DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of Inspector General
Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: February 6, 2003

Posted: February 13, 2003

[name and address redacted]

Re: OIG Advisory Opinion No. 03-5

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding an ambulatory surgery center (an "ASC") that would be jointly owned by a hospital and a multi-specialty group practice that has a substantial number of physician members who would not personally use the ASC (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the "Act") or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the Office of Inspector General ("OIG") could potentially impose administrative sanctions on [Company X]

under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

This opinion may not be relied on by any persons other than [Company X], the requestorof this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Company X] (the "Surgical Center") is an [state redacted] ("State") limited liability company formed for the purpose of planning, developing, and operating an ASC that will be certified by Medicare under 42 C.F.R. part 416. [Company Y], an acute care hospital (the "Hospital"), owns 49% of the Surgical Center, and [Company Z], a multi-specialty clinic (the "Group") owns 51% of the Surgical Center.[1] For each investor, the return on the Surgical Center investment will be directly proportional to the amount of capital that the investor contributed. The Surgical Center will maintain an open medical staff. It will be located on land owned by the Hospital and leased to the Surgical Center pursuant to a written lease.

The Group has fifty-two shareholders (the "Group Shareholders"), each of whom is a licensed physician and an employee of the Group. Each Group Shareholder owns one share of the Group's stock, and any dividends paid by the Group are divided equally among the Group Shareholders. In addition, the Group employs other physicians who do not own Group stock (the "Group Associates") and other health care professionals, such as physical therapists, optometrists, and licensed nurse practitioners. Group Shareholders and Group Associates are collectively referred to herein as "Group Physicians." Some Group Physicians are surgeons; however, most are not. For example, there are fourteen family practitioners, eleven internists, six pediatricians, five obstetricians/gynecologists, two general surgeons, three orthopedic surgeons, and two ophthalmologists. The Surgical Center has certified that the salaries, bonuses, and any other forms of employment-related remuneration payable to Group Physicians will not take into account the physicians' referrals of patients to the Surgical Center or the volume of surgical procedures

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[1]The Surgical Center has two classes of members: the voting, Class A Members, consisting solely of the Hospital and the Group, and the non-voting, Class B Members, each of whom must be either a State-licensed physician eligible for credentialing at the Surgical Center or a State legal entity with a majority of its owners being physicians who meet the foregoing requirements. No Class B memberships have been sold.

performed by the physicians at the Surgical Center or elsewhere.

The Hospital is wholly owned by a nonprofit corporation that is also the sole owner of two other hospitals. The Hospital employs forty-two physicians, including eight family practitioners, twelve internal medicine practitioners, eight obstetricians/gynecologists, and two pediatricians. Currently, the Hospital has eight operating suites for both inpatient and outpatient surgery, and physicians employed by the Group perform approximately 25% of all surgeries performed at the Hospital.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for investment interests in ambulatory surgical centers jointly owned by hospitals and physicians, 42 C.F.R. §1001.952(r)(4), is relevant to the Proposed Arrangement.[2] One condition of the hospital-physician ASC safe harbor is that investing physicians who are in a position to refer patients to the ASC can only invest as individuals who meet the requirements for surgeon-owned ASCs, single-specialty ASCs, or multi-specialty ASCs set forth at 42 C.F.R. § 1001.952(r)(1), (r)(2), or (r)(3), as applicable, or as group practices composed of such physicians or surgical group practices.[3] Since the Surgical Center's investing physicians are investing through a multi-specialty group practice, for safe harbor protection the group practice (i.e., the Group) must meet all the requirements of the group practice safe harbor at 42 C.F.R. § 1001.952(p) and the group practice must be composed of physicians who meet both the one-third practice income test at 42 C.F.R. § 1001.952(r)(3)(ii) and the one-third practice test at 42 C.F.R. § 1001.952(r)(3)(iii).[4]

B. Analysis

Surgical center joint ventures that include physician-investors in a position to generate surgical business are susceptible to fraud and abuse. Notwithstanding, in recognition that some physician-owned ASC ventures may be beneficial to the federal programs and their beneficiaries, the Department issued a narrow safe harbor for physician-owned ASCs that meet criteria carefully tailored to mitigate the risks of fraud and abuse. With respect to physician-investors, the safe harbor is carefully circumscribed to apply only to physicians who are unlikely to use the investment as a vehicle for profiting from their referrals to other physicians using the ASC. Accordingly, safe harbor protection is limited to physician-investors who actually use the ASC on a regular basis as part of their medical practices or who practice the same specialty as other physician-investors and are therefore unlikely to refer substantial business to "competing" physician-investors when they can earn the fees themselves.

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[2]In cases, such as the instant case, where the ASC is located in space owned by the hospital, the space rental safe harbor, 42 C.F.R. § 1001.952(b), is also relevant.

[3]The terms "group practice" and "surgical group practice" are defined at 42 C.F.R. § 1001.952(r)(5).

[4]Under the one-third practice income test, 42 C.F.R. § 1001.952(r)(3)(ii), 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. Under the one-third practice test, 42 C.F.R. § 1001.952(r)(3)(iii), 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 term "procedures" is defined at 42 C.F.R. § 1001.952(r)(5).

The majority of the Group Physicians fit neither category. Since the Group is a multi-specialty group, there is a substantial likelihood of cross-specialty referrals for services performed in the ASC. Moreover, few of the Group Physicians will actually use the Surgical Center on a regular basis as part of their medical practice. In other words, the Proposed Arrangement would allow those Group Physicians for whom the Surgical Center is not an extension of their office practices to profit from their referrals to the Surgical Center or to their partners who perform procedures there. In this respect, the Proposed Arrangement poses the same risks as an ASC owned directly by surgeons and primary care physicians in the same community. In these circumstances, the fact that the ownership of the ASC is held indirectly through a group practice whose membership includes both surgeons and other potential referring physicians does not reduce the risk that the venture may be used to reward referrals.

Accordingly, we cannot conclude that the Proposed Arrangement poses a minimal risk of fraud and abuse.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially impose administrative sanctions on [Company X] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Company X], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor of this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other federal, state, or local statute, rule,

regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General