CMS Takes On "Per-Click," Percentage-Based, and Under-Arrangement Agreements

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Practice Area: Health Law & Regulatory Compliance and Fraud and Abuse

On July 2, 2007, the Centers for Medicare and Medicaid Services ("CMS") proposed a number of revisions to the Stark Law. Several of these proposals could have a significant impact on hospital-physician financial arrangements, including "per-click" and percentage-based compensation arrangements as well as joint ventures involving services provided under arrangements. CMS also proposed important changes to the antimarkup provisions of the Medicare purchased diagnostic test rule. If adopted, these proposed changes could become effective as early as January 1, 2008. CMS is accepting comments on these proposed changes through August 31, 2007.

Per-Click Agreements
The Stark Law generally prohibits a physician from making referrals for "designated health services" payable under Medicare, where those services will be furnished by an entity with which the physician has a direct or indirect financial relationship. Stark includes a number of exceptions that allow referrals by physicians to entities with which the physicians have financial relationships, so long as certain safeguards are met. For example, Stark includes specific exceptions for space and equipment leases so long as the leases are commercially reasonable and have rental charges that are set in advance, consistent with market value, and not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

CMS has been troubled for some time about so-called "per-click" lease arrangements in which the rental charge is determined on a per-use basis. In the 1998 proposed rules, CMS asserted that per-click payments might violate the "volume or value" element of the Stark lease exceptions. A typical situation might involve a physician who leases equipment to a hospital and then makes referrals to the hospital for use of that equipment — referrals that translate to higher rental income.

When it issued Phase I of the final Stark rules in 2001, CMS substantially revised the "volume or value" standard to permit timebased or unit-of-service-based payments, even when the physician receiving the payment generated the payment through a referral of designated health services. The final rules allowed such per-click payments "so long as the payment per unit is at fair market value at inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals."

CMS has now reconsidered the issue. In its July 2007 proposed rules, CMS would prohibit unit-of-service-based payments to physician lessors in space and equipment leases, for DHS furnished by an entity to patients who were referred by the physician. CMS noted that *"such arrangements are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee.*"

As currently proposed, this change would only apply to space and equipment leases where the physician is the lessor and is making referrals to the entity/lessee. CMS has solicited comments on whether it should also prohibit per-click payments where the physician is the lessee and rents space or equipment from a hospital or other DHS entity on a per-click basis. As a result, hospitals and physicians should carefully re-consider all lease arrangements where the rental rate is determined using a time-based or unit-of-service-based calculation, and prepare for possible restructuring of these leases in the event that these proposals are adopted by CMS.

Percentage-Based Compensation Arrangements
CMS has proposed changes in the compensation provisions under Stark to address a perceived abuse of the percentage-based compensation provisions, particularly in equipment and office space leases. A common requirement under Stark exceptions is that compensation must be "set in advance." Phase II of the final Stark II rules allowed percentage compensation arrangements so long as they were based on a specific formula that was set forth in sufficient detail before the furnishing of the items or services, and so long as the formula is not modified during the term of the relationship in any manner that reflects the volume or value of referrals or other business generated between the parties.

In its July 2007 release, CMS declared that it had intended to permit percentage-based compensation for physician professional services but not in other contexts. CMS stated that percentage compensation arrangements are being used for other items and services, "such as equipment and office space that is leased on the basis of a percentage of the revenues raised by the equipment or in the medical office space." CMS has therefore proposed that percentage compensation arrangements may be used when paying for personally performed physician services.

While CMS was primarily concerned with stopping the use of percentage-based compensation methodologies in space and equipment leases, this proposed change could also impact percentage-based compensation arrangements in physician employment or services contracts. Under the proposed change, percentage-based compensation (even for physician services) must be based on the revenues directly resulting from those services. Compensation could not be based on some other factor, such as a percentage of the savings by a hospital department, that is not directly or indirectly related to the physician services provided. This provision may therefore narrow the range of options available to hospitals and other providers in structuring performance-based compensation incentives.

Under-arrangements Joint Ventures
A third major change proposed by CMS targets services provided under arrangements to hospitals and other providers, particularly imaging and other services provided through hospital-physician joint ventures. If adopted, this proposal may effectively bar physicians from investing in joint ventures that provide services under arrangements to hospitals and other providers. CMS expressed its belief that "there appears to be no legitimate reason for these arranged for services other than to allow referring physicians an opportunity to make money on referrals for separately payable services. Many of the services furnished by the joint venture were previously furnished directly by the hospitals, and in most cases, could continue to be furnished directly by the hospitals." CMS believes that these arrangements are "creating incentives for over-utilization and corrupting medical decision-making."

CMS proposes to address this concern by revising the Stark definition of "entity" so that the term includes not only the person or entity that submits the claims to Medicare but also the person or entity that actually performs the DHS. Under current regulations, a physician could order a test or other service from a joint venture in which the physician has an ownership interest without making a "referral" to the joint venture; instead, the referral is to the hospital, which is the entity billing for the service. Under the change recommended by CMS, the physician would also be deemed to have made a referral to the joint venture (the entity furnishing the service). Since there is no Stark exception that would protect a referral in that joint venture context, physicians would then be limited to providing such tests and other services within the parameters of the in-office ancillary services exception – an exception that is available to group practices but not to joint ventures with hospitals or other physicians who are not in the same group.

Anti-Markup Provisions
CMS also proposed significant changes to the reassignment and physician self-referral rules relating to diagnostic tests. CMS has expressed concern for some time regarding group practices and other suppliers that purchase diagnostic testing services and then realize a profit when billing Medicare, and proposed several options for addressing these concerns when it published its 2007 physician fee schedule last year. CMS now proposes to apply an anti-markup provision to the professional and technical components of purchased tests and services except where furnished by a full-time employee pursuant to a reassignment. The new anti-markup provisions would not apply to the professional component of tests ordered by independent laboratories that are not ordering the corresponding technical component. Due to the significance of this issue, the Health Law team of von Briesen & Roper will publish a separate Health Law Bulletin specifically devoted to these developments.

Other Proposed Changes
CMS proposed a number of other minor changes to the Stark rules:

- When a payment has been denied on the basis that the service was furnished pursuant to such a prohibited referral, CMS would require that the burden of proof rests with the entity that submitted the claim for payment (not on CMS) to establish that the service was not furnished pursuant to a prohibited referral.
- CMS would revise the Stark exception that excludes interests in retirement plans from the definition of ownership and investment interests. CMS stated that some physicians are using retirement plans to purchase DHS entities to which they refer patients for DHS. Under the proposed revision, if a physician's retirement plan purchases an interest in a DHS entity, that interest will be considered to be ownership or investment interest that is subject to the Stark referral prohibitions.
- The July 2007 proposed rule also provides that DHS entities will "stand in the shoes" of entities that they own or control for purposes of DHS referrals. For example, if a hospital controls a medical foundation that in turn contracts with a physician to provide physician services at a clinic owned by the foundation, the hospital would "stand in the shoes" of the foundation, and would be deemed to have a direct compensation relationship with the physician. As a result, any referrals from the physician to the hospital would have to meet an applicable exception, even if the physician had no other direct or indirect financial relationships with the hospital.

CMS Solicits Comments
CMS solicited comments on other areas where it believes the Stark rules can be improved:

- CMS solicited comments on a number of possible changes to the in-office ancillary services exception under Stark. This exception allows patients to receive ancillary services in the same building in which the referring physician or his or her group practice furnishes medical services, or in other space owned or leased on a full-time exclusive basis by the practice. CMS believes that the in-office ancillary services exception is being abused in situations where group practice physicians make DHS referrals to a specialist who is an independent contractor of the group practice. It is also concerned about the "proliferation of in-office laboratories and the migration of sophisticated and expensive imaging or other equipment to physician offices." Although CMS did not propose any specific amendment, it requested comments on whether to exclude certain services from the exception; whether to revise the building requirements under the definitions; whether non-specialist physicians should be allowed to use the exception to refer patients for specialized services involving the use of equipment owned by the nonspecialists; and whether any other restriction should be imposed to curtail abuse.
- CMS also sought comments on whether it should relax the exception for obstetrical malpractice insurance subsidies, such as the requirement that the physician practice in a primary care HPSA, and various other procedural requirements under that exception.
- CMS has requested comments on when a financial relationship ends. Specifically, CMS is focusing on the "period of disallowance" that applies when a referring physician and an entity have a financial relationship that fails to meet an exception. For example, CMS seeks comments on whether it should adopt a prescribed period of time following receipt of compensation; or whether the period of disallowance should end once the parties have returned the consideration that was paid.
- Finally, CMS commented extensively on whether it should adopt alternative criteria for satisfying exceptions in the event of "innocent and trivial violations" of "procedural requirements," such as the failure to obtain a signature on a lease. CMS is considering an alternative compliance method that would involve (a) self-disclosure; (b) a determination that noncompliance was limited to procedural requirements under the exception; (c) proof that the failure to meet the prescribed criteria was inadvertent; (d) a finding that any referrals of DHS (and resulting claims for payment) were not made with knowledge of noncompliance; (e) the arrangement did not pose a risk of abuse; and (f) the arrangement is not the subject of an ongoing federal investigation or other enforcement matter.

Conclusion

The healthcare community is currently awaiting CMS' release of the "Phase III" Stark regulations in Spring 2008. The proposals issued by CMS on July 2 may be taken as a sign that the Phase III rules will continue to restrict Stark's referral prohibitions due to perceived loopholes in the current law. While these latest proposals remain subject to public comment, and final rules will not be effective prior to the end of this year, physicians and hospitals should begin their review of existing financial relationships to determine which arrangements may need to be restructured or abandoned should these latest proposals become law.
