



[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: August 19, 2008

Posted: August 26, 2008

[Name and address redacted]

Re: OIG Advisory Opinion No. 08-10

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposal for a physician practice group to provide space, equipment and personnel to other physician practice groups through block leases (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, the Federal anti-kickback statute.

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 and that the Office of Inspector

General (“OIG”) could potentially 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 Proposed Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties’ intent, which determination is beyond the scope of the advisory opinion process.

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 IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] (the “Requestor”) is a physician group practice that provides cancer treatment services in a free-standing facility in [city redacted], [stated redacted] (the “Facility”). The Facility provides radiation and chemotherapy treatments for a wide range of cancers. One of the treatments offered at the Facility is intensity-modulated radiation therapy (“IMRT”). IMRT is frequently used to treat prostate cancer. Patients with prostate cancer who receive IMRT at the Facility are referred to the Requestor by urologists.

Some of the urologists who refer prostate cancer patients to the Requestor for IMRT at the Facility practice in physician groups in the greater [city redacted] metropolitan area. The Requestor proposes to enter the Proposed Arrangement with some of these physician groups (the “Urologist Groups”). The Urologist Groups participate in the Medicare program. At the present time, the Urologist Groups neither provide IMRT as part of their practices, nor own facilities that provide IMRT. Some of the Urologist Groups currently refer most of their prostate patients to the Requestor, and some refer primarily to a competing facility.

Under the Proposed Arrangement, the Requestor would enter into a series of written agreements with the Urologist Groups, whereby the Urologist Groups would lease, on a part-time basis, the space, equipment, and personnel services necessary to perform IMRT. Specifically, each Urologist Group would lease examination and treatment rooms at the Facility for fixed periods of at least eight hours per week, in the same space where the Requestor provides IMRT. The Urologist Groups would also lease from the Requestor equipment and personnel necessary to provide their patients with IMRT. The Requestor would provide the Urologist Groups with radiation supplies and billing services. Individual radiologists associated with the Requestor who normally perform services billed by the

Requestor (the “Radiologists”) would enter into contracts with the Urologist Groups to supervise the IMRT procedures, as independent contractors for the Urologist Groups.¹

In exchange for the space, equipment and services described above, the Urologist Groups would pay the Requestor premises rent, equipment rent, personnel expenses, and communication and administrative expenses. Compensation under the leases would be for fixed amounts set in advance and would not vary with the use of the premises, equipment or services. The Requestor has certified that the leases would be at fair market value pursuant to a fair market value study prepared by an independent third party. The agreements between the Requestor and the Urologist Groups would each have a one-year term, with an option to renew upon ninety-day advance written notice.

Currently, the Requestor bills the technical and professional components of IMRT services it provides to Medicare beneficiaries, using the Requestor’s billing number. Under the Proposed Arrangement, the professional and technical components of the IMRT would be billed to Medicare using billing numbers assigned to the Urologist Groups. The Urologist Groups would pay the amounts owed under the agreements with the Requestor, regardless of the number of patients they referred to the Facility and regardless of whether the Urologist Groups collected fees for the procedures from Medicare or other payers. The Urologist Groups would retain the difference between the fees collected and the amounts owed under the agreements with the Requestor.

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 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

¹ Referring physicians from the Urologist Groups would see patients at least six hours per week in the same building where the IMRT services are provided, where they would provide patients with some services unrelated to the IMRT services. The apparent purpose of this aspect of the Proposed Arrangement, as well as the separate contracts between the Urologist Groups and individual Radiologists, is to qualify for the in-office ancillary services exception to the prohibitions of the Physician Self-Referral Law, Section 1877 of the Act, 42 U.S.C. § 1395nn. See 42 C.F.R. § 411.355(b)(2). The Requestor has offered its judgment that the Proposed Arrangement would comply with this law and related regulations, and with the billing requirements of the Center for Medicare and Medicaid services. We express no opinion with regard to these issues.

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 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 space rental, 42 C.F.R. § 1001.952(b), equipment rental, 42 C.F.R. § 1001.952(c), and personal services and management contracts, 42 C.F.R. § 1001.952(d), are potentially applicable to the Proposed Arrangement.

B. Analysis

The series of agreements that would make up the Proposed Arrangement, in effect, establish a joint venture between the Requestor and the Urologist Groups. The OIG has longstanding concerns about certain problematic joint venture arrangements between those in a position to refer business, such as physicians, and those who furnish items or services for which Medicare or Medicaid pays, especially when all or most of the business of the joint venture is derived from one of the joint venturers. See, e.g., OIG’s 1989 Special Fraud Alert on Joint Venture Arrangements, reprinted in the Federal Register in 1994 (59 FR 65362, 65363 (Dec. 19, 1994)). As noted in this Special Fraud Alert, joint ventures may take a variety of forms and may be formed by equity or contract.

The OIG issued additional guidance on suspect contractual joint venture arrangements in our Special Advisory Bulletin on Contractual Joint Ventures (see 68 FR 23148 (April 30,

2003)) (the “Special Advisory Bulletin”). As set forth in that document, suspect joint venture arrangements typically exhibit certain common elements, several of which are present in the Proposed Arrangement. In fact, the Special Advisory Bulletin describes an arrangement very similar to the Proposed Arrangement:

[A] health care provider in one line of business (hereafter referred to as the “Owner”) expands into a related health care business by contracting with an existing provider of a related item or service (hereafter referred to as the “Manager/Supplier”) to provide the new item or service to the Owner’s existing patient population, including federal health care program patients. The Manager/Supplier not only manages the new line of business, but may also supply it with inventory, employees, space, billing and other services. In other words, the Owner contracts out substantially the entire operation of the related line of business to the Manager/Supplier – otherwise a potential competitor – receiving in return the profits of the business as remuneration for its federal program referrals.

68 FR at 23148. We believe that the Urologist Groups and the Requestor are in the same position as the Owner and Manager/Supplier described in the Special Advisory Bulletin.²

Under the Proposed Arrangement, as in the Special Advisory Bulletin, the Urologist Groups would be expanding into a related line of business, IMRT, which is dependent on referrals from the Urologist Groups. The Urologist Groups would not actually participate in performing the IMRT, but would contract out substantially all IMRT operations, including the professional services necessary to provide the IMRT. On the whole, the Urologist Group would commit little in the way of financial, capital, or human resources to the IMRT and, accordingly, would assume very little real business risk. Like the “Owner” in the Special Advisory Bulletin, a Urologist Group’s actual financial and business risk would be minimal. The Urologist Groups would be in a position to ensure the success of the business, not only by referring to the Requestor’s facility for IMRT, but by the choice of IMRT over other available therapies for prostate cancer. Although not essential to our conclusion, we note that, in negotiating the agreements that make up the Proposed Arrangement, the lease times as well as the amount of space, equipment and staff leased or contracted for could readily be determined based on the historical patterns of referrals by a

² While the Special Advisory Bulletin focused on joint ventures between physicians and other types of suppliers, the analysis set forth there applies equally to joint ventures involving physician groups of different specialties, where an arrangement would result in one physician group profiting from its referrals of patients for services to be performed by another.

particular Urologist Group. Thus the parties could easily ensure that the business generated by the Urologist Group would be sufficient to meet or exceed the rent and fees.

Other elements described in the Special Advisory Bulletin that are present in the Proposed Arrangement include the following:

- The Requestor is an established provider of the same services that a Urologist Group would provide via the Proposed Arrangement and is in a position to directly provide the IMRT in its own right, billing Medicare in its own name, and retaining all available reimbursement;
- A Urologist Group would use the premises, equipment and staff of the Requestor to serve its own patient base – the very patients some of the Urologist Groups have historically referred to the Requestor or other outside suppliers for the same services.
- The aggregate income to the Urologist Groups under the Proposed Arrangement would vary with referrals from the Urologist Groups to the Facility, and, because the various agreements could be tailored to fit the historical pattern of referrals by the Urologist Groups, so might the income to the Requestor.
- The Requestor (and its individual Radiologists engaged as independent contractors by the Urologist Groups) and the Urologist Groups would share in the economic benefit of the IMRT.

Accordingly, based on the facts presented here, we are unable to exclude the possibility that the parties' contractual relationship is designed to permit the Requestor to do indirectly what it cannot do directly; that is, pay the Urologist Groups a share of the profits from their IMRT referrals. In other words, the Requestor may be offering the Urologist Groups impermissible remuneration by giving them the opportunity to obtain the difference between the reimbursement received by the Urologist Groups from the Federal health care programs and the rent and fees paid by the Urologist Groups to the Requestor and the individual Radiologists (*i.e.*, the profit from IMRT ordered by the Urologist Groups.) By agreeing effectively to provide services it could otherwise provide in its own right for less than the available reimbursement, the Requestor and its Radiologists would potentially be providing a referral source – a Urologist Group – with the opportunity to generate a fee and a profit. If the intent of the Proposed Arrangement were to give the Urologist Groups remuneration through the IMRT to induce referrals to the Requestor, the anti-kickback

statute would be violated.³ Indeed, there is a significant risk that the Proposed Arrangement would be an improper contractual joint venture that would be used as a vehicle to reward the Urologist Groups for their referrals.

We do not reach, and accordingly express no opinion about, the applicability of any safe harbor to any individual contract under the Proposed Arrangement. Even if each of the individual agreements making up the Proposed Arrangement could satisfy the applicable safe harbor conditions under the space and equipment rental safe harbors and the personal services and management contracts safe harbor, the safe harbors would only protect the remuneration paid by the Urologist Groups to the Requestor or to the individual Radiologists for actual services rendered or space or equipment rented. In this opinion, we are concerned about potential compensation to the Urologist Groups, who are sources of referrals to the Requestor for the very services to be provided under the Proposed Arrangement. As we noted in the Special Advisory Bulletin, illegal remuneration can be the difference between the money paid by a referral source to a manager/supplier and the reimbursement received by the referral source from the Federal health care programs. By agreeing to provide services it could otherwise provide in its own right for less than the available reimbursement, the Requestor may provide the Urologist Groups with the opportunity to generate a fee and a profit. The opportunity to generate a fee is itself remuneration that may implicate the anti-kickback statute.

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 and that the OIG could potentially 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 Proposed Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

³ We would be equally concerned if the Urologist Groups solicited remuneration from the Requestor, in the form of an opportunity to obtain a portion of the reimbursement for IMRT resulting from their referrals, in return for their agreement to generate business for the Requestor.

IV. 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 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 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.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General