DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of Inspector General
Washington, D.C. 20201

[*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: May 22, 2003

Posted: May 29, 2003

[names and addresses redacted]

Re: OIG Advisory Opinion No. 03-12

Dear Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposed joint venture between a medical center and a radiology group to own and operate an outpatient open magnetic resonance imaging facility (the "Facility") and several related ancillary agreements (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed 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.

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 ownership interests of the Medical Center and the Radiology Group, both as hereinafter defined, in the Facility; (ii) a professional services agreement under which the Radiology Group will provide professional radiology services at the Facility; (iii) a staffing agreement under which the Medical Center will provide three of its employees to the Facility; (iv) an equipment sublease under which the Radiology Group will sublease equipment to the Facility; and (v) an assignment under which the Radiology Group will assign its space lease to the Facility.

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 of federal health care program business were present, but that the Office of Inspector General ("OIG") would not impose administrative sanctions on [Entity A] or [Entity B] 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 ancillary 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 [Entity A] and [Entity B], the requestors of this opinion (the "Requestors"), and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

1. FACTUAL BACKGROUND

Under the Proposed Arrangement, the Medical Center and the Radiology Group will form a joint venture to own and operate the Facility.

A. The Parties.

[Entity A] (the "Medical Center"), an acute care hospital, is a wholly-owned subsidiary of [Entity C], a health care system that also includes five provider-based clinics.[1] The Medical Center has a number of affiliations with referring physicians as employees, independent contractors, and medical staff members (collectively, the "Affiliated

[1]For purposes of this advisory opinion, we consider the Medical Center, [Entity C], 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 "Medical Center."

Physicians"), including ten employed physicians who provide primary care services at its clinics. The Medical Center currently owns and operates (and, after implementation of the Proposed Arrangement, will continue to own and operate) a radiology department, which provides inpatient and outpatient radiology services.

Six radiologists (the "Investing Radiologists") are the sole shareholders of [Entity D], a professional association that meets all of the requirements of the group practice safe harbor, 42 C.F.R. § 1001.952(p). The Investing Radiologists formed a holding company, [Entity B], for the sole purpose of investing in the Facility. Each Investing Radiologist contributed equally to, and owns an equal share in, the holding company. For purposes of this advisory opinion, we consider [Entity B] and [Entity D] to be sufficiently related to be treated as a single entity, which will be referred to individually and collectively as the "Radiology Group."

The Radiology Group is the exclusive provider of professional radiology services for the Medical Center. For services provided to the Medical Center's clinic patients, the Medical Center pays the Radiology Group a set fee per radiological read and report and bills patients and their third party payors for both the technical and professional components. For services provided to the Medical Center's inpatients and outpatients (excluding clinic patients), the Radiology Group bills patients and their third party payors directly for the professional component. The Requestors have certified that the compensation that the Radiology Group receives from the Medical Center for its services represents fair market value in arms'-length transactions.

B. The Proposed Arrangement.

The Medical Center and the Radiology Group will own 51% and 49% of the Facility, respectively, based on their capital contributions. The Facility's profits and losses, if any, will be distributed to each investor in direct proportion to the amount of capital invested by that investor. The terms upon which the investment interests in the Facility were offered to the investors were not related to the previous or expected volume of referrals, services furnished, or the amount of business that might otherwise be generated from the investor to the Facility. None of the capital contributed by the Medical Center or the Radiology Group was, or will be, obtained with funds loaned or guaranteed by the Facility, any direct or indirect investor, or any individual or entity acting on behalf of the Facility or any direct or indirect investor.

The Facility will be the only open magnetic resonance imaging ("MRI") facility within the Medical Center's three-county service area. Patients referred to the Facility by the Medical Center or by physicians employed by the Medical Center will be fully informed

in writing of the Medical Center's investment interest both through a written disclosure to each such patient and through a notice posted in the office of each employed physician. The Facility, the Medical Center, the Radiology Group, and the Investing Radiologists will treat patients receiving medical benefits or assistance under any federal health care program in a nondiscriminatory manner. The Medical Center has certified that it will not include on its cost report or any claim for payment from a federal health care program any costs associated with the Facility, unless such costs are required to be included by a federal health care program.

According to the Medical Center, less than 10% of the Facility's referrals will come from the Medical Center or physicians employed by the Medical Center. In order to limit its ability to control referrals to the Facility, the Medical Center has certified that:

- The Medical Center will refrain from taking any action to require or encourage Affiliated Physicians to refer patients to the Facility.

- The Medical Center will not track referrals made by Affiliated Physicians to the Facility.

- Compensation paid to 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 Facility. Such compensation will be consistent with fair market value in arms'-length transactions.

On an annual basis, the Medical Center will notify all Affiliated Physicians of the foregoing three measures.

The Facility will enter into four written ancillary agreements. There will be two services agreements: (i) a professional services agreement, pursuant to which the Radiology Group will be the exclusive provider of professional radiology services at the Facility and bill patients and their third party payors directly for the professional component, as payment in full for its services; and (ii) a staffing agreement, pursuant to which the Medical Center will provide to the Facility one clerical staff person and one technician to operate the Facility on a full-time basis and one administrator on a part-time basis not to exceed twenty hours per month, in exchange for a monthly payment equal to the Medical Center's payroll expenses for the leased employees, prorated accordingly for the part-time

employee.[2] There will be two pass-through agreements: (i) an equipment sublease, pursuant to which the Radiology Group will sublease to the Facility certain equipment, including the open MRI equipment; and (ii) an assignment, pursuant to which the Radiology Group will assign to the Facility the lease for the space where the Facility will be located. The Radiology Group leases the equipment and space from different, unrelated third parties. The Requestors have certified that the effect of the sublease and the assignment will be to subject the Facility to all material terms and conditions of the underlying leases and that payments under all four ancillary agreements will be consistent with fair market value in arms'-length transactions.[3]

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services payable 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 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, 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

---

[2]We express no opinion regarding payments made or received under the staffing agreement for the part-time administrator.

[3]The Requestors have also certified that the underlying space lease and the equipment sublease will meet all of the requirements of the applicable safe harbors (42 C.F.R. §§ 1001.952(b), (c)), except for the minimum one-year term requirement. If any ancillary agreement is terminated prior to the initial one-year term and, during that time period, the parties either renegotiate the agreement or enter into further financial arrangements, this opinion is without force and effect.

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.

Because the Proposed Arrangement involves ownership of a non-public entity by interested investors, the small entity investment safe harbor, 42 C.F.R. § 1001.952(a)(2), is potentially applicable. This safe harbor has eight elements, each of which must be satisfied in order for an arrangement to qualify for the exception. Of particular relevance here is one of the safe harbor's two "60-40" tests (the "investor test"), which requires that at least 60% of an entity's investment interests be held by persons that are not in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity ("disinterested investors"). See 42 C.F.R. § 1001.952(a)(2)(i).

B. Analysis.

The Proposed Arrangement will not fit into the small entity investment safe harbor. In particular, the investor test will not be met. The Medical Center will be in a position to influence referrals to the Facility and both investors will furnish services to the Facility. Therefore, the Facility will have no disinterested investors, and the Proposed Arrangement will not qualify for safe harbor protection. Consequently, 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 acceptably low.

A number of factors under the Proposed Arrangement mitigate the risk of fraud or abuse or otherwise merit consideration. First, unlike most hospital-physician joint ventures, the physician investors (i.e., the Investing Radiologists) are not referral sources for the Facility or the Medical Center. In general, radiologists do not order the radiological tests they perform; instead, such tests are ordered by a patient's treating physician. Although

there may be situations in which a radiologist can recommend additional testing during the course of a consultation and, as a practical matter, indirectly generate some additional business, those tests must be approved by the patient's treating physician, except in very limited, well-defined circumstances.[4]

Second, according to the Medical Center's certification, only a small percentage of the Facility's referrals (i.e., less than 10%) will come from the Medical Center or physicians employed by the Medical Center. Additionally, the Medical Center will continue to own and operate its own radiology department.

Third, although the Medical Center is in a position to direct or influence referrals to the Facility directly and by using its control and influence over its Affiliated Physicians, the Medical Center has certified that it will take the following steps to limit its ability to direct or influence such referrals:

- The Medical Center will refrain from taking any action to require or encourage Affiliated Physicians to refer patients to the Facility.

- The Medical Center will not track referrals made by Affiliated Physicians to the Facility.

- Compensation paid to 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 Facility. Such compensation will be consistent with fair market value in arms'-length transactions.

On an annual basis, the Medical Center will notify all Affiliated Physicians of the foregoing three measures.

Fourth, any return on the Medical Center's or the Radiology Group's investment in the Facility will be proportional to its respective capital investments and will not be based on the previous or expected volume of referrals, services furnished, or the amount of business that might otherwise be generated from either investor to the Facility.

Fifth, the four ancillary agreements do not appreciably increase the risk of fraud and abuse. Under the professional services agreement between the Facility and the Radiology

---

[4]See the Centers for Medicare & Medicaid Services' Carriers Manual (Pub. 14), Part 3, section 15021.D.

Group, the Radiology Group will be the exclusive provider of professional radiology services at the Facility and will accept, as payment in full for such services, reimbursement from patients and their third party payors. No payments will flow from the Facility to the Radiology Group or the Investing Radiologists for such services. The staffing agreement, equipment sublease, and assignment of the space lease will be, in effect, pass-through agreements, because the payments that the Facility will be required to make under each agreement will be equal to the expenses incurred (i.e., with respect to the equipment sublease and the space lease assignment, the Radiology Group's expenses under the underlying leases and, with respect to the leased employees, the Medical Center's payroll expenses for the leased employees, prorated accordingly for the part-time employee). Moreover, compensation paid under each agreement will be consistent with fair market value in arms'-length transactions.[5]

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

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 of federal health care program business were present, but that the OIG would not impose administrative sanctions on [Entity A] or [Entity B] 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 ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

---

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

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Entity A] and [Entity B], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor of this opinion.

- 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.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the 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