

## **CMS PROPOSED STARK REGULATIONS MATERIALLY IMPACT HOSPITAL-PHYSICIAN JOINT VENTURES AND VARIOUS OTHER PHYSICIAN ARRANGEMENTS**

Health care providers beware: Many commonplace hospital and physician arrangements are severely jeopardized by proposed changes to their governing regulations. The Centers for Medicare & Medicaid Services (“CMS”) recently issued material proposed changes to the Stark Law regulations, the purchased diagnostic test rule, and regulations governing independent diagnostic testing facilities (“IDTFs”) in a proposed rule regarding the 2008 Physician Fee Schedule published in the Federal Register on July 12, 2007 (the “Proposed Regulations”). In addition to the proposed changes to the Stark Law and the IDTF regulations (summarized below), the Proposed Regulations contain a number of other significant changes impacting hospitals, physicians and other health care providers.

The Proposed Regulations focus on physician arrangements where the physician is in a position to profit from the physician’s referrals of ancillary services or diagnostic tests, such as lab services, imaging services, and other services classified as “designated health services” under the Stark Law (“DHS”). If some or all of the changes proposed by CMS in the Proposed Regulations are adopted, these changes will have far-reaching implications on the ability of physicians to provide, or enter into contractual arrangements with respect to the provision of, ancillary services, and they will likely chill many collaborative hospital-physician joint ventures. The future legality of these types of activities is made even more uncertain by the impending release of the Stark Phase III Regulations.

The following (non-exhaustive) summary provides an example of some of the significant changes addressed in the Proposed Regulations:

### **“Under Arrangements” and Purchased Services Transactions:**

Whether the Proposed Regulations are adopted as proposed or another variant, it is anticipated that the final regulations will significantly limit the utility of the “under arrangements” and purchased services structures as hospital/physician affiliation models. The Proposed Regulations would materially impact any transactions in which a hospital has a contractual arrangement with a service provider to provide certain services “under arrangements” or pursuant to a purchased services arrangement to hospital inpatients or outpatients if the service provider were owned at least in part by referring physicians. In many cases, the service provider is a joint venture of the hospital and referring physicians.

If adopted as currently proposed, the Proposed Regulations would render most “under arrangements” and purchased services transactions illegal where the referring physician has an

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ownership interest in the entity “furnishing the DHS.” CMS has indicated its intent to analyze the relationship between the hospital and the referring physician as a direct ownership relationship rather than an indirect compensation relationship. As a result, the referring physician would need to satisfy the ownership/investment interest exception under Stark, instead of the indirect compensation arrangement exception.

The Proposed Regulations redefine when an entity is considered to be furnishing DHS to include “the person or entity that performs the DHS” as well as the entity that bills for the DHS. The practical effect of this change will require all referring physicians who own an interest in an entity that provides DHS to a hospital under an “under arrangements” or purchased services transaction to satisfy an ownership exception to the Stark Law, which may not be possible. In general, a referring physician could only comply with an ownership/compensation exception under Stark where: (i) the entity is a rural provider; (ii) the entity is a whole hospital; or (iii) the entity is owned solely by physicians who are not deemed to make a “referral” to the entity for purposes of the Stark Law (radiologists with respect to diagnostic imaging services, radiation oncologists with respect to radiation therapy services or pathologists with respect to lab services).

The utility of the ownership/investment exceptions provided under the Stark Law is even murkier due to the unknown fate of the SCHIP legislation. The House version that Congress passed on July 31, 2007, would overturn, with little exception, the “whole hospital” exception to the Stark law. Although the Senate Bill that passed on August 2, 2007 does not contain a similar provision, the competing versions of SCHIP must now be reconciled. There is speculation that key senators involved in this process support restricting specialty hospital development and, therefore, will likely support this change...stay tuned.

## **“Per Click” Lease Arrangements:**

The Proposed Regulations include changes to the space and equipment lease exceptions that would prevent “per click” lease arrangements where a physician is leasing space or equipment to a third party and the physician makes referrals to the third party lessee for services that are reflected through the “per click” lease rate. The Proposed Regulations do suggest amending the specific Stark Law exceptions that relate to the lease of space or equipment. Although these exceptions apply to direct arrangements with individual physician lessors rather than indirect arrangements such as leases from physician groups or physician-owned entities, CMS will likely impose an attribution rule whereby the compensation arrangements of an entity would be attributed to its physician owners. The Proposed Regulations indicate that the upcoming Stark Phase III regulations will contain an attribution rule that will treat physicians as “standing in the shoes” of their group practices.

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## **Block Lease Arrangements:**

Block lease arrangements, in which a physician or physician group leases space, equipment, and personnel from a third-party lessor on an exclusive use, fixed fee basis and provides, supervises and bills for the technical and professional component of the test in compliance with the in-office ancillary service exception to the Stark Law, are not directly addressed in the Proposed Regulations (except in the context of an IDTF being prohibited from sharing space, equipment, or staff through a lease arrangement, discussed herein). However, the attribution rule discussed previously will likely result in physicians “standing in the shoes” of their group practices and will therefore require analysis of a direct financial relationship rather than an indirect financial relationship. Fixed fee block lease arrangements have historically been construed as a lease arrangement rather than the purchase of a test from a supplier, and the proposed regulations do not alter this interpretation. Although no changes have currently been proposed, it is anticipated that CMS may be concerned with the employment and supervision arrangement between the technician who performs the test and the physician or physician group who bills for the test in block lease arrangements due to commentary it provides relating to the anti-markup rules and the in-office ancillary services exception to the Stark Law. Future requirements may mandate that the physician or physician group directly employ the technician who provides the test on a substantially full-time basis and prohibit any part-time employment or leased employee arrangements with respect to such technicians.

## **Percentage Fee Arrangements:**

The Proposed Regulations would essentially eliminate any form of percentage fee arrangement between an entity and a physician who refers DHS to the entity except in the context of percentage-based compensation to a physician for personally performed physician services. The Proposed Regulations include a change to the “set in advance” requirements of the Stark regulation’s special rules on compensation that specifies that percentage-based compensation to a physician would not be considered “set in advance” except in situations in which the compensation is based on revenues directly resulting from personally performed physician services. Any Stark Law exception that includes a requirement that compensation be “set in advance” would be subject to this restriction on percentage-based compensation arrangements. This includes the Stark Law exceptions for space and equipment leases, personal services, and fair market value arrangements. However, neither the bona fide employment relationship exception nor the indirect compensation arrangement exception contain a “set in advance” requirement.

## **Anti-Markup Purchased Diagnostic Tests and Reassignment Arrangements:**

The Proposed Regulations would impose an anti-markup provision that applies to both the technical component and the professional component of diagnostic tests when such components are purchased outright by the billing physician or medical group or when such components are obtained through reassignment from a physician or other supplier (except from

a full-time employee). The practical effect would further restrict the ability of physicians to realize any profit on the technical or professional component of diagnostic tests that are not provided directly by the physician or physician group. The anti-markup provision limits the amount payable to the lesser of (i) the performing physician's or supplier's net charge to the billing physician or medical group; (ii) the billing physician's or medical group's actual charge; or (iii) the Medicare fee schedule amount. CMS proposes to exclude from "net charge" any amount that takes into consideration charges for space or equipment leased to the performing physician or supplier.

### **In-Office Ancillary Services Exception:**

Not surprisingly, the Proposed Regulations emphasize CMS' concern that the in-office ancillary services exception is subject to abuse. CMS noted that many services currently being provided under the in-office ancillary services exception are not as closely connected to the physician practice as the services typically furnished at the time Congress created the in-office ancillary services exception. CMS also stated that a review of various industry trade articles heightened its awareness of the proliferation of in-office laboratories and the migration of sophisticated and expensive imaging equipment to physician offices and noted its awareness of "turn-key" operations involving such laboratories and other ventures being marketed to physicians over the internet. Due to these concerns, CMS solicited comments as to whether changes to the in-office ancillary services exception are necessary, but declined to issue a specific proposal for amending the exception in the Proposed Regulations.

### **Independent Diagnostic Testing Facility (IDTF) Standards:**

The Proposed Regulations also propose to revise the performance standards applicable to IDTFs and would prevent IDTFs from billing for services provided prior to the date the Medicare enrollment application was filed. One of the proposed changes would prohibit a non-mobile IDTF from sharing space (including waiting rooms), equipment or staff (including supervising physicians, nonphysician personnel or receptionists) or from subleasing its operations to another individual or organization. CMS also seeks comments on establishing a similar requirement for mobile IDTFs. If adopted as proposed, the rule would prohibit an IDTF from entering into arrangements with physician groups or other imaging companies for the use of the IDTF's space, equipment or personnel during periods in which such space, equipment or personnel is not being used by the IDTF.

### **Alternative Method of Complying with the Stark Law:**

The Proposed Regulations also contain a rule proposal which would give physicians and DHS entities an alternative method of complying with the Stark Law in instances of minor, trivial technical violations. Under this alternative method of compliance, CMS would be able, in its sole, unreviewable discretion, to excuse minor, unintentional technical violations that are self-disclosed to CMS, provided there is no risk of program or patient abuse, no more than a

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specified period of time has elapsed, referrals and claims are not made once the entity is aware of the noncompliance, the arrangement is not the subject of an investigation or other proceeding, and the parties have brought (or will bring as soon as possible) the arrangement into complete compliance with the prescribed criteria of the exception or have terminated (or will terminate as soon as possible) the financial relationship. The exception would apply only to "technical" inadvertent violations, such as a missing signature. The parameters of such an exception are not clear and CMS has solicited comments regarding the adoption of such an exception.

Comments to most portions of the Proposed Regulations are due by August 31, 2007. It is anticipated that final regulations will be released this fall with a possible effective date of January 1, 2008 (although CMS may allow a grace period for providers to unwind any non-compliant arrangements). While it is uncertain exactly how the finalized Proposed Regulations will dovetail with the much-anticipated release of the Stark Phase III Regulations, it is clear that big change is in store for health care providers.

To better prepare themselves to respond to the finalized regulations, health care providers are advised to take action now:

- 1) Hospitals and physicians should inventory and review their contractual arrangements in which an entity (owned at least partially by referring physicians) is providing health care items or services on behalf of the hospital and in which the hospital bills for these items or services as a hospital service. These types of contractual arrangements should be initially reviewed for compliance with the proposed regulations and plans should be put in place to reform or terminate non-compliant arrangements in the event that they remain non-compliant after the final regulations are issued.
- 2) Health care providers should review any variable rate space or equipment lease arrangements they may have with referring physicians (irrespective of whether the referring physicians are the lessors or lessees of the space or equipment). Noncompliant lease arrangements will likely need to be reformed to include fixed, fair market value compensation or time-based compensation, and it is possible that varying the numbers of time blocks based on utilization will also be restricted.
- 3) Health care providers review any percentage-based compensation arrangements they may have with any physician or physician-owned entity. Even agreements in which physicians provide professional physician services (outside of employment) should be reviewed to ensure that any percentage compensation is based solely on revenues directly resulting from personally performed physician services. Depending on the final outcome of the proposed changes, non-compliant arrangements may need to be restructured to include some other fair market value compensation methodology.

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- 4) Physicians and physician group practices should review any arrangements that involve another party (a “supplier”) performing the technical or professional component of diagnostic tests, whether the physician or medical group is purchasing such component from the supplier or is obtaining a reassignment from the supplier, and prepare to reform or terminate non-compliant arrangements as necessary to comply with any finalized anti-markup provisions.

**If you have any questions about this or any other health care-related issue, please contact Tricia Ochmann (330.208.1023) or your Vorys lawyer.**

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