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Physician - Hospital Ambulatory Surgery Center: A Compliance Guide - Part I *Healthcare Review*

In recent years hospitals and physicians have actively pursued joint ownership of free-standing ambulatory surgical centers ("ASC"s). This article will discuss the federal safe harbor provisions which set forth the limited circumstances under which joint ownership is permitted. Next month's article will explore how not-for-profit hospitals engaged in an ASC joint venture can preserve their Section 501(c)(3) status.

Anti-Kickback Statute

The anti-kickback statute is a criminal statute designed to protect the Medicare system against inappropriate physician or hospital patient referrals. It prohibits: (1) the solicitation or receipt of "remuneration" by physicians or hospitals for referring a patient for healthcare services; and (2) the offering or the paying of "remuneration" to induce referral of a patient for healthcare services. The statute may be implicated when a physician or hospital with an ownership interest in an ASC refers a patient to the ASC, because the referral may result in remuneration in the form of increased returns on the referring party's investment.

The Office of the Inspector General ("OIG") and the Department of Justice are responsible for ensuring compliance with the anti-kickback statute. Historically, hospital and physician ownership of freestanding ASCs was prohibited. However, this was viewed as an undue restraint on the development of ASCs at a time when the American healthcare system was seeking more efficient and economical ways to deliver services. In 1999 the OIG issued regulations (42 CFR §1001.952 *et seq.*) identifying the limited circumstances under which hospital and physician ownership of ASCs would not be challenged on the basis of inappropriate referrals. The OIG's rationale was that physicians whose practices include a substantial volume of ambulatory surgery would treat an ASC in which they held an interest as merely an extension of their office and, accordingly, would not likely alter their practice patterns.

The safe harbors authorize "surgeon-owned", "single-specialty", "multi-specialty" and "hospital/physician" ASCs if the arrangement and operation of the ASC meets certain standards. While there are numerous specific conditions that must be met, the tests that have received the greatest attention are the "1/3" tests. In the case of a surgeon-owned ASC or single-specialty ASC, it is necessary that the physician investors be general surgeons or surgeons engaged in the same surgical specialty (e.g., orthopedic surgeons) or the same medical practice specialty (e.g., gastroenterologists) and at least 1/3 of each physician investor's medical practice income from all sources during the prior fiscal year or 12-month period must come from performing procedures that are on the list of Medicare-covered procedures for ASCs. Meeting this test does not require that the physician perform any specific percentage of ASC procedures at any particular facility. In group practices, each individual physician must meet the 1/3 income test.

In the case of multi-specialty ASCs, the group and investors can be composed of various types of surgeons (e.g., general, orthopedic, etc.). In addition to the 1/3 income test, at least 1/3 of the ASC procedures performed by each physician during the applicable fiscal period must have been performed at the specific ASC. In the OIG's words, "[t]his second one-third test is designed to reduce the risk of cross referrals between physician investors



in different specialties."

The hospital/physician safe harbor rules require that physicians meet the rules for whichever of the physician categories is applicable. In addition, hospitals must take all necessary steps to avoid making referrals to the ASC. While there is no specific guidance, an accepted approach is a certification by the hospital that it will not allow its physician employees to make any such referrals coupled with ongoing diligence to enforce the certification.

Although not set forth in the regulations, the OIG has ruled that safe harbor protection is available if the physician-investors or their group practice invest directly in the ASC. Use of an intermediary entity may make safe harbor protection unavailable and will cause the OIG to scrutinize the arrangement to ensure that no prohibited referrals are made.

Stark Act

The Stark Act is another statute which governs physician referrals. It prohibits: (1) physicians from making referrals to an entity with which they have a "financial relationship"; and (2) the entity in question from presenting a Medicare/Medicaid claim for services to an individual who was referred by the interested physician. The Stark Act does not criminalize referrals, but rather imposes steep civil penalties, including exclusion from participation in the Medicare program and recoupment of Medicare payments.

The Centers for Medicare and Medicaid Services ("CMS") are responsible for overseeing compliance with the Stark Act. Although in early 2001 CMS said it intended to publish safe harbor regulations, to date it has not done so.