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A Stark Change: New Regulations Will Require the Restructuring of Many Hospital-Physician Arrangements

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During the past few years, the Centers for Medicare and Medicaid Services ("CMS") has suggested on several occasions that it might revise the Stark regulations to close perceived "loopholes" that permit allegedly abusive financial relationships between hospitals and physicians. On August 19, 2008, CMS finally took that step. *See* 73 Fed. Reg. 48434, 48688-48752 (August 19, 2008) (the "August 2008 Rule"). By making four key regulatory changes, CMS has created a new Stark framework for hospital-physician transactions that will require the restructuring of many existing arrangements over the next year.

The Basic Stark Prohibition

The Stark law prohibits hospitals and other entities ("DHS Entities") from billing Medicare for designated health services ("DHS") provided pursuant to a referral from a physician with whom the DHS Entity has a financial relationship unless that relationship fits within a Stark exception. DHS includes, among other things, radiology, radiation therapy, physical and occupational therapy, and inpatient and outpatient hospital services. A financial relationship may consist of a direct or indirect ownership interest or compensation arrangement. There are exceptions covering fair market value, space rental, equipment rental, employment and personal service contracts as well as other business arrangements deemed appropriate by CMS.

Key Changes in the August 2008 Rule

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New Definition of DHS Entity. The current Stark regulations define the DHS Entity as the entity that bills Medicare for DHS. The August 2008 Rule expands the definition of a DHS Entity to include the entity that "has performed the services that are billed as DHS," even if that entity does not bill Medicare. This change will implicate many existing "under arrangements" ventures where a hospital acquires a previously unavailable service from, or contracts out the operations of an existing department or service line to, a company owned by physicians. Under the current regulations, referring physicians are not deemed to have an ownership interest in the DHS Entity because they do not own the hospital billing the DHS. And the physicians' indirect compensation arrangements with the hospital can generally be structured to fit within the indirect compensation exception if the amount paid by the hospital to the physician-owned company is consistent with fair market value. In contrast, under the August 2008 Rule, if the physician-owned company has performed services that are billed as DHS, the physician-owned company will also be a DHS Entity, and the physicians will have an ownership interest in this entity that may not fit within a Stark exception.

Bar on Unit of Service Payments. Even if a physician or physician-owned company is not "performing" DHS and is therefore not a DHS Entity, more limited leasing arrangements may still be affected by the August 2008 Rule. The current Stark regulations permit hospitals to pay physicians for space or equipment on a unit of service basis (often referred to as a "click fee") as long as the click fee is consistent with fair market value and is not based on the volume or value of referrals. For example, under the current regulations, hospitals may lease diagnostic equipment on a click fee basis from a company owned by physicians who refer patients to the hospital for imaging services. The August 2008 Rule revises the space rental, equipment rental and indirect compensation arrangement exceptions to preclude the payment of click fees linked to services referred by the physicians receiving such payments, either directly or through a leasing company they own. The prohibition does not cover fees for personal services, which may still be linked to the volume or value of services personally performed by the physician.

Bar on Revenue-Based Payments. The August 2008 Rule establishes a prohibition similar to the click fee bar on space or equipment lease payments linked to the gross or net revenues generated by the leased space or equipment.

"Stand in the Shoes." One piece of good news for hospitals

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is that CMS substantially scaled back its earlier proposal to require physicians to "stand in the shoes" of any physician organizations with which they have a financial relationship. Under a November 2007 rule, mission support payments and other subsidies provided by hospitals to captive professional corporations, faculty practice plans and other physician organizations would have generally barred referrals by physicians employed by such organizations, even if the physicians received fair market value compensation for their services and had no ownership interest in the physician organization. This was the case because, under the stand in the shoes provision, the financial arrangement between the hospital and the physician organization must fit within a Stark exception, and no such exception covers most mission support payments or similar subsidies. The August 2008 Rule requires only owners of a physician organization to stand in the organization's shoes. As a result, non-profits or physician organizations with no true economic owners (such as captive PCs) will be unaffected by the stand in the shoes requirement and their financial relationships with hospitals will still be permissible as long as the compensation received by the physicians fits within a Stark exception.

Restructuring Deadlines

Another piece of good news is that CMS has recognized that it will take time for hospitals and physicians to restructure existing arrangements to comply with the August 2008 Rule. As a result, CMS has established a deferred effective date of October 1, 2009 for each of the changes described above except the stand in the shoes requirement, which becomes effective on October 1, 2008.

Next Steps

Hospitals and physicians have a year to catalogue their existing joint venture, leasing and service arrangements, evaluate whether these arrangements remain compliant with Stark, develop restructuring options as necessary and renegotiate non-compliant transactions. Given the sensitive business issues that are likely to be raised by restructuring proposals, health care organizations are well advised to start their internal review process as soon as possible.

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Robert D. Belfort Mr. Belfort has broad experience in the representation of healthcare organizations on regulatory and transactional matters. His clients include hospitals, community health centers, mental health providers, insurers, managed care plans, pharmaceutical manufacturers, pharmacy benefit managers, disease management companies, nursing homes and a variety of other businesses in the healthcare industry. He has also worked extensively with provider and health plan trade associations.

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