[*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 14, 2002

Posted: June 21, 2002

[name and address redacted]

Re: OIG Advisory Opinion No. 02-9

[name redacted]:

We are writing in response to your request for an advisory opinion regarding whether your ownership interest in a proposed ambulatory surgical center ("ASC"), in which you would be the sole owner and investor (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 satisfies the criteria set forth in 42 C.F.R. §1001.952(r)(2) (the safe harbor for investment interests in single-specialty ASCs) and, therefore, will not constitute prohibited remuneration under the anti-kickback statute, section 1128B(b) of the Act. Accordingly, the Proposed Arrangement will not constitute grounds for the imposition of administrative sanctions on [Physician 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).

This opinion may not be relied upon by any persons other than [Physician X], the requestor of this opinion, and is further qualified as set out in Part III below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Physician X] (the "Requestor") is a physician who derives at least one-third of his medical practice income from all sources from endoscopic procedures that he performs within his office or at one of the local hospitals.[1] Under the Proposed Arrangement, the Requestor will become the sole investor in, and sole owner of, a new legal entity, [entity name redacted] (the "Surgical Center"), that will own and operate a freestanding, Medicare-certified, single-specialty (endoscopy) ASC. The Requestor will perform endoscopic procedures at the Surgical Center, and the Surgical Center will bill and collect the corresponding facility fees. As the Surgical Center's sole owner, the Requestor will receive all distributions of the Surgical Center's profits and losses, if any.

The Requestor will continue to practice medicine as a member of [name of group practice redacted] (the "Group Practice"), a two-person medical group practice located in [city and state redacted] and equally owned by the Requestor and [Physician Y]. The Group Practice will continue to bill and collect the Requestor's professional fees. The Requestor has certified that, although the Group Practice will bill and collect the professional fees for endoscopic procedures that he performs at the Surgical Center or elsewhere, such fees will be distributed solely to him.[2]

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[1]The Requestor has certified that the endoscopic procedures meet the definition of "procedures" set forth in the ASC safe harbor at 42 C.F.R. § 1001.952(r)(5).

[2]This opinion only addresses the Requestor's return on his investment interest in the Surgical Center. We express no opinion on any financial arrangement between

In addition to the foregoing, the Requestor has made the following certifications:

- The Surgical Center's operating and recovery room space will be dedicated exclusively to the ASC;

- Patients referred to the Surgical Center by the Requestor will be fully informed of the Requestor's investment interest;

- Neither the Surgical Center nor the Group Practice (nor any individual or entity acting on behalf of the Surgical Center or the Group Practice) has or will loan funds to or guarantee a loan for the Requestor if any part of such loan will be used to obtain his investment interest;

- All ancillary services for Federal health care program beneficiaries performed at the Surgical Center will be directly and integrally related to primary procedures performed at the Surgical Center, and none will be separately billed to Medicare or other Federal health care programs; and

- The Surgical Center and the Requestor will treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

II. LEGAL ANALYSIS

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 paid for 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

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the Requestor and any other individual or entity, including any potential referral source to the Surgical Center.

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 Office of Inspector General ("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). The safe harbor for investment interests in single-specialty ASCs, 42 C.F.R. § 1001.952(r)(2), is pertinent here.

Based upon the Requestor's certifications, we conclude that the Proposed Arrangement will fit within the safe harbor for investment interests in single-specialty ASCs at 42 C.F.R. §1001.952(r)(2) and, therefore, will not constitute prohibited remuneration under the anti-kickback statute, section 1128B(b) of the Act. Accordingly, the Proposed Arrangement will not constitute grounds for the imposition of administrative sanctions on the Requestor, 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).

III. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Physician X], who is 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 herein expressed or implied 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 will not proceed against the Requestor with respect to any action that is part of the Proposed 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 Proposed 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 Requestor 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