Life After Under Arrangements

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Late last year, the Centers for Medicare and Medicaid Services (CMS) sounded the death knell for "many under arrangement" joint ventures. This article discusses these significant federal Stark regulatory changes and their impact on "under arrangement" relationships between hospitals and physicians who refer designated health services (DHS).[1] This article also addresses certain ambiguities in the new language and explains how CMS has chosen to handle the uncertainties that remain. Lastly, this article analyzes Clinical Co-Management Agreements (CCMA) as an alternative for hospitals and physicians who wish to align their interests while remaining compliant with the new regulations.

Overview of "Under Arrangements"

Under a typical "under arrangements" joint venture, a hospital contracts with a separate provider to furnish services to the hospital's patients, for which the hospital ultimately bills under its provider number.[2] Often, the separate provider is a limited liability company (LLC) or other joint venture entity owned by both the hospital and one or more physicians or physician group practice(s). The joint venture entity typically receives a "per case" or fixed fee compensation which covers the cost of providing the technical services, while allowing the joint venture entity to realize a profit margin. Over the past several years, these "under arrangement" structures have been commonly used in connection with specialized medical services requiring significant capital investment and/or clinical expertise, such as cardiac catheterization laboratories, sleep laboratories, imaging services ventures and radiation therapy service facilities.

CMS has long questioned whether these "under arrangements" are designed simply to allow referring physicians to share in the revenue generated by their referrals of DHS, thus creating a "loophole" in the self-referral prohibition.[3] CMS has also expressed concern that such abusive financial relationships between hospitals and physicians significantly increase the physician-owned entity's profits and investor returns, creating incentives for overutilization and corrupting medical decision-making with respect to DHS.[4]

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CMS Closes Perceived Loophole

In general, unless an applicable exception applies, the Stark law prohibits referrals of DHS by physicians to any entity in which the physician or a member of the physician's immediate family has a direct or indirect financial relationship.[56] Prior to October 1, 2009, the Stark Law did not expressly prohibit "under arrangements," because the Stark law's definition of "entity" only covered the person or entity to which CMS made payment for the DHS, or to which the right to payment was reassigned.[6] Effective October 1, 2009, however, this definition of "entity" has been expanded to cover both the entity which has "performed the services" that are billed as DHS (e.g. the physician, physician group, or joint-venture entity), as well as the entity billing for DHS.[7]

By changing the definition of "entity" to include persons or entities that perform DHS, CMS effectively gave "DHS entity" status to joint venture entities that provide in-patient and out-patient services "under arrangements" with hospitals. This means that any physician who has an ownership interest in an entity which has entered into an "under arrangement" contract with a hospital will not be able to make referrals of DHS to such hospital.[8] Thus, there is now a prohibited referral associated with many "under arrangement" joint ventures where previously CMS merely monitored such relationships for abuse.

In order for a joint venture entity to fall outside of Stark's new "under arrangement" prohibitions, the joint venture entity cannot "perform" DHS. Unfortunately, CMS has not provided any bright line tests as to whether an entity will be deemed to have "performed DHS." Instead, CMS has indicated that it will rely on the "common" meaning of the word "perform."[9] In addition, CMS has indicated that it considers a physician or physician organization to have "performed DHS," "if the physician or physician organization does the medical work for the services and could bill for the service, but the physician or physician organization has contracted with a hospital and the hospital bills for the services instead."[10] However, CMS has explained that an entity will not be considered to have performed DHS if the entity only: (1) leases equipment or space; (2) provides management, billing services or personnel; or (3) furnishes supplies that are not separately billed. As such, whether an entity is deemed to have "performed DHS" will depend on the specific nature of the resources provided by the entity to the hospital.

In addition to revising the definition of "entity," CMS simultaneously placed additional new limitations on hospital-physician joint ventures.[11] For instance, in the 2009 IPPS Final Rule Changes, CMS also restricted the use of "per-click" fees, such that these types of payments are now prohibited for arrangements seeking to comply with the Stark exceptions for rental of office space, rental of equipment, fair market value, and indirect compensation arrangements. Likewise, the final rule prohibits compensation arrangements based on percentage of revenues in the Stark Law exceptions for office and equipment leases, and in the exceptions for fair market value compensation and indirect compensation arrangements.[12] As a result of these changes and CMS concerns, caution must be exercised in connection with the creation of physician-owned entities that lease equipment to hospitals.

Based on the Stark law's expanded definition of "entity," if a physician and a hospital own an interest in an entity which provides space, equipment, personnel or other

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resources, and the physician intends to make referrals of DHS to such entity, then the resources provided by the entity to the hospital must be narrow enough to avoid classification of the contract as an "under arrangement." For example, the joint venture entity could provide some combination, but less than all, of the following resources to the hospital: (1) management and/or billing services; (2) equipment; (3); space; (4) clinical or technical personnel. In other words, in order to avoid being classified as an "entity" under the amended Stark regulations, the joint venture entity cannot provide all of the resources associated with the performance of DHS.

CMS Solicits Industry Comments

Uncertainty exists as to where CMS will draw the line in terms of the level of resources that a joint venture entity can provide to a hospital without being classified as an "entity" which is performing DHS. CMS has recognized that the ambiguity of the phrase "performed services" in the definition of "entity" has caused confusion within the healthcare industry, and CMS's preamble language in the FY 2009 IPPS final rule raised even more questions about its meaning. For example, what does "do[ing] the medical work" mean, as used by CMS in this context? Is leasing office space and furnishing supplies enough to have "performed services," or does an organization also have to provide personnel or management services? At the time of drafting the final rule, CMS has chosen not to specifically define "performed services." Instead, CMS provided only the following guidance:

> [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.[13]

Without conceding that the definition of "performed" is unclear, CMS has tacitly acknowledged such lack of clarity by asking for industry input regarding such definition on a post hoc basis, i.e. following the publication and implementation of the new rule. Specifically, on October 30, 2009, CMS released its Calendar Year (CY) 2010 Medicare Physician Fee Schedule (MPFS) Final Rule, announcing that it was soliciting industry comments regarding the revised definition of "entity." Even though CMS had determined in 2008 to use the common meaning of the phrase "performed services," it is now seeking to understand whether the industry believes that more clarification of the phrase is needed.[14] CMS is also interested in how the industry has dealt with the changed definition and how it has influenced their contracted services. Specifically, CMS has asked for input in the following areas:

- 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

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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.[15]

The deadline for submitting comments was January 25, 2010. Some industry leaders have asked CMS whether certain deals provide such a benefit to Medicare that they should be exempted from the new rule.[16] The American Medical Association, in various letters to CMS, has expressed concern that the new regulation could actually drive up health care costs and possibly eliminate long-standing and non-abusive relationships that actually created more efficient care.

It remains to be seen whether CMS intends to adopt any of the suggestions and note the objections, by re-defining or clarifying "entity" to narrow its scope, or perhaps begin carving out exceptions to the bright-line rule. Or, has CMS merely solicited the comments to educate itself about the restructured "under arrangements," so that it may someday regulate those relationships accordingly as well.

In the meantime, there is some level of regulatory risk for hospitals and physicians participating in joint venture entities which provide an array of resources to the hospital, such as equipment, space, personnel and services, because it remains unclear when, by providing such a package of services, an entity will cross the line into performing the DHS service. Further, it is important to keep in mind that, even if a joint venture entity is not deemed to be performing DHS, any contracts between such entity and a hospital must structured to fit within an applicable Stark exception, such as space or equipment rental, personal services arrangement exception and/or bona fide employment relationship exception.[17]

Applicability of "Under Arrangement" Rules to Imaging Arrangements

In general, radiologists are not deemed to make referrals of DHS.[18] Stark Law excludes from the definition of "referral" certain requests by radiologists (e.g., "radiologist referral exception"). So long as the radiologists who own an interest in the joint venture entity do not make referrals of DHS to the hospital (or to the joint venture entity which performs the DHS), the radiologists ownership interest in the

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joint venture entity will not violate Stark, even if the joint venture entity provides resources to the hospital "under arrangement."

However, hospitals and radiologists are often unable to enter into an "under arrangement" joint venture because of 42 C.F.R. § 413.65(i), which states that a provider-based hospital department may not provide all of its services "under arrangements."[19] In connection with joint ventures between hospitals and radiologists, the parties often find that reimbursement can be optimized if the "provider" of the service is a department of the Hospital. However, such reimbursement cannot be achieved if all of the department's resources are provided "under arrangement." Therefore, the resources provided by the entity to the hospital must be narrow enough to avoid classification of the contract an "under arrangement." For example, the joint venture entity could provide some combination, but less than all, of the following resources to the hospital: (1) management and/or billing services; (2) equipment; (3); space; (4) clinical or technical personnel.

Clinical Co-Management Arrangements

The recently-imposed constraints imposed on "under arrangements" have provided an impetus for hospitals and physicians to develop other partnering models. One such model which has recently gained traction is the Clinical Co-Management Arrangement (CCMA). Under a typical CCMA arrangement, physicians and a hospital form a new entity which, in turn, contracts with the hospital to provide management services, beyond the medical director role, with respect to a given clinical service line. Typical services include participation in the design and oversight of capital and operating budgets, the development and implementation of business plans and clinical strategies and other services designed to cultivate the efficient delivery of physician and staff services, and improve patient satisfaction and care. The managing entity may also provide certain staff, equipment or supplies; however, as indicated above, the array of resources provided must fall short of those which would cause the relationship to constitute an "under arrangement."

CCMAs thus allow physicians to integrate and align interests with the hospital, while remaining relatively independent. It also allows the hospital to gain from possible cost reductions and access the input of a key physician group in one of its service lines, if the hospital is willing to share control and reasonably compensate the physician or physician group for the value of that input and skill.

To comply with Stark, a CCMA arrangement must be structured to meet the "personal services" exception and be independently evaluated for fair market value and commercial reasonableness. Typically, under such an arrangement, a physician group or a physician group/hospital entity is paid for operational and clinical management activities, with some financial performance incentives. The fixed portion of the compensation is based on the amount of effort necessary to do the job, while the bonus portion is generally linked to achieving certain performance metrics that bring value to the hospital, such as clinical quality, clinical outcomes, patient satisfaction, referring doctor satisfaction and improvement in operating efficiency.

There have been at least two recent challenges to CMS's changes to the Stark rules applicable to "under arrangements." Last April, a district court in the District of

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Columbia dismissed an action seeking to invalidate the "under arrangement" portion of the Stark regulations and asserting that CMS did not have authority in enacting the new rule.[20] The court determined that it did not have the authority to rule on the action because Medicare rules require parties first to pursue an administrative appeal. A similar matter is currently pending in the same district wherein the plaintiffs, a trade group representing urologist-owned companies providing laser surgery, have challenged the provisions in the Stark regulations addressing "per-click" leases and "under-arrangement" transactions.[21]

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[1] Designated Health Services is defined under the Stark Law to include: clinical laboratory services; physical therapy, occupational therapy, and speech-language pathology services; radiology and certain other imaging services (now includes nuclear medicine); radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. 42 C.F.R. § 411.351.

[2] Sections 1832, 1835(b)(1), 1861(e), and 1861(w)(1) of the Act and § 413.65(i) provide for Medicare payment to providers for services furnished "under arrangements." The CMS Internet-Only Manual (IOM), publication 100-01, Medicare General Information, Eligibility and Entitlement Manual, Chapter 5, section 10.3 requires that the provider must exercise professional responsibility over an arranged-for service, using the same quality controls as applied to services furnished by the provider's salaried employees.

[3] In fact, CMS initially took the position in the Stark II Proposed Regulations that both the hospital purchasing the under arrangements service and the provider of the service were "entities" subject to the Stark Law prohibition. 63 Fed. Reg. 1659, 1706 (Jan. 9, 1998). In the Phase I Regulations, however, CMS determined to treat under arrangements relationships between hospitals and physician-owned service providers as compensation relationships, rather than to prohibit physician ownership of such service providers. In doing so, CMS stated, "We will, however, monitor these arrangements and may reconsider our decision if it appears that the arrangements are abused. We also caution physician groups and hospitals that these arrangements remain subject to the Federal anti-kickback statute." 66 Fed. Reg. 856, 942 (Jan. 4, 2001).

[4] CMS noted these concerns in the preamble to the 2009 Inpatient Prospective Payment System (IPPS) Final Rule. 73 Fed. Reg. 48434, 48721 through 48732 (Aug. 19, 2008).

[5] 42 C.F.R. § 411.353 provides, in pertinent part: "(a) Prohibition on referrals. Except as provided in this subpart, a physician who has a direct or indirect financial relationship with an

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entity, or who has an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare."

[6] Formerly, "entity" was defined in pertinent part as: "(1) A physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, not-for-profit corporation, or unincorporated association that furnishes DHS. An entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it—

(i) Is the person or entity to which CMS makes payment for the DHS, directly or upon assignment on the patient's behalf; or (ii) Is the person or entity to which the right to payment for the DHS has been reassigned pursuant to §424.80(b)(1) (employer), (b)(2) (facility), or (b)(3) (health care delivery system) of this chapter (other than a health care delivery system that is a health plan (as defined in §1001.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees). . ." 42 C.F.R. § 411.351.

[7] Currently, "entity" is defined in pertinent part as: '(1) A physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS. An entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it—

(i) Is the person or entity that has performed services that are billed as DHS; or (ii) Is the person or entity that has presented a claim to Medicare for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned in accordance with §424.80(b)(1) (employer) or (b)(2) (payment under a contractual arrangement) of this chapter (other than a health care delivery system that is a health plan (as defined at §1001.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees)." *See* 73 Fed. Reg. 48751 (August 19, 2008) (revising 42 C.F.R. § 411.351, effective October 1, 2009).

[8] 42 C.F.R. § 411.356 (2007).

[9] 73 Fed. Reg. 48726 (August 19, 2008).

[10] *Id.*

[11] 73 Fed. Reg. 48713 – 48720 (August 19, 2008).

[12] Once again, CMS was concerned that such arrangements could result in overutilization of services and greater referral rates to hospitals that lease a physician's space and equipment. CMS has also expressly questioned such arrangements, where "the lessee is performing sufficiently high volume of procedures, such that it would be economically feasible to purchase the equipment rather than continuing to lease it from a physician or physician entity that refers patients to the lessee for DHS." 74 Fed. Reg. 48714.

[13] 73 Fed. Reg. 48726 (August 19, 2008).

[14] 74 Fed. Reg. 61933 – 61934 (November 25, 2009).

[15] *Id.*

[16] *See e.g.* August 9, 2009 letter to CMS from the American College of Cardiology.

[17] 42 C.F.R. § 411.357(a)-(d) (2007).

[18] In addition, certain invasive radiology procedures are not included in the definition of DHS. The Definitions section of 42 C.F.R. § 411.351 provides that radiology and other imaging services are to be defined by reference to a list of CPT/ HCPCS codes, and that they do not include invasive radiology procedures such as certain x-ray fluoroscopy or ultrasound procedures that require insertion of a needle, catheter, tube, or probe and are integral to the performance of non-radiological medical procedures during or immediately following the non radiological procedure. 42 C.F.R. § 411.351 (2007).

[19] CMS expressed concern that the services furnished under arrangements to a hospital are furnished in a less medically-intensive setting than the hospital, but billed at higher outpatient hospital PPS rates, which not only costs the Medicare program more, but also costs

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Medicare beneficiaries more in the form of higher deductibles and coinsurance. 73 Fed. Reg. 48723 (August 19, 2008.)

[20] *Colorado Heart Institute, LLC v. Johnson*, No. 08-166-RMC (D.D.C. April 20, 2009)

[21] *Council for Urological Interests v. Johnson*, No. 1:09-cv-00546-HHK (D.D.C. March 23, 2009).

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