Proposed Stark Law Amendment and Rule Changes: Major Restructuring Ahead?

By James F. Owens and Paul A. Gomez

By now, most healthcare providers and suppliers are at least generally aware of proposed new rules affecting Stark law compliance. A lesser known legislative development is Section 651 in House Resolution 3162, which, if passed, will dramatically alter physician ownership in hospitals. Both the proposed amendment to the Stark law in H.R. 3162 and the recent proposed rule changes in the federal register may have a significant impact upon common business practices involved in hospital/physician joint ventures and other relationships.

PROPOSED AMENDMENT TO THE STARK LAW

The House of Representatives recently passed H.R. 3162, the “Children’s Health and Medicare Protection Act of 2007” (the “Bill”). Support for the Bill in the House was heavily partisan, and it passed by a relatively narrow margin. Of particular concern in the proposed legislation is Section 651 of the Bill, which imposes limitations on the exceptions to existing regulation of physician referrals to hospitals. According to a summary prepared by the Committees on Ways and Means and Energy and Commerce, Section 651:

- Eliminates the whole hospital exception so that physicians cannot self refer to hospitals in which they have ownership. Applies to all hospitals – not just specialty hospitals.
- Grandfathers hospitals that were in operation with Medicare provider agreements as of the date of introduction of [H.R. 3162]. Requires grandfathered hospitals to meet standards within 18 months of enactment that include: preventing growth, requiring disclosure of ownership, limiting physician ownership to an aggregate of no more than 40% of the facility and no more than 2% individually, and disclosing to patients if they fail to have 24-hour physician coverage.

Such changes may deter physicians from participating in ownership of hospitals whether they are new hospitals or those hospitals that would be “grandfathered” under the Bill and would limit their ability for referral within an institution in which they have ownership.

The Senate also recently passed legislation similar to the Bill before beginning its summer recess. Notably, however, the Senate legislation did not contain an equivalent of Section 651 of the Bill.

Is The Legislation Likely To Pass?

Given that next year is an election year, there appears to be great motivation among a substantial portion of the members of Congress to get some form of this legislation passed. There is also substantial support for the legislation from the American Medical Association, the American Academy of Pediatrics, the AARP and the National Governor’s Association, among others. As a result, it appears more likely than not that some form of the legislation will pass both houses of Congress and be presented to the President. However, it cannot be determined at this time whether the final version of the legislation that passes both houses of Congress will contain Section 651 of the Bill, or some equivalent.

In either event, President Bush has indicated that he will
veto either version of the legislation. It is not certain the legislation will end up with enough bipartisan support to override a veto.

PROPOSED CHANGES TO STARK REGULATIONS

On July 12, 2007, the Department of Health and Human Services (“DHS”) published their proposed Stark law changes to the Physician Fee Schedule, among other things, that could significantly impact several common types of joint ventures and the purchase or leasing of certain professional services and equipment by healthcare providers and suppliers. The major proposed changes and their possible impact are briefly described below:

In-Office Ancillary Exception

The Centers for Medicare and Medicaid Services (“CMS”) has yet to propose specific language aimed at revising the exception, but it has signaled its belief that many arrangements currently permitted under this exception have moved further and further away from the more limited scope of services provided in physicians’ offices that CMS maintains were originally intended for protection. At this time CMS has asked for comments from the healthcare community addressing what aspects of this exception should be changed and how they should be changed. For instance, CMS wants to know whether certain services should be excluded from the scope of the exception. It is also interested in comments regarding whether changes should be made to definitions of “same building” and/or “centralized building.”

Per-Click Leases

Notwithstanding CMS’s prior conclusion in 2001 in its Stark Phase I analysis that Congress intended that time-based or unit-of-service-based payments under space or equipment leases should be protected, CMS has proposed that per unit-of-service rental charges not be allowed to the extent that such payments reflect services provided to patients referred by a physician-lessee to the lessee. It is not clear whether this proposed rule will be applied to indirect leases from a joint venture with physician owners, but it could be. It appears that “per-click” leases would still be permitted where the physician-lessee does not refer patients for services provided with the leased space or equipment. However, CMS also requested comments as to whether “per-click” payments to a DHS entity lessor that leases space or equipment to a physician lessee should also be prohibited. Finally, it is possible that new proposed restrictions on markups (discussed below) could further reduce the profitability and desirability of certain per-click arrangements, although the ultimate impact in this regard is not clear at this time.

Percentage-based Compensation

CMS is concerned that percentage-based arrangements are susceptible to abuse. As a result, CMS has proposed permitting percentage-based compensation only for physician services personally performed by the physician. The proposed change would impact all exceptions with a “set in advance” requirement, including space and equipment leases, fair market value compensation and personal services. Since payment cannot be based on a percentage of cost savings, there are implications for gain-sharing programs as well.

Under-Arrangement Services

In a rather bold statement, CMS recently asserted that “there appears to be no legitimate reason” for certain hospital/physician joint venture arrangements other than to allow referring physicians an opportunity to make money on referrals for separately payable services which were previously furnished directly by the hospitals, and, in most cases, could continue to be furnished directly by the hospitals. As a result, CMS proposed to revise the definition of “entity” or “entities” to include both the entity that submits the claim to Medicare for DHS and the entity that performs the DHS (the entity providing the under-arrangement services). This could seriously threaten many under-arrangement joint ventures between hospitals and physicians.

Stand in the Shoes

CMS proposes that, in the case of a DHS entity that wholly owns or controls another DHS entity to which referrals are made, the controlling DHS entity would “stand in the shoes” of the controlled or owned DHS entity and would be considered to have the same compensation arrangement as the controlled DHS entity would have with a third party. In addition, CMS suggests that physicians may be treated as “standing in the shoes” of a physician group or other entity owned by physicians. The combination of these changes could change many “indirect compensation” arrangements to “direct compensation” arrangements.
**Anti-Markup and Reassignment Rule**

CMS proposed to expand the anti-markup provision of the purchased diagnostic rule in a manner that would prohibit marking up the professional or technical component of all purchased or reassigned services other than clinical diagnostic laboratory tests. These restrictions would not apply if the supplier of the test is a full-time employee of the billing entity.

**Alternate Compliance Method**

CMS has expressed concern about “innocent,” minor violations of the Stark law that can result in disproportionately large penalties. To address this issue CMS has proposed a form of self-disclosure protocol – an exception designed to protect mere “technical violations.” Providers seeking to avail themselves of this new exception would need to come forward and show substantial compliance with the core requirements of the law, that it was an inadvertent and unintentional mistake which led to the technical violation, that no claims were submitted with knowledge of the violation, and that prompt corrective action was taken, among other things. It is not clear at this point how CMS intends to integrate this alternate compliance method with existing self-disclosure protocols set forth by the Office of the Inspector General for the Department of Health and Human Services, or the Department of Justice.

**Burden of Proof**

CMS’s proposal would shift the burden of proof to the provider in the event a claim is denied based on an alleged violation of the Stark law. It is not clear at this point what factual basis, if any, CMS or a fiscal intermediary must set forth to support an allegation of a Stark law violation.

**What Should Healthcare Providers and Suppliers Do Now?**

None of the proposed changes and amendments briefly described above are effective yet, but collectively they are strong evidence of a desire on the part of Congress and CMS, and a willingness to act, to bring about significant change to the Stark law and regulations. These changes, should they become effective, would have a profound impact on how many healthcare providers and suppliers do business, obtain services and pay or receive compensation. As a result, healthcare providers and suppliers who are currently involved in any business relationship or practice implicated by these proposed changes, or are considering entering into such business relationships or practices, should begin to give careful thought as to what measures can be taken in order to minimize or eliminate any adverse impact the proposed changes may have when and if they become effective.

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**If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings Los Angeles lawyers:**

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