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Stark Law Definition of "Entity"

On October 30, 2009, the Centers for Medicare and Medicaid Services ("CMS") released its Calendar Year ("CY") 2010 Medicare Physician Fee Schedule ("MPFS") Final Rule.[1] In it, CMS announced that it is soliciting industry comments regarding the revised Stark Law regulatory definition of "entity" that was published in August 2008 and became effective October 1, 2009. This request for industry comments is unusual as it *follows* publication and implementation of the new Stark rule. Despite CMS's determination in 2008 to use the common meaning of the phrase "performed services" in the new definition of entity, CMS is now seeking to understand whether the industry believes that more clarification is necessary in the future.

Background on the Stark Law Definition of "Entity"

Under the Stark statute, if a physician (or an immediate family member) has a financial relationship with an "entity," the physician may not make a referral to the entity for the furnishing of a designated health service ("DHS"), unless a statutory exception is met.[2] Under CMS's prior regulations published in 2001, only the person or entity that *billed* Medicare for DHS was considered a DHS entity.[3] Over the following seven years, CMS indicated a concern that the definition of "entity" was too lenient and possibly permitted abuses of under arrangement agreements.[4] Consequently, in an effort to curb the perceived abuses, effective October 1, 2009, CMS expanded the definition of "entity" to include any person or entity that "*performed* services that are billed as DHS" in addition to those who *billed* DHS.[5] However, at the time the rule was published, CMS declined to define the word "perform."

Results of Change to the Definition of "Entity"

Under the newly expanded definition of "entity," a physician-owned organization that performs services under arrangement to a hospital is considered a DHS "entity." As a result, the ownership interest held by a physician in the organization performing the DHS is now required to meet a Stark exception. [6] Given the unavailability of a Stark exception, many physician-owned organizations were restructured and numerous "under arrangement" agreements were either restructured or terminated.

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[1] The MPFS Final Rule was published in the Federal Register on November 25, 2009. 74 Fed. Reg. 61,738 (Nov. 25, 2009).
[2] 42 U.S.C. 1395nn.
[3] 66 Fed. Reg. 855, 953 (Jan. 4, 2001).
[4] 74 Fed. Reg. 61,738, 61,933 (Nov. 25, 2009) *citing* 72 Fed. Reg. 38,122 38,186-38,187, 38,219, 38,224 (July 12, 2007). An under arrangement agreement is when a hospital contracts with a third party to provide services to the hospital and the hospital bills for the services.
[5] 73 Fed. Reg. 48,434, 48,751 (Aug. 19, 2008).
[6] 73 Fed. Reg. at 48,726.

At the time CMS published the expanded definition of "entity," it provided the following guidance in the preamble

[W]e consider a service to have been 'performed' by a physician or a physician organization service if the physician or physician organization does the medical work for the service and could bill for the service, but the physician or physician organization has contracted with a hospital and the hospital bills for the service instead. We do not mean to imply that a physician service provider can escape the reach of the physician self-referral statute by doing substantially all of the necessary medical work for a service, and arranging for the billing entity or some other entity to complete the service. We do not consider an entity that leases or sells space or equipment used for the performance of the service, or furnishes supplies that are not separately billable but used in the performance of the medical service, or that provides management, billing services, or personnel to the entity performing the service, to perform DHS.[7]

Given this limited guidance, as parties analyzed their current arrangements prior to the October 1, 2009 deadline, it was difficult to assess what combination of elements rose to the level of "performing" the service and therefore whether CMS would consider a particular physician-owned entity to be "performing" a DHS service in a particular instance.[8] Accordingly, numerous contracting parties decided, in the end, to unwind or restructure certain arrangements.

CY 2010 MPFS Final Rule and Solicitation of Comments on Definition of "Entity"

CMS has not stated that the definition of "perform" is unclear. However, more than a year after the change was published, and after many entities have already modified their structure or their contracts to comply with the rule, CMS is now soliciting comments from industry stakeholders to (1) keep itself informed of the health care industry's current view on the interpretation of "performing" DHS and (2) determine the need for further guidance on the definition.[9] Specifically, it seeks comments on the following:

- Whether CMS should define or clarify "performed services that are billed as DHS," and, if so, how.
- Whether "performed services that are billed as DHS" should be analyzed in the same manner for inpatient and outpatient services provided under arrangements.
- Whether performance of a service billed as DHS should be determined based on how many of the following elements are provided: (1) lease of space used for performance of the service; (2) lease of equipment used for performance of the service; (3) supplies that are not separately billable but used in the performance of the service; (4) management services; (5) billing services; and (6) nonphysician services that are not separately billable. If so, whether certain of these elements should be weighed more heavily than others in determining whether DHS are performed.
- Whether an interpretation of "medical work" was relied upon in restructuring arrangements and, if so, how.
- The degree to which the amount and nature of services provided by physician and nonphysician personnel (for example, technicians) should influence the determination of whether a person or organization has performed services billed as DHS.
- The degree to which the ability to bill separately for the service should influence the determination regarding whether a person or organization has "performed services that are billed as DHS."
- Whether there are other comments or alternative approaches or criteria that would address CMS's policy concerns about overutilization and other abuse while minimizing the impact on legitimate non-abusive arrangements.[10]

[7] *Id.*

[8] For instance, does providing some, but not substantially all of the "medical work" constitute performance?

[9] 74 Fed. Reg. at 61,933.

[10] *Id.* at 61,933-61,934.

CMS invites providers to share how they interpreted the new definition of "entity" and how they restructured their arrangements.[11] Comments must be submitted to CMS no later than 5 P.M. January 25, 2010.

CMS's request for input is a mixed message. It is encouraging that CMS is seeking industry input; however, it is discouraging that the request was not made until after the expanded definition became effective. Furthermore, while the questions posed are reasonable and thoughtful, they may portend an expansion of the definition or, at least, further elements to consider in analyzing arrangements.

Comments to CMS

Given the significance of the definition of "entity" under Stark and the unfortunate ambiguity created by the expanded definition, providers should consider responding to CMS's solicitation of comments. Even if a suggested change is rejected, CMS's written response to such a comment may provide more definitive guidance. Providers may want to consider commenting from either a technical language perspective or from a policy standpoint. Providers may also want to comment on the amount of time, effort, and expense that was involved in restructuring any "under arrangement" agreements to comply with the new rule and their opinion on the effectiveness of the change. For example, considering the time and expense involved in restructuring contracts to comply with the expanded definition, does the provider think the expanded definition is effective in making the industry more resilient to the abusive practices the CMS was attempting to target?

[11] *Id.* at 61,934.