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Implementing the Second Phase of Stark IV: A Glimpse of What's Ahead

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The Stark Law, also known as the physician self-referral law, prohibits a physician from making referrals to an entity with which the physician (or an immediate family member) has a financial relationship for the furnishing of designated health services ("DHS") that may be covered by Medicare unless an exception applies. Since the Stark Law was first passed in 1989 to prohibit physician referrals for clinical laboratory services, Congress has expanded the law to prohibit self-referrals for ten DHS and to grant the Secretary the authority to issue advisory opinions determining whether DHS referrals are prohibited under the self-referral law.

On August 19, 2008, the 2009 Medicare Inpatient Prospective Payment System ("IPPS") final rule was published in the Federal Register with Stark IV regulations taking effect in a two-part series—some on October 1, 2008, and the others on October 1, 2009. Under this payment rule, the Centers for Medicare and Medicaid Services ("CMS") proposed various changes that could require healthcare entities to restructure or unwind their current transactions, particularly "under arrangements" and per-click or percentage-based compensation arrangements.

The initial Stark IV provisions, including the "stand in the shoes" rule, were enacted on October 1, 2008, but three additional provisions will take effect on October 1, 2009. "Per click," or per-use or per unit-of-service, rental charges for office space or equipment

will be prohibited in leases between physicians and DHS entities if these charges result from referrals between the parties, regardless of whether the physician is the lessor or lessee of the space or equipment. The indirect compensation arrangement and fair market value exceptions will also be amended so that the exceptions will not apply to per-click lease arrangements. CMS acknowledged that the purpose of this new prohibition is to prevent overutilization of services due to the physician's incentive to refer a higher volume of patients to the lessee in order to increase profits under the lease. Existing leases will not be grandfathered in so DHS entities and physicians should review these leases to determine whether they contain per-click compensation arrangements, and if so, restructure the payment provisions to comply with the final rule.

Physicians and entities should also be aware that CMS has expressed its opinion that "on demand" block-time leases are identical to per-click leases. These leases, allowing physicians to lease office space or equipment "on demand," or without a prearranged schedule, for certain time periods would likely be viewed the same as per-click leases for Stark purposes, though the new regulations did not amend block lease provisions. To err on the side of caution, hospitals and entities should ensure that existing "on demand" block leases are restructured before October 1, 2009 and that no additional "on demand" block leases are created.

Although CMS has allowed physicians to receive percentage-based compensation for physician services they

personally perform, Stark IV will prohibit physician-owned companies from receiving compensation for their space or equipment on the basis of a percentage of the revenue raised, earned, billed, collected or otherwise attributable to the services performed or business generated in the office space or on or through the use of the equipment. As with the per-click provision, indirect compensation and fair market value exceptions will also prohibit percentage-based or charges. Physicians may continue to receive percentage-based compensation for personally performed physician services, but CMS has warned that it will monitor these arrangements as well as similar arrangements for billing and management services. As a result of this change, physicians and healthcare entities will need to restructure or unwind percentage-based compensation arrangements for services and items in order to be compliant by the effective date.

The 2009 IPPS final rule also broadens the definition of "entity." Previously, the entity responsible for billing Medicare was known as the DHS entity, but under Stark IV, CMS has expanded this definition to also include entities that do not directly bill Medicare but that perform "substantially all" of the medical work for services that are billed by another entity as DHS and that could have billed for the DHS. Thus, where one entity may perform DHS for which a physician clinic bills, both the first entity and the clinic will be considered "entities" under this provision so that all parties are required to comply with Stark.

Undoubtedly, CMS revised the definition of "entity" in its efforts to regulate "under arrangements." The

term "under arrangements" is used to describe the practice where hospitals seek reimbursement for services that are actually performed by entities owned by a physician organization or joint venture. Under the revised definition of entity, a physician organization or joint venture performing services for a hospital "under arrangement" is considered a DHS entity, and a physician with an ownership or investment interest in the physician organization or joint venture will not be allowed to make referrals to the entity unless a Stark exception applies. Physicians with ownership or investment interests in entities to which they make referrals may need to restructure existing arrangements to satisfy Stark, and hospitals should review contracts with physician-owned entities to determine the need for amendments prior to October 1, 2009.

With an effective date just three months away, physicians and healthcare entities should act promptly in evaluating both new and existing agreements for compliance with Stark IV. As with other Stark provisions, violations of Stark IV may result in denial of payment, mandatory refunds, civil money penalties, and/or exclusion from the Medicare program.



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