July 23, 2004

Stark Amendment Interim Final Rule Becomes Effective on July 26th

On March 26, 2004, the Centers for Medicare and Medicaid Services (CMS) published the second phase of the Stark II interim final rule. The Stark Act prohibits physicians from referring Medicare or Medicaid patients for specified designated health services (DHS) to entities with which they, directly or indirectly, have a financial relationship. The Phase II interim final rule becomes effective July 26th.

The interim final rule provides additional clarification of CMS's position with respect to controversial areas such as: exceptions related to compensation arrangements and rental of space and equipment; bona fide employment relationships; personal services arrangements; remuneration unrelated to the provision of DHS; physician recruitment; isolated transactions; certain group practice arrangements with hospitals; and sanctions and reporting requirements.

CMS creates seven new exceptions for arrangements that CMS deems to create a low risk of fraud and abuse. These exceptions include professional courtesy, charitable donations by physicians, hospital referral services, obstetrical malpractice insurance, payments to retain a physician in a health professional shortage area, provision of community-wide health information services, and intra-family referrals in rural areas. The new rule also creates a safe harbor for inadvertent and temporary lapses in complying with certain exceptions. In addition, CMS provides new tests for the in-office ancillary services exception and clarifies several existing exceptions, including leases and personal services arrangements. Finally, the rule improves the definitions for "volume or value," "set in advance," and "fair market value."

In the definition of compensation "set in advance," the new rule allows certain percentage compensation arrangements, "per use", "per service" or "per click" arrangements, and certain hourly payments to physicians, consistent with fair market value.

The new rule significantly revises the physician recruitment exception, which permits a hospital to pay to induce a physician to relocate to the "geographic area served by the hospital," provided certain conditions are met. Notably, CMS restricts the ability for recruiting

arrangements to contain non-compete clauses and clarifies the use of income guarantees. CMS now defines geographic area as the lowest number of contiguous postal zip codes from which the hospital draws at least 75 percent of its inpatients. On July 14, 2004, CMS indicated that it would not "grandfather" in existing physician recruitment arrangements that do not comply with the new rule. As such, hospitals and physicians likely need to review and revise all existing recruitment arrangements under these new rules.

In addition, CMS is now (a) protecting other legitimate arrangements involving specialty physician groups that primarily furnish oncology and radiology services, (b) making the academic medical center exception more flexible, (c) expanding the medical staff incidental benefits exception to include facilities other than hospitals, and (d) excepting certain dialysis drugs from the definition of DHS. However, the non-monetary compensation limitation of $300 remains in the new rule, and hospitals may only provide incidental benefits to physicians subject to a $25 threshold.

The new rules require compliance by health care providers by July 26, 2004. These new rules likely require most health care providers to evaluate many existing arrangements in light of these new rules. Please contact Deborah Gordon at 312-781-8620 (dgordon@seyfarth.com) or Joan Gale at 312-269-8862 (jgale@seyfarth.com) if you have any questions.