[*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 18, 2004

Posted: November 24, 2004

[name and address redacted]

Re: OIG Advisory Opinion No. 04-16

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposal to provide laboratory employees and related equipment and supplies at no cost to dialysis facilities for the purpose of preparing specimens for delivery to the laboratory (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

[Name redacted] (the "Lab") provides laboratory testing services to dialysis patients pursuant to service contracts with dialysis facilities (the "Dialysis Facilities"). The Lab provides: (a) composite rate tests, which are included in the composite rate that Medicare pays the Dialysis Facilities and, therefore, are not separately billable;[1] and (b) separately billable laboratory tests that are not covered by the Medicare composite rate reimbursement ("noncomposite rate tests").

Under the Proposed Arrangement, the Lab would provide the services of laboratory assistants employed by the Lab (the "Lab Assistants") for free to some of the Dialysis Facilities. The Lab Assistants would be based at the selected Dialysis Facilities and would prepare specimens for delivery to the Lab. The Lab Assistants' services would be limited to those laboratory test processing services that are necessary to perform the ordered laboratory tests, such as centrifuging, sorting, packing, and shipping. The Lab Assistants would not perform any other activity or service for the Dialysis Facilities. The Lab would supply all equipment and supplies needed for the Lab Assistants to perform their work at no cost to the Dialysis Facilities.

Under the Centers for Medicare & Medicaid Services's ("CMS's") payment regulations, laboratory test preparation services are included in the Medicare composite rate payments received by dialysis facilities, regardless of whether the preparation services are for a composite rate test or a noncomposite rate test. See Provider Reimbursement Manual (CMS

[1]Since the composite rate tests (also called "routine laboratory tests") are covered by the composite rate payments received by the Dialysis Facilities, the Lab bills the Dialysis Facilities for those tests pursuant to the terms of its service contracts.

Pub. 15-1) § 2711.1(B)(4). Medicare does not make separate payment for administrative tasks associated with laboratory tests, such as collecting, preparing, and handling specimens.[2]

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.

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.

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[2]In fact, if the Proposed Arrangement were implemented, the Dialysis Facilities could not include the costs associated with such tasks on their cost reports, to the extent that such costs were not incurred by the Dialysis Facilities because the services were provided by the Lab.

Although the safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Proposed Arrangement, the Proposed Arrangement does not qualify under this safe harbor. The personal services safe harbor requires, among other things, that the compensation paid for services be consistent with fair market value in an arm's-length transaction. See 42 C.F.R. §§ 1001.952(d)(5). Under the Proposed Arrangement, however, the Dialysis Facilities would not pay any compensation to the Lab for the services of the Lab Assistants or for the Lab's supplies, despite the fact that the services and supplies would have value to the Dialysis Facilities, given that laboratory specimen processing costs are included in the composite rate payments received by the Dialysis Facilities.

B. Analysis

The OIG's position on the provision of free or below-market goods or services to actual or potential referral sources is longstanding and clear: such arrangements are suspect and may violate the anti-kickback statute, depending on the circumstances. For example, in 1994, the OIG issued a Special Fraud Alert describing certain laboratory practices that implicate the anti-kickback statute. See Special Fraud Alert, "Arrangements for the Provision of Clinical Laboratory Services," 59 Fed. Reg. 65372, 65377 (Dec. 19, 1994). The Special Fraud Alert explained that when a laboratory offers or gives an item or service for free or less than fair market value to a referral source, an inference arises that the item or service is offered to induce the referral of business. Also, with respect to laboratory pricing at dialysis facilities, the Special Fraud Alert identified suspect "swapping" arrangements where a laboratory offers discounts to a dialysis facility for composite rate tests payable out of the facility's pocket, in exchange for referrals of all or most of a dialysis facility's noncomposite rate tests billable by the laboratory directly to Medicare or other Federal health care programs.[3] For the reasons set forth below, the Proposed Arrangement has all the hallmarks of the disfavored arrangements described in the Special Fraud Alert.

First, the provision of the Lab Assistants, along with all necessary testing supplies, to the Dialysis Facilities at no cost would be a tangible benefit to the Dialysis Facilities. It is likely that most, if not all, of the services provided by the Lab Assistants would substitute for services currently provided by the Dialysis Facilities at their own expense and for which they would be receiving reimbursement through their composite rate payments. Thus, there

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[3]The safe harbor for discounts does not protect price reductions – like those at issue here – that are offered to induce the referral of other tests or that are offered to one payor but not offered to Medicare or Medicaid. See 42 C.F.R. §§ 1001.952(h)(5)(ii)-(iii); 64 Fed. Reg. 63518, 63528 (Nov. 19, 1999).

would be a financial benefit to the Dialysis Facilities – the receipt of free services and supplies for which the Dialysis Facilities would otherwise be obligated to incur costs. In these circumstances, an inference arises that the free services and supplies are intended to influence the Dialysis Facilities' selection of a laboratory. By capturing referral streams from the Dialysis Facilities, the Lab would likely be able to generate substantial revenue, because dialysis patients typically need lifetime laboratory testing services associated with their receipt of dialysis services. Furthermore, we discern no safeguards in the Proposed Arrangement to rebut the inference that the free goods and services would be intended to induce referrals or to reduce the risk that the arrangement is designed to induce referrals.

Second, the free services and supplies may be viewed, functionally, as a price reduction or discount on the Lab's composite rate tests. There is a risk that the Lab would be offering a functional "discount" to the Dialysis Facilities in exchange for the referral of noncomposite rate tests to the Lab. In fact, the circumstances surrounding the Proposed Arrangement suggest that a nexus may exist between the free services and supplies and referrals of other Federal health care program business. Both parties have obvious motives for agreeing to swap nonmonetary "discounts" on composite rate business for referrals of noncomposite rate business: the Dialysis Facilities to maximize expense recoupment under the composite rate system and the Lab to secure lucrative business in a highly competitive market. Any evaluation to determine whether the effect of such a "discount" would result in swapping is more difficult where the discount is nonmonetary, as it would be here with the provision of free services and supplies. Thus, in this case, there is greater risk that the arrangement as a whole could involve a nexus between the composite rate business and the noncomposite rate business. In connection with items or services provided to the Dialysis Facilities, the presence of such a "discount" arrangement is particularly suspect under the anti-kickback statute.

Based on the facts presented here, we are unable to exclude the possibility that the Lab may be offering improper nonmonetary "discounts" to the Dialysis Facilities for their composite rate-covered business with the intent to induce referrals of more lucrative noncomposite rate business. Nor are we able to exclude the possibility that the Dialysis Facilities may be soliciting improper nonmonetary "discounts" on business for which they bear risk in exchange for referrals of business for which they bear no risk. Indeed, the Proposed Arrangement poses a significant risk of such improper "swapping" of business, especially in light of the Lab's representation that many of its competitors are agreeing to such "discounts." These competitor "discount" arrangements may similarly run afoul of 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.

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