AHLA Physicians Law Institute

Physician and Hospital Investment in Ambulatory Surgical Centers

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ASCs and the Anti-kickback Law

- The anti-kickback law prohibits offering, giving, soliciting, or receiving anything of value to induce or reward referrals of Federal health care program business. 42 U.S.C. § 1320a-7b(b).

- A regulatory safe harbor to the anti-kickback law applies to investment income from ASCs, in certain circumstances. 42 C.F.R. § 1001.952(r). Preambles to this rule are available at https://oig.hhs.gov/fraud/docs/safeharborregulations/092193.htm and https://oig.hhs.gov/fraud/docs/safeharborregulations/gtdoc1.pdf.
What does the safe harbor protect?

• The safe harbor excepts from the definition of “remuneration,” for purpose of the anti-kickback statute, a return on investment in a certified ASC, if certain conditions are met.
• The safe harbor does not protect any other form of remuneration associated with the ASC.

Examples of Remuneration the Safe Harbor Does Not Protect

• Referrals by an physician-investor in an ASC to another physician, for the purpose of inducing the other physician to perform procedures in the ASC.
• Income from affiliated entities (e.g., separate entity that provides anesthesia services)
Unique Requirements of the ASC Safe Harbor

• At least one-third of a physician-investor’s medical practice income must be derived from performance of procedures reimbursable by Medicare when performed in an ASC.

• In addition, if a multi-specialty ASC, at least one-third of these procedures performed by the physician-investor must be performed in the ASC.

No other safe harbor requires referrals to an investment entity.

• The second one-third test requires that physician-investors who are in a position to make or influence referrals to the ASC perform a minimum number of procedures there.

• Purpose is to ensure that the ASC is, for the physician-investor, “an extension of the physician’s office space and not a means to profit from referrals.” 64 Fed. Reg. 63535-63536 (Nov. 19, 1999).
Changes in Medicare Coverage

• Today, Medicare covers more procedures performed in ASCs, compared to when the safe harbor was adopted.
• More procedures often performed in a hospital setting are also covered by Medicare when performed in an ASC.
• As a result, it may be easier for some physician-investors to meet the first one-third test, but harder to meet the second.

Failure to Meet the Second One-third Test

• OIG Advisory Opinion 08-08 approved of an ASC with surgeon-investors who did not meet this test.
• Non-compliant surgeon-investors would not refer patients for procedures to be performed in the ASC, unless the referring surgeon-investors themselves were performing the procedure.
• The ASC would not be an extension of a non-compliant surgeon-investor’s office space, but it also would not be a means for such an investor to profit from referrals.
Who is required to meet the one-third tests?

Only physician-investors who are in a position to refer patients to the ASC and perform procedures on such referred patients are required to meet either one-third test.

Other Investors in the ASC

• Investors who are not in a position to refer patients to the ASC and to perform procedures on such referred patients
  – Must not be employed by the ASC or any investor
  – Must not be in a position to provide items or services to the ASC or any investor
  – Must not be in a position to make or influence referrals to the ASC or any of its investors
Other Investors in the ASC

- Investors that provide management services to the ASC disqualify the ASC from the safe harbor.
- Retired physician-investors or physician-investors who have moved away from the area may not disqualify the ASC from the safe harbor.

Hospital Investors in ASCs Jointly-Owned With Physicians

- The hospital must not be in a position to make or influence referrals to an ASC jointly owned with referring physicians, or to any investor in the ASC.
- Advisory Opinions 01-21, 03-02, 08-08 and 09-09 describe safeguards hospitals may adopt to avoid influencing referrals.
Proportional Returns on Capital

• Investment returns must be proportional to capital invested.
• OIG Advisory Opinions 01-21 and 09-09 (favorable) and 07-05 (unfavorable) reached different results in situations where this safe harbor requirement was not met.

Proportional Returns on Capital

• Question is why the returns on investment are not proportional.
• Did difference result from intent to reward or induce referrals?
What is the effect of failing to meet any safe harbor requirement?

- The effect is the same regardless of the requirement missed; there is no safe harbor protection.
- Protection from sanctions cannot be achieved by meeting one safe harbor requirement, where other requirements are not met.

Some AKS Pitfalls for ASCs

- Selective enforcement of safe harbor requirements
- Physician-investor referrals to other physicians to induce use of the ASC
- Sale or purchase of shares (including setting of share prices) to reward or induce referrals, or punish lack of referrals
- Ancillary arrangements intended to reward or induce referrals
OIG Advisory Opinions on ACS

- 98-12
- 01-17
- 01-21
- 02-09
- 03-2
- 03-5
- 07-05
- 08-08
- 09-09
- 12-06

All are available at https://oig.hhs.gov/compliance/advisory-opinions/index.asp.