



[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: November 16, 2001

Posted: November 26, 2001

[names and addresses redacted]

Re: OIG Advisory Opinion Request No. 01-21

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 operating ambulatory surgical center ("ASC") that is currently owned by a group of gastroenterologists, together with the execution of a series of ancillary contracts related thereto, 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 A] of a fifteen percent (15%) equity interest in [Surgical Center C], pursuant to the Option Agreement; (ii) the Management Services Agreement; (iii) the Facility Support Agreement; and (iv) the Surgical Center Lease.

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”) would not impose administrative sanctions on [Medical Center A], [Group B], or [Surgical Center C] 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 A], [Group B], and [Surgical Center C] (the “Requestors”), and is further qualified as set out in Part V below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. The Surgical Center and Its Physician-Investors

[Surgical Center C] (the “Surgical Center”) is a [State X] limited liability company that operates a free-standing ambulatory surgery center. The Surgical Center is licensed by the State of [State X] and certified by Medicare under 42 C.F.R. Part 416. It has two operating rooms, which are used to perform endoscopic procedures, and four recovery beds. All ancillary services for Federal health care beneficiaries performed at the Surgical Center are directly and integrally related to primary procedures performed at the Surgical Center, and none are separately billed to Medicare or any other Federal health care program.

The Surgical Center is currently owned by fifteen physicians who are licenced to practice medicine in the State of [State X] and who practice medicine in the specialty of

gastroenterology (the “Physician-Investors”).¹ The Physician-Investors are also the sole shareholders of [*Group B*], a [State X] professional corporation (the “Group”).

The Surgical Center’s profits and losses are distributed in direct proportion to each Physician-Investor’s percentage of equity ownership in the Surgical Center. There are currently 8,070 issued and outstanding units of interest in the Surgical Center (the “Units”). Eight of the Physician-Investors own 1,000 Units each and each contributed a significant amount of cash for the Units.² The remaining seven Physician-Investors are employees of the Group and each owns ten Units. These employed Physician-Investors’ interests in the Surgical Center were purchased for a nominal amount in order for the Surgical Center to qualify for favorable regulatory treatment under [State X]’s certificate of need (“CON”) law.³ The Requestors have certified that any difference in the price paid (or, with respect to [Health System A], as hereinafter defined, to be paid) per Unit is a result of the timing of the purchases, reflects the appreciation in value of the Surgical Center’s ongoing ASC, and is not related directly or indirectly to referrals to the Surgical Center or the Physician-Investors or business otherwise generated by such physicians or [Health System A]. None of the capital contributed by any Physician-Investor (or to be contributed by [Health System A]) was (or, with respect to [Health System A], will be) obtained with funds loaned or guaranteed by the Surgical Center, any Physician-Investor, [Health System A], or any individual or entity acting on behalf of any of the foregoing.

Each Physician-Investor meets the “one-third practice income test” set forth at 42 C.F.R. § 1001.952(r)(2)(ii).⁴ Moreover, each Physician-Investor is an active member of the

¹The Physician-Investors are [fifteen names redacted].

²Six of the eight Physician-Investors founded the Surgical Center, contributed an equal amount of cash for their Units, and personally guaranteed their pro rata share of a substantial loan to the Surgical Center from a commercial bank (the “Loan”). The other two of the eight Physician-Investors became members of the Surgical Center after it became an established and functioning ASC and paid a different, higher price than the founders because of appreciation. The Requestors have certified that the higher capital contributions represented fair market value for the Units at the time of purchase.

³Since all of the shareholders of the Group (i.e., the Physician-Investors) have an ownership interest in the Surgical Center, the Surgical Center qualifies for the physicians’ office exemption from the [State X] CON laws and, therefore, no CON is required. [Citation to applicable State X statutes redacted.]

⁴Under the one-third practice income test, at least one-third of each physician investor’s medical practice income from all sources for the previous fiscal year or previous 12-

medical staff of a hospital owned and controlled by [Health System A] (as hereinafter defined).⁵

B. The Hospital Investor

[Holding Company A], a [State X] non-profit corporation (“[Holding Company A]”), is a holding company that operates several hospitals and related health care entities in the [City Y] area. [Holding Company A] also operates a managed care network that contracts with various managed care plans for the provision of health care services to its members and enrollees. One of [Holding Company A’s] wholly-owned subsidiaries is *[Medical Center A]* (the “Medical Center”), a non-profit, tax-exempt corporation, that is the sole member of:

- *[Main Hospital A]*, a non-profit, tax-exempt corporation, which owns and operates a general, acute care hospital (the Hospital”). The Hospital currently operates (and, after implementation of the Proposed Arrangement, will continue to operate) its own gastroenterology laboratory (the “Hospital GI Lab”) which provides endoscopy and related gastroenterological diagnostic treatment procedures for the Hospital’s inpatients and outpatients, as well as for non-Hospital patients that are referred to the Hospital GI Lab;⁶
- *[Foundation A]*, a non-profit corporation, which employs approximately fifty-five physicians (the “Foundation”); and
- *[Management Company A]*, a non-profit corporation, which provides management and support services for a network of physicians and other providers whose practices are focused at the Hospital.

month period must be derived from the physician’s performance of procedures. See 42 C.F.R. § 1001.952(r)(2)(ii). The term “procedures” is defined at 42 C.F.R. § 1001.952(r)(5).

⁵Three of the employed Physician-Investors are active members of the medical staff of [Health System A Other Hospital]. All of the other Physician-Investors are active members of the medical staff of [Main Hospital A].

⁶The Medical Center is also the sole owner of [Health System A Other Hospital], a general acute care hospital in [City Z], [State X].

For the purposes of our analysis in this advisory opinion, we will 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 “[Health System A].” Also, for purposes of this advisory opinion (i) physicians employed by [Health System A], including, without limitation, physicians employed by the Foundation, will be referred to collectively as “[Health System A-Employed Physicians],” and (ii) [Health System A]-Employed Physicians and physicians affiliated with [Health System A], including, without limitation, physicians on the Hospital’s medical staff, will be referred to collectively as “[Health System A] Physicians.”

C. The Proposed Arrangement

The Proposed Arrangement consists of a series of agreements pursuant to which (i) [Health System A] will exercise an option to purchase approximately fifteen percent of the Surgical Center’s Units, and (ii) the Surgical Center will purchase management services from the Group and facility support services from [Health System A]. In addition, the Surgical Center will lease space from [Health System A] for its ASC.

1. The Surgical Center Investment

[Health System A] and the Surgical Center have entered into the Option Agreement pursuant to which the Surgical Center has granted [Health System A] an option (the “Option”) to acquire a fifteen percent (15%) equity interest in the Surgical Center, in exchange for a lump sum cash payment of [amount redacted].⁷ The Requestors have certified that [Health System A’s] capital contribution is commensurate with fair market value. Profits and losses will continue to be distributed in direct proportion to each investor’s percentage of equity ownership in the Surgical Center.

The Surgical Center will continue to be operated as a free-standing ASC. The operating and recovery room space in the Surgical Center will be dedicated exclusively to the Surgical Center and will not be shared with the inpatient or outpatient services of the Hospital. The Hospital will not report any costs associated with the development or operation of the Surgical Center or any expenses incurred in providing services to the Surgical Center in any claim for payment submitted to a Federal health care program or on the Hospital’s Federal health care program cost reports (except to the extent, if any, that Federal programs require such costs to be reflected as non-reimbursable costs).

⁷Moreover, upon exercise of the Option, [Health System A] will guarantee its pro rata portion of the Loan.

The Surgical Center, [Health System A], and the Physician-Investors will treat patients receiving medical benefits or assistance under any Federal health care program, including Medicaid, in a non-discriminatory manner. The Physician-Investors will disclose to each patient referred to the Surgical Center the Physician-Investors' and [Health System A's] ownership interests in the Surgical Center both through a written disclosure to each such patient and through a notice posted in each Physician-Investor's office.

Finally, in order to limit its ability to control referrals to the Surgical Center and the Physician-Investors, [Health System A] has agreed to take the following measures:

- [Health System A]-Employed Physicians will not make referrals directly to the Surgical Center, although they may refer patients to the Physician-Investors.
- [Health System A] will not take any actions to require or encourage [Health System A] Physicians to refer patients to the Surgical Center or any of the Physician-Investors.
- [Health System A] will not track referrals made by [Health System A] Physicians to the Surgical Center or to the Physician-Investors.
- Compensation paid to [Health System A] Physicians by [Health System A], whether pursuant to employment or personal services contracts, will not be related directly or indirectly to the volume or value of (i) referrals by such physicians to the Surgical Center or the Physician-Investors or (ii) business otherwise generated by such physicians. Such compensation will be consistent with fair market value in arm's-length transactions.

On an annual basis, [Health System A] will inform [Health System A] Physicians of these measures.

2. Ancillary Agreements

In addition to the joint venture, the Surgical Center has entered into the Management Services Agreement and, upon exercise of the Option, will enter into two other ancillary agreements -- the Facility Support Agreement and the Surgical Center Lease. The Requestors have certified that the Management Services Agreement and the Facility Support Agreement comply 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, the Surgical Center Lease complies with all of the requirements of the space rental safe harbor, 42 C.F.R. § 1001.952(b), and payments under each of the ancillary

agreements are at fair market value. Set forth below is a brief description of each such agreement.

Management Services Agreement. The Group and the Surgical Center have entered into an agreement pursuant to which the Group furnishes certain clinical and administrative management services, along with billing and collection services, to the Surgical Center for a fixed annual fee, which is subject to renegotiation under certain conditions, but not more often than annually.⁸ The initial term of the agreement begins on the date that the agreement was executed and continues until the Option is exercised. Upon exercise of the Option, the term is automatically extended for five years. The agreement permits termination for cause at any time.

Facility Support Agreement. Upon exercise of the Option, the Surgical Center will enter into an agreement with [Health System A], pursuant to which [Health System A] will provide the following services to the Surgical Center: (1) assistance with the design and implementation of quality assurance and utilization management procedures; and (2) medical management reporting services, oxygen services, and an uninterrupted power supply. In return, the Surgical Center will pay [Health System A] 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 permits [Health System A] to terminate if it ceases to own any of the Surgical Center's Units.

Surgical Center Lease. Currently, the Group leases two suites from [Health System A] pursuant to a medical office lease. The Group uses one of the suites for its medical practice and, pursuant to a sublease agreement, subleases one of the suites to the Surgical Center for its ASC.⁹ Upon exercise of the Option, the parties will terminate the medical office lease and the sublease agreement and [Health System A] and the Surgical Center will enter into a new five-year lease, the Surgical Center Lease, for the suite used for the

⁸As described below, the Facility Support Agreement contains a similar fee renegotiation provision. 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 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, and renegotiation will occur not more often than annually.

⁹The rental rate set forth in the sublease agreement is the same rate that the Group pays [Health System A] under the medical office lease.

Surgical Center.¹⁰ The rental rate set forth in the Surgical Center Lease is the same rate that [Health System A] currently charges the Group under the medical office lease.

II. THE 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 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 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, 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 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

¹⁰In addition, [Health System A] and the Group will enter into a new, five-year medical office lease for the suite used for the Group's clinical practice.

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) 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, 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. Therefore, in cases, such as the instant case, where the ASC is located in space owned by the 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.

III. ANALYSIS

The Proposed Arrangement does not qualify for safe harbor protection because the ASC hospital-physician joint venture and two of the ancillary agreements fail to fit in the relevant safe harbors discussed above. Therefore, we must carefully scrutinize the Proposed Arrangement in its entirety to determine whether, based upon a totality of the facts and circumstances presented, it poses a potential risk of fraud and abuse.

In the instant case, there are three elements of the Proposed Arrangement that might potentially make it particularly susceptible to fraud and abuse. First, the price per Unit has varied for different investors; while the six founding Physician-Investors contributed identical amounts of capital and received identical equity interests, subsequent investors have paid different amounts for their Units. Thus, while Surgical Center profits and losses are distributed based on each investor's equity ownership, distributions are not directly proportional to each investor's capital investment, as required by the ASC safe harbor. Nonetheless, there is a reasonable basis for the different prices that is not related to the value or volume of referrals or other business generated between the parties. With respect to the seven employed Physician-Investors, they were sold a token number of Surgical Center Units for a nominal amount in order for the Surgical Center to qualify for favorable regulatory treatment under [State X]'s CON law. With respect to the two other Physician-Investors and [Health System A], the Requestors have certified that any difference in the price paid (or, with respect to [Health System A], to be paid) per Unit is a result of the timing of the purchases, reflects the appreciation in value of the Surgical Center's ongoing ASC, and is not related directly or indirectly to referrals to the Surgical Center or the Physician-Investors or business otherwise generated by such physicians or [Health System A]. For all of the foregoing reasons, we believe that, in the instant case, the fact that the profit and losses are distributed in direct proportion to each investor's percentage of equity ownership in the Surgical Center does not increase the risk of fraud and abuse.

Second, [Health System A] is in a position to make or influence referrals to the Physician-Investors and the Surgical Center. Unlike the situation presented when a hospital and related physicians develop an ASC together, in which we are particularly concerned with the hospital offering the physicians favorable investment terms to induce referrals either to the ASC or the hospital, here we are faced with the opposite situation: namely, whether the physicians could be offering the hospital favorable investment terms (or the investment interest itself) to induce referrals to the ASC or the physicians. Specifically, we are concerned that [Health System A] may potentially direct or influence referrals to the Surgical Center or the Physician-Investors by using its control and influence over [Health System A] Physicians. However, [Health System A] has agreed to take the following measures:

- [Health System A] will not take any actions to require or encourage [Health System A] Physicians to refer patients to the Surgical Center or any of the Physician-Investors.
- [Health System A] will not track referrals made by [Health System A] Physicians to the Surgical Center or to the Physician-Investors.
- Compensation paid to [Health System A] Physicians by [Health System A], whether pursuant to employment or personal services contracts, will not be related directly or indirectly to the volume or value of (i) referrals by such physicians to the Surgical Center or the Physician-Investors or (ii) business otherwise generated by such physicians. Such compensation will be consistent with fair market value in arm's-length transactions.

On an annual basis, [Health System A] will inform [Health System A] Physicians of these measures. In light of these safeguards, the ability of [Health System A] to direct or influence the referrals of its [Health System A] Physicians will be significantly constrained.

Third, two of the ancillary agreements do not preclude termination prior to the initial one year term. 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. The one year term requirement ensures that the agreements cannot be readily renegotiated or terminated based upon the number of referrals or other business generated between the parties. In the preamble to the final safe harbor regulation set forth at 64 Fed. Reg. 63526 (Nov. 19, 1999) we stated that:

a “for cause” termination that (i) specifies the conditions under which the contract may be terminated “for cause,” and (ii) operates in conjunction with an absolute

prohibition on any renegotiation of the lease or contract or further financial arrangements between the parties for the duration of the original 1-year term would satisfy the 1-year term requirement.

Since the Management Services Agreement and the Facility Support Agreement permit termination for cause without prohibiting renegotiation and further arrangements, safe harbor protection is not available. Notwithstanding, when viewed in light of the Proposed Arrangement in its entirety, 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, in the event the fees are renegotiated prior to the expiration of a year, (i) the 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, and (ii) renegotiation will occur not more often than annually.¹¹ Therefore, if renegotiated fees are based upon referrals or other business generated, this opinion is without force and effect.

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 law.

IV. CONCLUSION

For all of the above reasons, and 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 would not impose administrative sanctions on [Health System A] Medical Center, Inc., [Group B], or [Surgical Center C] 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.

¹¹We caution, however, that our position regarding the 1-year term as stated in the preamble to the final safe harbor regulation 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 cannot be generalized to apply to similar provisions in other arrangements.

V. LIMITATIONS

The limitations applicable to this opinion include the following:

- C This advisory opinion is issued only to [Medical Center A], [Group B], and [Surgical Center C], who are the requestors of this opinion. This advisory opinion has no application, 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 to this opinion.
- C 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.
- 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, 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/

D. McCarty Thornton
Chief Counsel to the Inspector General