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 requestors.*]

Issued: October 10, 2001

Posted: October 17, 2001

[names and addresses redacted]

Re: [Surgical Center X]
OIG Advisory Opinion No. 01-17

Dear Sirs:

We are writing in response to your request for an advisory opinion regarding whether an existing ambulatory surgical center ("ASC") joint venture between a hospital-affiliated entity and an entity owned indirectly by five ophthalmologists, together with the execution of three related ancillary agreements (the "Arrangement"), constitutes 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 Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals were present, but that the Office of Inspector General ("OIG") will not impose administrative sanctions on [Surgical Center X] or [Hospital Y] (collectively, the "Requestors") 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 Arrangement.

This opinion may not be relied on by any persons other than [Surgical Center X] and [Hospital Y], the requestors of this opinion, and is further qualified as set out in Part V below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. The Investment Interests

[Surgical Center X] (the "Surgical Center") is a freestanding eye surgery center indirectly owned by [Hospital Y] (the "Hospital")[1] and five individual ophthalmologic surgeons (the "Investing Ophthalmologists"),[2] each of whom is a member of one of two group practices. Through holding companies, the Hospital owns 25% of the Surgical Center and the Investing Ophthalmologists jointly own 75%. For the Hospital and each Investing

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[1]The Hospital owns and operates an acute care hospital and employs twelve physicians and twenty-one residents. The Hospital is part of a group of affiliated entities owned and controlled, directly or indirectly, by [Parent Entity Z]. Affiliated entities include two physician practices and a real estate company. For purposes of this advisory opinion, we consider all of the foregoing and all other affiliated entities owned and controlled in whole or in part, directly or indirectly, by any of the foregoing to be sufficiently related to be treated as a single entity, which will be referred to individually and collectively as the "Hospital".

[2]The Investing Ophthalmologists are [3 names redacted] (affiliated with a group practice known as [group name redacted]) and [2 names redacted] (affiliated with a group practice known as [group name redacted]).

Ophthalmologist, the return on the Surgical Center investment is directly proportional to the amount of capital that the applicable investor contributed to the respective holding company compared to the total capital contributions to the Surgical Center from all investors.

The Investing Ophthalmologists own their interests in the Surgical Center indirectly. Each Investing Ophthalmologist's direct investment is in one of two limited liability companies, depending on their group practice. In turn, these two limited liability companies jointly own a third limited liability company that is the actual investor in the Surgery Center. The Requestors have certified that: (i) the terms on which the investment interests in the three limited liability companies were offered to the Investing Ophthalmologists were not related to the previous or expected volume of referrals, services furnished, or business otherwise generated to or for the Hospital or the Surgical Center; and (ii) none of the capital contributed by the Investing Ophthalmologists was obtained with funds loaned or guaranteed by the Surgical Center, any direct or indirect investor, or any individual or entity acting on behalf of the Surgical Center or any direct or indirect investor. Each Investing Ophthalmologist meets the "one-third practice income test" set forth at 42 C.F.R. § 1001.952(r)(2)(ii).[3]

The Requestors have certified that the Surgical Center meets all of the requirements of the hospital-physician ASC safe harbor, 42 C.F.R. § 1001.952(r)(4), except for the requirement that the hospital must not be in a position to make or influence referrals directly or indirectly to any investor or the ASC and the requirement that the physicians' interests must be held directly by physicians or their group practices.[4] In particular, the Hospital has a number of affiliations with referring physicians as employees, independent contractors, and medical staff members (collectively, "Hospital-Affiliated Physicians"). Consequently, the Hospital has certified that it will implement the following measures:

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[3]Under the one-third practice income test, 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. See 42 C.F.R. § 1001.952(r)(2)(ii). The term "procedures" is defined at 42 C.F.R. § 1001.952(r)(5).

[4]Since all of the Investing Ophthalmologists are engaged in the same medical practice specialty, they are not required to meet the additional "one-third of the procedures test" for multi-specialty ASCs, 42 C.F.R. § 1001.952(r)(3)(iii).

- Physicians employed by the Hospital will not make referrals directly to the Surgical Center, although they may refer patients to 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 notify all Hospital-Affiliated Physicians of these measures.

The Requestors have certified that the Surgical Center, each Investing Ophthalmologist, and the Investing Ophthalmologists' group practices have agreed to treat Federal health care program beneficiaries in a nondiscriminatory manner and that the Investing Ophthalmologists will fully inform patients referred to the Surgical Center by them or their group practices of the Hospital's and the Investing Ophthalmologists' investment interests through a written disclosure to each such patient and through a notice posted in each Investing Ophthalmologist's office.

B. The Ancillary Agreements

In addition to the investment interests, the Surgical Center leases space from the Hospital for the Surgical Center's ASC and shares its reception area with the Hospital's outpatient endoscopy ASC. These arrangements are structured in two agreements: (i) a lease of a surgical suite and an adjacent reception area suite from the Hospital to the Surgical Center; and (ii) a partial leaseback agreement under which the Surgical Center agrees to share its reception area with the Hospital's endoscopy ASC, in exchange for a proportional payment equal to half of the reception area rent payment under the primary

lease to the Surgical Center.[5] The Requestors have certified that the lease and the partial leaseback agreement meet all of the requirements of the space rental safe harbor, 42 C.F.R. § 1001.952(b), and that payments under each agreement are consistent with fair market value in arm's-length transactions.

Finally, the Surgical Center has engaged one of the Investing Ophthalmologists to serve as medical director of the Surgical Center for approximately three to fours hours per week. Based upon the medical director's daily log of services rendered and time spent, the Surgical Center pays the medical director $[m] per hour, subject to a cap of $[n] per month. The Requestors have certified that such services are provided through a medical director agreement, which meets all of the requirements of the personal services and management contracts safe harbor, 42 C.F.R. § 1001.952(d), except for (i) the requirement that, for services provided on a periodic, sporadic, or part-time basis, the contract must specify the exact schedule, precise length, and exact charge for the intervals, and (ii) the requirement that the aggregate compensation paid over the term of the contract must be set in advance. The Requestors have also certified that compensation paid under the medical director agreement is consistent with fair market value in arm's-length transactions for the services rendered.

II. THE 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 Federal health care programs. 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, in cash or in-kind, directly or indirectly, covertly or overtly.

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

[5]The Surgical Center and the Hospital's endoscopy ASC have hired separate receptionists.

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 published "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 section 1128B(b)(3) of the Act; 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. Strict compliance with all elements is required for safe harbor protection. See 56 Fed. Reg. 35952, 35954 (July 29, 1991).

Three safe harbors are relevant to the Arrangement. First, with respect to the Arrangement's investment interests, 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. Three of the conditions of the hospital-physician ASC safe harbor require that: (i) a hospital investor must not be in a position to refer directly or indirectly to, or otherwise generate business for, the ASC or any investor; (ii) 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) or as group practices composed of such physicians or surgical group practices; and (iii) any services, equipment, or space provided by the hospital to the ASC must comply with a safe harbor. Second, 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 relevant. Third, for services provided by the medical director, the safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), is relevant. Two of the conditions of this safe harbor are that (i) for services provided on a periodic, sporadic, or part-time basis, the contract must specify the exact schedule, precise length, and exact charge for the intervals, and (ii) the aggregate compensation paid over the term of the contract must be set in advance. See 42 C.F.R. § 1001.952(d)(3), (d)(5).

III. ANALYSIS

Although joint ventures by physicians and hospitals are often susceptible to fraud and abuse, the OIG recognizes that precluding joint ownership of ASCs may place hospitals at a competitive disadvantage by forcing them to compete with ASCs owned by physicians, who principally control referrals. Thus, the Department promulgated a safe harbor for ASCs that meet all of the applicable safe harbor conditions. However, the

Arrangement does not qualify for safe harbor protection because it fails to satisfy two such conditions (i.e., the Hospital is a potential referral source and the Investing Ophthalmologists are investing through holding companies, instead of investing directly as individuals or through their group practices). Therefore, we must carefully scrutinize the Arrangement in its entirety to determine whether, based upon a totality of the facts and circumstances presented, the potential risk of fraud and abuse is sufficiently low.

As a threshold matter, we consider the Arrangement's investment interests and ancillary agreements separately. With respect to the investment interests, 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.

In light of these safeguards, the Hospital's ability to direct or influence the referrals of its Hospital-Affiliated Physicians will be significantly constrained.

With respect to the investment interests of the Investing Ophthalmologists, in this case, the use of "pass through" entities rather than direct ownership does not substantively increase the risk of fraud or abuse. Each Investing Ophthalmologist meets the "one-third practice income" test. Each Investing Ophthalmologist will receive a return on his or her Surgical Center investment that is directly proportional to the percentage that his or her contribution bears to the total investment contributions in the Surgery Center. Moreover,

the terms on which the Investing Ophthalmologists were offered their direct and indirect investment interests were not based on the volume or value of referrals to the Surgery Center or the Hospital.

With respect to the ancillary agreements, the Requestors have certified that the lease for the Surgical Center's suites and the partial leaseback agreement for the Surgical Center's reception area meet all of the requirements of the space rental safe harbor at 42 C.F.R. § 1001.952(b). The Requestors have also certified that the medical director agreement meets all of the requirements of the personal services and management contract safe harbor at 42 C.F.R. § 1001.952(d), except for the requirement that, for services provided on a periodic, sporadic, or part-time basis, the contract must specify the exact schedule, precise length, and exact charge for the intervals and the requirement that the aggregate compensation paid over the term of the contract must be set in advance. See 42 C.F.R. §§ 1001.952(d)(3), (d)(5). However, the risk is substantially reduced in the instant case because the medical director agreement involves compensation that is certified to be consistent with fair market value, based upon a specified hourly rate, subject to a monthly payment cap, and paid only if there is written documentation of the hours and the services provided. Thus, given the totality of facts and circumstances presented, the ancillary agreements do not significantly increase the risk of fraud and abuse.

For all of the foregoing reasons, we conclude that, while the Arrangement poses some risk, the safeguards put in place by the Requestors make that risk sufficiently low that we would not subject the Arrangement to administrative sanctions in connection with the anti-kickback statute.

IV. CONCLUSION

For all of the above reasons, and based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals were present, but that the OIG will not impose administrative sanctions on [Surgical Center X] or [Hospital Y] 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 Arrangement.

V. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Surgical Center X] and [Hospital Y], which are the requestors of this opinion. This advisory opinion has no application, 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 Arrangement.

- 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 will not proceed against the Requestors with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. 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. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely and accurately disclosed to the OIG.

Sincerely,

/s/

D. McCarty Thornton
Chief Counsel to the Inspector General