

Phase II: Following the Trail of Indirect Relationships

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Practice Area: Health Law

This article focuses on issues raised by the treatment of indirect compensation arrangements in Phase II of the final Stark regulations, released on March 26, 2004. Stark's referral prohibitions may be triggered by a wide variety of financial relationships, both direct and indirect. In Phase I of the final Stark II rules issued in 2001, the Centers for Medicare and Medicaid Services ("CMS") substantially revised its approach for identifying when an indirect compensation arrangement might arise. In addition, Phase I created a new exception for indirect compensation arrangements that was intended to be consistent with the "fair market value" exception available for direct compensation arrangements. CMS attempts to clarify various aspects of indirect arrangements in Phase II, but in many cases, these clarifications only lead to more questions.

The Definition

Phase I established a three-part test in determining the existence of an indirect compensation arrangement:

1. An unbroken chain of financial relationships between the referring physician and the entity furnishing designated health services ("DHS").
2. Aggregate compensation received by the referring physician that varies with, or otherwise reflects the volume or value of referrals or other business generated by the referring physician for the DHS entity.
3. The DHS entity has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives such compensation.

The Exception

Even if a chain of relationships gives rise to a "indirect compensation arrangement," it will not constitute a prohibited "financial relationship" if the following conditions are met:

1. The compensation received by the physician is fair market value ("FMV"), and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.
2. The compensation arrangement is in writing, signed, and specifies the services covered by the arrangement.
3. An employment relationship need not be in writing, but must be for identifiable services and commercially reasonable even in the absence of referrals.
4. The arrangement does not violate the anti-kickback statute.

For both the definition and the exception, if the physician's link to the next entity in the chain is an ownership or investment interest, the analysis moves up the chain to the first compensation arrangement closest to the physician.

“Reflects” vs. “Takes into Account”

Much head-scratching followed Phase I, particularly as to the interplay between the definition of indirect compensation arrangements and the exception for those arrangements. What, for example, was the difference between an arrangement that “varies with or otherwise reflects” referrals and one that “takes into account” referrals? If they meant the same thing, any arrangement meeting the exception would not have qualified under the definition as an indirect arrangement in the first place. It did not help that Phase I provided no guidance on the distinction between the “takes into account” and the “varies with or otherwise reflects” language.

“Aggregate” Compensation

In the preamble to Phase II, CMS uses these phrases interchangeably, signaling that it never intended any distinction between these terms. Instead, CMS focuses on the concept of “aggregate” compensation: according to CMS, the *definition* of indirect compensation arrangements looks at the referring physician’s aggregate compensation, but the exception does not. By way of illustration, CMS notes that time-based and unit-of-service based payments may give rise to an indirect compensation arrangement, since aggregate compensation will always vary with the volume or value of referrals. These arrangements may still qualify for the indirect compensation exception (which does not focus on “aggregate” compensation) if the individual time or unit base is set in advance.

Presumably, CMS did not intend to limit the exception to time-based and unit-of-service based arrangements. Instead CMS appears to be saying that the focus in the exception is on the *methodology* of the payment. If that methodology is FMV, and does not vary over the term of the agreement in a manner that “takes into account” DHS referrals or other business, the arrangement should meet the exception even if the overall effect is that total compensation may rise or fall with referrals.

A focus on “methodology” would enhance the utility of the indirect compensation, and provide the “bright line” that is lacking in the current terminology. Further clarification is required from CMS to confirm this approach.

Fair Market Value and Indirect Arrangements

Under the three-part test mentioned earlier, an indirect relationship will not constitute an “indirect compensation arrangement” if the compensation paid to the physician does not “vary with or otherwise reflect” referrals or other business. Nothing in this definition requires that compensation also be fair market value in order to avoid characterization as an indirect arrangement. The preamble to Phase II suggests that such a FMV test is implicit in the regulation, however.

CMS states that below-FMV compensation can cause an arrangement to qualify as an indirect compensation arrangement, even if that compensation is fixed in advance. Moreover, because the payments would not be fair market value, the indirect compensation exception would not apply. CMS apparently believes that compensation below fair market value necessarily “reflects” or “takes into account” referrals, borrowing a presumption employed by the Office of Inspector General in the anti-kickback arena.

This is another area where further clarification is needed from CMS, since nothing in the text of the regulations mandates the conclusion that below-FMV compensation automatically takes into account referrals. Indeed, CMS’ apparent incorporation of a FMV test into the “takes into account” language creates a redundancy in the indirect compensation exception, which requires that compensation be “fair market value, not taking into account” referrals. Pending further guidance, physicians and DHS entities should include a FMV analysis in any inquiry into whether an arrangement meets the indirect definition.

Solely-Owned PCs

Phase I treated referring physicians and their solely-owned professional corporations as distinct legal entities in the indirect compensation analysis. As a result, a contract between a physician's professional corporation and a DHS entity resulted in an *indirect* financial relationship between the physician and the entity. The *only* exception available in this situation was the exception for indirect compensation arrangements.

CMS removes this artifice in Phase II, recognizing that it makes no sense to treat a referring physician as separate from a solely-owned professional corporation. Under the revised rules, a contract between the DHS entity and solely-owned PC creates a *direct* compensation arrangement between the DHS entity and the referring physician – the ownership interest of the physician in the PC is disregarded.

Direct Exceptions Inapplicable?

Note that this revision only applies to solely-owned PCs. When a practice group is an intervening entity in the chain, rather than a solely-owned PC, an indirect arrangement may still arise. Thus, while a physician is now considered to stand in the shoes of the physician's PC, physicians are not allowed to stand in the shoes of a practice group.

This is a significant distinction. If the intervening practice is not ignored, any compensation arrangement (such as a lease) between a DHS entity and the group potentially gives rise to an indirect compensation arrangement between the entity and the individual physician-owners in that group. According to CMS, even if the arrangement between the DHS entity and the practice group meets an exception, that exception does not break the chain of relationships giving rise to an indirect compensation arrangement. Thus, that indirect relationship must be separately analyzed under the indirect compensation exception. That, in turn, could mean that the DHS entity's compliance with Stark ultimately hinges not on whether the lease is compliant with the lease exception, but instead on whether the compensation paid by the group to its physicians is compliant with the indirect compensation exception – a factor over which the DHS entity has no control.

DHS entities have assumed that they could rely on direct exceptions in their dealings with physician practices. CMS' interpretation would suggest otherwise. If that interpretation stands, the utility of direct exceptions may be limited to those circumstances where a DHS entity contracts directly with the referring physician or solely-owned PC.

We expect further guidance from CMS on this following the comment period on Phase II.

Common Ownership

Phase II clarifies that common ownership of an entity does not create an ownership interest by one common investor in another. While the preamble discussion is not always helpful (CMS blurs the distinction between indirect compensation arrangements and indirect ownership arrangements), the regulation itself is fairly explicit.

Co-ownership will not create an ownership or investment interest by one common investor in the other. An indirect ownership or investment interest arises from a vertical series of ownership interests, in which each owner/investor holds an interest in the next entity in the chain. The definition of an indirect ownership arrangement does not include an arrangement where an ownership interest flows down to the owned entity and then up to a second investor.

Co-ownership arrangements should still be considered under an indirect compensation analysis, however. CMS cautioned that when the aggregate return on investment varies with referrals, an indirect compensation arrangement may rise.

No “Indirect Ownership” Exception

CMS confirms in Phase II that an indirect ownership or investment interest cannot be excepted under the indirect compensation exception. Following CMS’ announcement of the indirect compensation exception in Phase I, commenters requested that CMS adopt a similar exception for indirect ownership and investment interests. CMS rejects that request in Phase II. CMS notes that the definition of an indirect ownership or investment interest includes a knowledge element, which limits the scope of arrangements falling within that definition.

Nevertheless, where a physician’s direct ownership in a DHS entity would be protected under an exception (such as the whole hospital exception), a similar indirect ownership interest in that same DHS entity will also be excepted.

What’s Next

In its 1998 proposed rules, CMS said that it would analyze indirect relationships by starting at the DHS-entity end of the chain, focusing on the direct relationships between the DHS entity (such as a hospital) and the next link in the chain (such as a practice group). In the Phase I and Phase II final rules, CMS abandons this approach in favor of an analysis that centers on the compensation received at the physician end of the chain. This shift in emphasis has cast shadows on the “bright line” rules that CMS sought to provide.

We expect that CMS will continue to receive comments critical of this approach, and we anticipate further refinements to the indirect compensation analysis when CMS responds to those comments. Until “Phase III” arrives, though, hospitals and practice groups may need to take a direct interest in their indirect relationships with physicians and their practice groups.

Additional Resources

The Stark/Fraud & Abuse Team of von Briesen’s Health Law Group has assembled a number of resources on the Stark Phase II regulations.

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