



[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.]

Issued: January 13, 2003

Posted: January 21, 2003

[names and addresses redacted]

**Re: [Surgical Center A]
OIG Advisory Opinion No. 03-2**

Gentlemen:

We are writing in response to your request for an advisory opinion regarding whether a medical center's proposed acquisition of an ownership interest in an established single-specialty (orthopedic) ambulatory surgery center (an "ASC"), together with the execution of a series of related ancillary contracts, 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.

For purposes of this advisory opinion, the term "Proposed Arrangement" collectively includes the following arrangements or agreements described in your request letter and supplemental submissions: (i) the acquisition by [Medical Center B] of an equity interest in [Surgical Center A], pursuant to the "Option Agreement;" (ii) the "Credit Agreement;" (iii) the "Management Services Agreement;" (iv) the "Facility Support Agreement;" (v) the "Surgical Center Lease;" (vi) the "Group Lease;" and (vii) the "Noncompetition Agreement."

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 if the requisite intent to induce or reward referrals were present, but that the Office of Inspector General (“OIG”) will not impose administrative sanctions on [Medical Center B], [Group C], [Group Holding Company D], or [Surgical Center A] (collectively, 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 other agreements or any other arrangements disclosed or referenced in your request letter or supplemental submissions.

This opinion may not be relied on by any persons other than [Medical Center B], [Group C], [Group Holding Company D], and [Surgical Center A], 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

[Surgical Center A], a limited liability company (the “Surgical Center”), operates a freestanding single-specialty (orthopedic) ASC. The Surgical Center is currently owned by a physician group practice, [Group C] (the “Group”), indirectly through a wholly-owned holding company, [Group Holding Company D] (the “Group Holding Company”). Under the Proposed Arrangement, [Medical Center B] (the “Hospital”) would acquire an ownership interest in the Surgical Center.

A. The Investors

The Requestors have certified that the Group is a professional corporation that meets all of the requirements of the group practice safe harbor, 42 C.F.R. § 1001.952(p).¹ The Group has sixteen shareholders (the “Group Shareholders”), each of whom practices orthopedic surgery in the State of [State X].² Eight Group Shareholders meet the “one-third practice income test” set forth in the ASC safe harbor at 42 C.F.R. § 1001.952(r)(1)(ii), which requires that each surgeon investor’s medical practice income

¹If the Group does not meet all of the requirements of the group practice safe harbor, this opinion is without force and effect.

²The Group Shareholders are [sixteen names redacted].

from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon's performance of ASC procedures, as defined in the regulations. Each of the remaining eight Group Shareholders derived more than one-third of his or her medical practice income from all sources for the previous fiscal year or previous twelve-month period from the performance of procedures that either meet the definition of ASC surgical procedures at 42 C.F.R. § 1001.952(r)(5) or require a hospital operating room setting. All but one of the Group Shareholders are active members of the medical staff of the Hospital.

Currently, the Group Holding Company is the sole owner of the Surgical Center. The Requestors have certified that none of the substantial capital contributed by the Group Holding Company was obtained with funds loaned or guaranteed by the Surgical Center, the Hospital, any direct or indirect investor, or any individual or entity acting on behalf of the Surgical Center, the Hospital, or any direct or indirect investor.

The Hospital is a non-profit, tax-exempt corporation that owns and operates a general, acute care hospital.³ The Hospital has a number of affiliations with physicians as employees, independent contractors, and medical staff members (collectively, "Hospital-Affiliated Physicians"). The Hospital currently operates (and, after implementation of the Proposed Arrangement, will continue to operate) facilities that provide orthopedic surgery and related services to the Hospital's outpatients, as well as to non-Hospital patients that are referred to such facilities.

B. The Proposed Arrangement

Under the Proposed Arrangement and pursuant to the Option Agreement executed by the parties before the Surgical Center became operational, the Hospital will purchase an ownership interest in the Surgical Center in exchange for certain capital contributions and loans. The Option Agreement has two phases: Phase I, a mandatory option contingent upon the Requestors receiving a favorable OIG advisory opinion, and Phase II, a permissive option contingent upon certain regulatory approvals.⁴

³The Hospital is part of a group of affiliated entities owned and controlled, directly or indirectly, by [Health System E]. Affiliated entities include a foundation, a managed care network, and several other hospitals and related health care entities. For purposes of this advisory opinion, we consider all of the foregoing and all other affiliated entities owned and controlled in whole or in part, directly or indirectly, by any 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".

⁴The Hospital's investment interest in Phase I is limited to 15% in order for the Surgical Center to qualify for the physicians' office exemption under [State X's]

Under Phase I, the Hospital will purchase a 15% ownership interest in the Surgical Center in exchange for a capital contribution and a line of credit for the Surgical Center, and the Group will guarantee the Group Holding Company's pro rata share of the resulting loan. If the Hospital elects to exercise the Phase II option, the Hospital will increase its ownership interest in the Surgical Center to 40% in exchange for an additional capital contribution and an additional line of credit for the Surgical Center, and the Group Holding Company will make an additional capital contribution. The Requestors have certified that the Hospital's capital contributions under Phase I and Phase II are commensurate with fair market value at the time the parties entered into the Option Agreement and that, for each loan resulting from a respective line of credit, the applicable interest rate will be commensurate with fair market value on the closing date. The terms and conditions applicable to the foregoing acquisitions and loans are described in the Option Agreement and the Credit Agreement.

The Proposed Arrangement is contingent upon five ancillary agreements described more fully below.

Management Services Agreement. The Group and the Surgical Center have entered into a Management Services Agreement pursuant to which the Group furnishes management services, including financial, accounting, and employee benefit services, to the Surgical Center for a fixed annual fee, which is subject to renegotiation under certain conditions, but not more often than annually. The initial term of the agreement is five years. In addition to permitting termination for cause at any time, the agreement terminates immediately if the Group Holding Company no longer owns Surgical Center units. The Requestors have certified that the Management Services Agreement complies with all requirements of the personal services and management contracts safe harbor, 42 C.F.R. § 1001.952(d), except for the minimum one-year term requirement, and that payments under the agreement are consistent with fair market value in arms'-length transactions.

Facility Support Agreement. The Hospital and the Surgical Center have entered into a Facility Support Agreement pursuant to which the Hospital will provide the following services to the Surgical Center: (1) assistance with implementation of quality assurance and utilization management procedures; (2) coordination between the Surgical Center and the Hospital's existing outpatient surgery facilities in the area of shared purchasing of equipment, supplies, and services; (3) gas services, including oxygen services, suction, steam, equipment sterilization inspection services, heating, ventilation and air conditioning, biohazardous waste disposal, laundry services, and an uninterrupted power

certificate of need law. [Citation to applicable State X statutes redacted.] Phase II is contingent upon the Surgical Center receiving a certificate of need authorizing the Hospital to have a 40% equity interest and approving an upgrade of the Surgical Center's equipment, services, and capabilities.

supply; and (4) coverage of the Surgical Center by the Hospital's code team, including physician, employee, and crash cart coverage. In return, the Surgical Center will pay the Hospital a fixed annual fee, which is subject to renegotiation under certain conditions, but not more often than annually. The annual fee can also be renegotiated if the Hospital makes the proposed additional acquisition in Phase II and the net revenues of the Surgical Center after the upgrade are projected to exceed 150% of its net revenues immediately prior to the upgrade. The initial term of the agreement is five years. In addition to permitting termination for cause at any time, the agreement terminates immediately if the Hospital no longer owns Surgical Center units. The Requestors have certified that the Facility Support Agreement complies with all requirements of the personal services and management contracts safe harbor, 42 C.F.R. § 1001.952(d), except for the minimum one-year term requirement, and that payments under the agreement are consistent with fair market value in arms'-length transactions.

For the Management Services Agreement and the Facility Support Agreement, the Requestors have certified that, in the event the fees are renegotiated prior to the expiration of a year, the renegotiated fees will be consistent with fair market value in arms'-length transactions and will not take into account, directly or indirectly, the value or volume of any past or future referrals or other business generated between the parties, and renegotiation will occur not more often than annually.

Surgical Center Lease and Group Lease. Currently, the Surgical Center is leasing space from the Hospital for its ASC, and the Group is leasing space from the Hospital for its medical practice.⁵ When the Hospital makes the proposed acquisition in Phase I, the Hospital and the Surgical Center will enter into a new written lease for the Surgical Center's ASC space (the "Surgical Center Lease"), and the Hospital and the Group will enter into a new written lease for the Group's office space (the "Group Lease"). The initial term of both leases will be ten years. The Requestors have certified that the Surgical Center Lease and the Group Lease will comply with all of the requirements of the space rental safe harbor, 42 C.F.R. § 1001.952(b), and that payments under each lease will be consistent with fair market value in arms'-length transactions.

Noncompetition Agreement. The Noncompetition Agreement prohibits the Hospital, the Group, and the Group Shareholders from: (i) developing, managing, or investing in any ASC offering orthopedic services; (ii) entering into any joint marketing arrangement relating to orthopedic services with any other hospital system; and (iii) entering into any ASC managed care contracting participation agreement with any provider-sponsored system that competes with the Hospital. The Noncompetition Agreement does not prohibit referrals to, or use of, any other ASC, nor does it restrict the Group or the Group

⁵We express no opinion about the Hospital's current leases with the Surgical Center or the Group.

Shareholders from participating in provider networks with other health insurers or other payors.

The Requestors have certified that the Surgical Center will meet all of the requirements of the hospital-physician ASC safe harbor, 42 C.F.R. § 1001.952(r)(4), except for the following: (i) the requirement that hospital must not be in a position to make or influence referrals directly or indirectly to any investor or the ASC; (ii) the requirement that the physicians' interests must be held directly by physicians who meet all of the safe harbor requirements for surgeon-owned, single-specialty, or multi-specialty ASCs or their group practices;⁶ and (iii) the requirement that any services, equipment, or space provided by the hospital to the ASC must comply with a safe harbor.

With respect to the Hospital being a referral source, the Hospital has certified that it will implement the following measures:

- Physicians employed by the Hospital will not make referrals directly to the Surgical Center, although they may refer patients to the Group or the Group Shareholders.
- The Hospital will refrain from taking any actions to require or encourage Hospital-Affiliated Physicians to refer patients to the Surgical Center, the Group, or the Group Shareholders.
- The Hospital will not track referrals made by Hospital-Affiliated Physicians to the Surgical Center, the Group, or the Group Shareholders.
- Compensation paid to Hospital-Affiliated Physicians, whether pursuant to employment or personal services contracts, will not be related directly or indirectly to the volume or value of referrals or other business generated by such physicians to or for the Surgical Center, the Group, or the Group Shareholders. Such compensation will be consistent with fair market value in arm's-length transactions.

On an annual basis, the Hospital will notify all Hospital-Affiliated Physicians of these measures.

II. LEGAL ANALYSIS

⁶Since, in the instant case, all of the Group Shareholders are surgeons, they must meet all of the requirements for surgeon-owned ASCs, 42 C.F.R. § 1001.952(r)(1), including the one-third practice income test.

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 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 harbors for investment interests in ambulatory surgical centers jointly owned by hospitals and physicians, 42 C.F.R. § 1001.952(r)(4), and for personal services and management contracts, 42 C.F.R. § 1001.952(d), are relevant to the Proposed Arrangement. Three of the conditions of the ASC safe harbor require that (i) a hospital investor must not be in a position to refer directly or indirectly to, or otherwise generate business for, the ASC or any investor; (ii) investing physicians who are in a position to refer patients to the ASC can only invest as individuals who meet the requirements for surgeon-owned ASCs, single-specialty ASCs, or multi-specialty ASCs set forth at 42 C.F.R. § 1001.952(r)(1), (r)(2), or (r)(3), as applicable, or as group practices composed solely of such physicians or surgical group practices; and (iii) any services, equipment, or

space provided by the hospital to the ASC (e.g., the ancillary agreements) must comply with a safe harbor. In cases where the ASC is located in space owned by a co-investing hospital, the space rental safe harbor, 42 C.F.R. § 1001.952(b), is also relevant. Both the space rental safe harbor and the personal services and management agreement safe harbor require, in part, that the term of the agreement must be for at least one year.

B. Analysis

Although joint ventures by physicians and hospitals are susceptible to fraud and abuse, the OIG recognizes that precluding joint ownership of ASCs may place hospitals at a competitive disadvantage by forcing them to compete with ASCs owned by physicians, who principally control referrals. Thus, the OIG promulgated a safe harbor for jointly owned ASCs that meet certain conditions. The Proposed Arrangement does not qualify for safe harbor protection. Therefore, we must carefully scrutinize the Proposed Arrangement in its entirety to determine whether, based upon a totality of the facts and circumstances presented, the potential risk of fraud and abuse is sufficiently low.

There are five elements of the Proposed Arrangement that make it particularly susceptible to fraud and abuse. First, the Hospital is in a position to make or influence referrals to the Group, its Group Shareholders, and the Surgical Center by using its control and influence over Hospital-Affiliated Physicians. However, the Hospital has certified that it will take the following steps to limit its ability to direct or influence referrals to the Surgical Center, the Group, or the Group Shareholders:

- The Hospital will refrain from taking any actions to require or encourage Hospital-Affiliated Physicians to refer patients to the Surgical Center, the Group, or the Group Shareholders.
- The Hospital will not track referrals made by Hospital-Affiliated Physicians to the Surgical Center, the Group, or the Group Shareholders.
- Compensation paid to Hospital-Affiliated Physicians, whether pursuant to employment or personal services contracts, will not be related directly or indirectly to the volume or value of referrals or other business generated by such physicians to or for the Surgical Center, the Group, or the Group Shareholders. Such compensation will be consistent with fair market value in arm's-length transactions.
- On an annual basis, the Hospital will inform Hospital-Affiliated Physicians of the foregoing measures.

In light of these safeguards, the Hospital's ability to direct or influence the referrals of its

Hospital-Affiliated Physicians will be significantly constrained.

Second, eight of the Group Shareholders do not meet the one-third practice income test in the ASC safe harbor. However, each of the eight non-qualifying Group Shareholders derives more than one-third of his or her practice income from procedures that either qualify as ASC surgical procedures under 42 C.F.R. § 1001.952(r)(5) or require a hospital operating room setting. Like the one-third practice income test, this fact helps ensure that these eight Group Shareholders are physicians who routinely perform interventional procedures requiring at least an ASC level of support and, consequently, are more likely to be users of the ASC rather than passive referral sources for others.

Third, instead of the investment interest being held directly by the Group or by the individual Group Shareholders, the Group Holding Company holds the investment interest in the ASC. 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 investments. However, in this case, the use of a “pass-through” entity does not substantially increase the risk of fraud or abuse. The Group Holding Company is a wholly-owned subsidiary of the Group, which, relying on the Requestors’ certifications, meets all of the requirements of the group practice safe harbor. Thus, the Group will receive a return on its Surgical Center investment that is exactly the same as it would have received if it had invested directly.

Fourth, the Facility Support Agreement and the Management Services Agreement comply with all terms of the personal services and management contracts safe harbors other than the minimum one-year term requirement. In particular, each agreement permits fee renegotiation and termination for cause without prohibiting renegotiation and further arrangements. Such provisions defeat the one-year term requirement. Notwithstanding, when viewed in light of the entirety of the Proposed Arrangement, the termination and fee renegotiation provisions appear to be strictly limited to certain commercially reasonable and well-defined contingencies unrelated to referrals. Moreover, the Requestors have certified that fee renegotiation will not occur more often than annually and that any renegotiated fees will be at fair market value and will not take into account, directly or indirectly, the value or volume of any past or future referrals or other business generated between the parties. Therefore, if fees are renegotiated more often than annually (or are based upon referrals or other business generated) or if either agreement is terminated for cause and the parties enter into a new agreement during the original one-year term, then this opinion is without force and effect.⁷

⁷Our position regarding the one-year term as stated in the preamble to the final safe harbor regulation at 64 Fed. Reg. 63,526 (Nov. 19, 1999) remains unchanged. Our conclusion with respect to the termination and fee renegotiation provisions of the Proposed Arrangement is based upon facts specific to the Proposed Arrangement and

Fifth, the Proposed Arrangement is contingent upon execution of the Noncompetition Agreement, which precludes the Surgical Center and its direct and indirect investors from taking certain specified actions. However, the restrictions in the Noncompetition Agreement appear to be narrowly tailored to achieve a legitimate business purpose. In particular, the Group Shareholders and the Hospital-Affiliated Physicians are free to use other ASCs or hospitals. In these particular circumstances, we do not believe that the Noncompetition Agreement is objectionable under the anti-kickback statute, although such agreements require close scrutiny and a full analysis of the facts and circumstances.⁸

For all of the foregoing reasons, we conclude that, while the Proposed Arrangement poses some risk, the safeguards put in place by the Requestors make that risk sufficiently low that we would not subject the Proposed Arrangement to administrative sanctions in connection with the anti-kickback statute.

should not be generalized to apply to similar provisions in other arrangements.

⁸We express no opinion about the enforceability of the Noncompetition Agreement.

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 if the requisite intent to induce or reward referrals were present, but that the OIG will not impose administrative sanctions on [Medical Center B], [Group C], [Group Holding Company D], or [Surgical Center A] 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 other agreements or any other arrangements disclosed or referenced in your request letter or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- C This advisory opinion is issued only to [Medical Center B], [Group C], [Group Holding Company D], and [Surgical Center A], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- C 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.
- C 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.
- C This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- C 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.
- C 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General