DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 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 7, 2013

Posted: June 13, 2013

[Name and address redacted]

Re: OIG Advisory Opinion No. 13-03

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a clinical laboratory company's proposal to contract with physician practices to provide laboratory services to the physicians' patients who are not Federal health care program beneficiaries (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] (the "Parent Laboratory") is a [state name redacted] company that operates an independent clinical laboratory and is the requestor of this opinion. Under the Proposed Arrangement, the Parent Laboratory would establish a new legal entity (the "Management Company")[1] that would contract with physician groups (the "Physician Groups") to help them set up their own clinical laboratories (the "Physician Group Laboratories"). The Management Company would provide the Physician Groups with facility space and laboratory management and support and would offer to lease them personnel, equipment, and licenses for use of certain of the Parent Laboratory's proprietary methods of operation. Each Physician Group would own and operate its Physician Group Laboratory for purposes of CLIA compliance. Each Physician Group would be responsible for its own laboratory's data collection and quality review process, as well as its own billing for laboratory services.

The Parent Laboratory certified that, under the Proposed Arrangement, the Physician Groups would commit to provide testing by their Physician Group Laboratories only for patients who are not Federal health care program beneficiaries. The Physician Groups would send the specimens from patients who are Federal health care program beneficiaries, as well as specimens that require any esoteric or confirmation testing not performed by the Physician Group Laboratories, to another laboratory (possibly the Parent Laboratory). The Parent Laboratory certified that it would not require, pressure, or induce the Physician Groups to refer any testing to it, or to any other health care entity owned by or affiliated with it.

[1] The Management Company would be owned either by the Parent Laboratory or by the Parent Laboratory's owners, but it would have its own board of directors. The Management Company would have its own accounting systems, although it might contract with the Parent Laboratory for accounting support and other administrative services.

Under the Proposed Arrangement, each Physician Group would lease from the Management Company a separate laboratory suite in a building operated by the Management Company. The Physician Group would lease the individual suite exclusively and on a full-time basis. The lease agreement would describe fully the subject matter of the agreement, run for a term of not less than one year, and specify a fixed rate consistent with fair market value in an arms-length transaction.

In addition, each Physician Group would obtain from the Management Company various laboratory management services. These would include assistance from the Management Company in selecting and installing laboratory equipment and supplies in the leased laboratory suite. Each Physician Group would also receive certain support services on a "shared" basis from the Management Company. The Management Company would operate a common shipment receiving area and a shared business center with a fax machine, printer, and copier. The Management Company would also provide shared custodial help and waste collection services to all suites. The management services agreement would describe all of the specific services to be provided for the term of the agreement, run for not less than one year, and specify fixed rates consistent with fair market value in an arms-length transaction.

Each Physician Group would also have the option to license from the Management Company proprietary methods of operation for specimen accessioning, workflow, quality assurance standards, and test reporting. The license fee to be paid by the Physician Groups would be a fixed amount, based upon the number of specimens tested under the methodology. The licensing agreement would describe all of the specific licenses provided for the term of the arrangement, run for not less than one year, and specify royalty rates consistent with fair market value in an arms-length transaction that would not vary based on the value or volume of any Federal health care program referrals.

Each Physician Group would also have the option to lease laboratory personnel and equipment from the Management Company. If a Physician Group chose to lease the services of any laboratory personnel from the Management Company, the parties would enter into a written agreement that would describe all of the personnel leased between the parties for the term of the arrangement, specify the services to be provided, remain in effect for not less than one year, and specify rates consistent with fair market value in an arms-length transaction. If the Physician Group chose to lease equipment from the Management Company, the pertinent agreement would cover all of the equipment leased between the parties for the term of the lease, specify the equipment covered by the lease, remain in effect for not less than one year, and specify rates consistent with fair market value in an arms-length transaction.

The Parent Laboratory represented that each Physician Group's collected specimens would be segregated in the Physician Group's office by its own staff, which would use color-coded labels to distinguish private payor specimens for direction to the Physician

Group Laboratory from Federal health care programs specimens for direction to another laboratory provider (possibly the Parent Laboratory). The destination of the specimens would be determined by the Physician Group's office and staff.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully 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. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985), 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

Under the Proposed Arrangement, the Management Company would provide facility space, equipment, and laboratory management and other support services only with respect to specimens from patients who are not Federal health care program beneficiaries. Thus, as a threshold matter, we must address whether the "carve-out" of Federal business is dispositive of the question of whether the Proposed Arrangement implicates the anti-kickback statute. We conclude it is not.

The OIG has a long-standing concern about arrangements under which parties "carve out" referrals of Federal health care program beneficiaries or business generated by

Federal health care programs from otherwise questionable financial arrangements. Such arrangements implicate, and may violate, the anti-kickback statute by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business. Under the Proposed Arrangement, the Parent Laboratory would offer the Physician Groups remuneration in the form of the potentially lucrative opportunity to expand into the clinical laboratory business with little or no business risk. Although the Physician Group Laboratories would bill only for services for non-Federal health care program patients, participation in the Proposed Arrangement may increase the likelihood that physicians will order services from the Parent Laboratory for Federal health care program beneficiaries. This may occur for reasons of convenience, to demonstrate commitment to the Parent Laboratory and potentially secure more favorable pricing on private pay services, or simply because the Physician Groups fail to make a distinction between the Parent Laboratory and the laboratories operated with support from the Parent Laboratory-owned Management Company. Thus, we cannot conclude that there would be no nexus between the potential profits the Physician Groups may generate from the private pay clinical laboratory business, on the one hand, and orders of the Parent Laboratory's services for Federally insured patients, on the other.

Finally, we are concerned that the financial incentives offered through the private pay clinical laboratory business under the Proposed Arrangement are likely to affect a physician's decision-making with respect to all of his or her patients, including Federal health care program beneficiaries, potentially resulting in the overutilization of laboratory services generally and increased costs to the Federal health care programs.

For the above reasons, we cannot conclude that the Proposed Arrangement poses a sufficiently low level of risk that we should protect it.

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 by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- 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 (or that provision's application to the Medicaid program at section 1903(s) 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General