



[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: December 10, 2004

Posted: December 17, 2004

[name and address redacted]

Re: OIG Advisory Opinion No. 04-17

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a pathology services joint venture arrangement (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.

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.

1. FACTUAL BACKGROUND

Under the Proposed Arrangement, [name redacted] (the "Requestor"), a company that arranges for the provision of pathology laboratory services, would enter into a series of contracts with physician group practices (the "Physician Groups") to operate pathology laboratories ("Path Labs") for each group in an off-site location. Specifically, under the Proposed Arrangement, the Requestor proposes to furnish all necessary management and administrative services, equipment leasing, premises subleasing, technical, professional, and supervisory pathology services, and, if requested, billing services for each Physician Group to operate its own Path Lab.

The Requestor states that it is not a provider or supplier of health care services and does not participate in any Federal health care programs, including Medicare and Medicaid. However, the Requestor is part of a group of affiliated entities (the "Affiliated Entities") wholly owned and controlled by [name redacted] (the "Parent Corporation"). The other Affiliated Entities are [name redacted] (the "Affiliated Lab"), a licensed, Medicare-certified anatomic pathology laboratory, and [name redacted], a laboratory staffing company.¹

The Requestor plans to limit the Proposed Arrangement to Physician Groups specializing in urology, gastroenterology, or dermatology. The Requestor anticipates that most of the pathology services to be provided by the Path Labs will be surgical pathology services that have separate reimbursement for technical and professional components.²

¹The Requestor and the Parent Corporation have overlapping officers and directors and the contracts under the Proposed Arrangement can be assigned to the Affiliated Entities.

²The Physician Groups currently refer some of these services to the Affiliated Lab. The services to be provided by the Path Labs are a subset of the total services offered by the Affiliated Lab. Thus, if the Proposed Arrangement were implemented, the Requestor anticipates that the Physician Groups may continue to make referrals to the Affiliated Lab.

To implement the Proposed Arrangement, the Requestor will enter into four contracts with each Physician Group: (i) a Management Agreement, which includes equipment leasing and, if requested, billing services; (ii) a Sub-Lease Agreement;³ (iii) a Technical Personnel Agreement;⁴ and (iv) a Pathology Services Agreement for the part-time services of a pathologist from the Affiliated Lab (the “Pathologist”) for the provision of all professional and supervisory services necessary to operate the Path Lab.

For each Physician Group under the Proposed Arrangement, the Physician Group (or the Requestor on behalf of the Physician Group) will bill patients and their insurers, including Medicare, for pathology services furnished in the Path Lab. Under the Management Agreement, the Physician Group will pay the Requestor: (i) a flat, monthly fee (the “Monthly Fee”), which will include the fee for the Pathologist’s services; (ii) a per-specimen fee (the “Per Specimen Fee”); and (iii) if applicable, a fee for billing and collection services equal to 5% of the total net Path Lab revenue. The Monthly Fee will be set at an amount that takes into consideration historical utilization data. The Requestor will not engage in any marketing activities on behalf of the Physician Group. Finally, the Management Agreement states that the Physician Group retains the ultimate authority and responsibility for the operation of its Path Lab.

The Requestor states that it will establish up to five independent and self-contained Path Labs within a single building. Path Labs in the same building will not share space or equipment, because each Path Lab will have the full complement of laboratory equipment necessary to perform one Physician Group’s pathology services. Each Physician Group will lease its individual Path Lab space on a full-time basis, and each such space will be used exclusively by the Physician Group leasing the space. While the Pathologists and technical laboratory personnel will rotate among the Path Labs and be shared by the Path Labs, they will only provide services on behalf of one Physician Group’s Path Lab while located in that Physician Group’s subleased space and will only use that Physician Group’s leased equipment.

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

³The Requestor states that the Sub-Lease Agreement will comply with the space rental safe harbor and that the rental fee for the space will be a fair market value “pass-through” of the Requestor’s costs for leasing the space from an unrelated third party.

⁴The Requestor states that the fee for these services will be a “pass-through” of the costs associated with retaining the personnel.

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 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. Moreover, the safe harbors only protect the remuneration specified in the safe harbor.

B. Analysis

The OIG has longstanding concerns about certain problematic joint venture arrangements between those in a position to refer business, such as physicians, and those furnishing 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 Fed. Reg. 65372, 65373 (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 its Special Advisory Bulletin titled “Contractual Joint Ventures.” See 68 Fed. Reg. 23148 (April 30, 2003) (the “Special Advisory Bulletin”). As set forth in the Special Advisory Bulletin, 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 Fed. Reg. at 23148. We believe that the Physician Group and the Requestor are in the same position as the Owner and Manager/Supplier described in the Special Advisory Bulletin.

As an initial matter, we address the Requestor’s assertion that, as a management company, it is not in a position to solicit or receive Federal health care program business. A party need not be a provider or supplier to be liable under the anti-kickback statute.⁵ Moreover, given the close relationship between the Requestor and the Affiliated Entities – the overlapping officers and directors, common control by the Parent Company, and ability to assign the Proposed Arrangement contracts to other Affiliated Entities – we consider the Requestor and the Affiliated Entities sufficiently related to be treated as a single entity for purposes of this analysis. The Requestor shares the same overall corporate interest in the success of all of the Affiliated Entities. Thus, the Requestor, because of its affiliation with the Affiliated Lab, effectively stands in the shoes of a potential competitor of the Path Labs.

Under the Proposed Arrangement, as in the Special Advisory Bulletin, a Physician Group would be expanding into a related line of business, pathology services, which is dependent on referrals from the Physician Group. Despite language indicating otherwise in the Management Agreement, the Physician Group would not actually participate in the operation of the Path Lab, but would contract out substantially all Path Lab operations, including the professional services necessary to provide the pathology services. In fact, the Management Agreement only requires the Physician Group to maintain its qualifications, credentials, and group status; allow access to certain records; and provide billing information. On the whole, the Physician Group would commit almost nothing in the way of financial, capital, or human

⁵See Section 1128B(b) of the Act.

resources to the Path Lab, and, accordingly, would assume no or very little real business risk. Moreover, the requirement that the Physician Group maintain its qualifications and credentials further ensures that the Physician Group will retain its ability to order and bill for services rendered.

The Requestor asserts that the Physician Group would bear financial risk as a participant in the Proposed Arrangement, because it would pay the Monthly Fee regardless of its utilization of its Path Lab, and that the Physician Group would bear the business risk for the success or failure of its Path Lab, because it would retain the ultimate authority and responsibility for the operation of its Path Lab. However, like the “Owner” in the Special Advisory Bulletin, the Physician Group’s actual financial and business risk would be nonexistent or minimal, because it would have complete control over the amount of business it would send to the Path Lab and could make substantial referrals to the Path Lab. In fact, while our conclusion would be the same even absent the historical correlation, by basing the Monthly Fee for each Physician Group on historical utilization data for that Physician Group, the parties can easily ensure that the business generated by the Physician Group would be sufficient to meet or exceed the Monthly Fee. Similarly, the Management Agreement’s Per Specimen Fee and the percentage billing fee (based on net revenues) create virtually no financial risk for the Physician Group, because the fees would be based on actual utilization and billing of services.

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

- the Requestor, through its Affiliated Lab, is an established provider of the same services that a Physician Group’s Path Lab would provide and is in a position to directly provide the pathology services in its own right, billing insurers and patients in its own name, and retaining all available reimbursement;
- the aggregate payment to the Requestor under the Proposed Arrangement would vary with referrals from the Physician Group to its Path Lab, as would the Physician Group’s payments (that is, the difference between the net revenues from the Path Lab and its expenses, including payments to the Requestor); and
- the Requestor and the Physician Group would share in the economic benefit of the Physician Group’s Path Lab.

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 Physician Groups a share of the profits from their laboratory referrals. In other words, the Requestor may be offering the Physician Groups

impermissible remuneration by giving them the opportunity to obtain the difference between the reimbursement received by the Physician Groups from the Federal health care programs and the fees paid by the Physician Groups to the Requestor (*i.e.*, the profit from pathology services ordered by the Physician Groups). By agreeing effectively to provide services it could otherwise provide in its own right for less than the available reimbursement, the Requestor would potentially be providing a referral source – a Physician Group – with the opportunity to generate a fee and a profit. If the intent of the Proposed Arrangement were to give the Physician Groups remuneration through the Path Labs in return for referrals to: (i) the Path Labs; or (ii) the Requestor’s Affiliated Lab, the anti-kickback statute would be violated.⁶ 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 Physician Groups for their referrals.

It is important to note that 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 Physician Groups to the Requestor for actual services rendered or space or equipment rented.⁷ In the Proposed Arrangement, a Physician Group’s retained profit from the pathology services would not be protected by any safe harbor.

Finally, the Requestor states that it has structured the Proposed Arrangement to comply with the “in-office ancillary services” exception to the physician self-referral law (also known as the “Stark Law”), section 1877 of the Act. We express no opinion regarding the legality of the Proposed Arrangement under the Stark Law. Even if some features of the Proposed Arrangement were to comply with the Stark Law, such compliance would not affect our analysis under the anti-kickback statute.⁸ The Stark Law and the anti-kickback statute are

⁶We would be equally concerned if the Physician Groups solicited remuneration from the Requestor, in the form of an opportunity to obtain a portion of the reimbursement for pathology services resulting from their referrals, in exchange for their agreement to generate business for the Path Lab and/or the Affiliated Lab.

⁷We do not reach in this opinion, and accordingly express no opinion about, the applicability of any safe harbor to any contract under the Proposed Arrangement.

⁸To the extent that the Proposed Arrangement raises potential issues under the Stark Law, the Centers for Medicare & Medicaid Services is the agency with authority to issue opinions about the application of the Stark Law and issuance of an OIG advisory opinion is not intended to be, and should not be construed as, a determination about whether or not an arrangement complies with the Stark Law. We observe, however, that the actual operation of an arrangement is crucial to compliance with the law, and that the

independent legal authorities and each must be evaluated separately.⁹ Whether or not an arrangement complies with the Stark Law is immaterial to the application of the anti-kickback statute. Furthermore, actual or attempted compliance with the Stark Law is not determinative of whether one intends unlawfully to pay for referrals.

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.

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.

proposal to segregate space and equipment and rotate pathologists and technicians and account for their time spent in each Path Lab would be virtually impossible to monitor (particularly in an off-site facility) and therefore would be prone to substantial abuse, including, without limitation, the risk of inappropriate utilization and improper claims.

⁹See, e.g., 66 Fed. Reg. 855, 863 (Jan. 4, 2001); 69 Fed. Reg. 16053, 16063 (March 26, 2004) (reflecting clear distinction between the statutes).

- 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