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: November 1, 2006

Posted: November 8, 2006

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 06-20

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a durable medical equipment ("DME") supplier's practice of providing patients with free home oxygen until the patients qualify for Medicare coverage of oxygen (the "Existing Arrangement"), as well as the supplier's proposed arrangement to provide patients with a free overnight oximetry test (the "Proposed Arrangement"). Specifically, you have inquired whether the Existing Arrangement and the Proposed Arrangement (either separately or in combination) 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 both the Existing Arrangement and the Proposed Arrangement (separately or in combination) 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 Existing Arrangement and the Proposed Arrangement (separately or in combination) potentially generate 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 Existing Arrangement or the Proposed Arrangement, or both. 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.

I. FACTUAL BACKGROUND

[Name redacted] owns [name redacted]. The two companies (collectively referred to as "Requestor") 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. Requestor seeks our opinion regarding two arrangements, one existing and one proposed, involving home oxygen and oximetry testing.

By way of background, the Medicare program does not cover physician-prescribed home oxygen unless the coverage is justified by an oximetry test measuring blood-oxygen levels.[1] The oximetry test cannot be conducted by a DME supplier.[2] According to Requestor, the time lag from when the physician orders the test until the beneficiary actually completes his

[1] See Medicare Coverage Issues Manual, Pub. 06, Part 60, Section 60-4.

[2] See Medicare Carriers Manual, Pub. 14, Part 3, Chapter 4, Section 4105. An oximetry test administered by a DME supplier cannot qualify a beneficiary for Medicare, nor will Medicare pay for such a test. The rules contain an exception, not relevant here, for DME suppliers that are hospitals.

or her qualifying test can range from a few days to several weeks. The Medicare program does not cover so-called "interim oxygen" ordered or provided before completion of the qualifying test.

A. Requestor's Existing Arrangement.

Under the Existing Arrangement, Requestor does not charge the beneficiary for interim oxygen delivered to, and set up in, his or her home by Requestor's trained technicians. Beneficiaries typically learn about the free oxygen offer from their physicians. Such arrangements are common practice throughout the home oxygen industry, according to Requestor. Requestor claims it does not affirmatively market the Existing Arrangement to either beneficiaries or physicians. Requestor states that, while it does not volunteer information regarding the Existing Arrangement, it does truthfully respond to inquiries from beneficiaries, physicians, and others when they occur.

B. Requestor's Proposed Arrangement

Pursuant to the Proposed Arrangement, Requestor would provide beneficiaries with overnight oximetry testing free of charge. While an oximetry test administered by a DME supplier cannot qualify a beneficiary for oxygen coverage by the Medicare program, Requestor claims that it can yield useful preliminary data regarding the beneficiary's nighttime breathing. The testing equipment would be brought to a beneficiary's home on the evening of the test by one of Requestor's technicians. The technician would set up the equipment in the beneficiary's home for overnight use, and would show the beneficiary how to use the equipment. The next day the technician would return to the home to gather the equipment, document the results, and send the results to the patient's requesting physician. The Requestor estimates that the value of overnight oximetry testing is approximately $22, based on the non-geographically adjusted 2006 Medicare Physician Fee Schedule rates for independent testing facilities.

The Proposed Arrangement, according to Requestor, would not be referenced in any patient communications or marketing materials. Requestor states it would not volunteer information to beneficiaries or physicians regarding the Proposed Arrangement except in response to inquiries. Beneficiaries typically would learn of the Proposed Arrangement from their physicians. Requestor has certified that participants in the Proposed Arrangement would remain free to choose any oxygen supplier and that its 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 (the "CMP") provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or Medicaid program beneficiary 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 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,"[3] and has interpreted "nominal value to be no more than $10 per item, or $50 in the aggregate on an annual basis."[4]

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.

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[3]Preamble to the final rule on the CMP, 65 FR 24400, 24410 (April 26, 2000).

[4]Id. at 24411.

B. Analysis

The Existing Arrangement and the Proposed Arrangement implicate both the CMP and the anti-kickback statute. Under the Existing Arrangement, Requestor, a DME supplier, provides beneficiaries who have been prescribed home oxygen therapy with free interim oxygen. Pursuant to the Proposed Arrangement, Requestor would provide beneficiaries who are potential respiratory patients with free overnight oximetry testing. While neither interim oxygen, nor oximetry testing by a DME supplier, are covered by the Medicare program, many of Requestor's other 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 interim oxygen or oximetry testing provided under the Existing Arrangement or the Proposed Arrangement would constitute remuneration paid to the beneficiaries who receive them. With regard to the free oxygen available under the Existing Arrangement, the answer is clearly affirmative. When evaluating potential remuneration under the CMP, the appropriate focus of inquiry is the value of the gift to the beneficiary. Interim oxygen supplies, which may last a few days to several weeks, have clear and substantial value to the beneficiaries that receive them. Similarly, we conclude that the proposed overnight oximetry tests would also constitute remuneration under the CMP. The Requestor estimates that the test's economic value would be more than nominal. Moreover, and equally importantly, notwithstanding that the tests provided by Requestor would have no value for the purpose of qualifying for Medicare coverage, the Requestor proposes 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 interim oxygen or oximetry testing.

The second question under the CMP is whether the remuneration provided under the Existing Arrangement or the Proposed Arrangement would be likely to influence beneficiaries to select the Requestor 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 Requestor for interim oxygen or overnight oximetry. It would be reasonable and probable that a beneficiary would assume that his or her own physician similarly would recommend Requestor's other goods and services. While providing the free interim oxygen or the overnight oximetry, Requestor has or 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 interim oxygen and the overnight oximetry is or would be offered without charge increases the chances that a beneficiary would take advantage of the offers, thus maximizing opportunities for Requestor to initiate a relationship with the beneficiary prior to his or her selection of a supplier. While the receipt of free interim oxygen or free oximetry testing would not commit beneficiaries to retain Requestor as their supplier for future purchases of oxygen or other Medicare-payable supplies, it is certainly likely to influence them to select Requestor over competitors.[5]

The third and final issue under the CMP is whether the Requestor knows or should know that the provision of items and services under the Existing or Proposed Arrangements would be likely to influence beneficiaries' selection of the Requestor for oxygen or other Medicare-payable supplies. Aspects of the Existing Arrangement's and the Proposed Arrangement's structure and operation – including the offer of oxygen supplies and oximetry testing services without charge, the home delivery or administration of the oxygen supplies and oximetry testing services (also free of charge), and the role of a beneficiary's own physician in recommending Requestor – appear calculated to generate subsequent business for the Requestor. The Existing Arrangement and the Proposed Arrangement are offered to beneficiaries who are being considered for home oxygen therapy, a group that can be expected to require oxygen and other Federally-payable goods and services in the near future.[6] Thus, we believe that it is probable that Requestor knows or should know that the Existing and Proposed Arrangements are, or would be, likely to generate Federally-payable business for the Requestor. It is worth noting, finally, that the Proposed Arrangement poses an additional fraud and abuse risk insofar as it appears to be a thinly veiled scheme to evade the barrier interposed between beneficiaries and oxygen suppliers by the Medicare rule that bars DME suppliers (except hospitals) from performing the oximetry test necessary to qualify a beneficiary for covered oxygen.

For these reasons, we conclude that the Existing Arrangement and the Proposed Arrangement both potentially violate the CMP provision. For the same reasons, we conclude that they

[5]Requestor relies 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.

[6]Moreover, we note that free overnight oximetry tests would permit Requestor to identify beneficiaries who would likely qualify for Medicare covered home oxygen on completion of an independent oximetry test, thereby enabling Requestor to target its free interim oxygen to those beneficiaries.

both potentially violate the anti-kickback statute. Requestor's request letter asked us to review the Existing Arrangement and the Proposed Arrangement both alone and in combination. Since each appears to be problematic on its own, they would also be problematic in combination.[7]

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Existing Arrangement and the Proposed Arrangement either alone or in combination could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially impose administrative sanctions on Requestor 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 Existing Arrangement and 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.

- 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.

[7]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 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