



[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: October 3, 2011

Posted: October 11, 2011

[Name and address redacted]

Re: OIG Advisory Opinion No. 11-15

[Salutation redacted]:

We are writing in response to your request for an advisory opinion regarding a proposal under which physicians would invest in a company that would provide pathology laboratory management services to a third party (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 supplemental submissions, 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 Delaware limited liability company owned and managed by a physician (the "Owner/Manager"). Under the Proposed Arrangement, the Requestor would contract with another company, the identity of which has not yet been determined (the "Path Lab"), that either currently operates a licensed, Medicare-certified clinical anatomic pathology laboratory, or would form one for the purpose of doing business with the Requestor. The Owner/Manager cannot refer his or her own patients or otherwise generate business in connection with the Proposed Arrangement.

The Path Lab would enter into a management services contract (the "Management Contract") with the Requestor for a term of at least three years. Under the Management Contract, the Requestor would furnish the Path Lab the complete array of clinical laboratory pathology services for a fixed maximum number of hours each year, as well as utilities, furniture, fixtures, and the exclusive use of laboratory space and equipment. The Requestor would also provide the Path Lab marketing and billing services, and essential non-physician staff. In turn, the Path Lab would pay the Requestor a usage fee that would be calculated based on a percentage of the Path Lab's income, fixed in advance for a term of 12 months, which generally would correspond to the volume of the Path Lab's use of the Requestor's services, personnel, and equipment. The Path Lab's income could include payments from Federal health care programs for laboratory services provided to program beneficiaries. The Requestor has certified that any usage fees paid to it by the Path Lab would represent fair market value for the use of the Requestor's space, equipment, and services.¹

The Owner/Manager would offer the opportunity to invest in the Requestor to various additional, as-yet undetermined physicians, including urologists, gastroenterologists and dermatologists (each, individually, a "New Physician Investor," and collectively, the "New Physician Investors"). The Requestor stated that, while the Owner/Manager has some experience in the clinical laboratory services field, it anticipates that most of the New Physician Investors would have little or no such background. The Requestor stated that it plans to recruit individuals with the appropriate experience and expertise to

¹ We are not authorized to opine on whether fair market value shall be, or was, paid or received for any goods, services, or property. See section 1128D(b)(3) of the Act.

provide clinical laboratory services and retain them as employees or contractors. The Requestor certified that the value of the investment interests in the Requestor that would be held by physician investors in a position to generate business for the Requestor through referrals of laboratory specimens to the Path Lab would exceed 40 percent. The Requestor further anticipates that substantially more than 40 percent of the Requestor's gross revenue related to the furnishing of health care items and services would derive from business generated by its physician investors through referrals of laboratory specimens to the Path Lab.

The Requestor certified that each of the New Physician Investors would have the option of referring specimens to the Path Lab but that there would be no implicit or explicit agreement or condition that a New Physician Investor make referrals to, or use the services of, the Requestor or the Path Lab. Each New Physician Investor would purchase membership interests in the Requestor at a cost equal to the Requestor's book value times the pro rata share of the Requestor being purchased. The Requestor certified that the book value, and thus the per-share price, would not vary from investor to investor (including the Owner/Manager). All profit distributions would correspond to an investor's percentage membership interest in 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 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. 1985), 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. Potentially applicable to the Proposed Arrangement are the safe harbors for: small entity investments, 42 C.F.R. § 1001.952(a)(2); 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).

B. Analysis

We note, first, similarities between the Proposed Arrangement and questionable joint venture arrangements that have been the subject of OIG guidance. The OIG has in past publications warned the public about arrangements in which a health care provider expands into clinical diagnostic laboratory services by contracting with an existing provider of that laboratory services to operate a newly formed laboratory subsidiary on essentially a turn-key basis. See, e.g., OIG’s 1989 Special Fraud Alert on Joint Venture Arrangements, reprinted in the Federal Register in 1994 (59 Fed. Reg. 65,372, 65,373 (Dec. 19, 1994); OIG’s Special Advisory Bulletin on “Contractual Joint Ventures,” 68 Fed. Reg. 23,148 (Apr. 30, 2003); OIG Advisory Opinion 04-17. The Proposed Arrangement is the converse of such an arrangement; rather than contracting with an existing provider to obtain turn-key laboratory services for which a physician-owned entity would bill Federal health care programs, the Requestor, a physician-owned entity, would contract to provide such services to an entity that would, in turn, bill Federal health care programs. Under both types of arrangements, however, the income of the physician-owned entity would vary with the volume or value of referrals from physician investors. We therefore evaluate the Proposed Arrangement for compliance with any applicable safe harbor, and for the potential for abuse.

Under the Proposed Arrangement, the New Physician Investors would join the Owner/Manager as investors in the Requestor. Because the Proposed Arrangement would involve 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 protects profit distributions paid on investments in small entities; if applicable to the Proposed Arrangement, this safe harbor would protect the Requestor’s profit distributions to the New Physician Investors and the Owner/Manager.

Two of the small entity investment safe harbor’s eight elements are of particular relevance here: first, no more than 40 percent of an entity’s investment interests may be

held by investors that are in a position to make or influence referrals to, or otherwise generate business for, the entity; and second, no more than 40 percent of an entity's gross revenue may come from referrals or business otherwise generated from investors. 42 C.F.R. § 1001.952(a)(2)(i) & (vi). The Requestor certified that more than 40 percent of the Requestor would be held by physician investors in a position to generate business for the Requestor through referrals of laboratory specimens to the Path Lab, and, further, that substantially more than 40 percent of the Requestor's gross revenue related to furnishing health care items and services would come from laboratory business generated by its physician investors. As the result of noncompliance with these elements, the small entity safe harbor would be inapplicable and would not protect the Requestor's profit distributions to the New Physician Investors and the Owner/Manager.

Under the Proposed Arrangement, the Requestor would enter the Management Contract with the Path Lab to provide the Path Lab with the complete range of clinical laboratory management services, along with administrative and marketing personnel, rental space, furniture, and equipment in return for usage fees. The safe harbors for space rental, for equipment rental, and for personal services and management contracts—at 42 C.F.R. § 1001.952(b), (c), & (d), respectively—therefore are potentially applicable to the Proposed Arrangement. If applicable, these safe harbors would protect the usage fees paid by the Path Lab to the Requestor for space and equipment rental, and the payments made pursuant to the personal services and management contracts.

The safe harbors for space rental, for equipment rental, and for personal services and management contracts all share six basic elements: (i) the agreement must be set out in writing and signed by the parties; (ii) the agreement must specify the services to be performed; (iii) if the services are to be performed on a part-time basis, the schedule for performance must be specified in the contract; (iv) the agreement must be for not less than one year; (v) the aggregate amount of compensation must be fixed in advance, consistent with fair market value in an arms'-length transaction, and must not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made by Medicare or a State health care program; and (vi) the services contracted for must not exceed those reasonably necessary to accomplish the commercially reasonable business purpose of the services.² 42 C.F.R. § 1001.952(b), (c), & (d).

The Proposed Arrangement would not satisfy the requirements of the safe harbors for space rental, equipment rental, or personal services and management contracts because, among other reasons, the aggregate usage fees paid to the Requestor would not be set in advance; instead, the usage fees would be calculated based on a percentage of the Path

² The personal services and management contracts safe harbor adds a seventh element: the services performed under the agreement must not involve the promotion of business that violates any Federal or State law. 42 C.F.R. § 1001.952(d).

Lab's income. As a result, none of the three safe harbors would protect the fees paid by the Path Lab to the Requestor. Absent any safe harbor protection for the Proposed Arrangement, we must apply careful scrutiny to determine whether it poses no more than a minimal risk of fraud and abuse under the anti-kickback statute. For the combination of the following reasons, we conclude that the Proposed Arrangement would pose more than a minimal risk of fraud and abuse.

First, the usage fees to be paid by the Path Lab to the Requestor under the Management Contract would take into account the volume or value of business generated for the Path Lab by the New Physician Investors in the form of laboratory specimen referrals directed to the Path Lab. This fee structure would effectively link the New Physician Investors' profit distributions to the laboratory business they send the Path Lab, posing considerable risks of overutilization of laboratory services, distorted medical decision-making, and increased costs to Federal health care programs.

Second, the Requestor certified that more than 40 percent of the Requestor's investment interests would be held by physician investors in a position to generate business for the Path Lab in the form of referrals of laboratory specimens. The Requestor also anticipates that substantially more than 40 percent of its gross revenue would come from business generated from its investors. The absence of limits on such involvement by interested investors or other safeguards to restrain the Proposed Arrangement's reliance on investor-generated business further underscores the already-noted risks of overutilization, distorted medical decision-making, and increased program costs.

Third, the Requestor would be an entity largely owned by persons with no experience in providing clinical pathology services but with the ability to refer patients for these services. It would furnish the Path Lab, a company which may already operate a clinical anatomic pathology lab, the entire range of key services connected with the Path Lab's laboratory operation: day-to-day management; marketing and billing services; equipment; personnel and related administrative services; space, fixtures, and furniture; and the complete array of clinical laboratory pathology services. The Proposed Arrangement appears to have no business purpose other than to permit the physician investors to profit from the business they generate for the Path Lab in the form of their laboratory specimen referrals. The fact that the profits would be obtained indirectly, because the Path Lab, rather than the Requestor, would bill for the clinical laboratory services, is immaterial.³

³ We express no opinion regarding the legality of the Proposed Arrangement under the Stark Law or any payment rule. The Stark Law and the anti-kickback statute are independent legal authorities and each must be evaluated separately. *See, e.g.*, 66 Fed. Reg. 855, 863 (Jan. 4, 2001); 69 Fed. Reg. 16,053, 16,063 (Mar. 26, 2004) (reflecting clear distinction between the statutes).

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.
- 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,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General