

Stark IV: Old Questions Persist, New Questions Abound

The Centers for Medicare and Medicaid Services (CMS) has revisited its Stark Phase III regulations in its proposed inpatient prospective payment systems annual update rule, which was issued April 14, 2008. In this rule, CMS issued alternative proposals for altering the scope of the recently adopted physician “stand in the shoes” provisions and sought to clarify the time period for which billing is prohibited for arrangements that fail to comply with a Stark exception. CMS is accepting comments through June 13, 2008. Clients should keep these potential changes to the Stark law in mind in structuring new physician relationships.

New “Stand in the Shoes” Proposals Add Uncertainties

With the goal of adopting a “more refined approach” that would bring more financial relationships within the ambit of Stark, CMS has proposed two alternative methods of amending the physician “stand in the shoes” provisions adopted in its Phase III final rule.

Proposal one would limit application of the current “stand in the shoes” provisions if certain requirements are satisfied, including the following changes:

- A physician would not stand in the shoes of his physician organization (PO) if his compensation from the PO satisfies either of Stark’s employment, personal services, or fair market value exceptions;
- In the alternative, “stand in the shoes” would apply **only** where a physician has an ownership or investment interest in a PO;
- “Stand in the shoes” would not apply to compensation arrangements protected by the academic medical centers (AMC) exception; and
- “Stand in the shoes” would not apply to compensation paid by an AMC component to an affiliated PO under a contract that meets the Medicare graduate medical education rules for rotations to non-provider settings.

CMS emphasized that, in those PO-physician relationships that no longer trigger “stand in the shoes,” the indirect compensation arrangement will likely still exist within the Stark framework. Thus, if it adopts proposal one, CMS plans to clarify how the indirect compensation exception would apply in these settings.

Under proposal two, CMS would keep the “stand in the shoes” doctrine unchanged but would promulgate a new exception to cover nonabusive arrangements that do not currently receive protection under any exception. CMS suggested that a new exception may protect certain “mission support” payments, without defining this term, as well as compensation arrangements between components of narrowly defined integrated delivery systems. CMS is seeking comments regarding (1) how to define “mission support” payments, integrated delivery systems, or other arrangements that should be covered by the exception; (2) which parties should obtain protection from this exception (for example, whether “mission support” payments should be limited to AMCs); and (3) the conditions that should be imposed to minimize the risk of abuse.

Finally, CMS re-proposed a parallel “stand in the shoes” provision for entities providing designated health services (DHS) and proposed several conventions for determining the order in which “stand in the shoes” applies to a particular chain of financial relationships between physicians and DHS entities.

Lack of Clarity Regarding Periods of Disallowance Continues Despite New Proposal

Seeking to clarify the time period for which an entity is prohibited from billing Medicare when a financial relationship fails to satisfy a Stark exception, CMS proposed the following periods of disallowance:

Reason for failure to meet an exception	Period of disallowance
<ul style="list-style-type: none"> Unrelated to compensation (<i>i.e.</i>, a missing signature or an agreement is not in writing) 	<ul style="list-style-type: none"> From the original date of non-compliance to the date the arrangement became compliant
<ul style="list-style-type: none"> Excess compensation (<i>i.e.</i>, compensation exceeds fair market value) 	<ul style="list-style-type: none"> From the original date of non-compliance to the date the excess compensation plus interest was returned by the party receiving it to the party providing it and an exception is satisfied
<ul style="list-style-type: none"> Compensation insufficient to satisfy the requirements of an exception (<i>i.e.</i>, rental payments are below fair market value) 	<ul style="list-style-type: none"> From the original date of non-compliance to the date the shortfall was repaid and an exception is satisfied
<ul style="list-style-type: none"> Related to compensation, but not involving excess or shortfall (<i>i.e.</i>, volume variable) 	<ul style="list-style-type: none"> Case-by-case determination necessary

Comments Solicited on Additional Issues

CMS also solicited input on several topics for which no specific proposals were offered, including the following:

- Whether to adopt a new exception to protect certain gainsharing arrangements;
- Whether Stark should directly address physician investments in medical device manufacturing, distribution, and purchasing companies, and whether physician investment in these companies presents the concerns that Stark is intended to address (*i.e.*, overutilization, substandard care, and increased costs to the Medicare program); and
- Whether the burden of completing CMS's Disclosure of Financial Relationships Report is likely to exceed that estimated by CMS.

If you have any questions about the proposed regulations, please contact your regular Ropes & Gray attorney.

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