

Stark "Stand in the Shoes:" Common Sense Prevails

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Practice Area: Health Law

From the outset, the Stark law has been touted by the Centers for Medicare and Medicaid Services ("CMS") as a vehicle for providing "bright line" rules governing physician referrals to hospitals and other entities with which the physicians have financial relationships. The Stark reality has been quite different, as the healthcare industry has been forced to deal with an incredibly complex series of regulations where the very existence of any financial relationship frequently rests on subtle, hyper-technical distinctions. When it comes to the "stand in the shoes" rules, though, this unfortunate trend has been reversed. CMS recently released an advance copy of a revised "stand in the shoes" rule that addresses both CMS and industry concerns in a simple and understandable way. The new rule is scheduled for publication in the Federal Register on August 19, 2008.

What's the Issue? To understand the "stand in the shoes" doctrine, one must first be familiar with the concept of "financial relationships" under Stark. At its essence, Stark prohibits a physician from making referrals for certain "designated health services" ("DHS") to an entity with which the physician (or an immediate family member) has a financial relationship, unless an exception applies. Stark also prohibits that entity from billing or collecting for those referrals. Financial relationships may be in the form of ownership/investment interests (physician is a shareholder), or compensation arrangements such as leases or personal services contracts. Relationships may be either "direct" (meaning that there is no intervening person or entity between the referring physician and the DHS entity) or "indirect" (requiring not only an intervening entity, but also the satisfaction of other certain other criteria specified in the regulations).

This technical distinction between direct and indirect financial relationships is key to any Stark analysis. As noted earlier, the existence of a financial relationship may trigger the referral prohibition unless an exception applies. And the availability of any particular exception depends on whether the relationship is characterized as direct or indirect. The Stark regulations contain a single catch-all exception for indirect compensation arrangements, but over twenty separate direct compensation exceptions exist. Direct exceptions are typically more stringent; for example, those exceptions usually require a minimum term of one year and that compensation be set in advance. In addition, certain indirect relationships might actually fall outside the technical definition of an indirect compensation arrangement, such that they would not have to meet an exception at all. For example, the aggregate compensation in the compensation arrangement closest to the physician must reflect the volume or value of referrals in order for an "indirect compensation arrangement" to arise in the first place.

Due to these distinctions, there has been a perceived benefit in structuring arrangements as indirect rather than direct relationships. When an intermediary entity stands between the referring physician and the DHS entity, that could result in the arrangement being characterized as an indirect compensation arrangement rather than direct, and therefore subject to a less stringent exception. In some cases, that structure could take the arrangement outside the scope of regulated "financial relationships" altogether. CMS has made it clear in the past that it considers many of these efforts to be questionable at best, as they may circumvent the regulatory safeguards of Stark.

The 2007 Stand in the Shoes Rule. CMS announced the stand in the shoes doctrine in response to this perceived end-run around Stark. By requiring physicians to stand in the shoes of their physician organizations, CMS effectively eliminated those physician organizations as intermediary entities for purposes of the direct/indirect analysis. Absent any additional intermediary entities between the physician organization and the hospital or other DHS entity, the physician (standing in the shoes of the physician organization) would be deemed to have a direct financial relationship with the DHS entity. As a result, the arrangement would have to meet the tougher requirements of the direct compensation exceptions rather than qualify for the less restrictive indirect compensation exception. And certain arrangements that previously might have fallen outside of Stark's grasp altogether would now also have to comply with a direct exception.

The stand in the shoes provisions were included in the final Phase III Stark rules released in September 2007. Under the Phase III provisions, the referring physician would stand in the shoes of (1) any physician who employs the referring physician; (2) the physician's wholly-owned professional corporation; (3) a medical practice that employs or contracts with the referring physician, or in which the referring physician has an ownership interest; or (4) a group practice of which the referring physician is a member or independent contractor. Those rules were scheduled to go into effect as of December 2007.

AMC and IDS Issues. CMS immediately received a number of complaints regarding the rule's impact in circumstances where there is a transfer of funds between a DHS entity and a physician organization that, while not necessarily satisfying a "fair market value" standard, would not raise concerns of program abuse. The particular focus of these comments was on support payments within academic medical centers ("AMCs") and non-profit integrated delivery systems ("IDS"). In the absence of a fair market value exchange, these fund transfers would not qualify for a direct exception; and if physicians were then deemed to "stand in the shoes" of those physician organizations, those mission support payments would have the effect of outlawing referrals from the physicians to the hospital entities. CMS responded to those concerns last November by delaying the effective date of the stand in the shoes provisions until December 2008 while it studied the issue; that postponement only applied for AMCs and non-profit IDS, however.

In April 2008, CMS took another stab at addressing the concerns regarding the stand in the shoes doctrine. CMS solicited comments on alternative approaches where CMS would either (1) exempt indirect financial relationships where the compensation arrangement between the physician and physician organization would otherwise qualify for the employment, personal services, or fair market value direct exceptions; (2) limit the stand in the shoes doctrine to physicians who held ownership interests in their physician organizations; or (3) create a new exception specifically applicable to mission support payments.

The 2008 Final Rule. CMS has chosen the second option in its final rule. A physician who has an ownership or investment interest in a physician organization will stand in the shoes of that organization, but non-owner employees and independent contractors will not. Physicians with only a "titular" ownership interest are not required to stand in the shoes of their physician organizations, however. CMS considers an ownership or investment interest to be "titular" where the physician is not entitled to any of the financial benefits of ownership or investment, including but not limited to the distribution of profits, dividends, proceeds of sale, or similar returns on investment. Note that this carve-out for "titular" ownership or investment interests is consistent with an advisory opinion issued by CMS in 2005, in which CMS concluded that stock held by physician-shareholders in a nonprofit, tax-exempt medical practice would not constitute an ownership or investment interest within the meaning of Stark. In that advisory opinion, CMS agreed that the stock exhibited none of the benefits typical of stock ownership, and that the physicianshareholders had no right to distribution of the net income, assets or profits of the medical practice. CMS' approach has greatly simplified the "stand in the shoes" analysis. CMS rightly stated that "this approach comports with the common sense understanding of physician relationships." Given its focus solely on physician-owners of physician organizations, the stand in the shoes doctrine should not have the feared impact on AMCs or integrated delivery systems (including for-profit systems where physicians do not have ownership interests in the medical practices).

Implications. For the reasons stated above, the primary beneficiaries of this new rule are AMCs and IDS in which physician ownership is not present. These organizations no longer need to worry about the impact of the stand in the shoes doctrine on support payments within the AMC or health system. Note that the new rules also include a specific provision that excludes application of the doctrine to an organization that meets the definition of an AMC.

The new rule will have less of an impact on relationships between DHS entities and physician-owned physician organizations. For the most part, those arrangements will need to comply with a direct compensation exception, which was already the case under the Phase III final rule that went into effect last December, unless there is some other intervening party in the chain of relationships between the DHS entity and the physician organization. Referring physicians who are employees of the physician organization, but not owners, may still have their through-the-group relationships with the DHS entity analyzed under the indirect compensation rules since they do not stand in the shoes of the physician organization. That distinction may have little practical significance, however. Any contract between the DHS entity and the physician organization will still need to meet a direct compensation exception so long as any physician-owner is making referrals to the DHS entity. And contracts entered into directly between the DHS entity and the physicians, such as medical director arrangements, will need to meet a direct compensation exception regardless of whether the physician is an owner or employee of the physician organization.

Parties who restructured their arrangements to meet a direct exception in response to the Phase III rules last fall, but who are no longer subject to the stand in the shoes requirements, will not be required to make further changes in response to the new rule. The rule provides physicians with the option of standing in the shoes of their physician organizations even when not required to do so, which eliminates the need to restructure. In addition, any arrangement that was restructured to meet the stricter requirements of a direct exception will as a general rule also qualify for the indirect compensation exception.

The new "stand in the shoes" rules go into effect on October 1, 2008. Given the scope of these rules, the deferral of the Phase III "stand in the shoes" provisions for AMCs and nonprofit integrated delivery systems (which was in effect until December 4, 2008) is now moot.

Entity-Side Stand in the Shoes. The new final rule addresses the stand in the shoes doctrine on the physician side. When it issued the Phase III regulations last September, CMS solicited comments on whether it should also adopt a stand in the shoes rule on the entity side. Under this proposal, a DHS entity would stand in the shoes of any organization in which it had 100% ownership interest. This proposal was intended to safeguard against abusive business structures that attempted to transform a direct relationship into an indirect relationship by interposing a “shell” entity between the DHS entity and the referring physicians.

While CMS decided not to finalize that entity-side proposal at this time, it cautioned that any such arrangements would be considered “highly suspect” under the Stark law as a potential unlawful circumvention scheme, and might also violate the anti-kickback statute. CMS stated that any such arrangement would be subject to close scrutiny.

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