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: October 3, 2006

Posted: October 10, 2006

[Name and address redacted]

Re: OIG Advisory Opinion No. 06-16

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposed arrangement for a durable medical equipment ("DME") manufacturer to provide advertising assistance and reimbursement consulting services to some of its customers (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] ("Requestor") manufactures wheelchairs and other durable medical equipment ("DME"). Requestor primarily sells its products to DME suppliers. The DME suppliers then provide DME to patients, including beneficiaries of Federal health care programs, and obtain reimbursement from payers, including Federal health care programs. Requestor proposes providing some of its DME supplier customers with advertising assistance and reimbursement consulting services (the "Proposed Arrangement").

Advertising Assistance

The aspect of the Proposed Arrangement involving advertising assistance would entail Requestor providing free advertising for the DME suppliers or underwriting various advertising expenses the DME suppliers might otherwise incur. Under the Proposed Arrangement, advertising assistance would take various forms. The DME supplier might develop its own advertisements, but Requestor would reimburse the DME supplier for the money it spent on advertising. Such reimbursement might be in monetary form or in the form of free DME. Alternatively, Requestor might itself undertake advertising on behalf of the DME supplier. Under this scenario, Requestor would develop and pay for television, internet, and print advertising material featuring Requestor's products. Some advertising materials would display the DME supplier's name and contact information. Other advertising materials would display the DME supplier's name and a toll free telephone number for a call center operated by Requestor and staffed by Requestor's representatives, who would provide callers with information about Requestor's products. Requestor would maintain the call center and pay the customer service staff.

Requestor would determine which of its DME supplier customers to include in the Proposed Arrangement, and, if included, the value of advertising assistance it would provide, based on the demographics of the customer's market, historical market data, and projected market

potential. Requestor would reevaluate the value of advertising assistance it would provide to selected customers every six months.

Reimbursement Consulting Services

The aspect of the Proposed Arrangement involving reimbursement consulting services would entail Requestor providing various services free of charge to its DME supplier customers or underwriting expenses that the DME supplier might otherwise incur. The free reimbursement consulting services would include general claims submission information, such as advice on how to code products. The free services would also include assistance specific to obtaining reimbursement for products sold to particular patients, such as reviewing claims, helping to appeal denied claims, and providing assistance with issues related to assessing and documenting individual patients' medical needs and medical justification for receiving particular products. Requestor would also provide reimbursement training for the DME suppliers' staff.

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.

B. Analysis

Requestor's provision of advertising assistance and reimbursement consulting services under the Proposed Arrangement would constitute remuneration to the DME suppliers. Because the DME suppliers are in a position to generate Federal health care program business for Requestor, the Proposed Arrangement clearly implicates the anti-kickback statute.[1] Indeed, given the facts presented, there is a substantial risk that the Proposed Arrangement would be a disguised kickback scheme having as one of its purposes the generation of business payable by a Federal health care program for Requestor. We discern no safeguards against fraud and abuse in the Proposed Arrangement.

By subsidizing advertising expenses and maintaining and staffing call centers to field inquiries generated by these advertisements,[2] Requestor would provide valuable services to the selected DME suppliers, sparing them costs they would otherwise incur to promote and operate their businesses. With respect to the reimbursement consulting services, we have long recognized that manufacturers sometimes offer purchasers certain reimbursement support services in connection with the sale of their products. See OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23735 (May 5, 2003). In this regard, we have observed that:

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[1]This opinion addresses the question posed by Requestor: whether the Proposed Arrangement could constitute unlawful remuneration from Requestor to the DME suppliers in exchange for the DME suppliers' orders of Requestor's products. We note that shared advertising for manufacturers and suppliers can also give rise to the converse question: whether the advertising arrangement entails unlawful remuneration from the suppliers to the manufacturer in exchange for the manufacturer's recommendation of the suppliers. Depending on the underlying facts, it might be possible to characterize the advertising feature of the Proposed Arrangement as involving remuneration from the DME suppliers to Requestor (e.g., an agreement to generate business for Requestor) in exchange for free advertising. From this perspective, the Proposed Arrangement is equally suspect under the anti-kickback statute.

[2]The call center feature of the Proposed Arrangement is particularly troubling because patients may be confused or misled into choosing Requestor's products. Some of the advertising materials would display the DME supplier's name but would include a toll free telephone number for a call center operated by Requestor and staffed by Requestor's representatives. Thus, there is a significant risk that patients might mistakenly believe they are speaking with the DME supplier's customer service representatives and obtaining objective information about DME without bias favoring the products of any one manufacturer.

> "[s]tanding alone, [product support] services that have no substantial independent value to the purchaser may not implicate the anti-kickback statute. However, if a manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on the referring provider . . . the arrangement would raise kickback concerns."

Id. The reimbursement consulting services under the Proposed Arrangement would be neither limited in nature, nor free-standing. Indeed, the services would potentially confer substantial independent value upon the DME supplier.

The Proposed Arrangement poses all the usual risks associated with kickbacks. There is a substantial risk of driving overutilization and increasing program costs. The availability and value of the advertising assistance would be determined in a manner that takes into account the volume or value of a DME supplier's past or expected future purchases. Moreover, Requestor's help securing Federal reimbursement for individual beneficiaries to receive particular products could cause beneficiaries to receive greater quantities of, or more expensive, DME than they actually require (e.g., by encouraging a DME supplier to equip a patient with a power wheelchair when the patient does not require a power wheelchair, and then helping the DME supplier to obtain Federal payment for the unnecessary equipment). The Proposed Arrangement would give DME suppliers an incentive to steer patients to Requestor's products, even if products from other manufacturers were less expensive or more appropriate. Finally, the Proposed Arrangement poses a substantial risk of unfair competition, because Requestor's provision of remuneration would encourage DME suppliers to purchase DME from Requestor to the potential detriment of competitor DME manufacturers that do not provide similar unlawful benefits to their customers.

In short, there is substantial likelihood that the Proposed Arrangement would be a vehicle to pay unlawful kickbacks. Accordingly, we conclude that the Proposed Arrangement, if implemented, could be subject to sanctions.

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