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Health Law Newsletter

Stark Law Regulatory Changes Require Review of Financial Arrangements

The Centers for Medicare and Medicaid Services ("CMS") recently published regulations under the federal self-referral law (the "Stark Law"), which are effective on October 1, 2008 except for certain provisions that are effective October 1, 2009. The Stark Law prohibits physicians and certain other practitioners from ordering "designated health services" ("DHS") if the practitioner or a member of his or her family has an ownership interest in or compensation arrangement (directly or indirectly) with the DHS provider, unless an exception applies. The new regulations will make many common arrangements illegal unless they are restructured before the effective date.

"Under Arrangements" Providers. Medicare allows hospitals to bill for many services rendered by another entity "under arrangements" with the hospital. Under the old regulations, the other entity was not considered a DHS provider. The new rules state that the Stark Law applies to any entity that "performs" the services, even if it does so under arrangements with a hospital. Therefore, if the other entity is owned by one or more practitioners who order the services, their ownership interest must comply with an exception (such as the exception for ownership interests in certain rural area DHS providers). The rules do not define what constitutes "performing" the services. The preamble states that "it should have its common meaning." As an example, the preamble states that a physician practice is "performing" medical services if it does substantially all the medical work and could bill for the services if it chose to do so. The furnishing of management services, billing services or other personnel does not necessarily constitute "performing" the services. This change is effective October 1, 2009.

Space or Equipment-Related Arrangements. The new rules prohibit any arrangement under which a DHS provider either pays or receives rental payments based on (1) the amount of usage by the lessee (either a "per click" charge or a fixed per "unit-of-time" charge when the lessee pays for the time "on demand") **to the extent that such amounts reflect services provided to patients referred between the parties**; or (2) a percentage of collections or revenues attributable to services performed or business generated through the use of the space or equipment, **whether or not such amounts reflect services provided to patients referred between the parties**. These two prohibitions apply even if the use of space or equipment is merely one of the services provided under the arrangement along with other services. Unlike certain other requirements (such as the "exclusive use" requirement), these requirements apply to both "direct" and "indirect compensation arrangements." However, a compensation arrangement that is not "direct" (in itself or under the "stand in the shoes" rule) is not an "indirect compensation arrangement" unless the aggregate compensation varies with or otherwise takes into account the volume or value of business generated by the practitioner for the DHS provider. Thus, a physician-related entity that is not a "physician practice" (e.g. an equipment leasing organization or management services company that provides equipment) is subject to these requirements if the aggregate rent varies with or otherwise takes into account the business generated by the practitioner. These changes are effective October 1, 2009.

The "Stand in the Shoes" Rule. Since December 4, 2007, practitioners have been deemed to "stand in the shoes" of their practice entities, so that any compensation arrangement between a DHS provider and a practice entity had to meet an exception for direct compensation arrangements. (This rule was delayed for certain tax-exempt health organizations and academic medical centers until December 4, 2008.) The new rule provides that this requirement applies only if the practitioner has an ownership or investment interest (other than a "titular" ownership interest) in the practice entity. Practitioners who are merely employed by the practice entity may "stand in the shoes" of the entity at the option of the DHS provider.

Obstetrical Malpractice Insurance Subsidiaries. The rules will permit hospitals, rural health clients and federally qualified health centers to provide an obstetrical malpractice insurance subsidy to a physician who routinely provides obstetric services, if (1) the physician's practice is located in a rural area (i.e. an area not in a "metropolitan statistical area"), a "health professional shortage area," or an area with demonstrated need as determined by CMS in an advisory opinion, or (2) at least 75% of the practice's obstetric patients reside in a "medically underserved area" or are part of a "medically underserved population." Certain other requirements must be met.

Period of Disallowance. The regulations provide that the period during which referrals are prohibited due to an improper arrangement **may** extend until the **later** of (1) the date on which the arrangement is brought into compliance, (2) the date on which any compensation that exceeded the requirements of the exception is repaid (or any compensation that was less than required is paid).

Amendments. CMS relented on a prior rule that prohibited amendments to the terms of leases and other compensation arrangements during the first year of the arrangement. However, the **amended** arrangement will need to remain in place for at least one year from the date of **the amendmen**t.

Signature Requirements. If an arrangement meets all the requirements of an exception but for the failure to have a signed writing, this can be cured by obtaining the signature within 30 days of the commencement of the arrangement if the failure was not inadvertent, and within 90 days if the failure was inadvertent.

Ownership Interests in Retirement Plans. Until now, there has been a broad exception for ownership interests in retirement plans. Effective October 1, 2008 this exception will apply only to interests in DHS providers that were obtained through the practitioner's (or family member's) employment by that DHS provider.

The new regulations contain other changes that may affect practitioners and DHS providers. The above summary is not intended to be complete.

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If you have questions concerning this newsletter, please call one of our health law attorneys at 800-444-6659 (Toledo) or 800-677-7661 (Tampa).

This newsletter is designed to provide general information on matters of interest to health care providers and practitioners and is not intended to constitute legal advice.