

[Posted September 23, 1998]

[Issued September 16, 1998]

To: The Attached Distribution List [redacted]

Re: Advisory Opinion 98-12

Gentlemen:

We are writing in response to your request for an advisory opinion regarding whether a proposed joint venture among several orthopedic surgeons and anesthesiologists specializing in pain management to establish an ambulatory surgical center, as described in your request letter and supplemental submissions (the "Proposed Arrangement"), would generate prohibited remuneration within the meaning of the anti-kickback statute pursuant to section 1128B(b) of the Social Security Act.

Dr. A, Dr. B, Dr. C, Dr. D, and Dr. E (collectively, the "Requestors") have certified that all of the information provided in the request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties. The Requestors have also certified that, upon our approval, they will undertake to effectuate the Proposed Arrangement.

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, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce referrals were present, but that the OIG will not subject the Proposed Arrangement, as described in the request letter and supplemental submissions, to sanctions arising under the anti-kickback statute.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

The requesting physicians, Drs. A, B, C, D, and E (the "Physician-Investors"), propose establishing an ambulatory surgical center (the "ASC") designed primarily for the treatment of musculoskeletal conditions resulting from work and sports-related injuries. Two of the Physician-Investors are anesthesiologists specializing in pain management;⁽¹⁾ three are orthopedic surgeons specializing in work and/or sports-related injuries.

The ASC will be formed either as a State M corporation or a State M limited liability company. The Physician-Investors have represented that the ASC will be a certified ambulatory surgical center under 42 C.F.R. Part 416. The ASC will consist of two operating rooms and will offer a full range of state-of-the-art surgical equipment, including arthroscopy units, carbon-fiber tables, a fluoroscope, orthopedic surgical instrumentation, and other mechanical and implantable devices used in arthroscopic and pain management procedures. The ASC will employ a facility administrator to manage and administer services for the ASC, as well as nurses, surgical technicians, janitorial staff, and other administrative personnel.

The Physician-Investors will be the shareholders of the corporation, or the owner-members of the limited liability company, and will make substantial capital contributions to the ASC. The total capital contribution to establish the ASC will be approximately \$X. The capital contributions will vary, but each Physician-Investor will contribute at least \$Y. The Physician-Investors have certified that the amount of their capital contributions will not be based on any expected volume of referrals to the other Physician-Investors. The Physician-Investors will receive voting and distribution rights proportional to their investments. In addition to their capital contributions, the Physician-Investors will personally guarantee payment under the lease for the ASC's premises.

The Physician-Investors expect to utilize the ASC as their preferred ambulatory surgical center for procedures for which it is appropriately equipped. The Physician-Investors have represented that each Physician-Investor will perform the majority of his ambulatory surgical center procedures at the ASC. For purposes of this opinion, ambulatory surgical center procedures are Medicare-covered surgical and other medical procedures included on the applicable list of ambulatory surgical center covered procedures published by the Health Care Financing Administration (HCFA) in the Federal Register ("ASC Procedures"). See 42 C.F.R. § 416.65(c).⁽²⁾ ASC Procedures currently include certain pain management procedures performed by the Physician-Investors who are anesthesiologists.⁽³⁾ Although the ASC will be available for use by non-investor physicians, the Physician-Investors will be given priority scheduling and have represented that they will perform over 80% of the total procedures performed at the ASC. All ancillary services performed at or by the ASC will be integrally related to the primary procedure a Physician-Investor is performing at the ASC. The Physician-Investors have certified that Medicare reimbursement will account for approximately five percent of the ASC annual revenue.

The practice of procedures in ambulatory surgical centers is an integral and major part of each Physician-Investor's medical practice. For the period from January 1, 1998, through May 31, 1998, at least 40% of each Physician-Investor's total medical practice income was generated from performing ASC Procedures. The Physician-Investors anticipate continuing to derive this percentage of medical practice income from such procedures.⁽⁴⁾

Each of the Physician-Investors will directly bill his patients and related third-party payers, including Medicare and Medicaid, for the professional component of the ASC Procedures he performs. The ASC will separately bill the facility fee and any technical component to such patients and third-party payers. The Physician-Investors will provide their patients with a written disclosure of their ownership in the ASC, explaining that they are referring patients to the ASC.

II. LEGAL ANALYSIS

A. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit or receive any remuneration to induce referrals of items or services reimbursable by the Federal health care programs. 42 U.S.C. § 1320a-7b(b). Where remuneration is paid purposefully to induce referrals of items or services paid for by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is 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, 476 U.S. 988 (1985). Violations of the statute constitute 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. This Office may also initiate administrative proceedings to exclude persons from the Federal and State health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(5) of the Act.⁽⁵⁾

B. Joint Ventures

This Office has long been concerned with the risk of abuse posed by health care joint ventures in which investors are also sources of referrals or suppliers of items or services to the joint venture. In 1989, the Office of Inspector General issued a "Special Fraud Alert" specifically addressing joint venture arrangements.⁽⁶⁾ The Special Fraud Alert distinguishes between those joint ventures that are clearly legitimate and those that are suspect under the anti-kickback statute. A joint venture may be suspect when physicians are both investors in the joint venture and

are in a position to refer to the joint venture. Under these circumstances, remuneration paid to the physicians in exchange for referrals may be disguised as profit distributions. Such suspect joint ventures:

... may be intended not so much to raise investment capital legitimately to start a business, but to lock up a stream of referrals from the physician investors and to compensate them indirectly for these referrals. Because physician investors can benefit financially from their referrals, unnecessary procedures and tests may be ordered or performed, resulting in unnecessary program expenditures.

59 Fed. Reg. 65373-74 (Dec. 19, 1994). Substantial ownership by investors who are in a position to refer patients to the joint venture ("Interested Investors") is an indicator of a suspect joint venture because such ownership increases the likelihood that the joint venture's primary purpose is to control a stream of referrals. See 56 Fed. Reg. 35969 (July 29, 1991). Other factors that could indicate potentially unlawful activity include the Interested Investors' receiving a disproportionate return on their investments, and the joint venture being structured as a "shell" for use by on-going entities already engaged in a particular line of business.

Nevertheless, we recognize that some joint venture arrangements do not pose a risk of fraud and abuse under the anti-kickback statute. We have promulgated two safe harbors that describe joint ventures involving Interested Investors that do not violate the statute: the investment interests in large publicly traded entities safe harbor and the investment interests in small entities safe harbor. 42 C.F.R. § 1001.952(a)(1) & (2). An important common element in both safe harbors is evidence of a significant business operation independent of any "tainted referrals". The requirements of the safe harbor for investments in large publicly traded entities ensure that referring investors will own such a small share of the total stock issuance that the return on investment is, at most, tangentially related to any referrals. See 54 Fed. Reg. 3090 (Jan. 23, 1989). Similarly, the small entities safe harbor places substantial limitations both on the amount of investment in the business by referring investors and on the amount of business revenue generated by any "tainted" referrals.

In sum, the current safe harbors protect against possible illegal remuneration by ensuring that Interested Investors are not in a position to dominate the joint venture's business, thereby increasing the likelihood that the joint venture has an independent and legitimate business purpose, and that any return on investment derives predominantly from such business.

C. The Proposed Arrangement

The Proposed Arrangement is the antithesis of the small entity investment safe harbor business structure. All of the investors will be referral sources to the ASC, and virtually all such business of the ASC will be from investor referrals. Nevertheless, for the reasons and in the circumstances set out below, we conclude that although the Proposed Arrangement may potentially violate the anti-kickback statute, we would not impose sanctions.

At the outset, we note that the Health Care Financing Administration promotes ambulatory surgical centers as a cost-effective alternative to higher cost settings, such as hospital inpatient surgery facilities. Many patients prefer treatment in less intensive settings, such as ambulatory surgical centers. Thus, ambulatory surgical centers benefit both the Medicare program and its beneficiaries.

This Office has proposed a safe harbor to protect surgeons who, as an extension of their personal office practice, routinely perform procedures in ambulatory surgical centers in which they have investment interests. See 58 Fed. Reg. 49013 (Sept. 21, 1993). There are obvious and legitimate business and professional reasons for surgeons to want to own an ambulatory surgical center in which they will personally perform services on a routine basis. These reasons include personal and patient convenience, professional autonomy, accountability, and quality control. Moreover, any risk of overutilization or unnecessary surgery is already present by reason of the opportunity for a surgeon to generate his professional fee; the additional financial return from the ambulatory surgical center investment is not likely to increase the risk of overutilization substantially.

Notwithstanding, this Office is concerned about the potential for investments in ambulatory surgical centers to serve as vehicles to reward referring physicians indirectly. For example, a primary care physician, who performs little or no services in an ambulatory surgical center in which he has an ownership interest, may refer to surgeons

utilizing the ambulatory surgical center, thereby receiving indirect remuneration for the referral through the ambulatory surgical center's profit distribution. Similarly, an investment by orthopedic surgeons in an ambulatory surgical center that is not equipped for orthopedic surgical procedures, or that is exclusively used by anesthesiologists performing pain management procedures on patients referred by the orthopedic surgeons, would be suspect.

The situation presented here is very different. First, all Physician-Investors will be making substantial financial investments in the ASC and incurring financial exposure for the ASC's lease. Second, although not all Physician-Investors are surgeons, each Physician-Investor has certified that he currently derives, and anticipates continuing to derive, at least 40% of his aggregate medical practice income from ASC Procedures. In addition, each Physician-Investor has certified that he will perform the majority of his ASC Procedures in the ASC. Third, given that the revenue from procedures on Medicare beneficiaries is estimated to be only 5% of the ASC's total revenues, any income from procedures performed on referred Medicare patients will be insubstantial compared to the income from procedures performed on the Physician-Investors' own patients. Fourth, any return on investment to the Physician-Investors will be proportional to their capital investments, and not based on referrals. In these circumstances, the Proposed Arrangement is substantively equivalent to an "all surgeon" ambulatory surgical center and presents a minimal risk that the return on investment would be a disguised payment for referrals.

Finally, the Physician-Investors will provide their patients with a written disclosure of their ownership in the ASC, explaining that they are referring patients to the ASC. This written disclosure is required by State M law. [State M Statutory Compilation.] While we do not believe that disclosure to patients offers sufficient protection from program abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.

III. Conclusion

Based on the facts certified in the Physician-Investors' request for an advisory opinion and supplemental submissions, we conclude that while the Proposed Arrangement might technically violate the anti-kickback statute if the requisite intent to induce referrals were present, the OIG will not impose sanctions on the Physician-Investors under sections 1128(b)(7) (as it relates to kickbacks) or 1128A(a)(7) of the Act.

IV. Limitations

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Dr. A, Dr. B, Dr. C, Dr. D, and Dr. E, who are the Requesters of this opinion. This advisory opinion has no application, 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 to this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is herein expressed or implied with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement.
- 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.

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 Physician-Investors 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 Physician-Investors 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

1. The anesthesiologists will exclusively practice pain medicine at the ASC, except in emergency circumstances. Pain medicine involves treating those patients who suffer from disorders that result in pain emanating from a discrete cause, e.g., postoperative pain or pain associated with malignancy, or from a syndrome in which pain constitutes the primary problem, e.g., neuropathic pains or headaches. Treatments include central and peripheral neural blockade and monitored drug infusions. See Definition of "Pain Medicine" adopted by the Board of Directors of the American Academy of Pain Medicine (October 1997).
2. Section 416.65 establishes standards that surgical and other medical procedures must meet to be included on the HCFA list of procedures eligible for facility fee reimbursement when performed in an ambulatory surgical center. Eligible procedures include procedures that are commonly performed on an inpatient basis in hospitals, but that may be safely performed in ambulatory surgical centers; they do not include procedures that are not of a type commonly performed, or that may be safely performed, in physicians' offices. Additional standards address post-operative recovery, operating and recovery room space, the duration of procedures, and the use of anesthesia.
3. HCFA has proposed altering its list of ASC Procedures, eliminating Medicare ambulatory surgical center facility fee reimbursement for many, if not most, of the pain management procedures currently performed by the Physician-Investors. See Update of Ratesetting Methodology, Payment Rates, Payment Policies, and the List of Covered Surgical Procedures for Ambulatory Surgical Centers Effective October 1, 1998, 63 Fed. Reg. 32290 (1998) (to be codified at 42 C.F.R. Pts. 416, 488) (proposed June 12, 1998).
4. If the percentage of each Physician-Investor's total medical practice income generated from performing ASC Procedures drops below 33.3% for any reason, including publication of a new HCFA list of ASC Procedures, then this advisory opinion will be without force and effect.
5. Because both the criminal and administrative sanctions related to the Proposed Arrangement are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same for both.
6. ⁶See Special Fraud Alert, "Joint Venture Arrangements" (OIG-89-4), reprinted in 59 Fed. Reg. 65373 (December 19, 1994).