

Part 2

Key changes to the Stark II final rule

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On Sept. 5, 2007, the Centers for Medicare & Medicaid Services published the third phase of the Stark II final rule that covers physician referral arrangements for designated health services (DHS). In Part I of this article, published in the November 2007 issue of *NN&I*, we addressed some of the changes to the Phase III rule of Stark II. Those changes plus others, which are discussed below, have a direct impact on nephrology practices and dialysis providers and may require restructuring of existing arrangements, or be considered in the context of future arrangements. Providers should know that the proposed regulations became effective on Dec. 4, 2007, and therefore, any changes to existing arrangements that may be mandated by the Phase III rule must be implemented.

'Stand in the shoes' provisions

CMS, in an attempt to "clos[e] an unintended loophole in the definition of indirect compensation arrangement," has amended the Stark Act regulations to expand the "stand in the shoes" concept to group practices and other physician organizations when applying the rules to direct and indirect compensation relationships. Essentially, as a result of the change, compensation relationships between entities providing DHS and group practices where

there is an intervening entity (e.g., a professional corporation) between the entity providing the DHS and the physician, will be treated as a direct relationship between the DHS entity and the physician for Stark Act purposes. In other words, for purposes for determining whether a physician has a direct or indirect financial relationship with a DHS entity, the physician will "stand in the shoes" of his or her group practice.

The Phase III rule also makes clear that the parties covered by the "stand in the shoes" concept include all physician members, employees, and independent contractors of a physician organization and thus, each of these individuals must comply with an applicable Stark exception. CMS offered this example:

[I]f 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 an exception for rental of office space ... if the DHS entity wants to submit claims for DHS referrals from those physicians.¹

Although the regulations took effect Dec. 4, 2007, CMS has established a transition period for arrangements in effect prior to Sept. 5, 2007, providing they need not be amended during the original term of the arrangement or the current renewal term.

The impact of the change brought about by the expansion of the "stand in the shoes" concept is more likely to affect the relationships between nephrologists and a hospital or an academic medical center ("AMC") setting. In the situation of a hospital, the provision of services through the physician organization prior to the Phase III rule needed only to meet the indirect compensation exception that

required fair-market value payment for services, the agreement set out in writing, and an explanation of the services provided. Under Phase III, the same agreement must meet all the additional requirements of the personal service and space rental exceptions, as well as other exceptions to the Stark regulations. In addition, in light of the extent and intricacies of the relationships between hospitals and physician organizations in the AMC setting, CMS has agreed to delay applying the "stand in the shoes" changes to relationships between AMC and physicians until Dec. 4, 2008, in order to better assess the effective provisions in such relationships.

Shared space issues

The in-office ancillary service exception to the Stark Act permits physicians and group practices to order and provide many designated health services. DHS provided by many physicians or their practices include laboratory services, and in some cases, may be performed in shared space. DHS may be provided in the same building where the physician or the physician's practice routinely provides the full range of medical services. In the case where a physician provides DHS in a space shared with other physicians, CMS noted:

A physician sharing a DHS facility in the same building must control the facility and the staffing ... at the time the designated service is furnished to the patient ... As a practical matter, this likely necessitates a block lease arrangement for the space and equipment used to provide the designated health services.²

This change is likely to have less impact on nephrologist than those groups with arrangements for providing imaging services, such as CT/MRI procedures and pathology laboratories. However, as new



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1. 72 Fed. Reg. 51028 (Sept. 5, 2007).

2. *Id.* at 51033.

services are developed to treat the end-stage renal disease population, care must be taken in structuring these services.

Independent contractor contract requirements

An independent contractor physician who qualifies as a “physician in the group” is eligible for protection under the practice exception and the in-office ancillary services exception, such that the services performed by the independent contractor can be billed directly by the group practice. The Phase III rule modified the definition of “the physician in the group practice” so that it is now clear that that physician must furnish services for the group practice under a direct contractual relationship with the group and not between the group practice and another entity, such as a staffing entity or even another group practice. CMS also noted:

[I]n order to qualify as a group practice and receive such favorable treatment, the group practice’s physicians must have a strong and meaningful nexus to the group practice. An independent contractor in direct contractual privity with a group practice has such nexus; employees leased from other entities do not.³

CMS further stated that an independent contractor physician is considered in the group practice “only when he or she is performing services in the group practice’s facilities, and thus, has a clear and meaningful nexus with the group’s medical practice.”⁴

This provision is important for a nephrology practice. There are circumstances in which a nephrology group practice will retain the services of a nephrologist through a leasing organization on a limited basis. Also, a nephrology practice may retain the services of a vascular surgeon or interventional radiologist to provide access services. In the context of an access center, while most access centers are not providing DHS and may not otherwise meet the in-office ancillary

service exception, in those limited circumstances in which DHS are provided, the independent contractor physician must be retained directly or the group practice risks running afoul of Phase III rule clarification.

Productivity bonuses and “incident to” referrals

Current Stark regulations prohibit compensation arrangements to members of the group practice based upon the volume or value of the physician member’s referral of DHS. However, the

a productivity bonus based directly on physical therapy services provided “incident to” his or her service. However, the productivity bonus can not be directly related to any other DHS referral such as diagnostic tests.

The Stark Act does not provide an independent definition for referrals that are provided “incident to” a physician’s personally performed services. Instead, the Stark Act definition refers to Medicare coverage and the payment rules, as follows:

“Incident to” services means those

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regulations contain an exception that allows profit sharing and productivity bonuses based indirectly on referrals of DHS, as follows:

A physician in a group practice may be paid a share of overall profits of the group, or a productivity bonus based upon services that he or she has personally performed (including the services “incident to” those personally performed services as defined in §411.351), provided that the share or bonuses are not determined in a manner that is directly related to the volume or value of referrals of DHS by the physician.⁵

The Phase III regulation clarified that it is now appropriate to provide physicians with productivity bonuses based directly on the physician’s performance of services and on services “incident to” the physician’s performance of the service. For example, a physician can be paid

services that meet the requirements of... 42 C.F.R. section 410.26 and section 2050 of the Medicare Carriers Manual (CMS Pub. 14-3), Part 3.⁶

Amendments to compensation arrangements

Many compensation arrangement exceptions to the Stark Act, such as personal service, office space renting, and equipment exceptions, have certain similar requirements. For example, all three exceptions require that the compensation or rental rate be “set in advance,” the rate be at fair-market value, and the term be for at least one year. These conditions have raised questions pertaining to amendments to agreements protected by these exceptions. CMS has provided some guidance on amendments that

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3. Id. at 51018.

4. Id. at 51017.

5. 42 C.F.R. §411.352.

6. 42 C.F.R. §411.351.

[LEGAL continued from page 43]

may need to be made during or after the first year of an arrangement's term. CMS explained:

"Parties may amend a lease agreement multiple times during or after the first year of its term, provided that the rental charges are not changed and all other requirements of the exception are satisfied. However, changes to the terms that are material to the rental charges, such as the amount of space leased, may cause the rental charges to fall

out of compliance with the fair market value ... requirements."⁷

This further guidance by CMS would indicate that to the extent that solely non-economic terms are being amended, the amendment is likely acceptable and permitted under the Phase III rule guidance, so long as such changes do not in any way reflect the volume or value of physician referrals. This clarification is important in the dialysis industry, as there are many instances in which non-economic

7. 72 Fed. Reg. 51044.

terms of these arrangements may change, including an extension of the term, clarification of policies and procedures relating to either the use of the space of the performance of duties, or in the case of medical director agreements, a starting date for the performance of services.

Expansion of fair-market value exception

Prior to the Phase III rule, the fair-market value exception provided protection for an arrangement that met five criteria, including that the agreement be set out in writing, compensation be set in advance consistent with fair-market value, the arrangement be commercially reasonable, and the arrangement not violate the Anti-Kickback or other state or federal law. The covered arrangements are those where DHS entities purchased services from the referring physician or his/her affiliates. The Phase III regulations have now been expanded such that the fair-market value exception also includes payments made by a physician to a DHS entity. This change has a significantly larger impact. By expanding the fair-market value exception to include payments by a physician to an entity providing DHS, CMS has effectively eliminated the exception applicable to payment by physicians that simply require that the payment be at fair-market value and commercially reasonable. Thus, these arrangements must also meet the five criteria noted above.

These requirements under Phase III will in some ways expand exceptions for the benefit of providers in the health care industry but will also close some loopholes. Rental arrangements, shared space arrangements, independent contractor arrangements, and arrangements between DHS entities and physicians, particularly where services are purchased by the referring physicians from the DHS entity, may require modification in order to comply with these recent changes. All providers should review these arrangements in the context of the Phase III rule and determine whether any modifications are necessary. **N**