DEPARTMENT OF HEALTH AND 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: June 12, 2007

Posted: June 19, 2007

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 07-05

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposal for certain physician investors in an established ambulatory surgery center ("ASC") to sell a portion of their ownership interests to a local hospital (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 [names redacted] (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.

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

1. FACTUAL BACKGROUND

[Name of corporation redacted] is a [state redacted] nonprofit corporation, recognized by the Internal Revenue Service as a tax-exempt organization under Section 501(c)(3) of the Internal Revenue Code. It owns and operates [name of hospital redacted], a general acute care hospital in [city and state redacted]. For ease of reference in this opinion, [names of corporation and hospital redacted] will be referred to individually and collectively as the "Hospital."

[Name redacted] (the "Company"), a [state redacted] limited liability company, owns and operates a freestanding multi-specialty ASC. Three members of the Company are orthopedic surgeons (the "Orthopedic Surgeons"), two are gastroenterologists (the "Gastroenterologists"), and two are anesthesiologists (the "Anesthesiologists") (collectively, the "Physician Investors"). The Orthopedic Surgeons were the founding members of the Company, and together they own shares representing approximately 94 percent of the equity in the Company. Together the Gastroenterologists and the Anesthesiologists own shares representing approximately six percent of the equity in the Company.

The Physician Investors are the exclusive providers of professional services to patients of the ASC. The ASC, the Orthopedic Surgeons, and the Gastroenterologists bill third party payors, including Federal health care programs, for services provided in the ASC.

Under the Proposed Arrangement, the Orthopedic Surgeons would sell to the Hospital the number of ownership units necessary for the Hospital to own 40 percent of the Company, for a total purchase price of [amount redacted]. The Requestors have certified that the amount to be paid by the Hospital for these units is fair market value. The amount paid by the Hospital would exceed the amount originally invested by the Orthopedic Surgeons for this number of units. As a result, while each investor would receive a return on investment proportional to the investor's ownership share in the Company, distributions of profits and losses based on relative equity ownership interests would not be directly proportional to capital invested.

Because the Hospital would pay more per ownership unit than the Orthopedic Surgeons paid, the Orthopedic Surgeons would receive a higher rate of return on their remaining shares than the Hospital would receive on its newly-purchased shares.

The Orthopedic Surgeons did not make an offer of sale of ownership units in the Company to any other prospective buyer, including the other Physician Investors. The Physician Investors other than the Orthopedic Surgeons do not propose to sell any of their ownership interests in the Company.

The Hospital is in a position to make or influence referrals directly or indirectly to the ASC or its Physician Investors. Under the Proposed Arrangement, the Hospital would agree to certain steps to limit its ability to make such referrals. Any physicians employed by the Hospital would be prohibited from making referrals to the ASC. The Hospital would take no actions to require or encourage its medical staff to refer patients to the ASC or to any Physician Investor and would not track such referrals. Compensation paid to the Hospital's physicians would be consistent with fair market value in arm's-length transactions and would not be related, directly or indirectly, to the value or volume of referrals to the ASC or the Investing Physicians. The Hospital would provide notice to its medical staff of these measures and would continue to operate its own outpatient facilities for ambulatory surgery procedures.

The Requestors have certified that the Orthopedic Surgeons and the Gastroenterologists receive at least one-third of their medical practice income from all sources from their performance of ASC procedures as defined at 42 C.F.R. § 1001.952(r)(5). As to two of the Orthopedic Surgeons and both Gastroenterologists, at least one-third of the defined procedures performed by each physician are performed at the ASC. The remaining Orthopedic Surgeon does not meet this test, because he often performs the defined procedures in a hospital setting, rather than in the ASC. Although the Anesthesiologists provide services in connection with the performance of the defined procedures, they do not themselves perform the procedures defined in 42 C.F.R. § 1001.952(r)(5).

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.

There is a safe harbor for returns on investment in hospital/physician-owned ambulatory surgery centers. 42 C.F.R. § 1001.952(r)(4). Among the conditions of this safe harbor are that (i) the terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity (42 C.F.R. § 1001.952(r)(4)(i)); (ii) the amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment of that investor (42 C.F.R. § 1001.952(r)(4)(iii)); (iii) the hospital must not be in a position to make or influence referrals directly or indirectly to the ASC or any of its investors (42 C.F.R. § 1001.952(r)(4)(viii)); and (iv) investing physicians who are in a position to refer patients to the ASC must meet the requirements for surgeon-owned ASCs, single-specialty ASCs, or multi-specialty ASCs, as applicable. In the case of a multi-specialty ASC, each physician investor must receive at least one-third of his or her medical practice income from ASC procedures defined at 42 C.F.R. § 1001.952(r)(5), and must perform at least one-third of such procedures at the ASC in which he or she invests. 42 C.F.R. § 1001.952(r)(3)(ii) and (iii). If all the conditions of the safe harbor are met, it

protects "any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor" in the ASC.

B. Analysis

The OIG has longstanding concerns about problematic joint venture arrangements between those in a position to refer business, such as physicians, and those furnishing items or services for which a Federal health care program pays. See, e.g., OIG's 1989 Special Fraud Alert on Joint Venture Arrangements, reprinted in the Federal Register in 1994, 59 FR 65372, 65373 (Dec. 19, 1994) and Special Advisory Bulletin, "Contractual Joint Ventures," 68 FR 23148 (Apr. 30, 2003). As noted in both these publications, joint ventures may take a variety of forms and may be formed by equity or contract. Joint venture arrangements raise concerns under the anti-kickback statute because they pose a risk that income from the venture may be payment for referrals to the venture or to coinvestors.

ASCs that are owned by physicians and hospitals are a form of joint venture. The OIG has promulgated a safe harbor that protects investment income, such as dividends or interest, from ASCs jointly owned by physicians and hospitals, if certain conditions are met. For a number of reasons, the Proposed Arrangement does not qualify for safe harbor protection. For example, the amount of payment to an investor in return for the investment would not be directly proportional to the amount of the capital investment of that investor. Because no safe harbor would protect the investment income from the ASC, we must determine whether, given all the relevant facts, the Proposed Arrangement poses a minimal risk under the anti-kickback statute.

In this case, it is not clear that the Proposed Arrangement is not related, at least in part, to referrals of Federal health care program business. First, the Hospital's proposed investment takes the form of a purchase of shares from the Orthopedic Surgeons for cash, rather than an investment of capital in the Company itself. The investment is unrelated to the operation of the ASC (i.e., the funds invested by the Hospital would not be used to expand or enhance the ASC facility or fund its operations). Instead, the Proposed Arrangement would permit the Orthopedic Surgeons to realize a gain on their original investment in the Company.

Second, not all of the Investing Physicians are to sell a portion of their ownership units to the Hospital at an appreciated price. This raises the possibility that one purpose of the Hospital's investment is to reward or influence a subset of the Investing Physicians whose referrals of patients to the Hospital or to the ASC itself may be particularly valuable.

Third, the return on the investment would not be directly proportional to the amount of the capital invested by each investor. The amounts payable to the investors would be

proportional to their ownership interest in the Company; however, because the Hospital would pay more per ownership unit than the Orthopedic Surgeons paid, the Orthopedic Surgeons would receive a higher rate of return on their remaining shares than the Hospital would receive on its newly-purchased shares.

None of these factors, whether standing alone or in combination, necessarily indicates fraud or abuse. However, given all the facts, we cannot conclude that the difference in cost of capital acquisition, which results in financial gain to a subset of the physician investors whose referrals may be particularly valuable, is not related, directly or indirectly, to the value or volume of referrals or other business generated between the parties, including referrals by the selling Orthopedic Surgeons to the Hospital or the ASC. Accordingly, the Proposed Arrangement poses a heightened risk of fraud and abuse.

Because we have not been asked for an opinion on the existing ownership of the Company, except as it relates to the Proposed Arrangement, we express no opinion with regard to the ownership interests of the Physician Investors.

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 [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.

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 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