CMS Stands In Your Shoes: More on AMCs and IDS

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Practice Area: Health Law

Just when we thought we understood Stark II, Phase III, the Centers for Medicare and Medicaid Services ("CMS") issued proposed changes to significant portions of this rule as part of its Inpatient Prospective Payment System Proposed Rule for Fiscal Year 2009 (the "IPPS Proposed Rule"). In the IPPS Proposed Rule, CMS refines both the physician and DHS entity "stand in the shoes" concepts and makes a number of other Stark-related proposals. Significantly,by including these proposals in annual hospital inpatient hospital regulations, CMS is responding to provider concerns with the Stark law, albeit in a piecemeal manner. CMS seeks comments from providers regarding the following proposed changes.

Changes to Physician Stand in the Shoes Rule
In Phase III, CMS adopted a rule that a physician "stands in the shoes" of his or her physician organization (i.e., physician practice, group practice, physician sole proprietorship or wholly-owned professional corporation) for purposes of analyzing financial relationships. In other words, CMS treats a contract between an entity furnishing designated health services ("DHS") and a physician group as if it were a contract directly between the DHS entity and each individual physician in the practice when analyzing the arrangement under Stark. For more information regarding the underlying analysis, see "Stark III: The Indirect Compensation Two-Step," von Briesen & Roper Health Law Bulletin, Sept. 2007.

In response to Phase III, industry stakeholders urged CMS to reconsider the rule's effect on academic medical centers ("AMCs") and § 501(c)(3) integrated delivery systems ("IDS"). AMCs and IDS often make regular "support" payments to related physician organizations in furtherance of the related entities' mission. These payments had not previously been considered financial relationships under Stark. For example, before Phase III, a support payment made by an AMC to the AMC's faculty practice plan did not trigger application of Stark if certain conditions were met. Although the chain of compensation runs from the DHS entity through the faculty practice to the referring faculty physicians, no indirect compensation arrangements arise between the DHS entity and the faculty physicians so long as the physicians' aggregate compensation does not vary with or reflect referrals to the DHS entity. Under the physician stand in the shoes rule, CMS would consider the payment to be a direct compensation arrangement between the hospital and the physician. Thus, the arrangement would need to satisfy the requirements of a direct compensation arrangement exception under Stark in order for the faculty physician to refer patients to the hospital and bill Medicare for services. Because support payments generally are not tied to specific items or services, it is difficult to satisfy the fair market value requirement that is necessary under many direct compensation arrangement exceptions under Stark.

CMS responded to the stakeholders' concerns by issuing a final rule on November 15, 2007 that delayed the application of the physician stand in the shoes rule to AMCs and IDS. This delay is effective until December 4, 2008. See "Stark III: Stand By," von Briesen & Roper Health Law Bulletin, Nov. 2007.

CMS also issued the IPPS Proposed Rule, which revisited the physician stand in the shoes policy and regulations issued in Phase III. As part of the IPPS Proposed Rule, CMS proposes two alternative approaches to the stand in the shoes rule to address issues raised by stakeholders. See 73 Fed. Reg. 23685 - 23698 (April 30, 2008).

A. Multi-Faceted Approach

Under its first "alternative" approach, CMS recognizes that, if the ultimate compensation to a physician fits within certain direct compensation exceptions, it does not gain anything by applying the stand in the shoes doctrine. CMS proposes, therefore, that the physician stand in the shoes rule not apply if the compensation arrangement between the physician and the physician organization satisfies an existing compensation exception under Stark for bona fide employment relationships, personal service arrangements or fair market value arrangements. See 42 C.F.R. § 412.357(c) (bona fide employment), § 412.357(d) (personal service) & § 412.357(l) (fair market value). The analysis required by this approach focuses on only the compensation between the physician and the physician organization, disregarding any arrangements the physician organization may have with other entities.

As part of this approach, CMS addresses the concerns of AMCs. CMS proposes that (a) the physician stand in the shoes rule would not apply to arrangements protected by the AMC exception under Stark (42 C.F.R. § 411.355(e)), and (b) a physician would not stand in the shoes of a physician organization in connection with an AMC's payment to the physician organization for services required to satisfy the AMC's obligations under the Medicare graduate medical education ("GME") rules in Part 413, subpart F.

Inaddition, CMS seeks comments on whether the physician stand in the shoes rule should apply to physicians holding an ownership or investment interest in a physician organization, including whether any such approach should exclude ownership or investment interests that are "nominal in nature" (i.e., interests that do not entitle physicians to distributions of profits). CMS also seeks comments on whether only owners should stand in the shoes of physician organizations and how to apply this rule to physician organizations with no physician owners.

B. New Exception Approach

Different from its multi-faceted approach, CMS' second "alternative" approach does not involve revisions to Phase III stand in the shoes provisions, but rather proposes to promulgate a separate exception under the Stark law for arrangements that do not pose a risk of program or patient abuse. CMS does not provide specific regulatory text for this approach, but does note that the proposed exception would apply to compensation arrangements between DHS entities and physicians for mission support payments and payments between components of "welldefined" IDS. CMS seeks comments regarding any other types of arrangements that should be eligible for this proposed exception, including noting any safeguards that should be included to protect against risk of abuse.

Changes to DHS Entity Stand in the Shoes Proposal

In its 2008 Medicare Physician Fee Schedule Proposed Rule, CMS proposed a corollary provision to the physician stand in the shoes rule that addressed the DHS entity side of physician-DHS entity financial relationships. See 72 Fed. Reg. 38122 (July 12, 2007). Under that proposal, if one DHS entity "owns or controls" a second DHS entity that has a compensation arrangement with a physician, the first DHS entity would be deemed to also have a compensation arrangement with that physician. The first DHS entity stands in the shoes of the second DHS entity.

CMS reportedly proposed the DHS entity stand in the shoes provisions out of concern that parties could avoid application of the Stark law by merely inserting an entity in the chain of financial relationships linking a physician and DHS entity. Under the IPPS Proposed Rule, CMS tightens this approach, such that the first DHS entity only stands in the shoes of the second DHS entity if the first DHS entity holds a 100% ownership interest of the second. This would apply to any type of entity (LLC, partnership or corporation, regardless of status as nonprofit or tax exempt). CMS seeks comments on whether the DHS entity stand in the shoes rule should apply to entities that are less than 100% owned by another DHS entity and, if so, what percentage of ownership should trigger the application of these provisions.

Because the introduction of the DHS entity stand in the shoes rule could create confusion in analyzing chains of financial relationships, CMS proposes rules for applying both of the stand in the shoes provisions. Examples of these rules are provided as part of the IPPS Proposed Rule. See 73 Fed. Reg. at 23689.

Additional Stark Issues
In addition to the stand in the shoes proposals discussed above, CMS addressed other Stark issues in the IPPS Proposed Rule. Such issues included:

- **Period of Disallowance.** CMS proposes to define the specific time periods for prohibiting Medicare billing when Stark is violated. If the Stark violation is unrelated to compensation (i.e., contract not signed), the period of disallowance runs from the date that relationship failed to meet a Stark exception to the date that relationship fulfills a Stark exception. For Stark violations based on excess compensation, the period of disallowance runs from the date of the excess compensation to the date the excess compensation is returned to the party that paid it and the relationship satisfies a Stark exception. And for Stark violations based on insufficient compensation, the period of disallowance runs from the date of he insufficient compensation to the date the lacking compensationis paid to the party to which it is owed and the relationship satisfies a Stark exception. Periods of disallowance based on any other circumstances will be determined on a case-by-case basis.
- **Gainsharing Arrangements.** Notwithstanding its general concern regarding arrangements that involve the use of a percentage-based compensation formula, CMS states that it recognizes the value of aligning hospital and physician incentives to improve quality of care. Based on this recognition, CMS seeks comments regarding a proposed, new Stark exception for certain gainsharing arrangements.
- **Physician-Owned Implant and Medical Device Companies.** CMS seeks comments on whether the Stark regulations should address physician ownership of medical device distributors, group purchasing organizations and manufacturers. Alternatively, CMS questions whether the concerns surrounding physicianowned implant and medical device companies are better addressed through enforcement of the False Claims Act, the anti-kickback statute and similar fraud and abuse laws, other public laws and through other applicable federal, state and local regulations.
- **Stark Disclosures.** CMS proposes to send Disclosure of Financial Relationships Reports ("DFRR") to 500 hospitals nationwide in an attempt to assess Stark compliance throughout the hospital industry and assist in future rulemakings regarding Stark reporting. Hospitals will have 60 days to complete the DFRR before civil monetary penalties of $10,000 per day could result. CMS seeks comments on this timeframe and the contents of the DFRR form.

Conclusion
Through the IPPS Proposed Rule, CMS is responding directly to stakeholders' concerns regarding the Stark law and asking for input. If you have arrangements in place or are contemplating arrangements that would be affected by proposals in the IPPS Proposed Rule, this is the time to comment. It also is the time to start thinking ahead regarding the impact of the proposed changes on current and contemplated arrangements with referring physicians. All comments must be received by CMS no later than June 13, 2008.