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If At First We Don't Succeed... CMS Seeks Comments Regarding Self-Referral Provisions in FY 2009 Hospital IPPS Proposed Rule

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As part of the FY 2009 Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule, the Centers for Medicare and Medicaid Services (CMS) is seeking comments on several proposed arrangements relating to the physician self-referral law ("Stark Law"). In the proposed rule, CMS seeks industry input on proposals to resolve industry concerns related to the physician and entity "stand in the shoes" provisions that were initially published during the finalization of the Phase III rules in September 2007. Additionally, CMS proposes regulatory changes to prescribe how the agency will determine the period of disallowance applicable to financial relationships that do not meet an applicable exception to the Stark Law and corresponding regulations. CMS also requests comments on whether it should create an exception for "gainsharing arrangements." Finally, CMS uses the proposed rule to express its concerns related to physician-ownership in implant and other medical device companies and seeks comments on how the agency should address these issues. Each of these issues is discussed more fully below and comments are due to CMS by 5 p.m. on Friday, June 13, 2008.

Physician "Stand in the Shoes" Provisions

In response to industry stakeholders' concerns regarding the application of the "stand in the shoes" provisions promulgated as part of the Phase III final rule published on September 5, 2007, CMS delayed the effective date of the provisions as applied to academic medical centers (AMC) and 501(c)(3) health care systems until December 4, 2008.

CMS is now proposing two alternative methods for addressing the concerns related to "stand in the shoes" and is seeking comments from the industry on each proposal and other possible approaches. Under the first approach, CMS proposes revising its rules so that a referring physician would not be deemed to stand in the shoes of his or her physician organization if the compensation arrangement between the physician organization and the physician satisfies the requirements of the current exceptions for *bona fide* employment relationships, personal service arrangements, or fair market value

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compensation. If the compensation arrangement meets one of the exceptions, the referring physician is not deemed to stand in the shoes of the physician organization for purposes of applying the direct and indirect compensation provisions. Such arrangements may still create indirect compensation that must satisfy the requirements of the indirect compensation exception to be permitted. Under this proposal, physician owners and investors would continue to stand in the shoes of their physician organization. CMS, however, is concerned that a blanket rule considering all physician owners or investors as standing in the shoes may be over-inclusive and inappropriate where such owners or investors have no right to distributions of profits, etc. CMS is soliciting public comments on how to address the issue of physician ownership and possible exceptions for ownership interests that are nominal in value. Additionally, CMS is seeking industry input on a possible approach where *only* owners of a physician organization would stand in the shoes of the physician organization and physicians with compensation arrangements would not stand in the shoes, even if their compensation arrangement did not meet any of the exceptions described above. As part of this approach, CMS is seeking input on whether and how the "stand in the shoes" provisions should apply to physician organizations with no physician owners.

If the first arrangement is enacted, CMS states that it would revise the current "stand in the shoes" regulations so that they would not apply to referrals protected under the exception for AMC services. CMS is also seeking public comment as to whether it should revise the regulations to indicate that the "stand in the shoes" provisions are not applicable where *any* of the exceptions set out in 42 C.F.R. § 411.355 related to ownership/investment or compensation are satisfied. Additionally, CMS indicates that the "stand in the shoes" provision would not apply to a compensation arrangement between a component of an AMC and a physician organization if the arrangement is only for services required for the AMC to meet its Medicare graduate medical education (GME) requirements.

Alternatively, as a second approach to the "stand in the shoes" issues, CMS proposes adopting a new exception for nonabusive payments or arrangements that are not otherwise covered by existing exceptions (i.e., "mission support" payments). CMS is seeking comments on whether the exception should be limited to "mission support" payments and, if not so limited, CMS is seeking public input on the types of arrangements that would be covered under the exception and the parties that could avail themselves of such an exception. CMS posits that the exception might address compensation arrangements between components of particular integrated delivery systems and is soliciting public comments on how to define "integrated health care delivery system," what types of compensation arrangements would be covered, and what conditions should be incorporated to limit potential for program or patient abuse.

In addition to the forgoing proposals, CMS clarifies that the definition of "referring physician" revised in the Phase II rules to provide that a referring physician stands in the shoes of his or her wholly-owned professional corporation (PC) is to be read with the definition of "physician organization" set forth by the Phase III rules. As a result, the referring physician is first "collapsed" into his or her wholly-owned PC and then the physician/PC unit stands in the shoes of a physician organization, if one exists.

Entity "Stand in the Shoes" Provisions

In addition to the physician "stand in the shoes" provisions, CMS is again proposing to create a "stand in the shoes" provision that would apply to designated health services (DHS) entities that have 100 percent ownership interest in an organization. Under the proposal, a DHS entity would stand in the shoes of *any* wholly-owned organization, not just wholly-owned DHS entities, and would be deemed to have the same compensation arrangements with the same parties and on the same terms as the wholly-owned organization. CMS is soliciting industry guidance as to whether "stand in the

shoes" provisions should apply to DHS entities that hold less than 100 percent ownership interest in another organization and, if so, what amount of ownership should trigger the application of the "stand in the shoes" provisions. Furthermore, CMS seeks comments regarding whether a DHS entity should stand in the shoes of an organization that it controls, i.e, where the DHS entity has the power to directly or indirectly influence the policies of the organization, and what amount of control would trigger applicability.

Without proposing any regulation text, CMS also sets forth several conventions relating to the interplay and applicability of the physician "stand in the shoes" provisions with the entity "stand in the shoes" provisions. CMS notes that it is not finalizing any provisions at this time, but may in the future amend the regulatory text, as appropriate, to set forth requirements for the related application of both "stand in the shoes" provisions.

Period of Disallowance

As part of the FY 2009 Hospital IPPS rule, CMS addresses comments received regarding the period of disallowance applicable to financial relationships that fail to comply with the Stark Law and corresponding regulations. Such comments were solicited as part of the CY 2008 Physician Fee Schedule (PFS) proposed rule. CMS is now proposing regulatory amendments that would address when the period of disallowance would begin and end depending on the cause of the violation.

If noncompliance is due to reasons unrelated to compensation (i.e., a signature is missing or an agreement is not in writing), CMS proposes that the period of disallowance would begin on the date that the arrangement was first out of compliance and would end no later than the date the arrangement was brought into compliance. Alternatively, where the noncompliance is due to the payment or receipt of excess compensation (i.e., where a hospital provides nonmonetary compensation in excess of limits set out in 42 C.F.R. § 411.357 (k)(4)), the period of disallowance is to begin on the date the arrangement was first out of compliance and end no later than the date when the excess compensation is returned and all other requirements of the exception are met. Where noncompliance is related to the payment or receipt of insufficient compensation (i.e., below fair-market-value rent), CMS proposes that the disallowance would begin on the date the arrangement was first out of compliance and end no later than the date the shortfall was paid to the party who is owed and the arrangement meets all of the requirements for the applicable exception.

CMS notes that an arrangement may be noncompliant for reasons related to compensation, but which do not involve excess compensation or shortfalls in compensation, i.e., an arrangement is fair-market-value but takes into account the volume or value of referrals. CMS is not proposing a prescribed period of disallowance to address these situations but, rather, posits that the appropriate period of disallowance will need to be determined on a case-by-case basis. CMS further clarifies that its proposed periods of disallowance simply impose outside limits on the possible periods of disallowance and recognizes that there may be situations where an arrangement is never brought into compliance and there must be a case-by-case evaluation.

Gainsharing Arrangements

Recognizing that gainsharing arrangements may be effective in controlling the costs of patient care and aligning physician incentives with those of hospitals, CMS is soliciting comments regarding a potential exception to the Stark rules and regulations that would permit certain gainsharing arrangements. In the CY 2008 PFS proposed rule, CMS proposed to clarify that percentage-based compensation arrangements may be used only for services personally performed by a physician and that such arrangements must be based on the revenues directly resulting from the physician services rather than based on savings to the hospital. CMS now recognizes that this proposal, if finalized,

would prevent typical gainsharing arrangements between hospitals and referring physicians. Therefore, CMS is now considering whether to issue an exception for particular gainsharing arrangements and is requesting industry guidance as to whether it should establish such an exception and, if so, what safeguards should be put in place. CMS is predominantly interested in receiving comments on what types of requirements and safeguards should be included in an exception and if certain services or protocols should be excluded.

Physician-Owned Implant and Other Medical Device Companies

CMS notes in the FY 2009 IPPS proposed rule concern regarding the proliferation of physician investment in implant and other medical device manufacturing, distribution and purchasing companies. While recognizing that physician input in research, development and testing may add value to device manufacturing companies, CMS is wary of physician involvement in distribution and purchasing companies where physicians may earn economic benefits for merely ordering medical devices or other products. CMS notes that many of these arrangements would not satisfy the requirements for indirect compensation arrangements in 42 C.F.R. § 411.357(p), and the agency is not proposing any specific regulatory amendments to address physician-owned implant and medical device companies (POCs) at this time. Instead, CMS is soliciting comments as to whether the self-referral rules should address POCs more specifically, or if such arrangements are better addressed through enforcement of the False Claims Act, anti-kickback statute or other federal and state fraud and abuse laws. CMS seeks further guidance from industry stakeholders regarding the extent to which POCs lead to risks of overutilization, substandard care and increased costs to the Medicare program and its beneficiaries. Alternatively, CMS suggests and seeks comments as to whether the risk of POCs is confined to anti-competitive behavior. CMS encourages commenters to provide specific suggestions regarding actions the agency should take.

Ober|Kaler's Comments: CMS appears to have understood the problems for AMCs and integrated health systems created by the physician "stand in the shoes" provisions set forth in the Phase III final rules and is attempting to address these concerns in its two alternative proposals. Other than the "stand in the shoes" provisions and the period of disallowance, CMS is merely soliciting comments on how it should address certain issues. Providers should consider how further regulation in these areas would be beneficial or harmful to their current or prospective physician arrangements and consider commenting by June 13, 2008 to provide CMS with guidance with respect to these issues.