[*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 14, 2011

Posted: June 21, 2011

[Name and address redacted]

Re: OIG Advisory Opinion No. 11-08

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding an existing arrangement and a proposed arrangement involving contracts between a durable medical equipment ("DME") supplier and various independent diagnostic testing facilities ("IDTF"), pursuant to which IDTF staff members perform certain services on behalf of the DME supplier (the "Existing Arrangement" and the "Proposed Arrangement," respectively, and, together, the "Arrangements"). Specifically, you have inquired whether the Existing Arrangement constitutes, and 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 Existing Arrangement potentially generates, and 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 Arrangements. 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 "Requestor") is a Medicare-enrolled supplier of DME, including, but not limited to, continuous positive airway pressure blower units, masks, and supplies (the "CPAP"). A physician may prescribe the CPAP for patients diagnosed with obstructive sleep apnea ("OSA") based on the results of an overnight sleep study.[1] When a physician prescribes the CPAP, the patient chooses a DME supplier to supply the equipment. According to the Requestor, an additional sleep study may be necessary to determine the CPAP's most effective pressure settings. A licensed professional (e.g., a respiratory therapist, polysomnography technician, or a registered nurse) must then review the results of the sleep studies, adjust the CPAP to the prescribed setting, and educate the patient on the use and care of the equipment.

A. The Existing Arrangement

The Requestor has entered into contracts with several IDTFs. The IDTFs' ownership compositions vary, but physicians who are in a position to prescribe the CPAPs may have a financial interest in at least some of the IDTFs. Each contract between the Requestor and an IDTF is in writing, for a term of no less than one year, and non-exclusive. An IDTF may cancel its contract at any time, but the Requestor may terminate the contract only for breach or for cause.

Pursuant to the contracts, when a non-Federally insured patient selects the Requestor as a DME supplier, an appropriately licensed IDTF staff member performs certain services

[1] Overnight sleep studies are performed at IDTFs, among other locations.

related to setting up the CPAP for, and educating, the patient on behalf of the Requestor.[2] Federal health care program beneficiaries are excluded from the Existing Arrangement (i.e., the IDTFs do not provide the services to Federal health care program beneficiaries on behalf of the Requestor and, thus, the Requestor does not make any direct payments to the IDTFs for providing the services to those patients). The contracts also provide that the IDTF staff members are responsible for the display, inventory, care, and maintenance of the CPAPs that the Requestor consigns to the IDTF. The IDTFs are permitted to display and offer equipment from more than one DME supplier for the convenience of the IDTF's patients. Regardless of whether the IDTF stocks a competitor's equipment, IDTF staff members provide patients with a written list of local DME suppliers and advise the patients of their right to choose a DME supplier other than the Requestor before the patients select a DME supplier to supply the CPAP. The written list and the notice about the patient's right to choose may or may not include a direct or tacit endorsement by the IDTF as to the quality of the Requestor's products and services, at the sole discretion of the IDTF. In exchange for these services, the Requestor pays the IDTF[3] a per patient fee, which the Requestor has certified reflects fair market value[4] for the services. The Requestor has certified that all of the services provided pursuant to the contracts are compliant with the Requestor's accreditation and quality assurance process, as well as Medicare Quality Standards and local laws.

IDTF staff members, including those who perform these services, may interact with patients throughout the patients' entire experience at the IDTF, including the period of time before, during, and soon after the sleep studies, which occurs before the patients have selected a particular DME supplier. In those circumstances where physicians in a position to prescribe the Requestor's products have financial interests in the IDTFs, those physicians may interact with patients before the patients select a DME supplier.

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[2] The Requestor has certified that it would otherwise be obligated to provide these services itself.

[3] Generally, the Requestor pays the fee directly to an IDTF. In some limited circumstances, and at the request of an IDTF, the Requestor pays the fee directly to the IDTF staff member who performs the services. For ease of reference, throughout this opinion we will refer to both types of payments in terms of those made from the Requestor to an IDTF. The variation as to which party actually receives the payment is not, under these specific facts, material to our analysis.

[4] We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. 42 U.S.C. §1320a-7d(b)(3)(A).

B. The Proposed Arrangement

The Requestor also seeks to engage in the Proposed Arrangement. It is identical to the Existing Arrangement in all material respects, with the following notable exceptions. First, the Proposed Arrangement would apply to all patients who select the Requestor as their DME supplier, including Federal health care program beneficiaries. Second, the fee paid to an IDTF for the services would be a flat monthly or flat annual fee. And third, although the flat fee would not be altered, the Requestor would have the right to terminate the contract if the Requestor was not satisfied with the number of patients receiving the services. The Requestor has expressly stated that it cannot certify that the flat fee would reflect the fair market value of the services provided under the Proposed Arrangement.

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. 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.

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 Arrangements.

B. Analysis

The Existing Arrangement covers services provided to non-Federally insured patients only. Thus, as a threshold matter, we must address whether the "carve out" of Federal business is dispositive of the question of whether the Existing Arrangement implicates the anti-kickback statute. It is not. The OIG has a long-standing concern about arrangements pursuant to which parties "carve out" 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 business through the payment of amounts purportedly related to non-Federal business. Here, IDTFs participating in the Existing Arrangement may still influence referrals of Federal health care program beneficiaries to the Requestor for DME. Thus, we cannot conclude that there would be no nexus between the Requestor's payments to the IDTF for services provided to non-Federal patients and referrals to the Requestor of Federally insured patients.

Next, we consider whether the Existing Arrangement qualifies, and whether the Proposed Arrangement would qualify, for safe harbor protection under the personal services and management contracts safe harbor. We conclude that the Arrangements do not, and would not, respectively, because they do not meet all of the safe harbor's conditions, including the condition that for periodic, sporadic, or part-time services, the agreements must specify the exact schedule, precise length, and exact charge for the intervals. 42 C.F.R. § 1001.952(d)(3). However, the absence of safe harbor protection is not fatal. Instead, the Arrangements must each be subject to a case-by-case evaluation.

Careful scrutiny of the Arrangements is warranted because the Requestor, a DME supplier, plans to subcontract to IDTFs performance of several of its obligations. Those IDTFs are, through their staffs, potentially in a position to influence Federal health care program beneficiaries to select the Requestor's products. Further, in some cases, physicians who are able to prescribe the Requestor's products may have a financial interest in the IDTFs. Potential concerns with arrangements such as those at issue here, include, for example, payments that are above market rates—as is potentially the case

with the Proposed Arrangement—or payments that may be consistent with fair market value but otherwise reflect the volume or value of past or expected referrals—as is the case with the Existing Arrangement.

Moreover, we have long been concerned about aggressive marketing by DME suppliers, including those marketing activities that involve personal contact with Federal health care program beneficiaries. In-person sales pitches or "informational" sessions can be extremely coercive, particularly when such activities are targeted at senior citizens, Medicaid beneficiaries, and other particularly vulnerable patients. These marketing activities are highly susceptible to fraud and abuse, as they can lead to overutilization, increased costs to the Federal health care programs and beneficiaries, inappropriate medical choices, and adverse effects on the quality of care patients receive. Arrangements that closely tie DME suppliers to IDTF staff members, physicians with financial interests in the IDTFs who are in a position to prescribe, and patients—such as the Requestor's Arrangements—are particularly susceptible to problematic marketing schemes. The fraud and abuse risks are compounded where, as here, a physician or other health care professional is involved in the marketing activity—a practice sometimes referred to as "white coat" marketing. White coat marketing is closely scrutinized under the anti-kickback statute because physicians and other health care professionals are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services—especially when marketing to their patients. See, e.g., 56 Fed. Reg. 35952, 35974 (July 29, 1991). Given the nature of these relationships, when physicians or other health care professionals market items and services to their patients, patients may have difficulty distinguishing between professional medical advice and a commercial sales pitch.

The Arrangements contain hallmarks of these potentially problematic arrangements. Specifically, they involve direct payments to IDTFs that can closely tie the Requestor to IDTF staff members and, in some instances, to physicians with financial interests in the IDTF who are in a position to prescribe. That connection effectively allows the Requestor to obtain in-person contacts with patients—including Federal health care program beneficiaries—through health care professionals who are in a position of trust. Those contacts could occur before a patient selects a DME supplier, resulting in an increased risk that the IDTF staff members and, in some instances, physicians with financial interests in the IDTF, could inappropriately influence a beneficiary's selection of the Requestor as his or her DME supplier. Further, the Arrangements have the potential to influence the decisions of physicians with financial interests in the IDTFs to prescribe the CPAP in the first place.

The consignment component of each of the Arrangements raises additional concerns. Although the Requestor has certified that it would not make separate payments for rental

space and consignment services, the consignment component is part of the total package of services covered by the contract with an IDTF and is, therefore, inextricably tied to the payments made under each contract. Thus, at least some portion of the fee presumably would be attributable to the consignment component of each of the Arrangements. As we have noted in the past, consignment arrangements can pose fraud and abuse risks in certain circumstances, including arrangements involving any form of payment. The consignment component of each of the Arrangements poses such risks.

For the foregoing reasons, and based on all of the facts and circumstances, we cannot conclude that either the Existing Arrangement or the Proposed Arrangement poses a sufficiently low risk of fraud and abuse to provide prospective immunity under our administrative authorities.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Existing Arrangement potentially generates, and 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 Arrangements. 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 Existing

Arrangement or 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,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General