

FEWER STARK CHANGES THAN EXPECTED—BUT STILL SIGNIFICANT

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The Center for Medicare and Medicaid Services (“CMS”) issued the Phase III Final Rule (“Phase III Rule”) to the Federal Physician Self-Referral Law (“Stark Law”) on September 5, 2007. The Phase III Rule took effect December 4, 2007. Numerous new interpretations in the Phase III Rule will affect physicians and their relationships with health care entities. In addition to the Phase III Rule, CMS also modified the Stark Law in the 2008 Medicare Physician Fee Schedule (“MPFS”), effective January 1, 2008. As discussed below, CMS deferred many of the changes it had initially proposed in the MPFS, but promises that they will be addressed in future rulemaking.

I. A Stark Primer

The Stark Law prohibits physicians from referring patients to entities with which they have a financial relationship for certain “designated health services” (“DHS”) payable by Medicare or Medicaid. DHS include: clinical laboratory services; physical therapy services; occupational therapy services; radiology services (including CT scans, MRI, ultrasound, and nuclear medicine); radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. The Stark Law also prohibits an entity from making a claim for payment for a DHS furnished pursuant to a prohibited referral. Stark III is the third set of final rules published to interpret the Stark Law and establish exceptions to the prohibition.

II. What Made the Cut?

Some of the key provisions contained in the final Phase III Rule are as follows:

Fair Market Value Safe Harbor - Earlier Stark Law regulations had established a voluntary “safe harbor” within the definition of “fair market value” applicable to hourly payments to physicians for their personal services. Many commenters expressed concern that the “safe harbor” utilized methodology that was unworkable. In response, the Phase III Rule eliminated the “safe harbor.” CMS will still scrutinize the fair market value of arrangements that seek to fall within the exception. Parties must demonstrate that remuneration is consistent with fair market value for the services rendered, using any commercially reasonable methodology appropriate under the circumstances and that fits within the fair market value definition.

Stand in the Shoes - The Phase III Rule added new provisions regarding compensation arrangements where a group practice or other physician organization (newly defined in the Phase III Rule) is directly linked to the referring physician in a chain of financial relationships between the physician and a DHS entity. When determining whether a physician has a direct or indirect financial relationship with a DHS entity to which he or she refers, the physician is deemed to “stand in the shoes” of the physician’s practice entity or physician organization. In other words, an arrangement between a DHS entity and a physician’s practice will be evaluated as if it were a

direct arrangement between the individual physician and the DHS entity. This means that any arrangement that has relied on the “indirect compensation” exception should be reassessed to determine if the arrangement complies as a direct relationship (although certain indirect compensation arrangements will be considered “grandfathered” during the original or current renewal term of the agreement).

Group Practice Relationships and Payment Methodologies - Whether a physician is considered a “physician in the group” is of critical importance to whether the practice qualifies as a group practice under the Stark Law. The definition of “physician in the group practice” has been modified by the Phase III Rule to clarify that an independent contractor physician must furnish patient care services for the group under a direct contractual arrangement with the group, not one between the group and another entity, e.g., a staffing entity. Furthermore, an independent contractor can only be considered a “physician in the group” when performing services in the group practice’s facilities. CMS also interpreted “physician in the group” as applying only to members (owners or employees of the group) or independent contractors, and not to other types of employment arrangements, such as leased employees.

In a reversal of an earlier interpretation, the Phase III Rule states that *overall profit shares* in a group cannot relate directly to “incident to” services. However, *productivity bonuses* can be based directly on services that are “incident to” a physician’s directly performed services,

Shared Facilities under In-Office Ancillary Services Exception - In the realm of “be careful what you ask for, you might get it,” commenters had requested clarification from CMS as to how physicians could share space in the same building and provide DHS to their patients. CMS responded that physicians sharing a DHS facility in the same building must control the facility and the staff at the time the DHS is furnished to the referred patients. CMS goes on to state that this interpretation most likely requires a block lease for the space and equipment used to provide the DHS. It is also doubtful that the common “per click” or “per use” arrangements would satisfy the supervision requirements of the in-office ancillary services exception and also raise anti-kickback concerns.

Physician Recruitment Exception - The Phase III Rule makes several modifications to the physician recruitment exception that actually broadens the exception. The Stark Law provides an exception for certain remuneration from a hospital to a physician as an inducement for the physician to relocate his practice to the geographic area served by the hospital. Group practices that accept some financial support from hospitals for recruitment arrangements may now impose certain practice restrictions on the recruited physician so long as they do not “unreasonably restrict” the physician’s ability to practice in the hospital’s geographic service area. While non-competition restrictions are still prohibited, the group can impose “during term” restrictions, such as prohibiting moonlighting, and can prohibit solicitation of patients and staff. CMS did clarify, however, that the protection of the recruitment exception do not apply when a recruited physician simply shares space or otherwise co-locates with the group, but does not actually join the practice.

Professional Courtesy Exception - Although the Phase III Rule deleted the provision in the professional courtesy exception that required notification to the insurer when a professional

courtesy involves the partial or whole reduction of a co-insurance obligation, CMS noted that it is still good practice to do so and that an insurer may require such notice. The Phase III Rule also clarifies that the professional courtesy exception is not available to suppliers, such as laboratories or DME entities, but only to hospitals and other providers with formal medical staffs, which includes group practices.

Fair Market Value Exception - While it was clear that the fair market value exception applied to fair market value compensation paid by a physician to a DHS entity, the Phase III Rule clarified that the exception is also available to arrangements involving fair market value compensation paid by a DHS entity to a physician. The fair market value exception is *not* available for compensation paid under an office space arrangement, which must meet the more specific rental of office space exception.

Only two of the changes to the Stark Law proposed by CMS in its 2008 Proposed Physician Fee Schedule of July 2007, actually made the cut. These changes are as follows:

Anti-Markup of Purchased or Reassigned Tests - Long concerned about pathology pod lab arrangements (involving shared equipment, technologists and pathologists between physician practices and pathology labs), as well as some diagnostic testing arrangements between physicians and suppliers of diagnostic tests, the 2008 MPFS expands the restriction on marking up purchased technical services. It imposes an anti-markup provision applicable to both the technical *and* professional components of all diagnostic tests not ordered by a billing physician or other supplier if they are purchased from an outside supplier or performed at a site other than the office of the billing physician or supplier. Because the proposed version of this expanded anti-markup provision created such controversy and question, CMS opted to make it effective January 1, 2008, only for certain pathology lab arrangements. The prohibition on marking up the technical component is still in place, however, and prohibits marking up a technical component if the technologist and diagnostic testing equipment are not located in the office where the practice regularly conducts patient office visits.

Independent Diagnostic Testing Facilities - Although not a true Stark Law rule amendment, the 2008 MPFS imposed significant changes to the IDTF rules to address perceived fraud and abuse concerns. Fixed site (not mobile or hospital-based entities) IDTFs may not share, either through a lease or sublease, space or operations with another Medicare-enrolled person or organization; may not share diagnostic test equipment utilized in an initial diagnostic test with another Medicare-enrolled person or organization; and may not share a practice location with another Medicare-enrolled person or organization. As a result, an arrangement between an IDTF and a physician practice that otherwise would comply with the Stark Law, including a block lease arrangement, will need to be restructured.

III. **What's Warming the Bench?**

As noted above, there were many proposed changes in the 2008 MPFS that would have dramatically changed the way the Stark Law is currently interpreted and applied. But CMS has not abandoned them. These changes are anticipated to reappear in some form and are listed below:

- **Anti-Markup** - When the anti-markup rule, discussed above, becomes fully effective in January 2009, many existing diagnostic test arrangements will no longer be economically viable.
- **Percentage-based lease arrangements** - Would be prohibited; percentage-based compensation arrangements would be limited to arrangements involving personally performed physician services.
- **Per-click payments** - Would be prohibited in lease arrangements.
- **In-Office Ancillary Services Exception** - Possibly becoming unavailable for practices providing ancillary services that are not integrally connected to the physician's practice, e.g., physical therapy.
- **Stand in the Shoes** - Expanding its application beyond physician organizations.
- **Revised Definition of DHS Entity** - Would include any person causing a claim to be presented, thereby prohibiting popular "under arrangement" ventures where referring physicians lease equipment and facilities to hospitals.

IV. **No Rest for the Weary**

What should be clear from this review of new Stark and CMS fee schedule changes is that many existing arrangements between physicians and DHS entities, or involving physician diagnostic test arrangements, should be analyzed by competent healthcare counsel for continuing compliance with these new requirements. And if CMS keeps its promises, physicians are threatened with even more restrictions on their practice.

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