

## MEMORANDUM

**TO:** Clients and Friends

**FROM:** Powers, Pyles, Sutter & Verville, P.C.

**DATE:** September 12, 2007

**RE:** "Stark II, Phase III;" CMS Issues the Third and Final Part of its Self-Referral Regulations

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On September 5, 2007, CMS published Phase III of its regulations interpreting the Stark law's prohibition on physician self-referrals in the Federal Register. The regulation was long awaited, with Phase II having been published more than three years ago. Phase III adds another 187 pages of Federal Register text to the approximately 180 pages previously published in connection with Phase I and Phase II of the self-referral rule, proving once again that applying a relatively simple principle – that physicians should not profit from their own referrals – is extraordinarily difficult.

The Phase III rule does not have a comment period. It becomes effective on December 4, 2007. We have summarized below what we believe are the changes likely to have the greatest impact on our clients. The rule is very complex, however, and much of the value of the Phase III rule lies in the commentary published with it, rather than the actual changes to the regulation. We welcome any questions that you may have regarding the application of the rule to your particular arrangements.

### 1.0 KEY CHANGES TO DEFINITIONS

#### 1.1 "Fair Market Value" Amended to Eliminate Physician Compensation "Safe Harbor"

In Phase II, CMS established a voluntary safe harbor in the fair market value (FMV) definition that applied to physicians' hourly compensation for personal services rendered. This safe harbor protected hourly compensation if the payment was based on either the average hourly rate for emergency room physician services in a physician's geographic market area, or the average of four of six designated surveys' results indicating the 50<sup>th</sup> percentile national

compensation level for physicians in the same specialty. In Phase III, CMS eliminated this safe harbor, agreeing with the many commenters who asserted that the safe harbor provision was impractical. CMS emphasized that it will continue to scrutinize the FMV of arrangements, and that the burden of proof for establishing FMV rests with the parties, not the Government.

1.2 “Incident to” Services and the Group Practice Definition

CMS clarified that the definition of “incident to” services includes supplies (such as drugs) as well as services that meet the applicable requirements for “incident to” coverage. CMS also clarified that only services and supplies that do not have their own separate and independently listed benefit category qualify as services “incident to” a physician service, except where expressly permitted by statute. Diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests do not qualify as “incident to” services. The changes to the definition of “incident to” services affect their use in the calculation of productivity bonuses payable by group practices to their physicians. CMS revised the group practice definition to allow a physician to be paid a productivity bonus based on services rendered “incident to” his or her personally performed services, in addition to services rendered personally, even if those “incident to” services are otherwise DHS (e.g., physical therapy or outpatient drugs). The productivity bonus cannot be directly related to any other DHS referrals, such as diagnostic tests or hospital admissions. On the other hand, CMS reversed course with respect to profit shares and changed the group practice definition to prohibit profit shares from being distributed in a manner that is directly related to a physician’s “incident to” services. The rules regarding when a profit share or productivity bonus will be deemed not to directly take into account referrals remain unchanged.

CMS also responded to a number of comments regarding the group practice definition. It declined to adopt a blanket determination that all medical foundations qualify as group practices. In particular, in states where a foundation cannot provide physician services, but the foundation owns and operates all of the elements of the practice, the foundation is not likely to qualify as a group practice. CMS also declined to provide a blanket determination that faculty practice plans qualify as a group practice. Finally, CMS stated that there is no requirement for physicians to comprise a majority of the decision-making body of a group practice so long as the board is representative of the group practice.

1.3 “Physician in the Group Practice”

CMS modified the definition of “physician in the group practice,” which is important under the “in-office” exception, to clarify that an independent contractor physician must furnish patient care services for the group under a direct contractual arrangement with the group practice. A contract between the group and a third-party, such as a staffing agency, will not meet the “physician in the group practice” definition. Furthermore, an independently contracted physician is deemed a “physician in the group practice” only when he or she performs services in the group’s facility.

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1.4 “Radiology and Certain Other Imaging Services” and “Radiation Therapy”

CMS made no changes to the definition of “radiology and certain other imaging services” or “radiation therapy and supplies” in Phase III of the Stark Rule. However, radiologists should be aware that CMS proposed to include nuclear medicine services within the meaning of “radiology and certain other imaging services,” and therapeutic nuclear medicine services within the meaning of “radiation therapy and supplies” in the proposed CY 2007 physician fee schedule.

**2. ADOPTION OF “STAND IN THE SHOES” PROVISION**

CMS added a “stand in the shoes” provision to its definitions of “direct” and “indirect” compensation arrangements. For purposes of determining whether a physician has a direct or indirect compensation relationship with a designated health services (DHS) provider, a physician is now deemed to “stand in the shoes” of his or her “physician organization,” as newly 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.

Under the new regulations, a compensation arrangement between a DHS provider and a physician organization is deemed to be a direct compensation arrangement (with the same terms) between the DHS provider and the referring physician, so long as the only intervening entity between the physician and the DHS provider is the physician organization. This arrangement, which was previously considered indirect, must now comply with a direct compensation exception. Thus, a compensation arrangement between a hospital and a group practice, which previously appeared to create only an indirect compensation arrangement between the hospital and the physicians in the group, is now considered to constitute a direct compensation relationship between the hospital and each individual physician.

The scope of physician organizations subject to the “stand in the shoes” rule is unclear, at least as to practice entities that do not qualify as a “group practice” under the Stark group practice definition. For example, it is not clear whether a medical foundation, faculty practice, or nonprofit clinic that does not qualify as a “group practice” will be considered a “physician practice” subject to the “stand in the shoes” rule.

The “stand in the shoes” rule will require hospitals and other DHS providers to revise agreements with physician organizations that were structured to comply with the indirect compensation arrangements exception under Phase II of the Stark regulations. CMS, however, is exempting 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. 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 Phase III compliant.

**4. ACADEMIC MEDICAL CENTERS**

Phase III adopts the AMC exception set out in Phase II with only minor clarifications. First, CMS clarifies that, for purposes of determining whether the majority of physicians on a medical staff consist of faculty members, the affiliated hospital must either include or exclude all physicians holding the same class of privileges at the affiliated hospital.

Second, where a physician is paid by more than one component of an academic medical center, the payment by each component must use a methodology that qualifies under the “set in advance” test, and each payment arrangement must not take into account the volume or value of referrals or other business generated; however, the FMV test is applied only to the physician’s aggregate compensation, not to the compensation paid by each separate component.

Third, AMCs may no longer be able to rely on the indirect compensation arrangements exception to protect support arrangements between the teaching hospital and the medical school/faculty practice plan because of the new “stand in the shoes” rule. Thus, AMCs will need to confirm that they meet all of the requirements of the AMC exception.

**5. RENTAL OF OFFICE SPACE AND EQUIPMENT**

CMS did not make any substantive changes to the office space and equipment rental exceptions, but clarified the application of those exceptions in the preamble. CMS stated that any amendments to a lease agreement must continue to comply with the lease exception requirements, including the requirements that rental charges be (1) set in advance, (2) consistent with fair market value, (3) not determined in a manner that takes into account the volume of value of referrals or other business generated, and (4) continue for at least a one year term.

Because rental charges must be set in advance, CMS stated that parties to a lease may not change the rental charges at any time during the term of the agreement (even if it is for longer than one year). Instead, the parties must terminate the agreement and enter into a new agreement; however, the new agreement may only be entered into after the first year of the original lease term. The parties may, however, amend other parts of the lease agreement as long as the exception requirements continue to be met. If an agreement is amended and the amendment does not change the rental charges or cause the agreement to fall out of compliance with the exception requirements, the amended agreement may terminate on the original expiration date. If the parties terminate an agreement before the one year term, they may not enter into a new agreement for the same space or equipment until the one year term of the original lease has expired.

CMS also clarified that providers cannot use the “payments by a physician” exception or the “fair market value compensation” exception to protect space leases. Instead, a provider must use the “rental of office space” exception.

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CMS stated that office space and equipment cannot be shared; the lessee must “have exclusive use of the leased space or equipment when the lessee uses the space or equipment. In effect, § 411.357(a)(3) and (b)(4) require that space and equipment leases be for established blocks of time.”<sup>1</sup> Common areas (such as foyers and break rooms) may be shared if the rent is prorated, but exam rooms are not considered a common area. Finally, CMS agreed that lessors could charge higher fees during holdover tenancies as long as that higher amount is set in advance, is consistent with fair market value, and does not take into account the volume or value of referrals or other business generated between the parties.

## **6. PERSONAL SERVICE ARRANGEMENTS**

For personal services arrangements, CMS allowed the parties to include a “holdover” provision, similar to that previously authorized in Phase II for equipment and office space leases. Personal service contracts will now be allowed to continue for up to six months after expiration, provided there are no changes in the terms and conditions of the agreement.

## **7. PHYSICIAN RECRUITMENT**

Phase III made a number of changes to the physician recruitment exception, and provided some important clarification with respect to in-group recruitment arrangements. Generally, the physician recruitment exception permits a hospital to pay remuneration to induce a physician to relocate his or her medical practice to the geographic area served by the hospital so long as certain conditions are met.

In Phase III, CMS confirms that a recruited physician must relocate his or her practice from outside the hospital’s geographic service area to inside that area. Relocation from one part of a hospital’s service area to another is not permitted. CMS provided some additional leeway in determining the scope of a hospital’s geographic service area, although for most hospitals, the test will continue to be the area comprised of all the contiguous zip codes from which the hospital draws 75% of its inpatients.

In Phase III, CMS expands the types of recruited physicians who are not subject to the relocation requirement. Under the new rule, a physician (1) who has been in practice for less than a year; or (2) was employed on a full-time basis for at least two years immediately prior to the recruitment arrangement by a federal or state bureau of prisons; the Department of Defense or Department of Veterans Affairs; or facilities of the Indian Health Service; or (3) has been determined by CMS through an advisory opinion not to have an established medical practice, are exempt from the relocation requirement. The test for relocation continues to require moving a practice at least 25 miles; or relocating inside the hospital’s geographic service area and deriving at least 75% of new practice revenues from patients not previously seen at the prior medical practice site during the preceding three years.

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<sup>1</sup> 72 Fed. Reg. at 51045.

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Phase III provided some additional clarification and rule changes with respect to in-group recruitment arrangements:

1. The preamble clarifies that in-group recruitment agreements must be signed by all three parties (the hospital, the practice, and the recruited physician).
2. The hospital may require the practice group to repay any money it advanced to the group if the recruited physician does not fulfill his or her community service requirement; however, CMS cautions that such a practice can be risky. CMS states that if the guarantee is used to shield the recruited physician from any real liability for failure to fulfill his or her community service obligation, the parties would be at significant risk of noncompliance with the fraud and abuse laws, particularly if the recruiting hospital failed to collect amounts owed from the physician practice making the guarantee.
3. CMS declined to allow a group practice to be reimbursed for anything other than its "actual additional incremental costs" associated with the recruitment except in one narrow circumstance. CMS stated that if a recruited physician is joining a physician practice located in a rural area or HPSA, and the physician is recruited to replace a physician who, within the previous 12-month period, retired, relocated, or died, the group may choose to allocate the lower of a per capita allocation or 20% of the practice's aggregate cost to the recruited physician (in lieu of allocating the actual additional incremental costs).
4. CMS noted in the preamble that a group practice may impose certain restrictions on the recruited physician without violating the requirement that the practice may not impose additional practice restrictions other than conditions related to quality of care. Specifically, groups may impose:
  - Restrictions on moonlighting
  - Prohibitions on soliciting patients and/or employees of the physician practice
  - A requirement to accept Medicaid and indigent patients
  - Confidentiality restrictions
  - An obligation to repay losses of the recruited physician's practice that are absorbed by the physician practice in excess of any hospital recruitment payment
  - An obligation to pay liquidated damages if the physician leaves and competes with the practice