



[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: November 16, 2011

Posted: November 23, 2011

[Name and address redacted]

Re: OIG Advisory Opinion No. 11-17

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposed arrangement under which an entity would furnish allergy testing and immunotherapy laboratory services within various primary care physicians' medical offices (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] (“Requestor”) is a laboratory services management company. Under the Proposed Arrangement, Requestor proposes to provide allergy testing and immunotherapy laboratory services and related items to primary care physicians and physician practices (“Physicians”) within the Physicians’ medical offices. Specifically, Requestor would enter into exclusive contracts with the Physicians to operate an allergy testing laboratory on the Physicians’ behalf.

Requestor would provide all of the necessary laboratory personnel (including laboratory technicians), equipment, supplies, training, and billing and collection services to the Physicians on an as-needed basis. Additionally, Requestor would assist the Physicians with marketing allergy services to patients by providing patient education materials and reviewing patient files to identify candidates for allergy laboratory services.¹ The Physicians would provide: (1) space within their offices to operate the laboratory; (2) administrative staff for patient scheduling and other administrative tasks; (3) general medical office supplies and furniture; (4) general liability and malpractice insurance; and (5) physician supervision and interpretation of laboratory results.

The Physicians would bill Federal health care programs and third-party payors for the laboratory items and services provided under the Proposed Arrangement under the Physicians’ provider identification numbers. Requestor would provide billing and collection services on behalf of the Physicians for the allergy testing services.

The Physicians would pay Requestor a fee for the items and services provided by Requestor equal to sixty percent of the Physicians’ gross collections from allergy testing and

¹ We have not been asked to opine on, and we offer no opinion regarding, whether allowing Requestor to review patient information, would comply with state and Federal privacy laws.

immunotherapy items and services. According to Requestor, this percentage fee is equal to fair market value.²

Requestor certified that it would contract with Physicians who are not operating pre-existing allergy and immunotherapy laboratories. The Physicians would agree to use Requestor as their exclusive provider of antigen-based immunotherapy laboratory services and as the sole allergy testing unit for the Physicians' patients.

Requestor certified that it is wholly-owned and managed by [name redacted], who is not affiliated with any provider or supplier of health care items or services payable by Federal health care programs and who has no experience owning or operating an allergy laboratory. Requestor certified that [name redacted] would operate Requestor's proposed allergy and immunotherapy laboratory business by identifying and hiring individuals whom he believes have sufficient experience to provide, on Requestor's behalf, the services under the Proposed Arrangement.

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.), 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

² 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).

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 equipment leases and personal services and management contracts, 42 C.F.R. § 1001.952(c) and (d), respectively, are potentially applicable to the Proposed Arrangement. These safe harbors generally require that an equipment lease or services and management contract: (1) be set forth in a written agreement signed by the parties; (2) cover all equipment to be leased or services to be provided for the term of the lease or agreement, and specify the equipment or services covered by the agreement; (3) specify, in cases where the lease or agreement is intended to be on a periodic, sporadic, or part-time basis, the exact schedule of intervals, their precise length, and the charge for such intervals; (4) be for a term of at least one year; (5) set an aggregate rental or services fee in advance that is consistent with fair market value in arm's-length transactions and that is not determined in a manner that takes into account the expected volume or value of referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program; and (6) include aggregate rental items or services that do not exceed what is reasonably necessary to accomplish the commercially reasonable purpose for the rental or services agreement. In addition, the personal services and management contracts safe harbor requires that the agreement not include any services that involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

B. Analysis

The Proposed Arrangement would not qualify for safe harbor protection for two reasons. First, the services would be provided on an as-needed basis; the agreement therefore would not specify the schedule of intervals, the precise interval length, or the charge for such intervals. Second, the applicable safe harbors require that the aggregate compensation to be paid under the contract be set in advance and not be determined in a manner that takes into account the volume or value of any business generated between the parties that is payable by a Federal health care program. Because the Physicians would pay Requestor a percentage of their gross collections from allergy tests and immunotherapy items and services under the Proposed Arrangement, the aggregate charges would not be set in

advance, and they would be based, in part, on the volume or value of Federal health care program business.

The fact that the Proposed Arrangement would not fit in a safe harbor does not end the inquiry under the anti-kickback statute. We must examine the totality of the facts and circumstances to determine the extent of the risk posed by the Proposed Arrangement. For the combination of reasons set forth below, we cannot conclude that the Proposed Arrangement poses a sufficiently low risk under the anti-kickback statute that we should protect it.

First, Requestor's fee would not be tied to actual and necessary services provided by Requestor to the Physicians. Instead, Requestor would receive a percentage of the Physicians' gross collections from allergy testing and immunotherapy items and services. Percentage compensation arrangements are inherently problematic under the anti-kickback statute, because they relate to the volume and value of business generated between the parties, rather than the fair market value of the services provided.³

Second, Requestor's review of patient files to identify candidates for allergy testing services would be a suspect marketing activity. We are concerned that this type of marketing activity could encourage Physicians to order medically unnecessary tests⁴ that could pose a risk of patient harm.⁵ The Proposed Arrangement's fee structure would create a risk of overutilization, because Requestor would engage in marketing activities by identifying patients the Physicians could refer for allergy testing and would receive a percentage of revenues generated from such referrals.

We note that Requestor states that it 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

³ Although, as noted above, we are precluded from opining on whether fair market value shall be or was paid for goods, services, or property, we must evaluate whether the method used to determine that a fee represents fair market value appears reliable.

⁴ In a study conducted by the OIG, a significant percentage of allergen immunotherapy services provided on behalf of Medicare beneficiaries was found to be medically unnecessary. See Allergen Immunotherapy for Medicare Beneficiaries, OEI-09-00-00531, February, 2006.

⁵ Our concern is magnified here because the Physicians, who may not have significant, specialized allergen immunotherapy experience, may be influenced by Requestor, a non-physician, to order unnecessary services.

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.⁶ The Stark Law and the anti-kickback statute are independent legal authorities, and each transaction or arrangement must be separately evaluated under both statutes. 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 Requestor 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

⁶ The Centers for Medicare & Medicaid Services is the agency with the authority to issue opinions on the application of the Stark Law. The 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.

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