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

Issued: June 30, 2000

Posted: July 7, 2000

To: ATTACHED DISTRIBUTION LIST [redacted]

Re: National Emphysema Treatment Trial (NETT) Advisory Opinion No. 00-5

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion, in which you ask whether waiving Medicare Part A and Part B copayment and deductible obligations for participants in a clinical study sponsored by the Health Care Financing Administration and the National Heart, Lung, and Blood Institute (the "Proposed Arrangement") will subject you to sanction under section 1128A(a)(5) of the Social Security Act (the "Act"), or under the anti-kickback statute, section 1128B(b) of the Act.

You have certified that all of the information you provided in your request, including all supplementary letters, is true and correct, and constitutes a complete description of the material facts regarding the Proposed Arrangement. 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 information provided, we conclude that: (i) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, but that, based on the totality of the facts as described and certified in your request letter and supplemental submissions, the Office of Inspector General ("OIG") will not subject the individuals and entities listed on the attached Distribution List (the "Requestors") to sanctions for violations of the anti-kickback statute under sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Proposed Arrangement; and (ii) the OIG will not subject the Requestors to sanctions under section 1128A(a)(5) of the Act in connection with the Proposed Arrangement as described and certified in your request letter and supplemental submissions.[(1)] This advisory opinion may not be relied on by any person other than the individuals and entities listed on the attached Distribution List and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Procedural History

This opinion reflects a second request for an advisory opinion in connection with the National Emphysema Treatment Trial (the "NETT"), a clinical trial sponsored by the Health Care Financing Administration ("HCFA") and the National Heart, Lung, and Blood Institute ("NHLBI") of the National Institutes of Health. The first request was filed in 1997 by a number of clinics and physicians participating in the NETT ("NETT Request I"). NETT Request I sought an opinion about whether the practice of waiving copayments and deductibles for items and services covered by Medicare Part B and within the scope of the clinical protocol that governs the NETT (the "NETT Protocol") would be subject to sanction under sections 1128A(a)(5) and 1128B(b) of the Act. In response, the OIG issued OIG Advisory Opinion 98-6 on April 20, 1998. The opinion held that in the specific circumstances presented, the OIG would not subject the requestors of NETT Request I to sanctions arising under sections 1128A(a)(5) and 1128B(b) of the Act for their waivers of Part B copayments and deductibles for services within the scope of the NETT Protocol. As is the case with all OIG advisory opinions, Advisory Opinion 98-6 is binding only on the NETT clinics and physicians that signed on as requestors.

The second NETT advisory opinion request ("NETT Request II") gives rise to the present advisory opinion. NETT Request II was submitted by the NETT clinics and physicians, some of whom were requestors of NETT Request I (the "Original Requesting Parties"),(2) and some of whom were not (the "New Requesting Parties"). NETT Request II seeks (i) an opinion as to the same conduct raised in NETT Request I for the New Requesting Parties (i.e., waivers of Medicare Part B copayments and deductibles), and (ii) an opinion for both the New Requesting Parties and the Original Requesting Parties regarding waivers of Medicare Part A copayments and deductibles attributable to services provided under the NETT Protocol. Thus, the core difference between NETT Request II and NETT Request I is that NETT Request II deals with waivers of copayments and deductibles for the NETT Protocol services covered by both Medicare Parts A and B. The NETT seeks the expanded waiver authority in light of its continuing difficulties in securing adequate participation in the NETT clinical study (as further described below).

B. The Proposed Arrangement

The Proposed Arrangement at issue in NETT Request II is substantially the same as the program described in NETT Request I. Accordingly, the facts as described in Advisory Opinion 98-6 are incorporated into this opinion by reference.

As described in Advisory Opinion 98-6, the NETT is a multicenter, randomized clinical trial to study the effectiveness of lung volume reduction surgery ("LVRS") to treat moderate to severe emphysema. The trial is a collaboration between HCFA and the NHLBI. The NETT Protocol was independently peer reviewed by a panel comprised of individuals with appropriate expertise in a number of areas, including relevant areas of medicine and public health. HCFA has agreed to pay for Medicare allowable patient care services, including LVRS, covered by the NETT Protocol and hopes to use the trial's results to determine if LVRS should be covered by Medicare as a reasonable and necessary treatment.

NHLBI has contracted with numerous clinical centers around the country to be the NETT participating clinics that will provide services covered by the NETT Protocol. The trial will be conducted over a fifty-four month period and will involve 2,500 patients.(3) The NETT patients, who must meet the study's selection criteria, will be referred to the NETT contracting centers by their private physicians. The NETT patients must be Medicare beneficiaries or have other insurance to cover the cost of the NETT services. Eligible patients will be asked to consent to: (i) enrollment in a pulmonary rehabilitation program; and (ii) random assignment into one of two study groups, only one of which will receive LVRS.

Although overall responsibility for medical management of the NETT patients will remain with each patient's regular primary care physician, the NETT patients will be evaluated by the NETT physicians to ensure that the NETT treatment standards are met. Patients in the LVRS group will be managed pursuant to post-operative care and complication management procedures described in the NETT Protocol.

All of the NETT patients will be seen at the NETT participating clinics for follow-up visits, which are expected to last one to two days per visit, and for data collection at six-month intervals for two years after randomization and annually thereafter. In addition, the patients will be required to complete questionnaires at home and will be contacted by telephone according to a schedule set forth in the NETT Protocol.

Under sections 1813 and 1833 of the Act and implementing regulations, Medicare beneficiaries are obligated to pay certain copayment and deductible amounts for Medicare Part A and Part B covered services. See, e.g., 42 U.S.C. §§ 1395e & 1395*l*; 42 C.F.R. Parts 409 & 410. The Requestors seek to waive these copayments and deductibles for items and services that are (i) within the scope of the NETT Protocol and (ii) covered under Medicare Parts A and B, without regard to the patient's ability to pay. The following Medicare Part A covered services would be subject to the waiver when provided to the NETT patients within the scope of the NETT Protocol: (i) inpatient hospital services; (ii) skilled nursing facility services; and (iii) long-term care and rehabilitation hospital services. The Requestors have certified that they will not claim the waived Part A and Part B copayment and deductible amounts as bad debt on any Federal or state cost reports. Copayment and deductible

waivers for Part A and Part B services provided outside the scope of the NETT Protocol are not included in the Proposed Arrangement.

The Requestors assert that waiving copayment and deductible amounts for the NETT patients will enhance the reliability of the study and the validity of its results by promoting patient compliance with the NETT Protocol, including patient cooperation in follow-up data collection efforts. As noted in footnote 1, the NETT has experienced unexpected difficulties in recruiting sufficient eligible patients for the clinical trial. They anticipate that theaddition of Part A copayment and deductible waivers within the limited scope of the NETT Protocol may persuade more patients to enroll in the study. The Requestors are also concerned that requiring payment of Part A and Part B copayments and deductibles may cause an undue hardship on economically disadvantaged patients that would undermine their participation in the NETT study and compromise its integrity.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute, section 1128B(b) of the Act, makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce the referral of business covered by a Federal health care program. Specifically, the statute provides that:

"Whoever knowingly and willfully offers or pays [or solicits or receives] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -- to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony."

Section 1128B(b) of the Act. In other words, the statute prohibits payments made purposefully to induce referrals of business for which payment may be made by a Federal health care program. The statute ascribes liability to both sides of an impermissible "kickback" transaction. The statute has been interpreted to cover any arrangement where one purpose of the remuneration is 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). "Remuneration" for purposes of the anti-kickback statute includes the transfer of any thing of value, in cash or in-kind, directly or indirectly, covertly or overtly.

Violation of the anti-kickback 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. This Office may also initiate administrative proceedings to exclude persons from the Federal and State health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.[(4)]Section 231(h) of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), section 1128A(a)(5) of the Act, provides for the imposition of civil monetary penalties against any person who:

"offers or transfers remuneration to any individual eligible for benefits under [Federal health care programs (including Medicare or Medicaid)] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, [by a Federal health care program]."

Section 231(h) defines "remuneration" as including, inter alia, the waiver of copayment and deductible amounts (or any part thereof). The statute contains certain exceptions to the definition of remuneration for certain waivers of copayments that are not advertised, that are not routine, and that are granted to financially needy patients or for which reasonable collection efforts have been made.

B. Analysis

As was the case in OIG Advisory Opinion 98-6, under the Proposed Arrangement, the NETT participating clinics and providers would waive deductible and copayment amounts routinely and without regard to financial hardship.(5) Thus, the Proposed Arrangement implicates the anti-kickback statute's proscription against offering or paying something of value as an inducement to generate business payable by a Federal health care program. Nevertheless, for the reasons articulated in OIG Advisory Opinion 98-6 and summarized below, we conclude that in the particular circumstances presented here, we would not impose sanctions arising under the anti-kickback statute on the Requestors in connection with the Proposed Arrangement (including the waiver of both Medicare Part A and Part B copayment and deductible amounts). We further conclude that we would not impose sanctions under section 1128A(a)(5) of the Act, which prohibits giving something of value to a beneficiary that the donor knows or should know is likely to influence the beneficiary's choice of a particular provider, in connection with the Proposed Arrangement.

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

- The Proposed Arrangement is unlikely to influence beneficiaries to obtain Medicare covered services from the NETT providers. Medicare patients will enroll in the NETT because enrollment in the NETT is the only means of obtaining Medicare coverage of LVRS, not because copayments and deductibles are waived. As a practical matter, Medicare beneficiaries have no choice of LVRS providers outside of the NETT. Nor is the Proposed Arrangement likely to influence the choice of providers within the NETT because all providers will waive deductibles and copayments. In short, the purpose of the waivers of the NETT cost-sharing amounts is to induce participation in a HCFA-sponsored scientific study, not to induce utilization of Medicare covered services.

- The Proposed Arrangement will not increase the risk of overutilization of Medicare covered services. The NETT Protocol controls utilization of services, and the Proposed Arrangement would not apply to health care services that are not included in the NETT Protocol. Nor would it apply for any period of time during which a Medicare beneficiary ceases to be a NETT patient.(6) Thus, the Proposed Arrangement is unlikely to result in an increased risk of overutilization of Medicare covered services.(7) In addition, the risk of increased overutilization is minimized because the number of Medicare patients participating in the full NETT study will be limited to 2,500 over a fifty-four month period.(8) This number may be even smaller, because some of the NETT patients may be privately insured.

- The Proposed Arrangement is a reasonable means of enhancing the likelihood of success of the HCFA-sponsored NETT study. Patient compliance with all aspects of the study, including visits to the NETT participating clinics when required and cooperation with follow-up data collection efforts, is essential to producing valid study results. Patients may be disinclined to participate fully for the duration of the study if they are required to pay to participate. This may be particularly true for patients who are not randomized into the surgical group or who are not satisfied with the outcome of their surgery. The NETT reports that it is experiencing difficulties enrolling sufficient numbers of eligible patients. In these circumstances, waiving copayments and deductibles is a reasonable means of enhancing patient compliance with study requirements and retaining patients for the entire study period. Waiving copayments and deductibles will also ensure that economically disadvantaged patients are not precluded from participating in the study.

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

Nothing in this opinion should be taken to permit or protect waivers of Part A or Part B copayments and deductibles provided in the context of clinical studies generally. The Proposed Arrangement presents unique circumstances not found in the context of many other research programs, chief among them HCFA sponsorship of the NETT.

III. CONCLUSION

For the above-stated reasons, and based on the information provided, we conclude that: (i) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, but that, based on the totality of the facts as described and certified in your request letter and supplemental submissions, the OIG will not subject the Requestors to sanctions for violations of the anti-kickback statute under sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Proposed Arrangement; and (ii) the OIG will not subject the Requestors to sanctions under section 1128A(a)(5) of the Act in connection with the Proposed Arrangement as described and certified in your request letter and supplemental submissions.

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, 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 to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is herein expressed or implied 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.

- 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 Requestors 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 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, modify or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors 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/

D. McCarty Thornton
Chief Counsel to the Inspector General

[Attached Distribution List Redacted]

1. The legal effect of this conclusion is the same as that reached in OIG Advisory Opinion 98-6 (April 20, 1998), in that the OIG would not impose sanctions under sections 1128B(b) and 1128A(a)(5) of the Act on the advisory opinion's requestors, in connection with each respective advisory opinion request.

2. For purposes of this advisory opinion, "Original Requesting Parties" includes only those requesting parties from NETT Request I who have signed on as requestors of NETT Request II.

3. Since the issuance of Advisory Opinion 98-6, the expected patient sample size for the study has dropped from 4,700 to 2,500 due to revisions in the study's assumptions and the difficulties that the NETT participating clinics have encountered in recruiting patients for the study.

4. Because both the criminal and administrative sanctions related to the anti-kickback implications of the Proposed Arrangement are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same under both.

5. With respect to the NETT's economically disadvantaged patients, individualized determinations of indigency might suffice to exempt the NETT providers from their obligation to collect copayments and deductibles for those specific patients.

6. It is anticipated that some people may begin the initial screening process, be found ineligible for the study, but later reapply and be admitted to the study. HCFA would not consider these patients NETT patients for the period between the ineligibility determination and the reapplication.

7. Nothing in this advisory opinion should be construed as indicating that a showing of actual, or increased risk of, overutilization is a required element of an anti-kickback statute violation. A risk of overutilization is merely one potential indicator of potential fraud or abuse.

8. We recognize that an indeterminate number of patients who do not ultimately qualify for the NETT may obtain some copayment and deductible waivers during the screening process. The number of these patients will be limited by the initial screening criteria. HCFA has agreed to reimburse the NETT providers for services performed during the screening process in order to ensure that the NETT study can serve the purposes for which it is intended. We do not think that these limited waivers will lead to an increased risk of abuse of the Medicare program.