



[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: June 16, 2003

Posted: June 23, 2003

[name and address redacted]

Re: OIG Advisory Opinion Request No. 03-13

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding joint venture ownership of a freestanding magnetic resonance imaging center located on the campus of a rural community hospital (the "Arrangement"). You have asked whether the Arrangement would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the "Act") or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act.

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 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 [name redacted] 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 past and present investment interests relating to the Arrangement. We express no opinion about any future changes in investment interests relating to the Arrangement or about any other agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part V below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] (the “Requestor”) is a limited partnership that has owned and operated a freestanding center for magnetic resonance imaging services (the “MRI Center”) in a three-county rural area since 1990. The three-county area is a federally designated rural area, but is not a medically underserved area (“MUA”) under the regulations at 42 C.F.R. Part 51c. More than 85% of the MRI Center’s patients are residents of the three-county area. The MRI Center was established at a time when no MRI services were available in the three-county area.¹

To raise capital for the MRI Center, all members of the medical community in the three-county area, regardless of hospital affiliation, as well as all former members of the boards of directors of the three area hospitals, were offered limited partnership interests in the Requestor. All potential investors were offered the opportunity to purchase the partnership interests for \$[x] per unit on the same terms and conditions of ownership, regardless of their ability to refer patients to, or otherwise generate business for, the MRI Center. Under the terms of the partnership, returns on investments are, have been, and will continue to be directly proportional to the investors’ capital contributions.

¹Although other MRI service providers now exist in the area, the nearest MRI facility comparable to the MRI Center is twenty miles away from the town in which the MRI Center is located. The Requestor has certified that termination of the MRI Center’s services would create a hardship for many of the area’s poor and elderly residents, who would have to travel a significant distance to obtain comparable MRI services.

A large number of individuals and entities purchased units in the MRI Center.² [Name redacted] (the “Hospital”), a local nonprofit hospital, and its supporting foundation, [name redacted] (the “Foundation”), a tax-exempt organization, together own approximately 30% of the partnership units. The Foundation is the venture’s managing partner. Various parties in a position to influence or generate referrals, or provide items or services, to the MRI Center also own approximately 30% of the units. The remaining units (approximately 40% of the total) are owned by various community members or physicians who are not in a position to influence or generate referrals to the MRI Center, because they either have retired or practice in the area of radiology. The percentage of interests owned by non-referring investors has increased over time.

Investors generated approximately 37% of the MRI Center’s revenues in 2000 and 2001; approximately 24% of total revenues were generated by the Hospital, which contracts with the MRI Center for MRI services, while approximately 13% of total revenues were generated by investing physicians. The MRI Center’s remaining revenues (over 60% of the total) were generated from referrals by disinterested parties. The Requestor does not provide information on the sources of its referrals to any of its investors (other than aggregate numbers of referrals from interested and disinterested investors).

The MRI Center is located on the campus of the Hospital pursuant to a space lease (the “Space Lease”). The Requestor has certified that the Space Lease meets all of the conditions of the space rental safe harbor at 42 C.F.R. § 1001.952(b). The MRI Center is managed pursuant to a written contract (the “Management Agreement”) with [name redacted] (the “Management Company”), a radiology group practice that provides radiology services to, and clinical operation of, the MRI Center. Neither the Management Company, nor any of its physician members, is an investor in the MRI Center, and neither the Hospital, nor the Foundation, has any direct or indirect ownership interest in the Management Company. The Requestor has certified that the Management Agreement meets all of the conditions of the personal services and management contracts safe harbor at 42 C.F.R. § 1001.952(d).

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

²A complete list of current investors is attached to this opinion as Appendix A.

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 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 harbors for investments in small entities and rural area ventures, 42 C.F.R. § 1001.952(a)(2) and (3), respectively, are potentially applicable to the Arrangement.

III. ANALYSIS

This Office has long expressed concern about health care joint ventures in which investors are sources of referrals for, or suppliers of items or services to, the joint venture or other co-investors. Distributions from the joint venture may be disguised remuneration paid in return for referrals. Like any kickback scheme, such arrangements can lead to overutilization of services, increased costs for federal health care programs, corruption of professional judgment, and unfair competition.

Notwithstanding our concerns about joint ventures, the OIG has established several “safe harbors” applicable to joint ventures, two of which are potentially relevant to the Arrangement. The first, a safe harbor for small entity investments at 42 C.F.R. §

1001.952(a)(2), protects certain investments so long as interested investors³ own no more than 40% of the ownership interests in the entity and generate no more than 40% of the entity's revenues. In other words, the safe harbor looks to indicia that the joint venture represents something substantially more than an appendage of its referring investors. In addition, in recognition of the practical difficulties in raising capital for health care ventures in rural areas, the OIG has established a safe harbor at 42 C.F.R.

§ 1001.952(a)(3) that protects investments in medically underserved areas ("MUAs"), if interested investors own no more than 50% of the entity, even if all revenues are generated by interested investors.

In this opinion, we consider a rural joint venture that, while deriving less than 40% of its revenues from investors, cannot fit in the small entity safe harbor because interested investors own approximately 60% of the venture, and, while located in a clearly rural area and primarily serving rural patients, cannot fit in the rural entity safe harbor because it is not located in a MUA and has more than 50% interested investors.

Notwithstanding, based on a totality of the facts and circumstances presented, we conclude that, while the Arrangement poses some risk, the combination of factors described below sufficiently vitiates the potential for fraud and abuse under the anti-kickback statute.

First, the Arrangement possesses indicia of a legitimate, bona fide business. All potential investors, both physicians and non-physicians, were offered the opportunity to purchase investment interests on the same terms and conditions. Returns on the investment interests are, have been, and will continue to be proportional to the investors' capital contributions. Most importantly, less than 40% of revenue of the MRI Center is derived from business generated by interested investors. While not determinative, these revenue characteristics, in conjunction with the substantial participation of non-business-generating investors, provide strong evidence that the MRI Center is a legitimate, bona fide business venture.

³For purposes of the ownership test under the safe harbor, interested investors include parties in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. See 42 C.F.R. § 1001.952(a)(2)(i). Under the safe harbor's tainted revenues test, revenues derived from items or services furnished by investors would not be included. See 42 C.F.R. § 1001.952(a)(2)(vi); see also 64 Fed. Reg. 63518, 63521 (Nov. 19, 1999).

Second, the structure of the Arrangement comports with then-extant guidance related to the application of the anti-kickback statute to rural joint ventures. In particular, the joint venture's structure has none of the suspect characteristics identified in the OIG's 1989 Special Fraud Alert on Joint Ventures, such as nominal capital contributions, disproportionate return on investment, or selective investment opportunities based on referral volumes. See Special Fraud Alert, "Joint Venture Arrangements" (OIG-89-4), reprinted in 59 Fed. Reg. 65372 (Dec. 19, 1994). In addition, while not determinative, the fact that the Arrangement would have complied with the 1993 proposed safe harbor for rural entities (58 Fed. Reg. 49008 (Sept. 21, 1993)) – although not with the final safe harbor issued in 1999 – bears on the issue of the Arrangement's potential risk.

Third, the Arrangement was developed as a community-oriented effort to provide access to MRI services in the rural three-county area and has provided a substantial community benefit. The MRI Center continues to serve a large majority of rural patients, many of whom are elderly or indigent patients for whom travel to a distant MRI facility would be a hardship.

Fourth, the Requestor has certified that the Management Agreement and Space Lease comply with the relevant safe harbors.

Based on the totality of the facts and circumstances presented, we conclude that, while the Arrangement poses some risk, a combination of factors exists that renders that risk sufficiently low. Therefore, we would not subject the Requestor to administrative sanctions arising under the anti-kickback law in connection with the past and present investment interests under the Arrangement.

IV. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the 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 [name redacted] 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 past and present investment interests relating to the Arrangement. This opinion is limited to the past and present investment interests relating to the Arrangement. We express no opinion about any future changes in investment interests relating to the

Arrangement or about any other agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

V. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor 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 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 [name redacted] 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, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [name redacted] 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