



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: June 2, 2004

Posted: June 9, 2004

[name and address redacted]

Re: OIG Advisory Opinion No. 04-5

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding your participation as a volunteer pathology laboratory for a charitable foundation's medical assistance program for low-income, uninsured patients (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 would not generate prohibited

remuneration under the anti-kickback statute and, therefore, the Proposed Arrangement would not constitute grounds for the Office of Inspector General (“OIG”) to impose administrative sanctions on [Entity X] 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).

This opinion may not be relied on by any persons other than [Entity X], 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

[Entity Y], a non-profit tax-exempt corporation (the “Foundation”), administers [project name redacted] (the “Project”), a coordinated system of volunteer physician care, hospital care, diagnostic services, and medication assistance for low-income, uninsured residents of [county and state redacted] (the “County”).¹ To receive Project services, a patient must be a resident of the County who (i) has no medical insurance, (ii) is not eligible for government medical assistance, including Medicare or Medicaid, and (iii) has income that does not exceed 150% of the Federal poverty level guidelines.

[Entity X] (the “Lab”), a for-profit corporation partially owned by several pathologists, provides laboratory services throughout the State of [state redacted].² The Lab desires to participate in the Project as a volunteer pathology laboratory. As a Project participant, the Lab would agree to provide laboratory services at no charge for Project patients referred by one of the Project’s volunteer physicians.

The Lab has certified that, under the Proposed Arrangement, no remuneration will be provided directly or indirectly to any volunteer physician, the volunteer pathology laboratory, the pathologists performing the laboratory services, or the Project. Some of the Project’s volunteer physicians may make referrals to the Lab outside the scope of the Project, and some of these referrals may be payable in whole or in part by a Federal health care program. The Lab has certified that its participation in the Project is not related in any manner to any non-Project business.

¹For purposes of this opinion, the Foundation and its Project will be referred to individually and collectively as the “Project.”

²We express no opinion regarding the pathologists’ relationships with the Lab.

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 initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

B. Analysis

Based on the certified facts presented, the Lab’s voluntary participation in the Project -- a charitable medical assistance program of volunteer services for low-income, uninsured patients -- results in no economic value to any party in a position to refer Federal health care program business to the Lab. Rather, the economic benefit of the Lab’s participation inures to the public good in the form of increased availability of services for an underserved population. Accordingly, we conclude that the Proposed Arrangement poses no apparent risk of fraud and abuse under 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 would not generate prohibited

remuneration under the anti-kickback statute and, therefore, the Proposed Arrangement would not constitute grounds for the OIG to impose administrative sanctions on [Entity X] 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).

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Entity X], 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 will not proceed against the Lab 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 Lab 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