[*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: July 22, 2009

Posted: July 29, 2009

To: ATTACHED DISTRIBUTION LIST

Re: OIG Advisory Opinion No. 09-09

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposed joint venture involving ownership of an ambulatory surgery center by a hospital and physicians (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, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, 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 while the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, the Office of

Inspector General ("OIG") would not 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. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

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.

I. FACTUAL BACKGROUND

[Name redacted] owns and operates a general acute care hospital, [name redacted], in [city redacted] [state redacted]. (For purposes of this opinion, both of these entities will be designated as the "Hospital.")

[Name redacted] (the "Surgeon LLC") is a limited liability company organized under the laws of the State of [state redacted], owned by seven orthopedic surgeons (the "Surgeon Investors") who are members of a single physician group practice. The Requestors have certified that each Surgeon Investor's ownership in the Surgeon LLC is proportional to his or her capital investment and that each Surgeon Investor received at least one-third of his or her medical practice income for the previous fiscal year or previous 12-month period from the performance of procedures payable by Medicare when performed in an ambulatory surgery center ("ASC").

The Surgeon Investors (through the Surgeon LLC) and the Hospital desire to enter into a joint venture to own and operate an ASC with two operating rooms in a medical office building (the "Building") owned by the Hospital and located on its campus.

The Requestors have certified that, under state law, the development of an ASC requires obtaining a certificate of need ("CON"), except in certain circumstances. They have devised the Proposed Arrangement, by which they plan to develop a single two-operating room ASC by first developing two separate and adjacent ASCs, each consisting of one operating room and neither requiring a CON, and subsequently merging the two into a single ASC.[1]

In furtherance of this goal, the Surgeon LLC has developed an outpatient operating room in the Building and is operating it as a Medicare-certified ASC (the "Surgeon ASC"). The

[1] We express no opinion with respect to whether the Proposed Arrangement complies with state law.

Requestors have certified that the Surgeon ASC occupies space in the Building pursuant to a lease agreement that complies with the requirements of the space rental safe harbor at 42 C.F.R. § 1001.952(b).

Under the Proposed Arrangement, the Hospital will develop a single hospital operating room (the "OR") in space within the Building adjacent to the Surgeon ASC. Upon receipt of necessary regulatory approvals, it will then contribute the assets used to operate the OR to [name redacted] (the "Company"), after which the OR will be operated as a Medicare-certified ASC (the "Hospital ASC"). The Hospital currently is the sole member of the Company, which at the present time has no tangible assets.

The Requestors have certified that, upon receipt of necessary regulatory approvals, the Surgeon LLC will purchase 50 percent of the membership units in the Company. The purchase price will consist, at least in part, of the Surgeon ASC, which the Surgeon LLC will contribute to the Company. Prior to this contribution, appraisals will be conducted to determine the fair market value of the Company (whose sole asset at that time will be the Hospital ASC) and the fair market value of the Surgeon ASC. The Requestors have certified that the appraisals will not take into account the volume or value of referrals made or business otherwise generated among the parties to the transaction, including past or anticipated referrals to the ASCs, but will be based solely on the fair market value of the tangible assets of the Company and the Surgeon ASC, which will consist for the most part of equipment, furnishings, and supplies. If the fair market value of the tangible assets of the Surgeon ASC is determined to be less than the fair market value of the tangible assets of the Company, the Surgeon LLC will make a cash contribution to the Company in the amount of the difference. If the fair market value of the tangible assets of the Surgeon ASC is determined to be more than the fair market value of the tangible assets of the Company, the Hospital will make a cash contribution to the Company in the amount of the difference. At the time of this transaction, the lease for the space occupied by the Surgeon ASC will be terminated, and the Hospital (as lessor) and the Company (as lessee) will execute a lease for the combined space. The Requestors have certified that this lease will comply with the requirements of the safe harbor for space rental at 42 C.F.R. § 1001.952(b).

At the conclusion of this transaction, the Hospital and the Surgeon LLC will jointly own the Company, which in turn will own and operate a two-operating room ASC (the "Hospital-Surgeon ASC"). The Requestors have certified that this ASC will comply with all the requirements of the safe harbor for hospital/physicians-owned ASCs at 42 C.F.R. § 1001.952(r)(4), except for the requirements that (1) the hospital not be in a position to make or influence referrals directly or indirectly to any investor or the ASC (see 42 C.F.R. § 1001.952(r)(4)(viii)); (2) physician investors in the ASC invest directly or through a group practice composed of physicians who meet the requirements of paragraphs (r)(1), (r)(2) or (r)(3) of 42 C.F.R. § 1001.952(r) (see 42 C.F.R. § 1001.952(r)(4)); and (3) the amount of

payment to an investor in return for the investment be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor (see 42 C.F.R. § 1001.952(r)(4)(iii)).

The Requestors have certified that any physicians employed by the Hospital or its affiliates will not make referrals to the Hospital-Surgeon ASC; the Hospital will not take any actions to require or encourage its medical staff to refer patients to the Hospital-Surgeon ASC or the Surgeon Investors; neither the Hospital nor the Company will track referrals to the Hospital-Surgeon ASC or the Surgeon Investors by the Hospital or members of its medical staff; any compensation the Hospital pays its medical staff will be at fair market value and will not take into account any referrals its medical staff may make to the Hospital-Surgeon ASC or to its Surgeon Investors; and the Hospital will inform its medical staff annually of these measures. In addition, the Hospital will continue to operate its own facilities for outpatient surgery.

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 income from physician/hospital-owned ASCs, 42 C.F.R. § 1001.952(r)(4), is potentially applicable to the Proposed Arrangement.

B. Analysis

Although joint ventures by physicians and hospitals are susceptible to fraud and abuse, the OIG recognizes that hospitals may be at a competitive disadvantage when they compete with ASCs owned by physicians, who principally control referrals. Thus, the OIG promulgated a safe harbor for investment income from ASCs jointly-owned by physicians and hospitals that meet certain conditions, 42 C.F.R. § 1001.952(r)(4). Among the ownership arrangements potentially protected by this safe harbor are ASCs jointly owned by hospitals and general surgeons or surgeons engaged in the same surgical specialty. Because all the Surgeon Investors in the ASC are engaged in the same surgical specialty (orthopedics), the safe harbor is potentially applicable to the Proposed Arrangement.

The Requestors acknowledge that the Proposed Arrangement does not qualify for protection by this safe harbor, however, for the reasons noted below. Because no safe harbor would protect the investment income from the Hospital-Surgeon ASC, we must determine whether, given all the relevant facts, the Proposed Arrangement poses a minimal risk under the anti-kickback statute.

First, safe harbor protection requires that the Hospital not be in a position to make or influence referrals directly or indirectly to any investor or the ASC. 42 C.F.R. § 1001.952(r)(4)(viii). Here, the Hospital is in a position to make or influence referrals to the ASC and to the Surgeon Investors. However, the Proposed Arrangement includes certain commitments limiting the ability of the Hospital to direct or influence such referrals. The Requestors have certified that employees of the Hospital will not refer patients to the Hospital-Surgeon ASC, and the Hospital will refrain from any actions to require or encourage any members of its medical staff to refer patients to the ASC or to its Surgeon Investors. The Hospital will not track referrals, if any, by its medical staff to the Hospital-Surgeon ASC or to its Surgeon Investors; any compensation the Hospital pays its medical staff will be at fair market value and will not take into account any referrals to the Hospital-Surgeon ASC or to its Surgeon Investors; and the Hospital will inform its medical staff

annually of these measures. Also, the Hospital will continue to operate its own facilities for outpatient surgery. In light of these safeguards, the ability of the Hospital to direct or influence referrals to the Hospital-Surgeon ASC or to its Surgeon Investors is significantly constrained.

Second, safe harbor protection requires physician investors to hold their investment interests in an ASC either directly or through a group practice composed entirely of physicians who are qualified to invest directly. See 42 C.F.R. § 1001.952(r)(4). Each of the Surgeon Investors is qualified to invest in the ASC directly without destroying its eligibility for safe harbor protection.[2] In the Proposed Arrangement, they would invest in the Hospital-Surgeon ASC indirectly, through the Surgeon LLC, which would own 50 percent of the Company. The Company, in turn, would own and operate the Hospital-Surgeon ASC. We have previously expressed concern that intermediate investment entities could be used to redirect revenues to reward referrals or otherwise vitiate the safeguards provided by direct investment, including distributions of profits in proportion to capital investment. However, in this case, the use of a "pass-through" entity does not substantially increase the risk of fraud or abuse. Each Surgeon Investor's ownership in the Surgeon LLC is proportional to his or her capital investment, and the individual Surgeon Investors will receive a return on their investments that is the same as if they had invested in the Hospital-Surgeon ASC directly.

Third, safe harbor protection requires that the amount of payment to an investor in return for the investment be directly proportional to the amount of capital invested by that investor. 42 C.F.R. § 1001.952(r)(4)(iii). This requirement helps ensure that referral sources are not rewarded for their referrals through investment returns that are disproportionate to the capital they invested. In this case, the Surgeon Investors, through the Surgeon LLC, have developed the Surgeon ASC, and the Hospital is to develop the Hospital ASC. The Requestors propose to value the respective contributions to the jointly-owned Hospital-Surgeon ASC by obtaining appraisals of the tangible assets of the ASCs at the time of their merger, with either party (the Surgeon LLC or the Hospital) contributing cash, if necessary, to equalize the value of their respective contributions. The Requesters have certified that the appraisals will not take into account the volume or value of referrals made or business otherwise generated among the parties to the transaction, including past or anticipated referrals to the ASCs, but will be based solely on the fair market value of tangible assets.[3]

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[2] The Surgeon Investors are qualified to invest in the ASC directly because each of them practices a single surgical specialty (orthopedic surgery) and receives at least one-third of his or her medical practice income from performing procedures that are payable by Medicare when performed in an ASC. See 42 C.F.R. § 1001.952(r)(1).

[3] We are not authorized to opine on whether fair market value shall be, or was, paid or received for any goods, services, or property. See section 1128D(b)(3) of the Act.

Depending upon the amounts originally invested in the separate ASCs and the value of the tangible assets at the time of the planned merger, it is possible that the Hospital and the Surgeon LLC (and through the Surgeon LLC, the Surgeon Investors) will receive different returns on their investments.[4]

Given the facts presented here, however, we conclude that the risk of abuse resulting from any differences in return on capital is low. There are a number of factors that might influence the degree of such differences, including amounts paid for, and depreciation of, tangible assets. Nothing in the facts presented to us, however, suggests that any differences in return on capital might be related to the investors' past or anticipated referrals.[5]

For these reasons, taken together, we conclude that, while the Proposed Arrangement would result in income to investors that would not be protected by any safe harbor, it involves minimal risk of fraud or abuse.

Therefore, we rely on the certification of the Requestors with regard to whether the valuations described will represent fair market value, without taking into account the volume and value of referrals.

[4] In the particular circumstances of the Proposed Arrangement, where the Hospital and the Surgeon Investors developed two separate ASCs as part of a plan to form a single, jointly-owned Hospital-Surgeon ASC, we consider each investor's investment to be the amount that the investor contributes to develop a separate ASC, plus any additional cash that the investor contributes at the time the two ASCs are merged. We would measure each investor's return on investment accordingly.

[5]Our conclusion might be different if the valuation of the respective contributions of the investors included intangible assets. For example, given the circumstances of the Proposed Arrangement, we might be concerned if the valuation were based on a cash flow analysis of the Surgeon ASC as a going concern. Because the Surgeon Investors are referral sources for the Surgeon ASC, a cash flow-based valuation of that business potentially would include the value of the Surgeon Investors' referrals over the time that their ASC was in existence prior to the merger with the Hospital ASC. The result might be that the Surgeon Investors would receive a greater return on their capital investment than the Hospital, which could reflect the value of their referrals to the Surgeon ASC. (In these circumstances, the Hospital ASC, being newly developed at the time of the proposed merger, may have little or no cash flow record, but we might be similarly concerned with a valuation based on a cash flow analysis of a hospital-owned ASC for which the hospital could influence referrals.) We do not assert that a cash flow-based valuation or other valuation involving intangible assets would necessarily result in a violation of the anti-kickback statute; the existence of a violation depends upon all the facts and circumstances of a particular case.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that while the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not 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. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to 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 will not proceed against the Requestors 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 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,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General