

The Fraud and Abuse Statute and Investor-Owned Ambulatory Surgery Centers

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This article discusses the Medicare and Medicaid Anti-Kickback Statute¹ (the “Anti-Kickback Statute”) safe harbors for ambulatory surgery centers in the context of investor-owned ambulatory surgery centers (“ASCs”). The article provides a brief overview of the Anti-Kickback Statute, discusses the ASC safe harbor, and provides an overview of a number of recent Advisory Opinions issued by the Department of Health and Human Services Office of Inspector General (“OIG”) relative to ambulatory surgery centers. Finally, it discusses current issues that are currently arising out of the ASC safe harbor and provides guidance to surgery centers relative thereto.

FRAUD AND ABUSE STATUTE

The Anti-Kickback Statute generally prohibits the knowing and willful offer, provision, solicitation or receipt of any sort of remuneration in exchange for the referral of any service potentially reimbursable under Medicare, Medicaid, or other federal health care program. The Anti-Kickback Statute has been interpreted in case law to mean that an arrangement constitutes a violation if one purpose of the arrangement is to induce or reward referrals, and a second, legitimate motive for the arrangement is not a defense to liability.² The Anti-Kickback Statute itself provides, in pertinent part, the following:

(b) Illegal Remunerations:

- (1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
 - (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
 - (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in

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whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

- (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
- (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
- (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five year, or both.³

The Anti-Kickback Statute is applicable to all referrals for health care services which may be payable by Medicare, Medicaid, or other governmental payors. Unlike the federal “Stark Act,”⁴ which prohibits the referral of designated health services to entities with which the referring physician has a financial relationship, the Anti-Kickback Statute applies to all health care services. Another contrast with the Stark Act, however, is that an essential element of an Anti-Kickback Statute violation is the intent to induce or reward referrals, whereas a Stark Act violation does not require any such intent.

The Anti-Kickback Statute and the regulations promulgated thereunder contain a number of “safe harbors.” The safe harbors are descriptions of certain types of arrangements or transactions which, if all of the elements of the safe harbor are met, are immune from prosecution under the Anti-Kickback Statute. The Statute and regulations provide safe harbors for, among others, certain types of investments in publicly traded companies, space and equipment leases, discounts, and, discussed in detail below, certain investments in ambulatory surgery centers.

A number of issues have been discussed and/or litigated under the Anti-Kickback Statute in various contexts. First, the fact that a large number of referrals are derived from investors in a particular venture does not in and of itself make a venture unlawful. Second, it generally perceived that a requirement for an investor to make referrals to a venture as a condition of remaining a member in the venture is unlawful under the Anti-Kickback Statute. Third, it is unlawful to provide any

sort of special terms of investment for a potential referral source, such as discounts on the purchase price for the investment, an ability to purchase more or fewer shares than other investors, or special compensation factors for a investors based on the fact that they are in a position to make or influence referrals to the venture. Fourth, a number of recent court decisions have indicated specific disfavor where parties promoting investment in ventures make statements strongly implying that the failure of an investor to bring cases or make referrals will be viewed unfavorably. For example, where a party makes statements such as "if you bring two more cases per month, we would be much more profitable," or "we will fail if you do not bring in your cases," are perceived as creating problems from an Anti-Kickback Statute perspective.

SAFE HARBORS FOR AMBULATORY SURGERY CENTERS

The ASC safe harbors are set forth in four separate categories. Specifically, there are separate safe harbors for single-specialty surgical centers, for single surgical specialty surgical centers, for multi-specialty surgical centers, and for ventures that are any one of the three above types which include a hospital as an investor. Legal counsel, in providing advice regarding the ASC safe harbors, should remind parties that the OIG has repeatedly stated that the failure to comply with a safe harbor does not mean a venture is unlawful.

The four safe harbor categories were summarized below by the OIG in its explanatory preamble to the 1999 rulemaking which set forth the ASC Safe Harbor:

- *Surgeon-Owned ASCs.* The first category is designated to protect ASC investments where all of the physician investors are either general surgeons or surgeons engaged in the same surgical specialty. Specifically, category one protects certain investments in entities where all of the investors are either (i) general surgeons or surgeons engaged in the same surgical specialty all of whom are in a position to refer patients directly to the ASC and perform procedures on such referred patients; (ii) group practices that are composed of such surgeons and that meet all of the requirements of the group practice safe harbor (§ 1001.952(p)); or (iii) investors who (a) do not provide items or services to the ASC or its investors, (b) are not employed by the ASC or any investor, and (c) are not in a position to refer patients directly or indirectly to, or generate business for, the ASC or any of its investors. A surgeon is considered to be in a position to refer patients directly and perform procedures if he or she derives at least one-third of his or her medical practice income from all sources for the previous fiscal year or previous 12-month period from his or her own performance of procedures that require an ASC or hospital surgical setting in accordance with Medicare reimbursement rules (the "one-third practice income" test).
- *Single-Specialty ASCs.* The second category is similar to the first category, except that it is designed to protect ASC investments where all of the physician

investors are engaged in the same medical practice specialty (e.g., gastroenterologists), provided that they perform ASC procedures as a significant part of their medical practices. The physicians that qualify under this category need not be traditional surgeons. Specifically, category two protects certain investments in entities where all of the investors are either (i) physicians engaged in the same medical practice specialty who are in a position to refer patients directly to the ASC and perform procedures on such referred patients; (ii) group practices that are composed of such physicians and that meet all of the requirements of the group practice safe harbor (§ 1001.952(p)); or (iii) investors who (a) do not provide items or services to the ASC or its investors, (b) are not employed by the ASC or any investor, and (c) are not in a position to refer patients directly or indirectly to, or generate business for, the ASC or any of its investors. As with category one (Surgeon-Owned ASCs), physician investors must meet the “one-third practice income” test.

- *Multi-Specialty ASCs.* The third category is similar to the first two categories, but it allows a mix of the types of physicians addressed in those categories. Thus, the third category protects certain investments in entities where all of the investors are either (i) physicians (surgeons or non-surgeons) who are in a position to refer patients directly to the ASC and perform procedures on such referred patients; (ii) group practices that are composed of such physicians and that meet all of the requirements of the group practice safe harbor (§ 1001.952(p)); or (iii) investors who (a) do not provide items or services to the ASC or its investors, (b) are not employed by the ASC or any investor, and (c) are not in a position to refer patients directly or indirectly to, or generate business for, the ASC or any of its investors. The physicians must meet the “one-third practice income” test described in the preceding paragraphs. In addition, physicians in this category must meet a second standard related to practice income because of the increased risk of remuneration for referrals among physicians with different specialties. Specifically, the rule requires that at least one-third of the physician’s procedures that require an ASC or hospital surgical setting (in accordance with Medicare reimbursement rules) be performed at the ASC in which he or she is investing. We believe that for physicians who meet the “one-third/one-third” test, an investment in an ASC truly qualifies as an extension of the physician’s office. We believe such physician investors are unlikely to have significant incentives to generate referrals for other investors because of the minimal additional return on investment derived from such referrals.
- *Hospital/Physician ASCs.* The fourth category protects certain investments by hospitals in ASCs. To qualify for the safe harbor, at least one investor must be a hospital and the other investors must be (i) physicians or group practices that otherwise qualify under the safe harbor or (ii) non-referral source investors. The hospital must not be in a position to refer patients directly or indirectly to the ASC or any physician investor. The ASC space must be dedicated

exclusively to the ASC and not used by the hospital for the treatment of the hospital's inpatients or outpatients. The ASC may lease space this is located in or owned by a hospital investor, if the space lease qualifies for protection under the space rental safe harbor. Equipment and personal services provided by the hospital must similarly meet safe harbor requirements.⁵

The ASC Safe Harbor contains a number of tests that must be satisfied in order for a particular venture to meet its requirements. The two tests that have led to the most dialogue are the two "one-third tests," which provide as follows:

- *Rule 1:* At least one-third of each physician-investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the physician's performance of procedures.
- *Rule 2:* At least one-third of the procedures performed by each physician-investor for the previous fiscal year or previous 12-month period must be performed at the investment entity.

The ASC Safe Harbor defines "procedures" as any procedure or procedures on the list of Medicare-covered procedures for ambulatory surgical centers.⁶

OIG ADVISORY OPINIONS RELATIVE TO AMBULATORY SURGERY CENTERS

The Anti-Kickback Statute contains a provision whereby members of the public can request an Advisory Opinion relative to particular proposed arrangements, for a definitive statement from the OIG as to whether it would consider the arrangement to violate the Statute. Although OIG advisory opinions are binding only upon the requestor and may not be relied upon or used as a defense in litigation by any other party, Advisory Opinions provide insight as to how the OIG is likely to interpret similar arrangements. In recent years, the OIG has issued three important advisory opinions related to ambulatory surgery centers, each focusing on one or two core issues.

The first Advisory Opinion in which the OIG considered physician investment in ASCs was issued in 1998. In Advisory Opinion 98-12, the OIG determined that it would not seek sanctions against a particular arrangement which required referrals to the venture. In this arrangement, each physician certified that they would be using the surgery center as a part of his or her practice, and also that he or she would generate substantial portion of their practice income from performing outpatient surgical procedures. The OIG agreed that this was acceptable, but indicated that its conclusion was premised, in part, on the fact that the parties stipulated that less than 5 percent of their income would come from performing Medicare cases, evidencing that the venture was not intended to induce Medicare or Medicaid referrals. Specifically, the OIG stated that

this office is concerned about the potential for investments in ambulatory surgical centers to serve as vehicles to reward referring physicians indirectly. For example, a primary care physician, who performs little or no services in an ambulatory surgical center in which he has an ownership interest, may refer to surgeons utilizing the ambulatory surgical center, thereby receiving indirect remuneration for the referral through the ambulatory surgical center's profit distribution. Similarly, an investment by orthopedic surgeons in an ambulatory surgical center that is not equipped for orthopedic surgical procedures, or that is exclusively used by anesthesiologists performing pain management procedures on patients referred by the orthopedic surgeons, would be suspect.

The situation presented here is very different. First, all Physician-Investors will be making substantial financial investments in the ASC and incurring financial exposure for the ASC's lease. Second, although not all Physician-Investors are surgeons, each Physician-Investor has certified that he currently derives, and anticipates continuing to derive, at least 40% of his aggregate medical practice income from ASC Procedures. *In addition, each Physician-Investor has certified that he will perform the majority of his ASC Procedures in the ASC.* Third, given that the revenue from procedures on Medicare beneficiaries is estimated to be only 5% of the ASC's total revenues, any income from procedures performed on referred Medicare patients will be insubstantial compared to the income from procedures performed on the Physician-Investors' own patients. Fourth, any return on investment to the Physician-Investors will be proportional to their capital investment, and not based on referrals. In these circumstances, the Proposed Arrangement is substantively equivalent to an "all surgeon" ambulatory surgical center and presents a minimal risk that the return on investment would be a disguised payment for referrals.

Finally, the Physician-Investors will provide their patients with a written disclosure of their ownership in the ASC, explaining that they are referring patients to the ASC. This written disclosure is required by State M law. [State M Statutory Compilation.] While we do not believe that disclosure to patients offers sufficient protection from program abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.⁷

In 2001, the OIG issued a second Advisory Opinion regarding ASC ventures, which discussed investment by a hospital. Here, the OIG was satisfied that certain prophylactic rules adopted by the hospital investor minimized the risk that the inclusion of the hospital as an investor was intended to induce referrals to the venture. These rules were described in the Advisory Opinion as follows:

With respect to the investment interest, a primary concern is that the Hospital may potentially direct or influence referrals to the Surgical Center or the Investing Ophthalmologists by using its control and influence over Hospital-Affiliated Physicians. However, the Hospital has certified that it will take the following steps

to limit its ability to direct or influence referrals to the Surgical Center, the Investing Ophthalmologists, or their group practices:

- The Hospital will refrain from taking any actions to require or encourage Hospital-Affiliated Physicians to refer patients to the Surgical Center, the Investing Ophthalmologists, or their group practices.
- The Hospital will not track referrals made by Hospital-Affiliated Physicians to the Surgical Center, the Investing Ophthalmologists, or their group practices.
- Compensation paid to Hospital-Affiliated Physicians, whether pursuant to employment or personal services contracts, will not be related directly or indirectly to the volume or value of referrals or other business generated by such physicians to or for the Surgical Center, the Investing Ophthalmologists, or their group practices. Such compensation will be consistent with fair market value in arm's-length transactions.
- On an annual basis, the Hospital will inform Hospital-Affiliated Physicians of the foregoing measures.⁸

Also in 2001, the OIG issued a third Advisory Opinion relating to ASC venture investments. This Advisory Opinion is of particular importance because it acknowledges that investors may pay varying amounts for investment interests, depending upon when the investor makes his or her investment. Here, the OIG acknowledged that a particular percentage of ownership in a venture may be more or less valuable after the venture has been in operation for a period of time. The actual language of the ASC Safe Harbor discusses returns on investment in terms of the "capital contributed" by a particular investor. The OIG determined that if the actual price paid for a particular level of ownership interest is consistent with fair market value of the interest at the time the investment is made, basing returns on percentage of ownership rather than capital contributions is permissible for the arrangement considered in the Advisory Opinion. Specifically, the OIG stated:

First, the price per Unit has varied for different investors; while the six founding Physician-Investors contributed identical amounts of capital and received identical equity interests, subsequent investors have paid different amounts for their Units. Thus, while Surgical Center profits and losses are distributed based on each investor's equity ownership, distributions are not directly proportional to each investor's capital investment, as required by the ASC safe harbor. Nonetheless, there is a reasonable basis for the different prices that is not related to the value or volume of referrals or other business generated between the parties. With respect to the seven employed Physician-Investors, they were sold a token number of Surgical Center Units for a nominal amount in order for the Surgical Center to qualify for favorable regulatory treatment under [State X]'s CON law. With respect to the two other Physician-Investors and [Health System A], the Requestors have certified that any difference in the price paid (or, with respect to [Health System A], to be paid) per Unit is a result of the timing of the purchases, reflects the appreciation in value of the Surgical Center's

ongoing ASC, and is not related directly or indirectly to referrals to the Surgical Center or the Physician-Investors or business otherwise generated by such physicians or [Health System A]. For all of the foregoing reasons, we believe that, in the instant case, the fact that the profit and losses are distributed in direct proportion to each investor's percentage of equity ownership in the Surgical Center does not increase the risk of fraud and abuse.⁹

ISSUES RAISED BY THE SAFE HARBORS

The ambulatory surgery center safe harbors arguably raise more questions than answers. First, many surgeons do not comply with all of the requirements of the ASC safe harbor because, for example, they are not able to contract with certain managed care payors, or they practice at multiple locations, or for several other reasons. A failure to qualify for safe harbor protection may not be because the physician intends to generate direct or indirect referrals, or does not intend to use the center as an extension of his or her practice. Rather, a surgeon's failure to meet the various tests of the safe harbor may be based on unrelated market factors.

Second, safe harbors provide little guidance as to the manner of measuring medical practice income. For example, it is unclear whether "medical practice income" should be measured by the respective revenues of a physician derived from different types of practice (e.g., inpatient, outpatient, and clinical practice), or whether it should be based on actual income from each sector. The second type of measurement would allow a party to charge respective overhead based on the differences of practice overhead for the different locations. This may help physicians meet the one-third test, because many physicians have high overhead for their office part of their practice and much lower costs for the outpatient surgical part of the practice.

Third, the safe harbors are silent as to the means a venture should use to verify compliance by its physician investors. For example, should an ASC require annual certification by the physician, or should the surgery center have the right to audit the physicians, or is there some other means by which testing should be accomplished? Moreover, a venture must consider what actions it should take if it determines that inquiring into physician investor compliance is likely to reveal that many of the physician investors do not comply with the safe harbors.

Fourth, a surgery center venture must determine whether to require redemption of physicians who fail to comply with the safe harbor requirements. A primary inquiry should be whether such redemption would be truly focused on legal compliance, or whether it is actually intended to remove physicians who are not bringing cases to the venture. The redemption of physicians because they do not directly or indirectly refer patients to the surgery center could create a perception that a physician's investment opportunity in the center was intended to induce referrals.

Fifth, the safe harbor does not provide protection for employee ownership or management company ownership. This is challenging in that many surgery centers include management company owners that do not qualify for safe harbor protection, but arguably do not generate referrals to surgery centers.

Sixth, the safe harbor for ownership by hospitals is too narrow. This safe harbor requires that the hospital must not be in a position to make any referrals to the surgery center. In practice, most hospitals invest in local ASCs, meaning that members of the hospital investor's medical staff will likely be in a position to make referrals to the center. The potential for referrals usually is not the reason for extending an investment opportunity to a hospital. However, as the safe harbor currently exists, safe harbor compliance where a local hospital is an investor is almost impossible.

Seventh, many surgery centers are formed by large, multi-specialty physician practices which may include primary care physicians or other non-surgeons as owners. For many of these large multi-specialty groups, their surgery center is a core practice asset. However, because the group practice includes physicians who will not individually meet the "one-third" tests, safe harbor protection is not available. Again, this places many surgery centers in a legally challenging situation, being forced to determine whether their ownership in the surgery center should be unwound, or whether their sharing ownership of the center with their group as a whole is nevertheless permissible.

Eighth, many surgery centers now focus on more innovative and complex procedures which have not yet been included on the Medicare "ASC" list. Because compliance with the safe harbor income test and procedures test is based on the ASC list, surgical centers who perform a high number of non-listed procedures often do not technically comply with ASC safe harbor.

Ninth, many surgery centers are formed by members of single specialty groups of physicians, where several members of the group specialize in inpatient, outpatient and other procedures. Where a group includes physicians that focus solely on inpatient procedures, the group must determine whether it should extend the opportunity to invest to those physicians. Often, excluding particular members of a group practice from a venture will lead to substantial political and financial problems within the group. In many situations, this may be the beginning of the end of the group itself.

PRESCRIPTION SUGGESTIONS AND GUIDANCE

Perhaps the most challenging issue under the ASC safe harbor relates to how to handle physicians who do not comply with the various safe harbor tests. This section discusses issues relating to the redemption of such physicians who, for whatever reason, do not comply fully with the ASC safe harbors. It also provides general guidance for ambulatory surgery centers.

Redemption of Non-Compliant Physicians

An ASC should address whether physicians who fail to meet or comply with the safe harbor should be redeemed from the venture. Here, in redeeming such physicians, it is important to consider a number of issues.

First, the venture must assess whether its operating agreement or shareholder agreement provides for redemption upon such event.

Second, the ASC should consider whether the redemption will likely lead to regulatory or litigation risk. As to civil litigation risk side, it often makes sense to attempt to offer the physician investor fair market value for his or her shares, particularly if he or she is not purposely breaching the safe harbor test. It may also be sensible to provide the person substantial opportunity to come into compliance with the safe harbors. In cases where the safe harbor tests have been adopted as part of the operating agreement after the venture was formed, it may also make sense to “grandfather” existing physicians into the venture, or to provide them with a period of time to hold their shares and come into compliance with the newly-adopted tests. Grandfathering such physicians into the ASC may make particular sense where the physicians do not generate indirect referrals to the venture.

Third, if a venture does choose to redeem physician investors due to a lack of compliance, it should be careful that it applies the tests consistently to all physicians. For example, redeeming a physician that does not bring cases to the venture, while allowing another physician who does not generate 33 percent of their income from performing surgical procedures to keep his or her investment, may lead a physician to bring suit on the basis that the test is being applied on a discriminatory basis based on the value or volume of referrals. This, in turn, may generate attention from the OIG. In short, the OIG or third party can argue that the decision is being made based on making or not making referrals, and not based on legal compliance with the Anti-Kickback Statute.

Fourth, any ASC planning to redeem persons based on their failure to meet the safe harbors should take steps to make sure that they are making all efforts to comply with all health care regulatory laws and have implemented a health care compliance plan.

Fifth, to the extent the redemption is being handled as a “breach” event under the Company’s shareholder or operating agreement, the payment of amounts that are less than fair market value are not based on an intent to penalize someone for not bringing referrals. Rather, it must be able to show that the treatment of the event as a breach event, intended to ensure that the venture remains stable, and that the breach event serves as a trigger for redemption along the lines of many other redemption events that occur prior to a certain date or due to other breaches of the agreements.

General Guidance

The following is a summary list of several of the guidelines that should be adopted by an ASC, to help further avoid liability under the Anti-Kickback Statute.

- (1) The ASC should be Medicare certified.
- (2) The ASC should provide for no discrimination against Medicare, Medicaid or indigent patients.
- (3) All investors offered shares at the same time should be offered equal shares without regard to the value or volume of referrals.
- (4) All shares sold at the same time should be sold at the same price.
- (5) All shares should be sold at fair market value.
- (6) There should be no pressure to make indirect referrals.
- (7) The ASC should not distribute referral information, particularly indirect referral information.
- (8) The ASC should not make loans to investors—real capital should be contributed.
- (9) The ASC should not bill for ancillary services.
- (10) Physician investment interests should be disclosed to patients.
- (11) Hospital investors should not steer or encourage referrals or compensate its doctors for referrals to the ASC.
- (12) Other compensation arrangements relative to the venture should be fixed and at fair market value.
- (13) The ASC should adopt and use a health care regulatory compliance plan.

SUMMARY

The growth in the number of ambulatory surgery centers, coupled with the unique guidance provided by the OIG in this area, provide a fascinating legal and regulatory environment for ambulatory surgery centers.

NOTES

1. 42 U.S.C. § 1320a-7b(b).

2. *See, e.g., United States v. Greber*, 760 F.2d 68 (3rd Cir. 1985).

3. 42 U.S.C. § 1320a-7(b)(1)–(2).

4. 42 U.S.C. § 1395nn.

5. 64 Fed. Reg. 63,518, 63,535 (Nov. 19, 1999).

6. *See* 42 C.F.R. § 1001.952(r).

7. OIG Advisory Opinion 98-12 (Sept. 16, 1988),

<http://oig.hhs.gov/fraud/advisoryopinions/opinions.html> (emphasis added).

8. OIG Advisory Opinion 01-17 (Oct. 10, 2001), <http://oig.hhs.gov/fraud/advisoryopinions/opinions.html> (emphasis added).

9. OIG Advisory Opinion 01-21 (Nov. 16, 2001), <http://oig.hhs.gov/fraud/advisoryopinions/opinions.html> (emphasis added). 