



[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 18, 2008

Posted: July 25, 2008

To: ATTACHED DISTRIBUTION LIST

Re: OIG Advisory Opinion No. 08-08

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding an investment in an ambulatory surgery center by a group of surgeons and a health care corporation that owns hospitals (the "Arrangement"). Specifically, you have inquired whether 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, the Federal anti-kickback statute.

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 while the 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”) will 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 Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions, except as explicitly stated in this opinion.

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] (the “Hospital Corporation”)¹ is [state redacted] not-for-profit corporation that owns three hospitals and other healthcare-related entities, including a large physician group practice consisting of primary-care and specialty-care physicians (the “Hospital-Owned Physician Practice”).

[Name redacted] (the “Surgeon Partnership”), is [state redacted] limited liability company whose members (the “Surgeon Investors”) are also members of two divisions of [name redacted], a large, multi-site physician group (the “Surgeon Group”). (The Surgeon Group is not the Hospital-Owned Physician Practice, nor do their memberships overlap.) All of the Surgeon Investors are orthopedic surgeons. Each Surgeon Investor made an initial capital contribution of \$50,000 and a subsequent capital contribution of \$11,000 to the Surgeon Partnership. Each of the Surgeon Investors owns an equal share of the Surgeon Partnership.

[Name redacted] (the “Company”) is an entity owned 70 percent by the Surgeon Partnership and 30 percent by the Hospital Corporation. Under the Arrangement, the Company owns and operates an ambulatory surgery center (the “ASC”). The Surgeon Partnership and the Hospital Corporation made financial contributions to the Company proportional to their ownership interests, in order to finance the development and operation of this ASC.

There are eighteen Surgeon Investors, of whom fourteen meet the following test: Each 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

¹ For the purpose of this opinion, “Hospital Corporation” will refer to [name redacted] and entities owned or controlled by it.

Medicare when performed in an ambulatory surgery center (“ASC-Qualified Procedures”). The four remaining Surgeon Investors (the “Inpatient Surgeons”) do not meet this test. Each of the Inpatient Surgeons derives at least one-third of his or her medical practice income from procedures requiring a hospital operating room setting, but receives little or no medical practice income from the performance of ASC-Qualified Procedures. The Requestors have certified that the Inpatient Surgeons rarely have the occasion to refer patients to other physicians for ASC-Qualified Procedures, except for pain management procedures. The Requestors also have certified that none of the Surgeon Investors will refer patients for pain management procedures to be performed at the ASC, unless the pain management procedure is to be performed personally by the referring Surgeon Investor.

The Surgeon Investors inform patients of their ownership interest in the ASC by posting notices in the two offices in which the Surgeon Investors practice and through a written notice to each individual patient. The Requestors have certified that, in the future, in the absence of exigent circumstances, such written notice to individual patients will be provided prior to the date of the procedure in the ASC.

The Hospital Corporation is in a position to make or influence referrals to the ASC. The Requestors have certified that, in order to limit such ability, the Hospital Corporation has refrained and will refrain from any actions to require or encourage physicians who are employees, independent contractors, and medical staff members (“Hospital-Affiliated Physicians”) to refer patients to the ASC or to its Surgeon Investors, and has not and will not track referrals, if any, by Hospital-Affiliated Physicians to the ASC or to its Surgeon Investors. The Requestors have further certified that any compensation paid by the Hospital Corporation to Hospital-Affiliated Physicians has been and will be consistent with fair market value and has not been and will not be related, directly or indirectly, to the volume or value of any referrals Hospital-Affiliated Physicians may make to the ASC, its Surgeon Investors, or the Surgeon Group. The Hospital Corporation will inform Hospital-Affiliated Physicians annually of these measures.

The Company entered a written agreement (the “Anesthesia Agreement”) with the Hospital-Owned Physician Practice to be the exclusive provider of anesthesiology (except for pain management services) at the ASC through its employed anesthesiologists and certified registered nurse anesthetists. The Hospital-Owned Physician Practice obtains payment for anesthesia services from third-party payers, including Federal health care programs, and from patients for uninsured amounts. Pursuant to the Anesthesia Agreement, one of the anesthesiologists employed by the Hospital-Owned Physician Practice serves, on a part-time basis, as Director of Anesthesiology and Medical Director of the ASC, for an annual fixed stipend paid by the Company to the Department of

Anesthesiology of the Hospital-Owned Physician Practice. The duties of this individual, which are administrative and supervisory, are described in detail in the Anesthesia Agreement, and the Requestors have certified that the stipend is fair market value for these services and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties.

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 ambulatory surgery centers jointly owned by physicians and hospitals, 42 C.F.R. § 1001.952(r)(4), and the safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), are potentially applicable to our analysis of the 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 Arrangement. The 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 ASC, we must determine whether, given all the relevant facts, the Arrangement poses a minimal risk under the anti-kickback statute.

First, the Arrangement does not qualify for the protection of the hospital/physician-owned ASC safe harbor, because the Surgeon Investors do not hold their investment interests in the ASC either directly or through a group practice composed of qualifying physicians. Rather, the Surgeon Investors hold their individual ownership interests in the Surgeon Partnership. The Surgeon Partnership, in turn, holds an interest in the Company that owns and operates the 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 Partnership is proportional to his or her capital investment.² The Surgeon Partnership’s ownership interest in the Company is, in turn, proportional to its capital investment. Thus the individual Surgeon Investors receive a return on their ASC investments that is exactly the same as if they had invested directly.

² We express no opinion with regard to any future sales of membership interests in the Surgeon Partnership that may result in individual investors having ownership interests that are not proportional to their investment.

Second, four of the eighteen Surgeon Investors (the Inpatient Surgeons) fail to meet the safe harbor requirement that at least one-third of a physician investor's income from medical practice for the previous fiscal year or previous 12-month period be derived from the performance of ASC-Qualified Procedures.³ This "one third" test helps ensure that the safe harbor applies only to investment income to physicians who are unlikely to use the investment as a vehicle for profiting from their referrals to other physicians using the ASC. Safe harbor protection is limited to physician-investors who, because they perform a substantial number of ASC-Qualified Procedures, are likely to use the ASC on a regular basis as part of their medical practices.

In the circumstances presented, notwithstanding that four Inpatient Surgeons will not regularly practice at the ASC, we conclude that the ASC is unlikely to be a vehicle for them to profit from referrals. The Requestors have certified that, as practitioners of subspecialties of orthopedic surgery that require a hospital operating room setting, the Inpatient Surgeons rarely have occasion to refer patients for ASC-Qualified Procedures (other than pain management procedures, which are discussed below).⁴ Moreover, like the other Surgeon Investors, the Inpatient Surgeons are regularly engaged in a genuine surgical practice, deriving at least one-third of their medical practice income from procedures requiring a hospital operating room setting. The Inpatient Surgeons are qualified to perform surgeries at the ASC and may choose to do so (and earn the professional fees) in medically appropriate cases. Also, the Inpatient Surgeons comprise a small proportion of the Surgeon Investors, a majority of whom will use the ASC on a regular basis as part of their medical practice. This Arrangement is readily distinguishable from potentially riskier arrangements in which few investing physicians actually use the ASC on a regular basis or in which investing physicians are significant potential referral sources for other investors or the ASC, as when primary care physicians invest in a surgical ASC or cardiologists invest in a cardiac surgery ASC.

As noted above, the Inpatient Surgeons do have occasion to refer patients for pain management procedures that are ASC-Qualified Procedures. This raises the possibility that an Inpatient Surgeon or other Surgeon Investor might refer patients to other practitioners for pain management procedures performed at the ASC, for the purpose of generating a facility fee for the ASC. The Requestors have certified, however, that no Surgeon Investor will refer patients for pain management procedures to be performed at

³ The safe harbor for hospital/physician-owned ASCs (42 C.F.R. § 1001.952(r)(4)) incorporates by reference this requirement of the safe harbor for surgeon-owned ASCs (42 C.F.R. § 1001.952(r)(1)(ii)).

⁴ If this certification proves incorrect, this advisory opinion is without force and effect.

the ASC, unless the procedure is to be performed personally by the referring Surgeon Investor. This serves to mitigate the potential for abusive referrals, with regard to this type of procedure.

Third, the Arrangement does not qualify for the safe harbor for ASCs jointly owned by physicians and hospitals, because the Hospital Corporation is in a position to make or influence referrals to the ASC and to the Surgeon Investors. However, the Arrangement includes certain commitments limiting the ability of the Hospital Corporation to direct or influence such referrals. The Hospital Corporation refrains from any actions to require or encourage Hospital-Affiliated Physicians to refer patients to the ASC or to its Surgeon Investors; it does not track referrals, if any, by Hospital-Affiliated Physicians to the ASC or to its Surgeon Investors; any compensation paid to Hospital-Affiliated Physicians is at fair market value and does not take into account any referrals Hospital-Affiliated Physicians may make to the ASC or to its Surgeon Investors; and the Hospital Corporation informs Hospital-Affiliated Physicians annually of these measures. In light of these safeguards, the ability of the Hospital Corporation to direct or influence referrals to the ASC is significantly constrained.

Fourth, the Arrangement does not meet the requirement of the hospital/physician-owned ASC safe harbor that any services provided by the Hospital Corporation to the ASC must be pursuant to a contract that complies with the personal services and management contracts safe harbor set forth at 42 C.F.R. § 1001.952(d). Among the conditions of the personal services and management contracts safe harbor is that, if the agreement is intended to provide for services on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement must specify exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.

The Anesthesia Agreement does not meet this requirement. It provides for an employee of the Hospital-Owned Physician Practice to serve as Director of Anesthesiology and Medical Director of the ASC on less than a full-time basis, but does not specify a schedule for the services to be provided by this individual. However, all of the services to be provided are set out in the Anesthesia Agreement in detail, and the Requestors have certified that the services are reasonable and necessary for the ASC. They have further certified that the amount to be paid under the agreement – a fixed fee set in advance in the contract – is fair market value for the services described, as determined in an arms length transaction, and not determined in a manner that takes into account the volume or

value of any referrals or business otherwise generated between the parties.⁵ The parties will keep accurate and contemporaneous records, such as time cards, of the services provided by the Medical Director, and make them available to the Secretary and the OIG upon request. In these circumstances and given the nature of the contracted services, the lack of specificity of the schedule of services does not raise the risk of fraud and abuse under the Arrangement.

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.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that while the 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 will 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 Arrangement.

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.

⁵ We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). For purposes of this advisory opinion, we rely on the Requestors' certifications of fair market value. If the compensation is not fair market value, this opinion is without force and effect.

- 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, 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 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/

Lewis Morris
Chief Counsel to the Inspector General

DISTRIBUTION LIST

OIG ADVISORY OPINION 08-8

[Names and addresses redacted]