[*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: October 12, 2007

Posted: October 19, 2007

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 07-13

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding the addition of optometrists as owners of three single-specialty ophthalmology ambulatory surgical centers (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 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, we conclude that (i) 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 [names redacted] 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 [names redacted], the requestors of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] (the "Group Practice") and [name redacted] (the "Surgical Center") are both [state redacted] limited liability companies (collectively, the "Requestors"). The Group Practice is composed of eighteen members: eight ophthalmologists (the "Ophthalmologists"), nine optometrists (the "Optometrists"),[1] and one wholly-owned subsidiary of a nonprofit hospital system (the "Hospital").[2] The Ophthalmologists and Optometrists own 68.23% of the membership interests in the Group Practice, and the Hospital owns the remaining 31.77%.[3] The Group Practice employs the Ophthalmologists and the Optometrists.[4]

The Surgical Center operates three single-specialty ophthalmology ambulatory surgical centers (ASCs) that are Medicare certified. Currently, only the Ophthalmologists and the Hospital have ownership interests in the Surgical Center; the Optometrists do not have

[1] The Optometrists are classified as either primary care optometrists or medical optometrists. The primary care optometrist is a practitioner with ongoing responsibility for the total visual, ocular, and related care of his or her patients; the primary care optometrist makes referrals to the Ophthalmologists for the treatment of specific eye disease or injury. Unlike a primary care optometrist, the medical optometrist does not perform refractions on patients; receives referrals from other optometrists (including those outside the Group Practice) to evaluate or provide a second opinion regarding specific eye disease or injury; and assists the ophthalmologist or surgeon in pre- and post-operative work. The medical optometrists also make referrals to the Ophthalmologists.

[2] [Name redacted], a for-profit corporation, is the wholly-owned subsidiary of a nonprofit hospital system, [name redacted]. For purposes of this advisory opinion, we consider the foregoing and all other affiliated entities owned and controlled in whole or in part, directly or indirectly, by either 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."

[3] We express no opinion with respect to the current ownership of the Group Practice.

[4] One of the owners of the Group Practice is now retired from the practice of ophthalmology. Accordingly, there are seven practicing ophthalmologists and one retired ophthalmologist who are owners of the Group Practice.

any. The eight Ophthalmologists own 54.33% of the membership interests in the Surgical Center, and the Hospital owns the remaining 45.67%.[5]

The Optometrists make referrals to the Ophthalmologists for the treatment of specific eye disease or injury that is either identified or suspected. As employees of the Group Practice, they agree to refer patients for non-inpatient services to Group Practice facilities or to the Surgical Center ASCs (subject to certain express exceptions related to patient choice and appropriate facilities). The Ophthalmologists perform surgical procedures in the Surgical Center ASCs. Some of the Optometrists assist the Ophthalmologists in pre- and post-operative work in the Surgical Center ASCs, but the Optometrists do not perform any surgical procedures in the Surgical Center ASCs.

Under the Proposed Arrangement, the Optometrists would join the Ophthalmologists and the Hospital as owners of the Surgical Center.[6] In order to allow the Optometrists to become owners of the Surgical Center, the Hospital is proposing to sell some of its ownership interests in the Surgical Center to the Optometrists over a three-year period.[7] In all cases, no investor would, directly or indirectly, receive financing help from the Surgical Center, the Group Practice, or another investor, and the same terms would be offered to each investor without regard to the potential volume or value of referrals. Each investor would execute a membership purchase agreement to purchase a specific number of shares over a three year period at a price to be determined in accordance with an independent appraisal of fair market value.

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 referral 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 statue is violated. By its terms, the statue ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration"

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[5] The retired ophthalmologist retains his membership interests in the Surgical Center as well as the Group Practice. Specifically, he owns 23.93% of the membership interests in the Surgical Center. We express no opinion with respect to the current ownership of the Surgical Center.

[6] Additionally, the Requestors plan to reallocate ownership interests in the Group Practice to increase the current ownership interests of the individual Ophthalmologists and Optometrists. We express no opinion with respect to this ancillary arrangement.

[7] Some shares would also be reallocated to the Ophthalmologists.

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 (the "Department") 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.

B. Analysis

Surgical center joint ventures that include investors in a position to generate surgical business are susceptible to fraud and abuse. OIG has a long-standing concern about the potential for investments in ASCs to serve as vehicles to reward referrals indirectly. Notwithstanding, in recognition that some physician-owned ASC ventures may be beneficial to the Federal programs and their beneficiaries, the Department issued a safe harbor for physician-owned ASCs that meet criteria carefully tailored to mitigate the risks of fraud and abuse. The safe harbor for investment interests in Hospital/Physician-Owned ASCs, 42 C.F.R. § 1001.952(r)(4), is relevant to the Proposed Arrangement.[8] Among the requirements of this safe harbor is that ownership is limited to physicians who perform ASC procedures on a regular basis, as demonstrated by meeting a one-third

[8] Neither the small entity investments safe harbor nor the underserved entities investment safe harbor at 42 C.F.R. §§ 1001.952(a)(2) and (a)(3) would apply to the Proposed Arrangement, which contemplates approximately 76% ownership by investors in a position to make referrals to, or generate business for, the Surgical Center ASCs (noting that the retired ophthalmologist, who owns 23.93% of the Surgical Center, makes no referrals).

practice income test,[9] and other investors who are not in a position to generate referrals to the ASC or its investors.

The Proposed Arrangement fails to satisfy these requirements of the safe harbor. The Optometrists perform no ASC procedures as defined at 42 C.F.R. § 1001.952(r)(5), but they do generate referrals to other investors (e.g., the Ophthalmologists) and, indirectly, to the Surgical Center ASCs. Because no safe harbor would protect the addition of the Optometrists as owners of the Surgical Center, we must determine whether, given all of the relevant facts, the Proposed Arrangement poses a minimal risk under the anti-kickback statute. In this case, there are no discernible safeguards to minimize the significant risk that the Proposed Arrangement would be a vehicle to provide the Optometrists with a share of the profits from their referrals to the Ophthalmologists utilizing the Surgical Center ASCs. As we have previously stated in the preamble to the 1999 Final Rule establishing the ASC safe harbor,

> The gravamen of an anti-kickback offense is payment of remuneration to induce the referral of Federal health care program business. In the context of an ASC, our chief concern is that a return on an investment in an ASC might be disguised as payment for referrals. . . . [P]hysicians in specialties that typically refer to one another could jointly invest in an ASC so that they are positioned to earn a profit from such referrals or so that one physician specialty provides the ASC services and the other provides the referrals. In such cases, medical decision-making may be corrupted by financial incentives offered to potential referral sources who stand to profit from services provided by another physician.

64 Fed. Reg. 63518, 63536 (November 19, 1999).

The Ophthalmologists and Optometrists are in distinctly different positions here. The Ophthalmologists personally perform surgical procedures at the Surgical Center ASCs, and such surgical business is effectively an extension of their office practices. For the Optometrists, however, the Surgical Center ASCs are not a comparable extension of their office practices. As a result, the likelihood that they are using their investment in the Surgical Center simply as a vehicle for receiving remuneration for referrals of patients to the Ophthalmologists increases significantly. There are no safeguards to obviate the risk

[9] Under the one-third practice income test, which also comprises part of the Surgeon-Owned ASC safe harbor, the Single-Specialty ASC safe harbor, and the Multi-Specialty ASC safe harbor, 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 performance of ASC procedures. See 42 C.F.R. § 1001.952(r)(1) - (4). The term "procedures" is defined at 42 C.F.R. § 1001.952(r)(5).

that their investment in the Surgical Center is for the purpose of inducing or rewarding 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 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 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 [names redacted], the requestors 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 Existing Arrangement or 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