CLIENT ALERT

CMS Determines Not to Proceed With Specialty Hospital Amendment to Stark Rule

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The United States Department for Health and Human Services' Centers for Medicare and Medicaid Services (CMS) has determined not to proceed with an amendment to the "whole hospital" exception to the physician self-referral rule (Stark) rule, 42 U.S.C. § 411.350 et seq. CMS had previously indicated that it would publish a proposed rule in July 2003 to amend the exception to exclude certain physician ownership or investment interests in specialty hospitals would no longer qualify for the so-called "whole hospital" exception to the self-referral prohibitions. See 68 Fed. Reg. 30214, 30258 (May 27, 2003). CMS will proceed with another issue addressed in the proposed rule -- the amendment of the definitions of certain designated health services covered by the Stark rule to include nuclear medicine procedures.

The "whole hospital" exception to the Stark rule, set forth at 42 C.F.R. § 411.356(c)(3)(i), provides that for purposes of the rule, a physician's ownership or investment in a hospital does not constitute a financial relationship between the physician and the hospital if the physician is authorized to perform services at the hospital and the physician's ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital. Originally, the rationale for the exception was that the services provided in a traditional hospital were so broad that concerns about self-referral conflicts of interest were greatly minimized. Today, however, many commentators fear that physicians have exploited the exception and circumvented the self-referral prohibitions by investing in, and referring to, hospitals that provide only a particular medical procedure or specialty.

CMS' decision not to pursue a regulatory remedy to this problem may have stemmed from concern over the agency's authority to make such a significant change in the law and a desire to let Congress address the issue instead. Indeed, on April 1, 2003, U.S. Rep. Pete Stark (R-Cal.) and U.S. Rep. Jerry Kleczka (D-Wis.) introduced H.R. 1539, The Hospital Investment Act, a bill which, if enacted, would permit physician ownership in joint ventures and specialty hospitals only if the ownership or investment interest is offered to the physicians on terms that are generally available to the public as well. The bill's sponsors have said that their intent is not to prohibit physician investments in such ventures outright, but to ensure that the investments are not the result of special arrangements available only to physicians and specifically designed to skirt the law.

With respect to nuclear medicine services and supplies, such services and supplies currently are specifically excluded from the definitions of the designated health services "radiology and certain other imaging services" and "radiation therapy and supplies" set forth in 42 C.F.R. § 411.351. The semi-annual regulatory agenda published by CMS on May 27, 2003 indicates that the rule that CMS originally proposed to publish in July would amend the definitions of these services to include diagnostic and therapeutic nuclear medicine services and supplies, respectively. CMS has indicated that while the agency intends to proceed with this effort, the time frame or format for doing so has not yet been determined.

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