

# HEALTH LAW

## Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

## Stark Phase III Regulations Second of Two-Part Series: “More Than Meets the Eye”

October 12, 2007

This Health Law Update is the second in a two-part series on the long-awaited “Phase III” regulations that further implement the federal physician self-referral statute known as the “Stark Law.” The Phase III regulations appear in their official form in the Federal Register dated September 5, 2007,<sup>1</sup> and are effective on December 4, 2007.

As we mentioned in the first part of our two-part series,<sup>2</sup> the Phase III provisions contain fewer changes to the actual text of the Stark Law regulations than many observers expected. However, the commentary to the Phase III provisions includes a significant number of “clarifying” statements and other statements by CMS that may have an impact on the way that enforcement authorities interpret existing provisions. Moreover, there are significant proposed changes to the Stark Law regulations that are currently pending outside of the Phase III provisions, including in the proposed 2008 Medicare Physician Fee Schedule (the “2008 MPFS”).<sup>3</sup> While the first part of our two-part series addressed the actual changes to the regulatory text, or “what meets the eye,” this Health Law Update will highlight certain significant interpretive statements of CMS and certain changes pending outside of Phase III that are “more than meets the eye.”

### **Definition of Entity – Pending Change In Proposed 2008 MPFS - “Under Arrangements” at Risk**

Interestingly, in the Phase III commentary, CMS notes that “[w]e are making no substantive changes to the definition of ‘entity’ in this Phase III final rule,”<sup>4</sup> but does not explicitly mention a major change to this definition that is pending in the proposed 2008 MPFS. Under the current Stark Law regulations, an “entity” is not deemed to be furnishing designated health services (“DHS”) unless it is

<sup>1</sup> See 72 Fed. Reg. 51012 *et seq.* (September 5, 2007).

<sup>2</sup> See Health Law Update entitled “Stark Phase III Regulations, First of Two-Part Series: ‘What Meets the Eye,’” dated September 14, 2007, available at [www.bassberry.com](http://www.bassberry.com).

<sup>3</sup> See 72 Fed. Reg. 38122 *et seq.* (July 12, 2007). Portions of this Update are reprinted from our earlier Health Law Update, entitled “CMS Proposes Dramatic Changes to Stark Rules and Medicare Payment Rules,” dated July 23, 2007, available at [www.bassberry.com](http://www.bassberry.com).

<sup>4</sup> 72 Fed. Reg. 51014.

the entity that receives payment from Medicare for the services provided. Therefore, a physician's interest in an entity that does not receive payment from Medicare for DHS is not an "ownership or investment interest" in a DHS entity for purposes of the Stark Law, and such an arrangement does not have to fit within one of the limited exceptions under the law for ownership or investment interests.

This result currently applies even if the entity in which the physician has an interest performs DHS "under arrangements" for a hospital (or other DHS entity), since it is the hospital (or other DHS entity) that receives payment from Medicare for those services. CMS states in the proposed 2008 MPFS that a risk of overutilization currently exists for services provided "under arrangements" by physician-owned entities, particularly in the case of hospital outpatient services for which Medicare pays on a per-service basis. Accordingly, CMS proposes in the 2008 MPFS to revise the definition of "entity" under the Stark Law regulations so that a DHS entity includes both the person and entity that performs the DHS and the person or entity that submits claims or causes claims to be submitted to Medicare for the DHS.

In addition, CMS is seeking comments on whether the agency should implement the recommendation from the Medicare Payment Advisory Commission (MedPAC) Report to Congress in March of 2005 to expand the definition of physician ownership under the Stark Law to include interests in an entity that derives a substantial proportion of its revenue from a provider of DHS, and, if so, what should constitute "substantial" in those circumstances. If either the CMS proposal or the MedPAC recommendation is adopted, many hospital-physician "under arrangements" joint ventures will have to be unwound or restructured. Since such arrangements have proliferated in recent years, the potential impact on the industry could be significant.

## Group Practices

### *On-Site Requirement for Supervision Services and Other Services by "Physicians in the Group"*

A general goal cited by CMS throughout the Phase III commentary is to "conform the physician self-referral regulations as much as possible to existing Medicare coverage and payment rules."<sup>5</sup> However, despite this general goal, CMS specifically declines in at least two places in the Phase III commentary to conform Stark Law rules to coverage and payment rules. First, although coverage rules might require only a general level of supervision for certain procedures, which does not require the physical presence of the physician on the premises, CMS has stated that an independent contractor whom a group practice wishes to qualify as a "physician in the group" must supervise services on the premises of the group practice.<sup>6</sup> In addition, although the payment rules have been liberalized in recent years to permit reassignment of services performed off-site pursuant to a contractual arrangement, CMS remains firm that all services (including supervision services) performed by independent contractors whom the group will count as "physicians in the group" must be performed on-site.<sup>7</sup>

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<sup>5</sup> See, e.g., 72 Fed. Reg. at 51016.

<sup>6</sup> 72 Fed. Reg. at 51035. Services performed by an independent contractor who is a "physician in the group" qualify for important "group practice" exceptions such as the physician services exception and the in-office ancillary services exception.

<sup>7</sup> 72 Fed. Reg. at 51017. CMS explains: "[A]lthough section 1842(b)(6) of the Act grants us general authority to honor certain reassignments made pursuant to a contractual arrangement, it does not require us to honor those we believe are potentially abusive."

*In-Office Ancillary Services Exception – Shared Space in the Same Building*

Although CMS makes no changes to actual the regulatory text of the in-office ancillary services exception, which is one of the important “group practice” exceptions, some of CMS’ comments with respect to its interpretation of this exception have surprised many industry observers. For example, one of the ways in which a group practice can meet the location requirements of the in-office ancillary services exception is to provide DHS in the “same building” where the group routinely provides the full range of its medical services. The “same building” test, unlike the “centralized building” test (which is the other way to meet the location requirement), does not require that the group exclusively occupy on a full-time basis the space where the DHS is performed. Therefore, a common practice over the years has been for physician groups to share the costs and administration of the DHS space, perhaps on a per-use fee basis.

CMS notes that a physician sharing a DHS facility in the “same building” must control the facility and the staff (including the supervision of the services) at the time the DHS is furnished to the patient. CMS then concludes in a rather sweeping way that, because of these types of control requirements, “common per-use fee arrangements are unlikely to satisfy the supervision requirements of the in-office ancillary services exception.”<sup>8</sup> Rather, according to CMS, such an arrangement “likely necessitates a block lease arrangement for the space and equipment used to provide the designated health services.”<sup>9</sup>

*In-Office Ancillary Services Exception – Centralized Building*

Perhaps less surprising than CMS’ comments on the “same building” standard is CMS’ continued articulation of concerns in the Phase III commentary about groups who satisfy the location standard of the in-office ancillary services exception through the “centralized building” test. Although the “centralized” building test requires that the group use the centralized space on an exclusive basis, CMS worries that groups may comply only “nominally” with this standard through arrangements such as “condominium” arrangements, in which physician groups rent small suites on an exclusive basis and then retain independent contractor personnel and equipment to rotate among the suites to provide the DHS.<sup>10</sup> CMS reiterates its intent to issue a separate rulemaking on these arrangements, which it considers to raise “substantial concerns” under the anti-kickback statute and which, in CMS’ view, may comply with the in-office ancillary requirements only “on paper.”<sup>11</sup>

**Compensation***Per-Click Lease Arrangements*

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<sup>8</sup> 72 Fed. Reg. at 51033.

<sup>9</sup> Id. In a recent teleconference sponsored by the American Health Lawyers Association (AHLA), CMS representatives informally confirmed this view and, while stating that it is not “impossible” for common per-use fee arrangements in shared space to meet the requirements of the in-office ancillary exception, CMS remains “skeptical” that the physician group billing for the DHS can, as a practical matter, control the supervision of the DHS to the extent needed to satisfy the in-office ancillary services exception. See AHLA-sponsored teleconference, “Stark Phase III Final Regulation Part I: Phase III Stark II: The Journey Continues” (September 27, 2007).

<sup>10</sup> 72 Fed. Reg. at 51018.

<sup>11</sup> 72 Fed. Reg. at 51033-34. For example, in CMS’s view, an arrangement is in danger of mere “paper” compliance unless a physician who is an independent contractor of a group practice is “in the group practice’s specific premises at the specific time a designated health services is furnished (and supervised) for a group practice patient.”

While the Phase III regulations do not themselves affect the viability of per-click lease arrangements, a major change affecting such arrangements is pending in the proposed 2008 MPFS. The Stark Law regulations currently allow healthcare providers to enter into space and equipment lease arrangements that include per-unit-of-service (or per-click) lease payments, provided the payments are fair market value and do not change during the term of the arrangement in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

In the proposed 2008 MPFS, in an apparent reversal of its former thinking, CMS now states that per-click space and equipment lease arrangements, particularly those arrangements where a physician (or presumably an entity owned in whole or in part by physicians) leases space or equipment to a DHS entity, are “inherently susceptible to abuse.”<sup>12</sup> Accordingly, CMS is proposing in the 2008 MPFS to prohibit per-click lease payments to a space or equipment *lessor* to the extent that such charges reflect services provided by a lessee to patients who are referred by the lessor.

CMS is also soliciting comments on whether the agency should prohibit time-based or per-click payments to an entity-lessor by a physician-lessee, to the extent that such payments reflect services rendered to patients sent to the physician-lessee by the entity-lessor. CMS gives the example of a physician renting an MRI machine from a hospital only when the physician refers a patient for an MRI and then provides the facility portion of the MRI service under arrangements with the hospital.

#### *Percentage-Based Compensation Arrangements*

Several of the compensation exceptions under the Stark Law require that the compensation be “set in advance.” Under the current regulations, percentage-based compensation is deemed to be “set in advance” as long as the percentage is determined by a specific formula that is set forth in detail before the furnishing of items or services, and the formula is not modified during the arrangement in any manner that reflects the volume or value of referrals or any other business generated between the parties.

While CMS reaffirms in the Phase III commentary that percentage-based compensation will continue to be considered “set in advance,” CMS has disconcerted many industry observers by refusing to clarify explicitly that percentage-based compensation arrangements of the type just described can also meet the standard that compensation not vary with the volume or value of referrals or other business between the parties (another key component of several of the compensation exceptions under the Stark Law). Therefore, CMS has cast a degree of uncertainty on many current percentage-based compensation arrangements.

In addition, in the proposed 2008 MPFS, CMS notes that percentage-based compensation is being used in a potentially abusive manner in the context of equipment and office space leases, such as arrangements in which equipment or office space is leased on the basis of a percentage of the revenues generated by the equipment or in the medical office space. According to CMS, the use of percentage-based compensation extends beyond the agency’s original intent that such compensation should only be used for compensating physicians for personally performed services. In response, CMS proposes in the 2008 MPFS that percentage-based compensation be considered “set in advance” only when used for paying for personally performed physician services and that such compensation must be based on the revenues directly resulting from the physician services. In all other instances, percentage-based compensation would not be deemed to be “set in advance.”

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<sup>12</sup> 72 Fed. Reg. at 38183.

### *Amendments to Existing Compensation Arrangements*

In somewhat surprising commentary intended to clarify the requirement in the context of leases that rental charges be “set in advance,” CMS states that “parties may not change the rental charges at any time during the term of this agreement.”<sup>13</sup> In other words, CMS is apparently indicating that, even after the first-year of a multi-year lease, the parties cannot amend the agreement to change the rental charges. Rather, “[p]arties wishing to change the rental charges must terminate the agreement and enter into a new agreement with different rental charges and/or other terms; however, the new agreement may be entered into only after the first year of the original lease term (regardless of the length of the original term).”<sup>14</sup>

Since CMS states elsewhere in the Phase III commentary that personal service contracts are amended in the same manner as an office space or equipment lease,<sup>15</sup> then presumably the compensation under a personal services arrangement may not change at any time during the term (even a multi-year term), and the parties would have to terminate the existing agreement after year one and then enter into a new agreement.<sup>16</sup> Some commenters have suggested, based on informal conversations with CMS, that the new agreement could consist a one-page document that technically terminates the old agreement but incorporates all of the terms of the old agreement by reference (except for the amended terms).<sup>17</sup> However, there is no written confirmation from CMS to this effect.

## **Recruitment**

### *Practice Restrictions*

In the Phase III regulations, CMS changes its previous position on whether physician practices may impose practice restrictions upon a recruited physician. Under the Phase II regulations, a physician group practice could not impose any noncompete restrictions on the recruited physician if he or she left the practice. CMS’ position was based on its belief that noncompete restrictions were contrary to its goal of ensuring medical care for the community served by the hospital. However, in response to concerns raised by commenters, CMS includes in the Phase III regulations a list of restrictions that will not be viewed as having a substantial effect on the recruited physician’s ability to remain in the hospital’s geographic service area. Among these restrictions are reasonable non-compete clauses as

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<sup>13</sup> 72 Fed. Reg. at 51044.

<sup>14</sup> Id.

<sup>15</sup> 72 Fed. Reg. at 51047.

<sup>16</sup> These statements by CMS are all the more puzzling in light of the fact that, in earlier portions of the Phase III commentary, CMS seems to agree with a commenter who argues that the definition of “set in advance” implies that amendments may be permissible if not related to the volume or value of referrals or other business generated between the parties. 72 Fed. Reg. at 51031. The specific language of the “set in advance” definition says that a specific formula for calculating compensation may be considered to be “set in advance” so long as it is set forth in sufficient detail so that it can be objectively verified and so long as it is not “changed or modified during the course of the agreement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.” 42 CFR 411.354(d)(1). As suggested by the commenter, the definition implies that amendments **may** be made so long as they do not relate to the volume or value of referrals. Despite this implication, CMS officials in a recent AHLA-sponsored teleconference adhered to the position that multi-year leases and personal service contracts must be terminated in order to change the compensation terms, even if one year has already elapsed. See AHLA-sponsored teleconference, “Stark Phase III Final Regulation Part I: Phase III Stark II: The Journey Continues” (September 27, 2007).

<sup>17</sup> See, e.g., the discussion on the AHLA-sponsored Stark Law ListServe entitled “Amendment of Contracts under Stark III,” October 4, 2007.

well as restrictions “requiring the recruited physician to pay a pre-determined amount of reasonable damages (that is, liquidated damages) if the physician leaves the physician practice and remains in the community.”<sup>18</sup>

However, along with this new flexibility comes the uncertainty of determining whether certain restrictions such as noncompetes are reasonable. CMS has provided no guidance on how a hospital can be certain that the amount of damages is reasonable or that the scope of the noncompete is reasonable. To further confuse the issue, CMS notes that if a noncompete restriction fails to comply with applicable state law, it could be deemed unreasonable (and, by converse implication, a noncompete fully complying with state law may not automatically qualify as reasonable under CMS standards). The Phase III regulations do not address whether any recruitment arrangement failing to comply with state law is therefore outside of the Stark exception from inception. Many agreements have savings provisions allowing for the severing or rewriting of noncompete restrictions or other provisions that might be otherwise deemed unenforceable. The CMS commentary does not address how these provisions and the related revisions to the agreements will be treated under the Stark exception.

### *To Join The Medical Staff*

In addition to the relocation requirement, the Phase II regulations left open the question whether a physician was eligible to receive recruitment payments from a hospital if the physician had any medical staff privileges, whether active or non-active. In Phase III, CMS clarifies that a physician cannot have any kind of medical staff privileges at the entity making the recruitment payment, regardless of whether they otherwise meet the relocation requirement. Apparently, fellows and residents who are on a hospital’s medical staff temporarily while finishing their medical education do not qualify for a recruitment arrangement - even if they will be relocating once their residency program or fellowship ends. Perhaps this is an unintended consequence of CMS’ position that will be clarified in the future.

### **Other Commentary and Potential Future Changes**

- *Definition of “Radiology and Certain Other Imaging Services”* – Although CMS does not alter the definition of “radiology and certain other imaging services” within Phase III, CMS has proposed a change to this definition in the proposed outpatient prospective payment system (OPPS) rule for 2008.<sup>19</sup> Specifically, CMS proposes to exclude from the current Stark Law definition radiology procedures that are “covered ancillary services” for the purposes of the revised ambulatory surgical center (ASC) payment system.<sup>20</sup> The term “covered ancillary services” includes radiology services that are integral to, and performed on the same day as, a covered ambulatory surgical procedure. As a result, this proposed rule excluding certain radiology and imaging services from the definition would allow physicians to refer the covered ancillary services to an ASC, and an ASC to bill Medicare, without violating the Stark Law.
- *Definition of “Referral” – Durable Medical Equipment (DME) Personally Furnished by a Physician* – The definition of “referral” excludes services personally performed or provided by the referring physician, but includes services performed or provided by anyone else. CMS states

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<sup>18</sup> 72 Fed. Reg. 51053.

<sup>19</sup> See 72 Fed. Reg. 42627 *et seq.* (August 2, 2007).

<sup>20</sup> See 42 C.F.R. § 416.164(b)

in the Phase III commentary that the furnishing of durable medical equipment (DME) and supplies, including continuous positive airway pressure (CPAP) equipment, would almost always constitute a referral, since it is highly unlikely that a physician could personally furnish DME and supplies to a patient.<sup>21</sup> In order to do so, the physician would have to enroll in Medicare as a DME supplier, adhere to the DME regulations, and personally perform all of the supplier duties. These requirements, according to CMS, are not waived when a physician furnishes DME directly to a patient. Additionally, CMS notes that CPAP equipment is DME that does not qualify for the in-office ancillary services exception.

- *“Stand in the Shoes”* – While the “stand in the shoes” provisions of Phase III focus on the physician side of the financial relationship between physicians and DHS entities, the proposed 2008 MPFS contains suggestions that may impact the DHS entity side of the financial relationship. Specifically, CMS solicits comments as to whether a DHS entity should stand in the shoes of any entity that it owns or controls and to which a physician refers patients for DHS. If the changes considered by CMS in the proposed 2008 MPFS are adopted in addition to the Phase III changes, an even greater number of relationships between physicians and DHS entities that are currently indirect relationships (or that do not qualify under the technical Stark definition of “indirect compensation arrangement” and thus are entirely outside Stark) may be converted into direct compensation relationships.
- *Temporary Non-Compliance and Alternatives to Compliance* – In the Phase III regulations, CMS states that it lacks authority to waive minor or technical violations of the Stark Law.<sup>22</sup> In addition, CMS refuses in the Phase III regulations to relax certain requirements of the exception for temporary non-compliance.<sup>23</sup> By contrast, in the proposed 2008 MPFS, CMS discusses the use of possible alternative methods of compliance for inadvertent violations of the Stark Law (limited though they may be, as discussed in our earlier Health Law Update on the proposed 2008 MPFS).<sup>24</sup>
- *Burden Of Proof* - Although not addressed in the Phase III regulations, the proposed 2008 MPFS would add a new provision providing that, where a payment of a claim is denied on the grounds of violating the Stark Law, the burden is on the appealing provider to establish that the service was not furnished pursuant to a prohibited referral. This additional requirement could significantly impact both the number of claims denied by CMS or its contractors, as well as the amount of litigation in this area.

## Conclusion

The Phase III regulations are “more than meets the eye,” not only because of the interpretive comments of CMS that extend beyond the relatively few changes to the actual regulatory text, but also because of the other significant proposed changes to the Stark regulations that CMS has made

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<sup>21</sup> CMS contrasts this situation with the situation where a physician personally prepares and furnishes antigens or personally refills an implant pump. See 72 Fed. Reg. at 51019.

<sup>22</sup> 72 Fed. Reg. 51026.

<sup>23</sup> For example, CMS clarifies that, even if on-call services are urgently needed, the failure to have in place a written, signed on-call agreement before the initial services is rendered is not something that CMS would consider beyond an entity’s control. See 72 Fed. Reg. 51025.

<sup>24</sup> See Health Law Update, entitled “CMS Proposes Dramatic Changes to Stark Rules and Medicare Payment Rules,” dated July 23, 2007, available at [www.bassberry.com](http://www.bassberry.com).

outside of Phase III. If you have any questions or would like additional information, please contact one of our attorneys in the Healthcare Practice Area listed below.

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