HONIGMAN

Health Care Alert

April 22, 2008

CMS Proposes Changes to the Stark Law Regulations and Solicits Comments

On April 14, 2008, the Centers for Medicare & Medicaid Services ("CMS") published proposed changes to the Stark Law regulations and solicited further comments regarding the Department of Health and Human Services' initiative to collect information from hospitals regarding their investment and compensation relationships with physicians. These proposals were issued along with the fiscal year 2009 proposed hospital inpatient prospective payment system rule. The proposed rules can be viewed in their entirety by clicking here: proposed rules. CMS will accept comments on the proposed rules until June 13, 2008.

Proposed Changes to the Stark Law Regulations

"Stand in the Shoes"

After publication of Phase III of the Stark Law regulations and the introduction of the "stand in the shoes" provisions, academic medical centers ("AMCs") and integrated tax-exempt health care delivery systems raised concerns regarding application of the "stand in the shoes" rule to compensation arrangements involving so-called "mission support payments. " In response, CMS delayed until December 4, 2008 the effective date of the "stand in the shoes" provisions for certain arrangements involving AMCs and integrated section 501(c)(3) health care systems. CMS is now, however, reconsidering the impact of "stand in the shoes" on support payments and seeks comments on two proposed approaches for addressing the concerns raised.

Under one approach, no revisions to the Phase III "stand in the shoes" provisions would be made. Instead, CMS would create a new Stark Law exception for certain support payment arrangements. CMS seeks comments on this proposal, including whether the exception should be limited to "mission support" payments, whether other types of payments should be included in the exception and the types of parties that should be permitted to use the exception (*e.g.*, AMC components, physician practices).

Under the second approach, CMS proposes to modify the definition of indirect compensation arrangement to provide that the "stand in the shoes" provisions do not apply if the compensation arrangement between a physician and his or her physician organization meets one of the following exceptions: bona fide employment relationship, personal service arrangement or fair market value compensation. Currently, under Phase III, all physicians "stand in the shoes" of their physician organizations, regardless of the nature of the compensation they receive from the physician organization. Under this second approach, CMS also proposes to modify the regulations to provide that the "stand in the shoes" rule does not apply to arrangements that meet the requirements of the AMC exception.

CMS also reintroduces the so-called entity "stand in the shoes" provision. Under the proposed revisions, an entity that furnishes DHS would be deemed to "stand in the shoes" of an organization in which it has a 100% ownership interest. A DHS entity would stand in the shoes of any wholly-owned organization, not just a wholly-owned DHS entity.

"Physician" and "Physician Organization"

CMS proposes revisions to the definitions of "Physician" and "Physician Organization" to clarify that a physician and the professional corporation of which he or she is the sole owner are always treated as being the same under the Stark Law. Should this proposal be finalized, a chain of financial relationships that flows:

hospital →group practice→PC→physician would, after application of the "stand in the shoes" provisions, flow: hospital→group practice/PC/physician.

Period of Disallowance

The Stark Law generally prohibits Medicare payment for a designated health service that is furnished pursuant to a prohibited referral. CMS proposes to revise the Stark Law regulations to clarify when this period of payment disallowance begins and ends. Where the prohibited referral is unrelated to compensation (*e.g.*, a missing signature on an agreement), the period of disallowance begins at the time the financial arrangement fails to satisfy the requirements of an applicable exception and ends on the date the arrangement is brought into compliance (*e.g.*, the date on which the missing signature was obtained). In an arrangement where noncompliance is due to the payment of excess compensation or too little compensation, the latest the period of disallowance would end is the date that the excess compensation is returned, or the date on which the shortfall in compensation was paid.

Gainsharing Arrangements

Gainsharing, an arrangement in which a hospital gives a physician a share of the hospital's cost savings attributable in part to the physician's efforts, is viewed as a way to align hospital and physician incentives. Statutory impediments to gainsharing include the Stark Law because the provision of monetary or nonmonetary remuneration by a hospital to a physician through a gainsharing arrangement constitutes a financial relationship for purposes of the Stark Law. Similarly, gainsharing arrangements implicate the federal Anti-Kickback Statute if one purpose of the cost savings payment is to influence referrals.

CMS is now considering whether to create a Stark Law exception for gainsharing. CMS seeks comments as to whether it should establish an exception for gainsharing and if so, what requirements should be included in the exception and whether certain services, clinical protocols or arrangements should not qualify for the exception.

Physician-Owned Implant and Other Medical Device Companies

CMS is concerned about the increase in physician investment in implant and other medical device manufacturing, distribution and purchasing companies. CMS notes that the Stark Law and regulations, particularly those related to indirect compensation arrangements, already address many such companies. Nonetheless, CMS seeks comments as to whether the Stark Law regulations should more specifically address physician-owned implant and medical device companies.

Reporting Initiative— Financial Relationships Between Hospitals and Physicians

In previous Health Care Alerts, we have described the Department of Health and Human Services' initiative to require all hospitals participating in a Medicare program to provide information concerning their investment and compensation relationships with physicians. CMS has created a tool for gathering this information—the Disclosure of Financial Relationships Report form ("DFRR") (see Appendix C of the proposed rule). CMS has not yet implemented this initiative but notes that the information sought with respect to financial relationships between hospitals and physicians is information "hospitals should already be keeping in the normal course of their business activities."

CMS now proposes to send the DFRR to 500 hospitals and seeks further comments on the DFRR form, including the following:

- The accuracy of the time estimates associated with completion of the DFRR (estimated to be, on average, 31 hours);
- The adequacy of the proposed 60-day period allotted to hospitals for completion of the DFRRs; and
- Whether CMS is collecting too much or not enough information, and whether the DFRR captures the correct type of information.

Action Steps

All organizations potentially affected by these proposed changes to the Stark Law regulations and the DFRR should:

1. Carefully review the proposed rules;
2. Consider submitting comments to CMS; and
3. Ensure that hospital-physician relationships are properly inventoried and that documentation sufficient to meet reporting requirements are in place with respect to such relationships.

For further information regarding these proposed changes or assistance with inventorying hospital-physician relationships or Stark Law compliance, please contact any member of the Honigman Health Care Department listed below.

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