[*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: July 23, 2007

Posted: July 30, 2007

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 07-08

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a durable medical equipment ("DME") supplier's proposed arrangement to provide patients with a free in-home congestive heart failure assessment (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the civil monetary penalty provision for violations of the prohibition against inducements to beneficiaries under section 1128A(a)(5) of the Social Security Act (the "Act"), as well as under the exclusion authority at section 1128(b)(7) of 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 constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act (the "CMP"). We also conclude that the Proposed Arrangement potentially generates prohibited remuneration under the anti-kickback statute, and that the Office of Inspector

General ("OIG") could potentially 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) 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 [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.

A. FACTUAL BACKGROUND

[Name redacted] owns [name redacted]. The two companies (collectively referred to as "the Requestors") operate as DME suppliers, furnishing, among other things, home oxygen products and services to a national patient population that includes Medicare and Medicaid program beneficiaries. The Requestors seek our opinion regarding a proposed arrangement involving an in-home congestive heart failure ("CHF") assessment with oximetry testing (the "Proposed Arrangement").

By way of background, the Medicare program will only cover home oxygen for patients with certain underlying disease states or diagnoses, one of which is recurring CHF due to chronic cor pulmonale. Medicare does not cover physician-prescribed home oxygen unless the coverage is justified by an oximetry test measuring blood-oxygen levels. The oximetry test cannot be conducted by a DME supplier.[1] According to the Requestors, the time lag from when the physician orders the test until the patient actually completes his or her qualifying test can range from a few days to several weeks.

A. The Requestors' Proposed Arrangement

Pursuant to the Proposed Arrangement, the Requestors would provide patients diagnosed with CHF with an in-home CHF assessment with oximetry testing, free of charge. The clinical assessment would include a subjective functional assessment; heart rate, respiratory rate, and blood pressure measurements; assessment of breath sounds and level of dyspnea; a check for peripheral edema, abdominal pain or swelling; and a medication profile and mobility analysis. The patient would also receive education regarding his/her condition and tips in the recognition and self-management of

[1] See Medicare Claims Processing Manual, Pub. 100-04, Chapter 20, Section 100.2.3. An oximetry test administered by a DME supplier cannot qualify a beneficiary for Medicare, nor will Medicare pay for such a test. There is an exception, not relevant here, for DME suppliers that are hospitals.

symptoms. During the in-home assessment, the patient would also undergo pulse oximetries conducted at rest, with activity, and overnight. The Requestors claim that such oximetry testing can yield useful preliminary data regarding the beneficiary's breathing.

The Medicare and Medicaid programs cover home-based oximetry tests under the direction of a Medicare-enrolled Independent Diagnostic Testing Facility ("IDTF"). The Requestors estimate, for example, that the value of IDTF overnight oximetry testing is approximately $22, based on the non-geographically adjusted 2006 Medicare Physician Fee Schedule rates for IDTFs. The Requestors indicate that some Medicaid programs would cover oximetries provided by oxygen suppliers such as the Requestors. The Requestors have indicated, nevertheless, that they would not seek Federal reimbursement for any oximetry tests, or any other evaluative or educational services performed in connection with the Proposed Arrangement.

The Proposed Arrangement would be publicized through communications from the Requestors' sales and marketing personnel directed exclusively to physicians and their staffs. The Proposed Arrangement, according to the Requestors, would not be referenced in any patient communications or marketing materials. Physician orders are required for all assessments that are part of the Proposed Arrangement. Beneficiaries typically would learn of the Proposed Arrangement from their physicians. The Requestors have certified that participants in the Proposed Arrangement would remain free to choose any healthcare goods and services supplier and that their standard practice is to provide each participant with a written freedom of choice disclosure.

II. LEGAL ANALYSIS

A. Law

Section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who gives something of value to a beneficiary of Medicare or a state health care program, including Medicaid, that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state health care program, including Medicaid. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of section 1128A(a)(5) as including "transfers of items or services for free or for other than fair market value." The OIG has previously taken the position that "incentives that are only nominal in value are not prohibited by the statute," and has interpreted "nominal value to be no more than $10 per item, or $50 in the aggregate on an annual basis." 65 F.R. 24400, 24410 – 24411 (April 26, 2000) (preamble to the final rule on the CMP).

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

The Proposed Arrangement implicates both the CMP and the anti-kickback statute. Pursuant to the Proposed Arrangement, the Requestors would provide patients who have been diagnosed with CHF with a free CHF assessment with oximetry testing. However, the Requestors indicate that they would not seek Medicare payment for any aspect of the CHF assessment with oximetry testing. Nevertheless, many of the Requestors' DME and home care goods and services are reimbursable by Federal health care programs. Arrangements whereby a prospective provider or supplier of Federally-payable items and services offers beneficiaries a non-covered item or service free of charge implicate the fraud and abuse laws and must be closely scrutinized.

The threshold question under the CMP is whether the free CHF assessment with oximetry testing provided under the Proposed Arrangement would constitute remuneration paid to the beneficiaries who receive them. When evaluating potential remuneration under the CMP, the appropriate focus of inquiry is the value of the gift to the beneficiary. We conclude that the proposed CHF assessment with oximetry testing would constitute remuneration under the CMP. The Requestors estimate that the economic value of overnight oximetry, just one component of the assessment, would

itself be more than nominal. Moreover, and equally important, even were the tests provided by the Requestors to have no value for the purpose of qualifying for Medicare coverage, the Requestors propose to deliver the testing service to beneficiaries in a manner that would lead a reasonable beneficiary to believe that he or she is receiving a valuable service that may expedite access to covered oxygen supplies and contribute to a successful clinical outcome. No statutory exception to the CMP applies to the free CHF assessment with oximetry testing.

The second question under the CMP is whether the remuneration provided under the Proposed Arrangement would be likely to influence beneficiaries to select the Requestors as their supplier of oxygen or other Medicare-payable goods and services. For several reasons we believe that the answer is yes. Typically, the beneficiary's own physician will have recommended the Requestors for the CHF assessment with oximetry testing. It would be reasonable and probable that a beneficiary would assume that his or her own physician similarly would recommend the Requestors' other goods and services. While providing the free CHF assessment with oximetry testing, the Requestors would have the opportunity to initiate a relationship with the beneficiary, and it is reasonable and probable that for future purchases the beneficiary would select a supplier with whom he or she is already familiar. The fact that the CHF assessment with oximetry testing would be offered at-home and without charge increases the chances that a beneficiary would take advantage of the offer, thus maximizing opportunities for the Requestors to initiate a relationship with the beneficiary prior to his or her selection of a supplier. The Requestors do not indicate whether the recipients of the free CHF assessment with oximetry testing would be obligated to retain the Requestors as their supplier for future purchases of oxygen or other Medicare-payable supplies. Even were there no such obligation, however, the Proposed Arrangement would certainly be likely to influence them to select the Requestors over competitors.[2]

The third and final issue under the CMP is whether the Requestors know or should know that the provision of services under the Proposed Arrangement would be likely to influence beneficiaries' selection of the Requestors for oxygen or other Medicare-payable supplies. Aspects of the Proposed Arrangement's structure and operation – including the offer of CHF assessment with oximetry testing services without charge, the home administration of the services (also free of charge), and the role of a beneficiary's own physician in recommending the Requestors – appear calculated to generate subsequent business for the Requestors. The Requestors indicate that the Proposed

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[2]The Requestors rely on freedom of choice disclosures made to the beneficiaries to safeguard against improper influence. While such disclosures further the desired goal of informed decision-making, we do not believe that such disclosures are sufficient to safeguard against improper beneficiary inducements.

Arrangement would be offered to beneficiaries who are diagnosed with CHF. These represent a group of patients that can be expected to require oxygen and other Federally-payable goods and services in the near future.[3] Thus, we believe that it is probable that the Requestors know or should know that the Proposed Arrangement would be likely to generate Federally-payable business for the Requestors.

For these reasons, we conclude that the Proposed Arrangement would potentially violate the CMP provision. For the same reasons, we conclude that it would potentially violate the anti-kickback statute.[4]

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 the Requestors 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 [names redacted], 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.

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[3]Moreover, we note that free CHF assessment with oximetry testing would permit the Requestors to identify beneficiaries who would likely qualify for Medicare-covered home oxygen on completion of an independent oximetry test, thereby enabling the Requestors to target their free interim oxygen to those beneficiaries.

[4]We note that nothing in this opinion addresses whether beneficiaries might benefit from interim oxygen or overnight oximetry testing or whether these goods and services could be furnished for an appropriate fee.

- 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General