirement to compensation arrangements between DHS entities and physician groups for an entire year because of the need to be flexible and amend the compensation terms to address fluctuating patient and community needs. A second commenter urged CMS to permit parties to modify compensation arrangements within certain parameters. CMS decided to not make any changes to the provisions of the final regulations to address these concerns, but did address them in the preamble language of this final rule.

In the preamble, CMS indicated that amendments during the first year of an arrangement could be consistent with the "set in advance" and one-year term requirements. To meet this new interpretation, for those arrangements structured under one of the exceptions requiring a one-year minimum term and "set in advance" compensation, any amendment to such an arrangement within the first year of its term would have to meet four standards:

1) All the requirements of an applicable exception must be satisfied;

2) The amended rental charges or other compensation (or the formula for the amended rental charges or other compensation) must be determined before the amendment is implemented and the formula must be sufficiently detailed so that it can be verified objectively;

3) The formula for the amended rental charges must not take into account the value or volume of referrals or other business generated by the referring physician; and

4) The amended rental charges or compensation (or formula for determining either) must remain in place for at least one year from the date of amendment.

Furthermore, CMS clarified that this rule regarding amendments of arrangements between DHS entities and physicians or physician organizations applies to all exceptions to the Stark law that require a minimum one-year term (e.g., space rental, equipment rental, personal service arrangements).

It is critical to note that this new process for amending arrangements should not be used simply to increase the rate of compensation or rental payments without a corresponding increase in services or items provided.

An example of an arrangement where the new amendment process could be utilized is found where a hospital arranges with a specialty practice group to provide services to its inpatients, such as a group of doctors providing hospitalist services. The agreement is for two years and the hospital provides salary support to the group for maintaining 24/7 hospitalist coverage. In the event that the hospital determines that it needs additional FTE coverage from the practice group to adequately provide hospitalist services to its patients, under the new amendment standards, the hospital and practice group can amend the arrangement within the first year to provide for greater compensation to the practice group within the first year of the arrangement without violating the Stark law.

Affected regulations: provisions included only in preamble, not codified in regulations
Effective date: clarification of interpretation effective immediately

3. Alternative Method for Compliance with Signature Requirements in Certain Exceptions

In the FY 2008 PFS proposed rule, CMS considered whether to amend some of the Stark law exceptions to provide an alternative method for satisfying certain requirements of the exceptions. The specific example cited was where all requirements of an exception were met except for the signature requirement. CMS also clearly indicated that such an alternative method to comply would only apply to those situations where the violation was "inadvertent" and related to a procedural, or "form" requirement.

To support this alternative method, CMS initially proposed eight criteria, which included self-disclosure of the facts and circumstances of the financial relationship and depended upon a finding by the government that the arrangement satisfied all of the requirements of a valid exception except for the procedural or form requirements. Unsurprisingly, a large number of

comments were submitted that supported the underlying concept of providing an alternative means of compliance but disputing the need for self-disclosure.

CMS responded by adopting a more flexible alternative method of compliance, and dropping most of its proposed criteria, including the self-disclosure requirement. But CMS restricted the use of this alternative method to situations where the failure to meet the "form" requirements of an exception consisted only of missing signatures.

Further, CMS distinguished between "inadvertent" and "not inadvertent" failures to obtain signatures, with the former being granted 90 days following the commencement of the financial relationship to obtain the signatures while the latter only has 30 days to do so. CMS determined that it was not necessary to define the term "inadvertent," and that parties should attach the ordinary meaning of the word.[4] CMS also stated that it intends to distinguish between "inadvertent" and "knowing" failures to comply with the signature requirements of the Stark law exceptions. Thus, where a signature is not obtained on an agreement at the outset due to time constraints or other known limitations, the 30-day timeframe is the applicable period in which to rectify the technical violation.

One final issue to consider is the limitation put in place by CMS to restrict use of this alternative method of compliance by an entity to only once every three years with respect to the same referring physician. Thus, where a physician fails to sign a one-year agreement to provide services to a hospital but signs within 30 days of the commencement of the arrangement, if the physician fails to sign another one-year agreement the following year, the alternative method of compliance is not available and a technical violation has occurred.

Affected regulations: 42 C.F.R. § 411.353(g)
Effective date: October 1, 2008

4. Percentage-Based Compensation Formulae

CMS originally proposed to limit the use of percentage-based compensation formulae to paying for personally performed physician services based on the revenues directly resulting from the physician services. In the final changes, however, CMS decided not to restrict the use of percentage-based compensation formulae so severely; instead, it prohibited the use of percentage-based compensation formulae only with respect to the determination of rental charges for the lease of office space or equipment. CMS stated that it intends to monitor compensation formulae in arrangements between DHS entities and physicians, and may further restrict the use of percentage-based formulae if appropriate. In the meantime, CMS noted that properly structured, nonabusive incentive payment and shared savings programs are permissible.

[4] The Merriam-Webster Dictionary defines the term as "1. Not focusing the mind on the matter: Inattentive. 2. Unintentional."

Affected regulations: 42 C.F.R. §§ 411.357(a), (b), (*l*), and (p)
Effective date: delayed until October 1, 2009

* * * * *

This memorandum is intended as general guidance, and does not constitute legal advice with respect to any particular matter. We encourage you to call us with any questions that you may have. Please feel free to contact Mark Fitzgerald (Telephone No.: 202-872-6771; Email: mark.fitzgerald@ppsv.com) or the other principal in the firm with whom you regularly work.