

CMS Proposes Additional Changes to Stark Law

In apparent haste to move forward with a significant expansion of the Stark self-referral ban, the Centers for Medicare and Medicaid Services (CMS) has included a number of changes to the Stark Phase I and Phase II regulations in its proposed Medicare Physician Fee Schedule (PFS) annual update rule. If finalized, the proposed amendments would significantly narrow certain regulatory exceptions. In planning proposed transactions, clients should consider incorporating contractual provisions that would ease renegotiation of any contract term that is inconsistent with the proposed rules. Clients should also consider structuring new transactions to comply with these rules, if practicable.

CMS has previously indicated that it expects to issue the long-awaited Stark Phase III rules before March 26, 2008. In the Phase III rule-making, CMS is expected to address questions that remained unresolved in the Stark Phase II final rule and respond to public comment on these questions. CMS is accepting comments to the PFS proposed annual update rule through August 31, 2007, and is expected to finalize it soon thereafter. The rule's significant changes to Stark could thus take effect as early as January 1, 2008.

Proposed Changes to Stark Law Exceptions and the Anti-Markup Rules

According to CMS, its proposed PFS amendments are intended to close what it deems "loopholes" in the existing regulations. If implemented, the amendments would significantly restrict the ability of hospitals and physicians to continue certain arrangements that are currently permissible under the Phase II rules. Such proposed changes include:

- **Prohibiting certain "per click" or "per unit" payments** made under space or equipment leases in which a referring physician owns the space or equipment;
- **Limiting "set in advance" percentage compensation arrangements** to personally performed physician services and requiring that the compensation be based solely on revenues directly resulting from the physician's professional services;
- Limiting the applicability of the indirect compensation rules by requiring an entity to "stand in the shoes" of any entity that it owns or controls so that the owning or controlling entity would be deemed to have the same direct financial relationships as the entity it owns or controls (this would **curtail the scope of the existing indirect compensation relationship exception**);
- Expanding the type of "entity" that is prohibited from receiving referrals from physician owners and investors to include entities that perform designated health services **under arrangement** with other entities (this provision is primarily aimed at joint ventures in which referring physicians obtain a share of a former hospital service, such as diagnostic imaging);
- Applying the current **anti-markup rules** that cap Medicare Part B payment made for certain purchased diagnostic tests so that the rules apply to both the professional and technical component of diagnostic tests when such a component is performed by a third-party supplier and contractually reassigned to a different entity (e.g., an individual physician or medical group) for billing purposes; and
- Clarifying that the **burden of proof** is on the provider to demonstrate that any referral was consistent with the Stark law.

Comments Solicited on Additional Issues

In addition to the proposed changes to the Stark Law described above, CMS also solicited input on a variety of topics, including the following:

- Whether to expand the current scope of prohibited ownership and investment relationships by adopting MedPAC's recommendation to **prohibit physician ownership or investment in any entity that derives a "substantial portion" of revenues from a provider of designated health services;**
- Whether to **narrow the in-office ancillary services exception** by specifying certain services that would not qualify for the exception, changing the definition of "same building" or "centralized building," and/or restricting the right of nonspecialist physicians to refer patients for specialized services involving the use of equipment owned by the nonspecialists;
- Whether to **prohibit certain time-based or "per click" payments** by a physician who leases equipment from an entity that sends patients to the physician;
- Whether to prohibit an individual or entity from relying on an exception to the Stark Law for a specified period of time if the individual or entity **failed to satisfy the exception in the past;**
- Whether to extend the application of the current **anti-markup rule** to payments made for a diagnostic test performed by a part-time or leased employee of a medical group in a "centralized building" if the medical group does not receive a reassignment or purchase the service outright; and
- Whether to expand the exception for **obstetrical malpractice subsidies.**

Next Steps

We expect that CMS will receive numerous comments in response to the PFS proposed regulations. In the interim, however, the proposed rules should be considered in structuring any new relationships. Clients should also consider reviewing existing arrangements and identifying any changes that should be made if the proposed PFS regulations are finalized.

Contact Information

If you have any questions about the proposed regulations, please do not hesitate to contact one of our attorneys below or your regular Ropes & Gray contact.

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