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The Stark Aspects of the Proposed IPPS Rule: A New Era of Incremental Regulation and Some New Sources of Heartburn

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On April 14, 2008, the Centers for Medicare & Medicaid Services ("CMS") issued the proposed update to the hospital inpatient prospective payment system ("IPPS") for fiscal year 2009 ("the Proposed IPPS Rule").[1] In addition to payment updates, this proposed rule includes a number of provisions relating to the federal physician self-referral statute commonly referred to as the "Stark Law." CMS representatives have informally indicated that CMS is likely in the future to modify Stark regulations through periodic rulemakings such as the annual IPPS update instead of through wholesale Stark-specific rulemakings (as occurred with Phases I, II, and III of the Stark regulations). This *Health Law Update* will discuss the proposed changes to the Stark regulations contained in the Proposed IPPS Rule. Note that there are other significant provisions of the Proposed IPPS Rule, including provisions related to disclosure of physicians' financial relationships with hospitals, which we will address in future updates.

Stand in the Shoes

Physician "Stand in the Shoes"

Under Phase III of the Stark Regulations,[2] effective on December 4, 2007, referring physicians are treated as "standing in the shoes" of their physician organizations for purposes of applying the rules that govern direct and indirect compensation arrangements.[3] This "stand in the shoes" rule imputes to the individual physician the same compensation arrangements (with the same parties and on the same terms) as the physician organization has with designated health services ("DHS") entities. The effect of this "stand in the shoes" provision is that many compensation

[1] CMS anticipates publishing the Proposed IPPS Rule in the April 30, 2008 Federal Register.
[2] 72 Fed. Reg. 51012-51099.
[3] *See* 42 C.F.R. § 411.654(c).

arrangements that previously were permissible under the rules for indirect compensation arrangements must now meet a direct compensation exception.[4]

In the Proposed IPPS Rule, CMS acknowledges the "potential widespread impact" of the "stand in the shoes" provision and states that it is considering a "more refined approach."[5] CMS has therefore set forth two alternative approaches to address industry concerns regarding the physician "stand in the shoes" provisions (although only the first approach involves actual proposed changes to the regulatory text). In addition, CMS has requested comments on other possible approaches that it might consider.

Under CMS' first proposed approach to refine the scope of the physician "stand in the shoes" provision, a physician would not stand in the shoes of the physician organization under any one of the following circumstances:

- *Bona fide employment* – the compensation arrangement between the physician and physician organization satisfies the requirements of the bona fide employment relationship exception.[6]

- *Personal services* – the compensation arrangement between the physician and physician organization satisfies the requirements of the personal services arrangements exception.[7]

- *Fair market value* – the compensation arrangement between the physician and physician organization satisfies the requirements of the fair market value compensation exception.[8]

- *Services provided by AMCs* – the physician's referrals of DHS are protected by the exception for services provided by an AMC.[9]

- *Graduate medical education* – the compensation is provided by a component of an AMC to an affiliated physician organization through a written contract to provide services required to satisfy the AMC's obligations under the Medicare graduate medical education ("GME") rules where the contract is limited to those services necessary to fulfill the regulatory GME obligations.[10]

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[4] For more background on the physician "stand in the shoes" provision or Stark Phase III in general, please see our September 14, 2007 *Health Law Update*, entitled "Stark Phase III Regulations, First of Two-Part Series: 'What Meets the Eye,'" available at www.bassberry.com/communicationscenter/newsletters/. In response to industry concerns about the scope of the "stand in the shoes" provision, on November 15, 2007, CMS delayed the application of the "stand in the shoes" provision until December 4, 2008 for academic medical centers ("AMC") and integrated 501(c)(3) health care systems.
[5] CMS-1390-P at 581.
[6] *See* 42 C.F.R. § 411.357(c).
[7] *See* 42 C.F.R. § 411.357(d).
[8] *See* 42 C.F.R. § 411.357(l).
[9] *See* 42 C.F.R. § 411.355(e).
[10] *See* 42 C.F.R. § 413.75 *et seq.*

CMS notes that under this first approach, physician owners and investors would continue to stand in the shoes of their physician organizations and requests public comments on whether, and under what circumstances, CMS should not apply the physician "stand in the shoes" provisions to physician owners and investors. CMS states that it is also considering an alternative whereby the "stand in the shoes" provisions would apply *only* to physician owners and investors of a physician organization.

Finally, CMS indicates that it may provide additional guidance on the application of the definition of "indirect compensation arrangement" in the FY 2009 IPPS final rule. CMS is concerned that, where physicians do not stand in the shoes of their physician organizations (and therefore where only the rules on indirect compensation arrangements apply), some potentially abusive arrangements might be viewed incorrectly as falling outside the definition of an "indirect compensation arrangement."[11] For example, CMS believes that parties may too narrowly construe the definitional component of an indirect compensation relationship that requires that, for an indirect compensation relationship to exist, aggregate compensation to the referring physician must vary with the volume or value of referrals to the DHS entity. CMS states that it believes that aggregate compensation can vary with or take into account the volume or value of referrals to, or business generated for, DHS entities "in a wide range of circumstances, including, without limitation, arrangements involving: variable, per-click, or percentage-based compensation; exclusive contracts; inflated fixed payments; or explicit or implicit tying of compensation to other referrals."[12] This comment by CMS indicates that CMS is actively pursuing the goal of "reducing program abuse by bringing more financial relationships within the ambit of the physician self-referral law."[13]

Under CMS' second proposed approach, CMS would not make any revisions to the physician "stand in the shoes" provisions in 42 C.F.R. § 411.354, but would instead promulgate separate regulatory exceptions to protect certain arrangements that do not pose a risk of program or patient abuse. At this time CMS is not proposing text for any such separate exceptions, but has indicated that it is considering excepting compensation arrangements such as "mission support" payments between components of certain integrated health care delivery systems. CMS is soliciting public comments regarding what types of compensation arrangements should be protected and how key terms, such as "integrated health care delivery system," should be defined.

DHS Entity "Stand in the Shoes"

In the proposed 2008 Medicare Physician Fee Schedule ("Proposed 2008 MPFS"), which was published in the July 12, 2007 Federal Register,[14] CMS proposed a corollary provision to the physician "stand in the shoes" provision that addressed the DHS entity side of financial relationships. Under this proposed rule, a DHS entity that owns or controls an entity to which a physician refers Medicare patients for DHS would stand in the shoes of the entity that it owns or controls. The DHS entity thus would be deemed to have the same compensation arrangements with the same parties and on the same terms as does the entity that it owns or controls.

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[11] *See* 42 C.F.R. § 411.354(c)(2).
[12] CMS-1390-P at 587-88.
[13] CMS-1390-P at 593.
[14] *See* 72 Fed. Reg. 38122.

CMS did not finalize the DHS entity "stand in the shoes" provision in the final 2008 MPFS, but is now proposing a modified version in the Proposed IPPS Rule. Under the modified proposal, a DHS entity would stand in the shoes of an organization only if the DHS entity wholly owns the organization. In this respect, the Proposed IPPS Rule is narrower in application than the Proposed 2008 MPFS. However, one respect in which the Proposed IPPS Rule is broader than the Proposed 2008 MPFS is that, under the Proposed IPPS Rule, a DHS entity would stand in the shoes of *any* wholly-owned organization, not just a wholly-owned DHS entity. CMS is also seeking public comments on whether it should expand the DHS entity "stand in the shoes" provision such that a DHS entity would stand in the shoes of an organization that it controls (such as a nonprofit organization of which it is the sole member) in addition to an organization that it wholly owns.

Simultaneous Application of Physician "Stand in the Shoes" and Entity "Stand in the Shoes"

CMS has proposed (although not in the form of actual regulatory text) that certain conventions should apply when the "stand in the shoes" provisions may apply to both the physician and the DHS entity ends of a chain of financial relationships. These conventions, according to CMS, will ensure that at least one compensation arrangement remains between the DHS entity and the referring physician for purposes of analyzing the chain of relationships under the Stark Law. These conventions are analogous to the mathematical "order of operations" and are as follows:

- First, parties would apply the physician "stand in the shoes" provisions and deem the physician to stand in the shoes of his physician organization (in those instances in which the physician "stand in the shoes" provisions apply to the particular physician and physician organization).

- However, if applying the physician "stand in the shoes" provisions would result in *only one* financial relationship remaining between the DHS entity and the "collapsed" physician/physician organization <u>and</u> that relationship is an ownership interest, the physician "stand in the shoes" provisions would not be applied and the DHS entity "stand in the shoes" provisions would instead be applied first. The example that CMS gives is a hospital that wholly owns a group practice. If the relationship between the hospital and the group is solely an ownership interest (that is, there is no separate compensation arrangement between them), applying the physician "stand in the shoes" provision first, so that the physician-employee stands in the shoes of the group practice, would result in one remaining financial link between the group practice and the hospital, and that relationship would be an ownership interest. In those circumstances, the entity "stand in the shoes" provision would be applied first and the hospital would stand in the shoes of its wholly-owned group practice. The physician would not stand in the shoes of the group practice. The remaining financial relationship would be deemed to be a direct compensation relationship between the hospital (standing in the shoes of the group practice) and the physician.[15]

- If *more than two* organizations, i.e., *at least two links* in the chain of financial relationships, remain after first "collapsing" the physician and the physician

[15] CMS-1390-P at 596.

organization, the next step would be to apply the entity "stand in the shoes" provisions. However, if *only two* organizations remain, i.e., *only one link* in the chain of financial relationships remains, the entity "stand in the shoes" provisions would not be applied. The example that CMS gives is a hospital that both wholly owns and has a compensation arrangement, e.g., a space rental agreement, with a group practice. In this example, the physician would stand in the shoes of the group practice, but the hospital would not stand in the shoes of the group practice because, after first applying the physician "stand in the shoes" provisions, only two organizations (that is, only one link in the chain of financial relationships) would remain. The remaining financial relationship created by the rental agreement would be deemed to be a direct compensation arrangement between the hospital and the physician, which would need to satisfy the requirements of an exception.[16]

Definitions of "Physician" and "Physician Organization"

In the Proposed IPPS Rule, CMS states its intent that, when applying the physician "stand in the shoes" provisions, a physician would stand in the shoes of: (1) another physician who employs the physician, (2) his wholly-owned professional corporation ("PC"), (3) a physician practice that employs or contracts with the physician or in which the physician has an ownership interest, or (4) a group practice of which the physician is a member or independent contractor. To clarify this intent, CMS proposes revisions to the definitions of "physician" and "physician organization" to clarify that: (1) a physician and the PC of which he is the sole owner are always treated the same for purposes of applying the physician self-referral rules; and (2) a physician who stands in the shoes of his wholly-owned PC also stands in the shoes of his physician organization where the physician's ownership interest in or compensation arrangement with the physician organization is held through his wholly-owned PC. CMS believes that this clarification is necessary to avoid any interpretation of the rules as requiring only that a physician stand in the shoes of his or her wholly-owned PC without further requiring the "collapsed" physician/PC unit to stand in the shoes of the physician organization.

Period of Disallowance

In the 2008 Proposed MPFS, CMS responded to questions regarding the duration of the time period for which a physician could not refer patients for DHS to an entity and for which the entity could not bill Medicare (the "period of disallowance") where a financial relationship between a referring physician and the entity violated the Stark Law. Essentially, the 2008 Proposed MPFS stated that the period of disallowance begins on the date that the financial relationship fails to comply with the Stark Law and ends on the date that the arrangement comes into compliance or ends, but noted that in some cases it may not be clear when a financial relationship has ended.[17]

CMS did not finalize the period of disallowance in the final 2008 MPFS, but has now proposed in the Proposed IPPS Rule that the period of disallowance be determined as follows:

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[16] CMS-1390-P at 579.
[17] *See* 72 Fed. Reg. 38183.

- *Unrelated to compensation.* Where a financial relationship does not meet any applicable exception for a reason that is unrelated to compensation (for example, because an agreement is not in writing or a signature is missing), the period of disallowance would begin on the date the arrangement first was out of compliance and end no later than the date the arrangement was brought into compliance (for example, by executing or signing an agreement). In proposing this rule, CMS uses an example that may cause more heartburn than clarity. CMS states that, "where a hospital and a physician enter into a personal service arrangement for medical director services and begin performing under the arrangement on January 1, but do not execute a written agreement until January 31, … the period of disallowance would begin on January 1 and end no later than January 31."[18] CMS appears to be explicitly asserting that what many would consider to be a mere "technical" violation of Stark will cause a period of disallowance. It is unclear what CMS' position would be if the agreement were dated *effective as of* January 1, even though signed January 31.

- *Insufficient compensation.* Where a financial relationship does not meet any applicable exception for a reason related to the payment or receipt of insufficient compensation (for example, space or equipment rental payments that are below fair market value), the period of disallowance would begin on the date the arrangement was first out of compliance and end no later than the date the shortfall (including interest, as appropriate) is paid and all other requirements of the applicable exception are met. Again, the example that CMS uses may provide more heartburn than clarity. In this example, CMS assumes that "a hospital and physician entered into a 2-year office space rental agreement on January 1 (of Year 1) which specified rental charges (consistent with fair market value) of $20 per square foot during Year 1 and automatically adjusted upward each January 1 by any increase in CPI-U."[19] If, on January 1 of Year 2 of the agreement, the rental charges increase to $21 per square foot based on the amount of increase in the CPI-U, but the physician continues to pay $20 per square foot until the compliance failure is identified on June 30 of Year 2, "the period of disallowance would run from January 1 of Year 2 until no later than June 30 of Year 2 … ."[20] CMS' comments could be construed to mean that, even if the landlord inadvertently fails to add the CPI escalator to the invoices for Year 2, and the physician promptly remits the difference upon discovery (again, what many would consider a "technical" violation), a period of disallowance will still result.

- *Excess compensation.* Where a financial relationship does not meet any applicable exception for a reason that is related to the payment or receipt of excess compensation (for example, the compensation paid to a physician exceeds fair market value), the period of disallowance would begin on the date the arrangement was first out of compliance and end no later than the date the excess compensation (with interest, as appropriate) was returned by the party receiving it to the party that provided it and all other requirements of the applicable exception are met.

- *Case-by-case.* In the event that an arrangement ends prior to the excess compensation or shortfall being repaid, CMS would determine the period of disallowance on a case-by-case

[18] CMS-1390-P at 602.
[19] CMS-1390-P at 604.
[20] Id.

basis in consideration of the particular facts and circumstances. Similarly, when an arrangement is noncompliant for reasons that are related to compensation, but do not involve payment or receipt of excess or insufficient compensation, CMS would determine the period of disallowance on a case-by-case basis.

Gainsharing

Gainsharing arrangements are designed to align the incentives of physicians and hospitals to implement cost-saving strategies by offering a portion of the hospital's savings to the physicians. In the Proposed IPPS Rule, CMS acknowledges that, when properly structured, gainsharing arrangements may offer opportunities for hospitals to reduce costs without causing inappropriate reductions in medical services or rewarding referrals of federal health care program patients. However, CMS also cautions that gainsharing arrangements that provide remuneration by a hospital to a physician constitute financial relationships with an entity under the Stark Law.

In the Proposed 2008 MPFS, CMS proposed that percentage-based compensation arrangements may be used only for paying for personally performed physician services and that those arrangements must be based on revenues directly resulting from physician services, not on some other factor, such as a percentage of a hospital department's savings. This proposed change, which CMS states is still under "active consideration," could prevent typical gainsharing arrangements between physicians and hospitals to which they refer patients for DHS.[21] Therefore, CMS solicits comments on whether it should issue a Stark exception specific to gainsharing arrangements. Specifically, CMS is asking for comments on what types of safeguards should be included in a gainsharing exception and whether certain services, protocols, or other arrangements should be excluded from an exception.

Physician-Owned Implant and Other Medical Device Companies

CMS notes in the Proposed IPPS Rule that it has recently become aware of an increase in physician investment in implant and other medical device manufacturing, distribution, and purchasing companies. In particular, CMS questions the added value of physician involvement in distribution and purchasing companies, which it refers to as "middlemen companies."[22] The primary purpose of some physician-owned organizations, according to CMS, may be to provide physicians the opportunity to earn economic benefits in exchange for ordering medical devices or other products that the physician-investors use on their patients. Accordingly, CMS is soliciting public comments on whether, and to what degree, physician investment in these medical device and implant companies present risks of overutilization, substandard care, and increased costs to the Medicare program and beneficiaries. CMS also queries whether its concerns would be better addressed through the False Claims Act, the Anti-Kickback Statute, or other fraud and abuse laws.

Conclusion

CMS has specified that all comments in response to these proposals must be received by June 13, 2008. It is unclear how many, if any, of these proposals will be finalized in the FY 2009 IPPS

[21] CMS-1390-P at 614.
[22] CMS-1390-P at 615.

final rule, which CMS expects to issue by August 1, 2008. Please contact one of our attorneys in the Healthcare Practice Area listed below if you have any questions, would like additional information, or are interested in submitting comments.

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