DEPARTMENT OF HEALTH AND HUMAN SERVICES **Office of Inspector General**

Washington, D.C. 20201

[*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 6, 2005

Posted: June 13, 2005

[name and address redacted]

Re: OIG Advisory Opinion No. 05-08

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding your laboratory's proposal to provide free blood collection supplies to physicians and pay those physicians for the collection of blood samples (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 in [state redacted]. Currently, physicians send their patients to the Lab, which performs blood draws and laboratory tests on-site. The Lab submits claims for these blood draws and blood tests to patients' insurers, including Federal health care programs. Some of the referring physicians have told the Lab that they would like to draw their patients' blood during office visits, rather than send their patients to the Lab for blood draws, and have the Lab pick up the specimens from the physicians' offices. These physicians have requested that the Lab: (1) provide blood drawing supplies at no charge to the physicians; and (2) pay the physicians a per-patient amount for the physicians' services in collecting the blood specimens (collectively, the "blood draw remuneration").

Medicare pays $3 per patient encounter for specimen collection fees charged by physicians, independent laboratories, or hospital laboratories for the services and supplies they use in collecting blood samples, payable only to the person or entity that actually extracted the specimen from the patient. See Medicare Claims Processing Manual, CMS Pub. 100-04, Chap. 16, section 60.1 - 60.1.4, available at http://www.cms.hhs.gov/manuals/104_claims/clm104index.asp. Under the Proposed Arrangement, the amount the Lab would pay to each physician would be determined according to negotiations between the Lab and the physician, but would likely be between $3 and $6 for each patient receiving a blood draw, although the payment would be made no more than once each day for each patient. The Lab states that it wishes to enter into the Proposed Arrangement, because competing laboratories are paying referring physicians to perform blood draws.

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.

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 aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Proposed Arrangement would not fit in the safe harbor because the physicians will be paid on a per-patient basis, and, thus, the compensation would not be set in advance. 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 Proposed Arrangement, by which the Lab would provide referring physicians with free blood drawing supplies and payments for blood drawing services that may exceed what the Lab receives for such services and supplies from Medicare, would clearly implicate the anti-kickback statute.

There is a substantial risk that the Lab would be offering the blood draw remuneration to the physicians in exchange for referrals to the Lab. Under the Proposed Arrangement, the physicians could receive up to twice the $3 amount Medicare pays for blood specimen collection, plus any necessary blood-drawing supplies free of charge. Particularly when viewed in the aggregate, this compensation provides an obvious financial benefit to the referring physician, and it may be inferred that this benefit would be in exchange for referrals to the Lab. Where a laboratory pays a referring physician to perform blood draws, particularly where the amount paid is more than the laboratory receives in Medicare reimbursement, an inference arises that the compensation is paid as an inducement to the physician to refer patients to the laboratory, particularly in the circumstances presented here.

Based on the facts presented here, it appears that the physicians may well be soliciting the blood draw remuneration as a condition of sending new or continued referrals to the Lab. In addition, we cannot exclude the possibility that the Lab may be offering the blood draw remuneration to the physicians with the intent to induce new or continued referrals to the Lab, especially in light of the Lab's representation that the Proposed Arrangement is a reaction to competitors' arrangements to provide such blood draw remuneration to referring physicians. These competitor arrangements similarly may run afoul of the anti-kickback statute.

Furthermore, the Proposed Arrangement essentially would give the physicians the opportunity to earn a fee otherwise earned by the Lab. Because the physicians would receive a portion of the Lab's reimbursement for blood tests resulting from the physicians' referrals, the physicians have a strong incentive to order more blood tests. As a result, there is a risk of overutilization and inappropriate higher costs to the Federal health care programs. We discern no safeguards in the Proposed Arrangement to rebut the inference or reduce the risk that the blood draw remuneration would be intended to induce referrals.

Finally, we note that any specimen collection claims submitted by the Lab to Medicare for blood draws performed by the referring physicians would be improper claims and would implicate the Federal False Claims Act, at 31 U.S.C. § 3729, and the Civil Monetary Penalties Law, at section 1128A(a)(1) of the Act. As noted, Medicare pays only the person or entity that actually extracted the specimen from the patient. As such, Medicare rules would prohibit the Lab from billing Medicare for blood collection services rendered by the

referring physicians. In addition, while under certain conditions physicians can bill Medicare directly for collecting blood specimens,[1] if the Lab were to pay a physician to perform a blood draw, the physician would be impermissibly "double dipping" if the physician also billed Medicare for that blood draw.[2]

Accordingly, based on the totality of facts and circumstances, we conclude that the Proposed Arrangement poses a substantial risk of program fraud and abuse.

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.

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[1]Physician charges for specimen collection fee are allowed when: (1) it is the accepted and prevailing practice among physicians in the locality to make separate charges for drawing or collecting a specimen; and (2) it is the customary practice of the physician performing such services to bill separate charges for them. See Medicare Claims Processing Manual, CMS Pub. 100-04, Chap. 16, section 60.1.1.

[2]Only one collection fee is allowed per patient encounter, regardless of the number of blood specimens drawn. See id. at section 60.1.

- 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