

STARK/ANTI-KICKBACK LAW ISSUES

Luncheon Roundtable Discussion
September 19, 2007

Discussion Leaders: David Rogers and Monica Wilkinson

I. JULY 2007: PROPOSED CHANGES TO PHYSICIAN SELF REFERRAL RULES AND MEDICARE ANTI-MARKUP PROVISION

Commentary published as part of Proposed Physician Fee Schedule revisions:
72 FR 38122, 38179 *et seq.* (July 12, 2007)

Proposed Stark Regulations revisions: 72 FR 38224 (July 12, 2007)

Selected Provisions:

- **"Set in Advance" and Percentage-Based Compensation Arrangements**

"[W]e are proposing to clarify that percentage compensation arrangements: (1) May be used only for paying for personally performed physician services; and (2) must be based on the revenues directly resulting from the physician services rather than based on some other factor such as a percentage of the savings by a hospital department (which is not directly or indirectly related to the physician services provided)."

- **Unit-of-Service (Per-Click) Payments in Space and Equipment Leases**

"After reconsidering the issue, we are proposing that space and equipment leases may not include unit-of-service-based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a physician lessor to the entity. We believe that such arrangements are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee, and we would disallow such per-click payments, using our authority under section 1877(e)(1) of the Act, even if the statute does not expressly forbid per-click payments to a lessor for patient referred to the lessee.

"Finally, we are soliciting comments on whether, using our authority under section 1877(e)(1) of the Act, we should prohibit time-based or unit-of-service-based payments to an entity lessor by a physician lessee, to the extent that such payments reflect services rendered to patients sent to the physician lessee by the entity lessor."

- **Services Furnished "Under Arrangements"**

"We agree ... that arrangements structured so that referring physicians own leasing, staffing, and similar entities that furnish items and services to entities furnishing DHS but do not submit claims, raise significant concerns under the fraud and abuse laws. We believe such arrangements to be contrary to the plain intent of the physician self-referral law. Arrangements so structured are particularly problematic because referrals by physician-

owners of leasing, staffing, and similar entities to a contracting DHS entity can significantly increase the physician-owned entity's profits and investor returns, creating incentives for overutilization and corrupting medical decision-making.

“We are attempting to determine the best approach to prohibit certain arrangements under which physicians supply items and services to DHS entities. We note that some of the arrangements described by MedPAC are subject to the physician self-referral prohibition and more may become subject to the physician self-referral prohibition through provisions we may implement in the upcoming Phase III final rule.”

- **“Stand in the Shoes”**

“We propose to amend §411.354(c) to provide that, where a DHS entity owns or controls an entity to which a physician refers Medicare patients for DHS, the DHS entity would stand in the shoes of the entity that it owns or controls and would be deemed to have the same compensation arrangements with the same parties and on the same terms as does the entity that it owns or controls. For example, a hospital would stand in the shoes of a medical foundation that it owns or controls (such as where the hospital is the sole member of a non-profit corporation). Thus, if a hospital owns or controls a medical foundation that contracts with a physician to provide physician services at a clinic owned by the medical foundation, the hospital would stand in the shoes of the medical foundation, and would be deemed to have a direct compensation relationship with the contractor physician.”

“We believe that it is necessary to collapse the type of relationship discussed above to safeguard against program abuse by parties who endeavor to avoid the application of the physician self-referral requirements by simply inserting an entity or contract into a chain of financial relationships linking a DHS entity and a referring physician. We are soliciting comments as to whether and how we would employ a stand in the shoes approach for the type of relationship discussed above, as well as for other types of financial relationships. In submitting comments, commenters should be mindful that we finalize (or may already have finalized) a provision that treats physicians as standing on the shoes of their group practices or other physician practices.”

- **Anti-Markup Rule**

“[W]e are proposing to impose an anti-markup provision on the TC and PC of diagnostic tests. We would apply the anti-markup provision irrespective of whether the billing physician or medical group outright purchases the PC or the TC, or whether the physician or other supplier performing the TC or PC reassigns his or her right to bill to the billing physician or medical group (unless the performing supplier is a full-time employee of the billing entity).”

“[W]e are proposing in §414.50 that --(1) The PC of a purchased test be subject to an anti-markup provision; (2) the anti-markup provision for the TC and PC apply to all arrangements not involving a reassignment from a full-time employee of the billing entity; (3) the performing physician's or other supplier's net charge be calculated exclusive of any charge that reflects the cost of space or equipment leased to the performing physician or other supplier by the billing entity; and (4) the anti-markup provision not apply to independent labs that have not ordered the TC.”

II. SEPTEMBER 2007: STARK II PHASE III

Commentary and Revised Regulations: 72 FR 51012 (September 5, 2007)

Unofficial Redlined Regulation Text:

www.cms.hhs.gov/PhysicianSelfReferral/Downloads/Unofficial_Redlined_411_350.pdf

Selected Provisions:

- **Fair Market Value Compensation** – deletion of compensation survey safe harbors.
- **“Incident to” Services:** “[W]e are revising the definition of “ ‘incident to’ services” at §411.351 to clarify that the term includes both services and supplies (such as drugs) that meet the applicable requirements set forth in section 1861(s)(2)(A) of the Act, § 410.26 of our regulations, and relevant manual provisions. We are also making a minor revision to make clear that the definition covers the terms “ ‘incident to’ services” and “services ‘incident to’ ” for purposes of these regulations.”
- **Physician in the Group Practice:** “We are modifying the definition of “physician in the group practice” to clarify that an independent contractor physician must furnish patient care services for the group under a contractual arrangement directly with the group practice.”
- **Group Practice:** “This Phase III final rule makes one minor change to §411.352 to reflect more closely the statutory scheme and our original intent in the Phase I final regulation that the “incident to” services need not themselves be personally performed by the referring physician: we are changing the parenthetical language in § 411.352(i)(1) to permit a physician in the group to be paid a productivity bonus based on services that he or she has personally performed, or services “incident to” such personally performed services or both.”

“Upon further reflection, we have concluded that this interpretation is inconsistent with the clear statutory language, which includes ‘incident to’ services only in the context of productivity bonuses, and with our Phase I interpretation (66 FR 908–909). Thus, we are withdrawing our statement in Phase II at 69 FR 16080 with respect to overall profit shares and ‘incident to’ services. Because an overall profit share under § 411.352(i)(2) means the aggregation of profits derived from DHS of the group as a whole or of a component of at least five physicians, an overall profit share will necessarily include profits from DHS that are billed as ‘incident to’ services (66 FR 876,909). Under this Phase III final rule, profits must be allocated in a manner that does not relate directly to DHS referrals, including any DHS that is billed as an ‘incident to’ service. We note that the regulations provide a number of methods that satisfy this requirement.”

- **Compensation – “Stand in the Shoes”:** [W]e are concerned that arrangements between DHS entities and group practices are often viewed as outside the application of the statute. The new “stand in the shoes” provisions should close this unintended loophole by treating compensation arrangements between DHS entities and group practices as if the arrangements are with the group’s referring physicians. This approach

incorporates a commonsense understanding of the relationship between group practices and their physicians. Thus, if a DHS entity leases office space to a group practice, the lease will be deemed to be a direct compensation arrangement with each physician in the group practice, and the lease will need to fit in the exception for rental of office space in §411.357(a) if the DHS entity wants to submit claims for DHS referrals from those physicians. For purposes of the “stand in the shoes” provision, we are including in the definition of “physician organizations,” in whose shoes the referring physician will stand, the referring physician’s professional corporation, physician practice, or group practice.”

“Specifically, under the new provision, a physician is deemed to have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the DHS entity is his or her physician organization. In addition, for purposes of the definition of “indirect compensation arrangement,” a physician will be deemed to stand in the shoes of the physician organization with which he or she has a direct financial relationship (that is, the physician organization with which he or she is directly linked). When a physician stands in the shoes of his or her physician organization, he or she will be deemed to have the same compensation arrangement (with the same parties and on the same terms) as the physician organization has with the DHS entity.”

- **Special Rules on Compensation:** “This Phase III final rule retains flexibility for utilizing unit-based and percentage-based compensation formulae for arrangements.”
- **In-office Ancillary Services:** “We are making no substantive changes to the in-office ancillary services exception.”
- **Rental of Office Space and Equipment:** “‘Per-click’ rental payments are permitted for DHS referred by the referring physician provided that the payments are fair market value and do not take into account the volume or value of referrals or other business generated by the referring physician, as those concepts are defined at § 411.351 and § 411.354.” “We are making no substantive changes to § 411.357(a) or (b).”
- **Fair Market Value Compensation Exception:** “[W]e are amending the exception to provide that it may apply to compensation provided to a physician from an entity and to compensation provided to an entity from a physician. We are also clarifying that the exception is not applicable to leases for office space; rather, such lease arrangements must comply with § 411.357(a).”

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