[*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: September 17, 2008

Posted: September 24, 2008

[Name and address redacted]

SEE ALSO ATTACHED DISTRIBUTION LIST

Re: OIG Advisory Opinion 08-11

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion, in which you ask whether waiving cost-sharing obligations for protocol-required clinical services and oxygen therapy provided to Medicare beneficiaries who participate in the Long-term Oxygen Treatment Trial (the "LOTT"), sponsored by the National Heart, Lung, and Blood Institute and the Centers for Medicare and Medicaid Services (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, or under the civil monetary penalty provision prohibiting inducements to beneficiaries at section 1128A(a)(5) 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 constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act, and, while the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute (if the requisite intent to induce or reward referrals of Federal health care program business were present), the Office of Inspector General (OIG) would not impose administrative sanctions on the individuals and entities listed on the attached Distribution List in connection with the Proposed Arrangement 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 the individuals and entities listed on the attached Distribution List, 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

The LOTT is a randomized, controlled trial designed to investigate the possible benefits of providing continuous oxygen therapy to patients with chronic obstructive pulmonary disease (COPD) and moderate hypoxemia at rest. The benefits of continuous oxygen therapy have previously been demonstrated in patients with severe COPD, but there is insufficient evidence to determine the benefits, if any, of this therapy for patients with milder forms of the disease.

The National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health and the Centers for Medicare and Medicaid Services (CMS) are working together to conduct this study of long-term oxygen treatment in COPD patients with moderate hypoxemia. CMS has issued a National Coverage Determination for Home Use of Oxygen in Approved Clinical Trials (the "NCD") extending Medicare coverage to home use of oxygen for beneficiaries with moderate hypoxemia who are enrolled subjects in clinical trials approved by CMS and sponsored by NHLBI. See Medicare National Coverage Determinations Manual, Ch. 1, Part 4, § 240.2.1 (March 20, 2006). In the NCD, CMS explains that "medical literature documents health benefits as well as serious adverse events associated with supplemental oxygen use" and that "the decision to initiate, continue, or discontinue use of supplemental oxygen should be guided by quality scientific evidence." Id. Pursuant to a Memorandum of Understanding between CMS and NHLBI executed in October 2007 (the "MOU"), CMS has agreed to pay health care providers delivering care and other items or services under the LOTT directly for costs that are allowable for Medicare beneficiaries who participate in the trial, which include protocol-required clinical care and oxygen supply costs.

NHLBI has agreed to be responsible for all activities relating to negotiating, awarding, funding, directing, and terminating contracts with participating health care facilities and for monitoring and evaluating program progress. NHLBI selected [name redacted] as the Data Coordinating Center for the LOTT, and it selected fourteen Regional Clinical Centers.[1] Investigators from these centers are charged with the design and conduct of the trial. The LOTT is led by a Steering Committee composed of a representative from each Regional Clinical Center, a representative from the Data Coordinating Center, a study Chairman selected by NHLBI, a representative from NHLBI, and a representative from CMS. All study decisions are governed by the Steering Committee with the approval of NHLBI, and all members will comply with a well-defined process for identifying and managing any conflicts of interest. CMS will receive frequent updates of the study's progress via meetings of the Steering Committee and from NHLBI.

The LOTT will consist of two treatment groups: one group that will receive continuous oxygen therapy and another group that will receive no oxygen therapy, the control group. Enrolled patients will be allocated to one of these two treatment groups by random assignment in equal numbers (1:1 randomization). All patients undergoing any evaluation for the LOTT will give informed consent. The study will be monitored by NHLBI and by a Data and Safety Monitoring Board (the "Monitoring Board") to be appointed by the NHLBI and composed of physicians, scientists, statisticians, and ethicists not otherwise associated with the study. The Monitoring Board will review the performance and conduct of the study at regular intervals and will evaluate the accumulating data to ensure that continued conduct of the study is appropriate. In addition, each Regional Clinical Center (and any affiliated care sites) will obtain initial and ongoing approval to participate by independent Institutional Review Boards (IRBs).

The overall recruitment goal is 3,285 patients, which is the minimum number of patients determined to be needed to provide a statistically valid conclusion in the study. Recruitment is expected to last 3.5 years, and all enrolled patients will be followed for a minimum of one year; thus, some patients will be followed for as long as 4.5 years. The total number of patients to be enrolled in the LOTT will not be increased without extensive review and prior approval of NHLBI, CMS, and independent monitors such as the

[1] NHBLI published Requests for Proposals (RFPs) for a Data Coordinating Center and the Regional Clinical Centers to study long-term oxygen treatment in COPD patients with moderate hypoxemia in November 2005. Independent scientific peer review groups convened by NHLBI evaluated the merits of each proposal received using the review criteria contained in the RFPs. On the basis of this scientific peer review, NHLBI selected [name redacted] as the Data Coordinating Center for the LOTT. NHLBI selected the following fourteen Regional Clinical Centers: [list redacted].

Monitoring Board and the IRBs. Utilization of oxygen therapy and clinical services by each enrolled patient will also be strictly controlled, with both the specific permissible items and services and their frequency of use dictated by the LOTT treatment protocol.

Only patients with Medicare, or those with other insurance or payors willing to provide coverage for the costs of participation, will be eligible to participate in the LOTT. Currently, most or all patients with moderate COPD would be ineligible for Medicare reimbursement for the oxygen therapy, as coverage is currently limited to patients with more severe cases of the disease. CMS has agreed, however, as set forth in the NCD and the MOU, to provide Medicare coverage to LOTT participants and payment to LOTT providers for LOTT-required items and services. Providers will use specific billing identifiers to identify the LOTT-required items and services as directed by CMS when submitting claims for reimbursement.[2]

Under the Proposed Arrangement, the Regional Clinical Centers and other providers, practitioners, and suppliers participating in the LOTT will waive cost-sharing obligations for protocol-required clinical services and oxygen therapy provided to Medicare beneficiaries who agree to enroll in the LOTT. The requestors assert that waiving patient cost-sharing obligations will enhance the reliability of the study and the validity of its results by promoting patient compliance with the LOTT protocol. The requestors further assert that requiring payment of cost-sharing amounts may cause an undue hardship on economically disadvantaged patients that would undermine their participation in the LOTT study and compromise its integrity. Moreover, only half the patients will be assigned to oxygen therapy, which will result in a differential of financial burden for study participants if cost-sharing obligations are not waived.

The LOTT is a scientific study that CMS considers essential to informed decision-making about Medicare coverage for oxygen therapy. The LOTT is neither a commercial study nor a product-oriented or product-specific study. All CMS-approved providers and suppliers that are able to demonstrate the ability to comply with eligibility criteria approved by the Steering Committee are eligible to participate in the LOTT.[3] The selection of providers and

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[2] The bulk of the costs that CMS has agreed to pay will be for home oxygen therapy, which, under the trial design, will be provided to only fifty percent of the enrolled patients. Additional costs borne by CMS will arise from the evaluations required by the LOTT protocol in the Regional Clinical Centers and their satellite facilities, such as tests for breathing capacity, functional status, oxygen level measurements, and physician office visits.

[3] Each Regional Clinical Center selects its satellites and associated practitioners. Each prescribing practitioner, the associated Regional Clinical Center, and the patient will be responsible for selecting the patient's oxygen supplier.

suppliers will be an open process supervised closely by the NHLBI. LOTT participants will be able to receive LOTT-required items and services only from approved entities.

The requestors have certified that the Proposed Arrangement is not dependent upon, and does not operate in conjunction with (either explicitly or implicitly), any other arrangement or agreement between or among the Data Coordinating Center, the Regional Clinical Centers, NHLBI, CMS, LOTT suppliers and providers, LOTT patients, or any other party with respect to LOTT-required items and services.[4]

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.

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 Medicare or a state health care

[4] The Proposed Arrangement is the complete and entire arrangement that is the subject of this advisory opinion. The Proposed Arrangement may become illegal when considered in the context of other related conduct or arrangements. In such circumstances, this advisory opinion is without force and effect.

program, including Medicaid, 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 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" as including, inter alia, the waiver of cost-sharing obligations (or any part thereof).[5]

B. Analysis

Under sections 1833(a)-1833(b) of the Act and implementing regulations, Medicare beneficiaries are obligated to pay certain coinsurance and deductible amounts for Medicare Part B covered services. See, e.g., 42 U.S.C. §§ 1395l(a)-1395l(b); 42 C.F.R. § 410.3(b). CMS's National Coverage Determination for Routine Costs in Clinical Trials permits Medicare coverage for the routine costs of qualifying clinical trials, "which include all items and services that are otherwise generally available to Medicare beneficiaries."[6] See Medicare National Coverage Determinations Manual, Ch. 1, Part 4, § 310.1 (July 9, 2007). The NCD specifies that "all other Medicare rules apply." Id. Accordingly, as a general matter, all Medicare program requirements, including all applicable cost-sharing obligations, apply to items and services provided through qualifying clinical trials. The NCD specific to the LOTT, the NCD for Home Use of Oxygen in Approved Clinical Trials (discussed above), extends Medicare coverage – and applicable beneficiary cost-sharing obligations – to home use of oxygen for beneficiaries with moderate hypoxemia who are enrolled subjects in clinical trials approved by CMS and sponsored by NHLBI.

The Proposed Arrangement, which would waive Medicare cost-sharing amounts routinely and without regard to financial hardship,[7] implicates the anti-kickback statute's proscription against offering or paying something of value as an inducement to generate business

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[5] The statute contains an exception, not applicable here, to the definition of remuneration for certain waivers of cost-sharing amounts that are not advertised, that are not routine, and that are either granted to financially needy patients or waived after making reasonable collection efforts.

[6] The NCD sets forth certain exceptions to the items and services that will be covered by Medicare. For instance, the investigational item or service itself will not be covered, unless it is otherwise covered outside of the clinical trial. See Medicare National Coverage Determinations Manual, Ch. 1, Part 4, § 310.1 (July 9, 2007).

[7] With respect to the LOTT's economically disadvantaged patients, individualized determinations of indigence might suffice to exempt LOTT providers, practitioners, and suppliers from their obligation to collect cost-sharing amounts for those specific patients.

payable by a Federal health care program, as well as the proscription against beneficiary inducements under section 1128A(a)(5).

Our concerns about routine waivers of Medicare cost-sharing amounts in the context of clinical trials are long-standing. Many clinical trials, including trials qualifying for Medicare coverage, will study items and services for which there are effective, well-established treatments already available. In such cases, enrollees could well be induced to forgo equally effective or more appropriate care. Moreover, some trial sponsors pay physicians or other providers substantial amounts to recruit patients for, and provide services in, clinical studies. Payments to providers and participating patients present a risk of fraud and abuse.

Nevertheless, for the reasons elaborated below, we conclude that in the particular circumstances presented here, the Proposed Arrangement would not be subject to sanction under the anti-kickback statute or imposition of civil monetary penalties under section 1128A(a)(5).

Based on the facts presented, we find that the following factors adequately protect the Proposed Arrangement against the risk of fraud or abuse:

First, the LOTT is a government study co-sponsored by NHLBI and CMS and will be closely monitored by them as well as a number of independent entities. NHLBI has competitively selected the Data Coordinating Center and all of the Regional Clinical Centers in accordance with its own specifications. The overall study is led by a Steering Committee consisting of a representative from each of the fourteen Regional Clinical Centers, a representative from the Data Coordinating Center, a study Chairman selected by NHLBI, a representative from NHLBI, and a representative from CMS. All study decisions are governed by this body with the approval of NHLBI, and all members will comply with a well-defined process for identifying and managing any conflicts of interest. CMS will receive frequent updates of the study's progress via meetings of the Steering Committee and from NHLBI. In addition, the study is required to be monitored by the Monitoring Board, composed of members of the scientific and ethics communities selected by NHLBI that are not otherwise associated with the LOTT.

Second, the LOTT is neither a commercial study nor a product-oriented or product-specific study. Unlike many privately sponsored clinical trials, the LOTT is not intended to develop, study, or benefit any specific commercial product or entity. All CMS-approved providers and suppliers that are able to demonstrate the ability to comply with eligibility criteria approved by the Steering Committee are eligible to participate in the LOTT. In particular, utilization of oxygen therapy and clinical services will be closely monitored and

controlled in accordance with the LOTT protocol, which effectively replicates the prudent purchaser protection of usual cost-sharing requirements.

Third, the Proposed Arrangement is a reasonable means of enhancing the likelihood of success of the LOTT. The study is specifically designed to develop the quality scientific evidence CMS needs to ascertain the suitability of providing reimbursement for continuous oxygen therapy in patients with moderate COPD. See Medicare National Coverage Determinations Manual, Ch. 1, Part 4, § 240.2.1 (March 20, 2006). Patient compliance with all aspects of the study is essential to producing valid study results, and Medicare beneficiaries may be disinclined to participate fully for the duration of the study if they are required to pay to participate. In these circumstances, waiving cost-sharing obligations is a reasonable means of enhancing patient compliance with study requirements and retaining patients for the entire study period. Waiving cost-sharing obligations will also ensure that economically disadvantaged Medicare patients are not precluded from the study. Lastly, only half the patients will be assigned to oxygen therapy, which will result in a differential of financial burden for study participants if cost-sharing obligations are not waived.

In contrast to the LOTT, many clinical trials are initiated, organized, funded, managed, or otherwise sponsored by pharmaceutical companies or other private interests with no, or only limited, government involvement. Since commercial or private studies pose significantly different risks under the fraud and abuse authorities, waivers of Medicare cost-sharing amounts for enrollees in such studies would not necessarily be sheltered from civil monetary penalties under section 1128A(a)(5) of the Act or sanction under the anti-kickback statute, absent an applicable exception.

In sum, the Proposed Arrangement reasonably accommodates the needs of an important, government-sponsored scientific study, without posing a significant risk of fraud and abuse of the Medicare program.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act, and, while the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute (if the requisite intent to induce or reward referrals of Federal health care program business were present), the OIG would not impose administrative sanctions on the individuals and entities listed on the attached Distribution List in connection with the Proposed Arrangement 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 the individuals and entities listed on the attached Distribution List, 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 the individuals and entities listed on the attached Distribution List 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 the individuals and entities listed on the attached Distribution List, 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General

DISTRIBUTION LIST

OIG ADVISORY OPINION 08-11

[Names and addresses redacted]