[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.*]

Issued: November 19, 2008

Posted: November 26, 2008

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 08-20

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposal whereby two suppliers of durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") will (i) place an inventory of DMEPOS in consignment closets on-site at certain hospitals and (ii) have licensed personnel on-call or on-site at the hospitals to train and educate patients who have been prescribed respiratory equipment and have selected one of the companies as their supplier upon discharge to their homes (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement will 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 would not generate prohibited remuneration under the anti-kickback statute and, therefore, the Proposed Arrangement would not constitute grounds for the Office of Inspector General ("OIG") to impose

administrative sanctions on [names 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).

This opinion may not be relied on by any persons other than [names redacted], the requestors 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

[Names redacted] (the "Suppliers") are Medicare-approved suppliers of DMEPOS. Under the Proposed Arrangement, the Suppliers will enter into contracts with various hospitals in [States redacted] allowing the Suppliers to place an inventory of DMEPOS[1] in consignment closets on-site at each hospital for distribution to those patients who are bound for home, whose physicians have ordered the DMEPOS for home use, and who have elected to obtain the DMEPOS from one of the Suppliers. The Suppliers have certified that they will not pay any remuneration to the hospitals (or anyone affiliated with the hospitals) for the use of the consignment closets.

The hospital discharge planners will provide each patient who is in need of DMEPOS with a list of local DMEPOS suppliers. While a Supplier will be identified as the DMEPOS supplier utilized by the hospital, the patients will be free to select the DMEPOS supplier of their choice. If the patient chooses a Supplier as the patient's DMEPOS supplier, then that Supplier will bill the patient and/or his or her third party payor, including Medicare and/or Medicaid, for the DMEPOS ordered.

For the Suppliers' DMEPOS that is respiratory equipment, the Suppliers will also provide licensed personnel, such as respiratory therapists or registered nurses ("Licensed Personnel"), on-call or on-site at the hospitals to provide training and education for patients who have been prescribed the respiratory equipment and selected a Supplier to be their supplier upon discharge to their homes.[2]

The Suppliers have represented that Licensed Personnel will perform training, education, and coordination of care services in order to comply with the Final October 2008 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards (the "Quality Standards") recently issued by the Centers for Medicare & Medicaid

[1] The inventory of DMEPOS will consist of items such as portable oxygen, walkers, wheelchairs, canes, and continuous positive airway pressure devices. Other DMEPOS will be available for home delivery.

[2] The Suppliers collectively employ over forty Licensed Personnel.

Services ("CMS").[3] Section 1834(a)(20) of the Act requires all suppliers of DMEPOS to comply with the quality standards specified by the Secretary of the United States Department of Health and Human Services in order to furnish items or services for which payment is made under Medicare Part B and to receive or retain a supplier number used to submit claims for reimbursement for any such item or service for which payment may be made under Medicare.[4]

For the patients who choose a Supplier as their supplier of respiratory equipment, the Suppliers will comply with the Quality Standards by utilizing Licensed Personnel to: (a) consult with the prescribing physician as needed to confirm the order and to recommend any necessary changes or refinements or additional evaluations in connection with the prescription of respiratory equipment; (b) assure that the respiratory equipment delivered to the patient is consistent with the prescribing physician's order and other identified patient needs, risks, and limitations of which the Supplier is aware; (c) provide appropriate information to the patient or caregiver related to the setup, features, routine use, troubleshooting, cleaning, and maintenance of the respiratory equipment; (d) ensure that the patient or caregiver can use all equipment and items provided safely and effectively in the settings of anticipated use; (e) provide relevant information and/or instructions about infection control issues related to the use of the respiratory equipment; (f) verify that the patient has received training and instructions on the use of the respiratory equipment; (g) record in the patient's record that such instruction was provided; (h) provide patients with essential contact information for rental equipment and options for patients to rent or purchase equipment and items, if applicable; and (i) provide the patient with information and telephone numbers for customer service assistance regarding regular business hours, after-hours access, item repair, and emergency coverage.

The hospitals will provide the Licensed Personnel with a desk and phone connected to the hospital's internal telephone system to facilitate the coordination of these services with the patient's treating physician, other clinicians, and the hospital's discharge planning staff. The hospitals will not charge the Suppliers for the use of the desk or telephone. The Licensed Personnel will not provide any other services to the patients of the hospital (e.g., discharge planning or case management services), nor will they have any type of

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[3] CMS originally released Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies on Aug. 14, 2006. The revised final 2008 Quality Standards are available on the CMS web site at http://www.cms.hhs.gov/MedicareProviderSupEnroll/Downloads/DMEPOSAccreditationStandards.pdf.

[4] In addition, as mandated by Section 1834(j)(1)(B) of the Act, in order for a DMEPOS supplier to obtain and maintain Medicare billing privileges, that supplier must satisfy certain supplier standards, which are set forth at 42 C.F.R. § 424.57.

contact with the patients prior to the patients' selection of a Supplier for respiratory equipment. If a patient selects a Supplier as his or her supplier of respiratory equipment, then and only then will the Licensed Personnel provide the required education, training, and coordination of care services to that patient in accordance with the Quality Standards. The Licensed Personnel will not provide training, education, or coordination of care services to patients who elect to obtain respiratory equipment from DMEPOS suppliers other than the Suppliers.

The details of the Proposed Arrangement described above between each Supplier and the hospitals will be memorialized in a written agreement signed by both parties. The Suppliers have certified that there will be no other arrangements or understandings between or among the Suppliers and the hospitals, anyone affiliated with the hospitals, or any physicians or their patients in connection with 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.), 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

We have long been concerned about aggressive marketing by DMEPOS suppliers, including those marketing activities that involve personal contact with beneficiaries. For example, door-to-door marketing, telephone solicitations, direct mailings, and 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 activities are highly susceptible to fraud and abuse, as they can lead to overutilization, increased costs to the Federal health care programs and beneficiaries, and inappropriate medical choices, as well as adverse effects on the quality of care patients receive.[5] Arrangements, like the Proposed Arrangement, that offer DMEPOS suppliers opportunities for access to hospital staff and patients are particularly susceptible to problematic marketing schemes.

Notwithstanding our serious concerns about DMEPOS marketing tactics, for the reasons set forth below, we conclude that the Proposed Arrangement between the Suppliers and the hospitals does not implicate the anti-kickback statute in the specific circumstances presented here. Under the Proposed Arrangement, no remuneration will flow from the Suppliers to their potential referral sources, the hospitals and their staff and physicians, in connection with the hospitals' provision of consignment closets to the Suppliers for placement of an inventory of DMEPOS on-site at the hospitals. The consignment closets will be provided at no cost to the Suppliers. Similarly, no remuneration will flow from the Suppliers to their potential referral sources in connection with the hospitals' provision of telephones and desks on-site at the hospitals at no cost to the Suppliers. In short, under the Proposed Arrangement, the remuneration (the free telephones, desks, and consignment closets) and the referrals run the same way.[6] Therefore, we conclude that this aspect of the Proposed Arrangement does not implicate the anti-kickback statute.[7]

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[5] The Suppliers have certified that the Licensed Personnel will not have any type of contact with the patients prior to the selection of a Supplier as their supplier of respiratory equipment. If a patient selects a Supplier as his or her supplier of respiratory equipment, then and only then will the Licensed Personnel provide the required education, training, and coordination of care services to that patient in accordance with the Quality Standards. We express no opinion here with respect to any interactions that the Suppliers may have with Federal health care program beneficiaries, including any kind of marketing or advertising activities. Our analysis and conclusions in this opinion apply only to the Proposed Arrangement between the Suppliers and the hospitals.

[6] In other circumstances, free telephones, desks, and space could constitute impermissible remuneration under the anti-kickback statute. Here, however, the Suppliers are in no discernable position to be referral sources for the hospitals that are providing the free items and space.

[7] We express no opinion as to whether the Suppliers are satisfying applicable CMS

With respect to the Suppliers' proposal to provide Licensed Personnel on-call or on-site at the hospitals to provide specified training, education, and care coordination services, there is also no remuneration from the Suppliers to the hospitals. The Quality Standards issued by CMS set forth the obligations of the Suppliers. The Licensed Personnel will provide only those services necessary for the Suppliers to comply with the Quality Standards. The Licensed Personnel will not provide any services that the hospitals are otherwise obligated to provide (e.g., discharge planning or case management services), nor will the services that the Licensed Personnel provide serve as any kind of substitute for services currently provided by the hospitals at their expense.[8] In these circumstances, there will be no financial benefit to the hospitals with respect to the Licensed Personnel.[9]

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental

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supplier standards with respect to the Proposed Arrangement. In addition, notwithstanding the outcome here, consignment arrangements can pose fraud and abuse risks in other circumstances, including arrangements involving any form of payment.

[8] The OIG has stated on numerous occasions its view that the provision of free services to an actual or potential referral source may violate the anti-kickback statute, depending on the circumstances. For example, OIG issued a Special Fraud Alert relating to the provision of free services by a clinical laboratory phlebotomist placed in a physician's office, stating:

> While the mere placement of a laboratory employee in the physician's office would not necessarily serve as an inducement prohibited by the anti-kickback statute, the statute is implicated when the phlebotomist performs additional tasks that are not normally the responsibility of the physician's office staff. These tasks can include taking vital signs or other nursing functions, testing for the physician's office laboratory, or performing clerical services.
>
> Where the phlebotomist performs clerical or medical functions not directly related to the collection or processing of laboratory specimens, a strong inference arises that he or she is providing a benefit in return for the physician's referrals to the laboratory. In such a case, the physician, the phlebotomist, and the laboratory may have exposure under the anti-kickback statute.

OIG Special Fraud Alert, 59 Fed. Reg. 65372, 65377 (Dec. 19, 1994).

[9] The Suppliers have certified that there will be no other arrangements or understandings between or among the Suppliers and the hospitals, persons affiliated with the hospitals, or any physicians or their patients in connection with the Proposed Arrangement.

submissions, we conclude that the Proposed Arrangement would not generate prohibited remuneration under the anti-kickback statute and, therefore, the Proposed Arrangement would not constitute grounds for the OIG to impose administrative sanctions on the Suppliers 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).

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], which are the requestors 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 will not proceed against [names redacted] with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. 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. In

the event that this advisory opinion is modified or terminated, the OIG will not proceed against [names redacted] with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General