[*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: May 2, 2008

Posted: May 9, 2008

[Name and address redacted]

Re: OIG Advisory Opinion No. 08-06

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a laboratory's proposal to provide services consisting of the labeling of test tubes and specimen collection containers at no cost to dialysis facilities (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 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 is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

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 "Lab"), provides laboratory testing services to dialysis patients pursuant to service contracts with dialysis facilities (individually a "Dialysis Facility" and collectively, the "Dialysis Facilities").[1] 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;[2] and (b) separately billable laboratory tests that are not covered by the Medicare composite rate reimbursement and are billed to Medicare by the Lab ("noncomposite rate tests"). Other than the service contracts, there currently are no financial arrangements between the Lab and the Dialysis Facilities.

Under the Proposed Arrangement, the Lab would provide some of the Dialysis Facilities with services consisting of the labeling of test tubes and specimen collection containers that are used by such Dialysis Facilities in sending specimens to the Lab for testing. The Lab would retain sole discretion regarding the selection of which Dialysis Facilities would be offered the labeling services and, according to the Lab, such selection would be based upon whether offering such services would be necessary to obtain or retain the business from a

[1] We note that we have not been asked, and express no opinion, about the application of the fraud and abuse laws to the service contracts between the Lab and the Dialysis Facilities.

[2] 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.

particular Dialysis Facility. The Lab would not charge the selected Dialysis Facilities for the labeling services, which are currently performed internally, by such Dialysis Facilities' own personnel. The Lab represents that its competitors currently offer the same types of services that it would offer under the Proposed Arrangement.

Under the Centers for Medicare & Medicaid Services's ("CMS") 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 Pub. 15-1) § 2711.1(B)(4). Medicare does not make separate payment for administrative tasks associated with laboratory tests, such as labeling test tubes and specimen collection containers.[3]

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.

[3] However, dialysis facilities must file accurate Medicare cost reports. Accordingly, the selected Dialysis Facilities could face potential exposure if their Medicare cost reports include costs that they do not actually incur.

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 harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the compensation paid for services be consistent with fair market value in an arms-length transaction. See 42 C.F.R. § 1001.952(d)(5). The Proposed Arrangement would not fit in the safe harbor because the selected Dialysis Facilities would not pay any compensation to the Lab for the labeling services, despite that fact that the labeling services would have value to the selected Dialysis Facilities, given that laboratory specimen processing costs (including those associated with labeling) are included in the composite rate payments received by the selected Dialysis Facilities. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

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 Lab 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 the dialysis facility's noncomposite rate tests billable by the laboratory directly to Medicare or other Federal

health care programs.[4] 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 labeling services to the selected Dialysis Facilities at no cost would be a tangible benefit to those Dialysis Facilities. It is likely that most, if not all, of the labeling services would substitute for services currently provided by the selected Dialysis Facilities at their own expense and for which they receive reimbursement through their composite rate payments. Thus, there would be a financial benefit to the selected Dialysis Facilities—the receipt of free labeling services for which they would otherwise be obligated to incur costs. In these circumstances, an inference arises that the free labeling services are intended to influence the selected Dialysis Facilities' choice of a laboratory. This inference is consistent with, and supported by, the Lab's representation that the labeling services would be offered to the selected Dialysis Facilities when necessary to retain or obtain their business. By capturing referral streams from the selected 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.

Second, the free labeling services may be viewed, functionally, as a price reduction or discount on the amount the selected Dialysis Facilities pay the Lab for composite rate tests. In general, there is a risk that the Lab would be offering a functional "discount" to the selected Dialysis Facilities in exchange for the referral of noncomposite rate tests to the Lab. In fact, the circumstances surrounding the Proposed Arrangement demonstrate that a nexus would exist between the free labeling services 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 selected Dialysis Facilities to maximize expense recoupment under the composite rate system and the Lab to secure lucrative business in a highly competitive market. Evaluation of 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 labeling services. Nevertheless, in connection with the Proposed Arrangement, the presence of such a "discount" arrangement would be particularly suspect under the anti-kickback statute.

Based on the facts presented here, under the Proposed Arrangement the Lab would appear to be offering nonmonetary "discounts" to the selected Dialysis Facilities for their composite rate-covered business with the intent to induce referrals of more lucrative

[4] 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).

noncomposite rate business. Further, it appears possible that the selected Dialysis Facilities are 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 improper "swapping" of business, especially in light of the Lab's representation that its competitors are offering 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