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CMS Proposes Changes to Stark (Again)

On April 14, 2008, the Centers for Medicare & Medicaid Services (CMS) released its annual proposed inpatient prospective payment systems regulations (Proposed IPPS Rule), which contains important quality initiatives and reimbursement changes that we will address in separate Legal News Alerts, and a number of proposed changes to the Stark regulations. The proposed Stark revisions would (1) modify when physicians are deemed to “stand in the shoes” of their physician organizations, (2) add a new stand in the shoes approach for entities wholly owned by providers of designated health services, (3) mandate that hospitals report to the CMS all of their financial relationships with physicians, (4) require physician-owned hospitals to disclose these ownership interests to patients, and (5) establish precise time periods for disallowing Medicare claims for services performed in violation of Stark regulations. Also, the CMS invites comments on whether a Stark exception is necessary and appropriate for physician-owned implant and medical device companies, or for gainsharing arrangements.

The proposed changes are the latest in a flurry of proposed and actual revisions to the Stark regulations that the CMS has issued in the past eight months, including the Phase III rules that became effective December 4, 2007 (Phase III), and reflect recent efforts to clarify, refine, and strengthen the Stark regulations. The following are some of the more significant proposed changes:

Greater Flexibility for Stand in the Shoes

One of the most important changes in Phase III was the stand in the shoes (SITS) rule, which jeopardizes many arrangements between “physician organizations” (POs) and entities such as hospitals, to which physicians refer certain designated health services (DHS). Prior to Phase III, if the relationship between the physician and the PO satisfied requirements under the definition and exception for “indirect compensation,” then referrals of DHS to the entity were permitted under Stark regulations. The SITS rule changed that framework and requires all compensation arrangements between a PO and a DHS entity to meet a direct Stark exception. The Stark-compliant relationship between the physicians and the POs is irrelevant because the physician stands in the shoes of the PO. One unintended consequence that the CMS soon came to

recognize is that this potentially prohibited many support payments and other beneficial and customary financial relationships among components of a health care delivery system. Accordingly, the CMS delayed application of the SITS rule to certain nonprofit health systems and academic medical centers, although it left the SITS rule in place to threaten many other arrangements, including arrangements with for-profit entities and POs.

The CMS now proposes a compromise to limit the potential harsh results of the SITS rule. This proposal seems to return to an analysis similar to the framework in effect prior to Phase III — where the relationship between the physician and the PO can satisfy a Stark exception and protect referrals to the DHS entity. The CMS proposes to insulate these referrals so long as the physician's relationship with the PO meets a Stark exception for employment, personal services, or fair-market-value compensation. A physician will continue to stand in the shoes of his or her PO if the physician is (1) an owner of the PO or (2) has **a financial relationship** that does not meet one of the three listed Stark exceptions.

Although we believe that the CMS intended to require SITS to continue to apply only for (1) physician-owners and (2) physicians who received compensation **for physician services** that did not meet an exception, the plain language of the proposed regulation suggests that it would **not** protect referrals from physicians who have **financial relationships other than those protected by the exceptions for employment, personal services, or fair-market-value compensation**. For example, physicians who lease office space or equipment to a PO and also are employed by the PO, which is common in practice purchase situations, could be read to trigger SITS and therefore fall outside of the protections of the revised SITS rule. Presumably, this was not the CMS' intent. However, pending a correction or other clarification, the proposed modification of SITS appears to represent an incomplete fix.

"Entity Stands in the Shoes" Rule

While discussed in prior proposed Stark regulations, the CMS previously has not issued specific proposed regulations for a so-called "entity stand in the shoes" (ESITS) rule. The concept of ESITS is that a

physician's financial relationship with an entity (subsidiary) that is owned or controlled by another entity that provides DHS (DHS entity) also should be regulated under the Stark rule. The ESITS principle could apply, for example, where a hospital owned or controlled a medical foundation that contracted with a physician for services. In that case, the hospital would be deemed to have a direct contractual relationship with the physician, by virtue of its subsidiary medical foundation's contract.

The CMS has now proposed a specific ESITS rule, applicable only when the DHS entity **owns** but **does not control** 100 percent of the subsidiary entity. The CMS states: "We are proposing to revise §411.354(a) to provide that an entity that furnishes DHS would be deemed to stand in the shoes of an organization in which it has a 100 percent ownership interest and would be deemed to have the same compensation arrangements with the same parties and on the same terms as does the organization that it owns." As with the SITS rule, the ESITS rule may prove to have unintended and adverse consequences, once enough time has passed for its full impact to be analyzed in a variety of different situations.

Disclosure of Financial Relationships Reports

The CMS previously proposed mandatory reporting by all Medicare-participating hospitals of their physician financial relationships using Disclosure of Financial Relationships Reports (DFRR). In fact, the CMS had been trying to accomplish this since summer 2007 through a less-formal regulatory process, but apparently was stymied in this effort. The CMS is now undertaking a somewhat more formal effort and seeking public comments on its initiative. This mandatory reporting requirement represents a **dramatic change in the CMS' enforcement posture, from reactive** (i.e., from responding to Stark issues only when they are brought to the CMS' attention) to proactive (i.e., actively reviewing all potential hospital-physician arrangements for compliance issues).

Physician-Owned Hospital Disclosures to Patients

The CMS proposes to add a requirement that physician-owned hospitals disclose to patients the ownership interests of physician

referrers. Disclosure also would be required by the physician-owners themselves, at the time of their referrals, and would become a medical staff bylaws requirement.

Period of Disallowance

The CMS proposes that when a financial relationship does not meet an exception for reasons unrelated to compensation (e.g., a signature is missing or there is no written agreement), then the period of disallowance would be from the date upon which the arrangement was first noncompliant to the date upon which the arrangement became compliant. On the other hand, when a financial relationship fails to meet a Stark exception due to the compensation provided under the arrangement (e.g., compensation in excess of fair market value), then the period of disallowance would be from the date upon which the arrangement was first noncompliant until the date upon which any excess compensation is repaid, or any shortfall in compensation is made up (and all other requirements of the exception are satisfied). These comments answer the concerns many in the health care community have raised about whether a relationship that violates Stark (even inadvertently) would prohibit referrals between parties after reform of the relationship. It is an important step for providers seeking to understand the scope of risk in a Stark case as well as the impact of reforming noncompliant relationships.

Physician-Owned Implant and Device Companies

The CMS also solicits comments on the impact of physician-owned implant and other medical device companies (POCs) and whether the Stark regulations should be amended to address them more specifically. According to the preamble, the CMS recently became aware of an increase in POCs, including manufacturers, distributorships, and group purchasing organizations in which physicians have ownership interests. While the CMS acknowledges that the importance of physician participation in research, development, and testing, it expresses concern that in many POCs, the physicians play no such role and that such entities “may serve little purpose other than providing physicians the opportunity to earn economic benefits in exchange for nothing more than ordering medical devices or other products [for] their own patients.” The Office of the Inspector General of the Department of

Health and Human Services (OIG) also expressed concerns about such companies in a letter issued in 2006 in response to an inquiry by AdvaMed, a medical device trade association.

Currently, depending on their structure, POCs do not trigger a Stark referral prohibition for their physician-investors. The CMS previously proposed changes in the Stark rules that would deem POCs to be DHS entities under certain circumstances but has never finalized such changes. However, the CMS solicits comments as to: (1) whether, and to what degree, physician investment in POCs is detrimental to federal health programs and their beneficiaries; and (2) whether the Stark rules should address POCs more specifically or whether existing fraud and abuse laws adequately address the issues they raise.

Gainsharing

In the preamble to the proposed rule, the CMS solicits comments as to whether it should establish an additional Stark exception for gainsharing arrangements and if so, what safeguards should be included in the exception.

The term “gainsharing” refers to an arrangement under which a hospital gives physicians a share in the hospital’s cost savings attributable to the physicians’ efforts in implementing specified cost-saving measures such as the use of less-expensive medical devices or supplies or by implementation of protocols. Gainsharing raises an issue under Stark because the hospital’s payment of part of the resulting cost-savings to the participating physicians creates a financial relationship. Depending upon the structure of the program, these payments may or may not fall within an existing Stark exception.

Gainsharing also implicates two specific fraud and abuse statutes. First, the Civil Monetary Penalty Law prohibits a hospital from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit items or services furnished to Medicare or Medicaid beneficiaries. Second, gainsharing arrangements may implicate the Anti-Kickback Statute if one purpose of the cost-savings payment is to influence referrals of federal health care program business by the physicians.

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Historically, the OIG has been wary of gainsharing arrangements, but has issued a series of advisory opinions permitting them when accompanied by certain safeguards. MedPAC also has recommended to the U.S. Congress that appropriately structured gainsharing arrangements be permitted, and Congress has established statutory authority for gainsharing demonstration projects, some of which are currently in progress.

Against this backdrop, the CMS solicits comments in the proposed rule regarding whether a specific Stark exception should be created for gainsharing. If so, the CMS asks for comments on (1) what types of requirements and safeguards should be included; and (2) whether certain types of arrangements should be excluded from the exception.

What to Do Now

These changes are proposed only, so there is no immediate impact on existing arrangements. It is not yet known whether these proposed changes will become final and, if so, when. However, **anyone contemplating or currently party to an arrangement that would be affected by the proposed changes** is well advised to consider the potential effect on the arrangement if and when the proposed changes become final. In addition, **hospitals must take heed of the CMS' continuing efforts to mandate disclosure of financial relationships**. Additionally, hospitals should ensure that documentation of physician relationships is centralized and that these relationships are Stark-compliant. Any problems identified in these arrangements must be fixed promptly. For those hospitals that have not done so before, now is the time to **ensure all physician financial relationships are ready to be submitted to the CMS for scrutiny**.

Finally, hospitals may wish to consider submitting a formal comment letter to the CMS in response to the proposed changes or asking that such a submission be made by a trade association of which they are members. Such comments are due by **June 14, 2008**.

The 1,200-page display copy of the Proposed IPPS Rule can be found at the following address: <http://www.cms.hhs.gov/AcuteInpatientPPS/downloads/CMS-1390-P.pdf>.