

Posted: May 1, 1998

To: **ATTACHED DISTRIBUTION LIST [redacted]**

**Re: National Emphysema Treatment Trial (NETT)
Advisory Opinion No. 98-6**

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion, in which you ask whether waiving coinsurance 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") [42 U.S.C. §1320a-7a(a)(5)] or under the anti-kickback statute, section 1128B(b) of the Act [42 U.S.C. § 1320a-7b(b)].

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 you presented to us. We have not undertaken any independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed, this opinion is without force and effect.

Based on the information provided and subject to certain conditions described below, we conclude that the Proposed Arrangement would not constitute grounds for the imposition of sanctions under sections 1128A(a)(5) or 1128B(b) of the Act. This opinion may not be relied on by any person other than the individuals and entities listed on the attached Distribution List [redacted] and is further qualified as set out in Part III below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. NETT

1. Parties to NETT

The National Emphysema Treatment Trial ("NETT") is a multicenter, randomized clinical trial of medical therapy alone versus medical therapy plus Lung Volume

Reduction Surgery (“LVRS”) for treatment of moderate to severe emphysema. The primary purpose of NETT is to determine whether the addition of LVRS results in improved survival of emphysema patients. In addition, NETT will be used to evaluate the relative benefits and risks of surgical versus medical therapy, including health care utilization and costs.

NETT is a collaborative effort between the Health Care Financing Administration (“HCFA”) and the National Heart, Lung, and Blood Institute (“NHLBI”) of the National Institutes of Health. Pursuant to a Memorandum of Understanding (the “MOU”) between HCFA and NHLBI executed in June 1996, HCFA has agreed to pay for Medicare allowable patient care services, including LVRS, covered by the NETT protocol (see section B.1 below). NHLBI has agreed to be responsible for all activities relating to negotiating, awarding, directing, and terminating contracts with participating health care facilities and for monitoring and evaluating program progress. HCFA hopes to use the results of NETT to determine whether and under what circumstances LVRS should be considered a reasonable and necessary treatment and hence whether and under what circumstances it should be a Medicare covered service.

NHLBI has contracted with Johns Hopkins Center for Clinical Trials to be the coordinating center for the trial and with certain clinical centers around the country to be NETT participating clinics. In addition, some contracting centers have subcontracted with rehabilitation facilities to provide services covered by the NETT protocol.¹ Pursuant to these contracts, investigators from these centers will conduct the randomized clinical trial and establish an associated registry of patients. The trial will consist of a main protocol, performed by all participating centers and involving all enrolled patients, and several sub-studies, performed by selected centers and involving only patients enrolled at those centers.

¹Johns Hopkins Center for Clinical Trials, and those clinical centers, rehabilitation facilities, and individual providers listed on the attached Distribution List [redacted] are collectively the “Requesters” of this opinion. Only those entities and individuals specifically named on the attached Distribution list [redacted] are “Requesters” for purposes of this opinion. NHLBI anticipates that the identities of the NETT participating facilities and individuals may change from time to time during the course of the trial. This opinion is not binding on facilities or individuals that are not Requesters for purposes of this opinion.

2. Treatment Protocol

NETT will be conducted over a fifty-four month period and will involve 4,700 patients, post-randomization.² Patients will be referred to NETT contracting centers by their private physicians, who will provide NETT investigators with certain background information and test results.³ Participating patients must be Medicare beneficiaries or have other insurance to cover the costs of participation in NETT. Eligible patients will be asked to consent to enrollment in a pulmonary rehabilitation program and to randomization, which will occur after six to ten weeks of pulmonary rehabilitation, further eligibility determinations, and pre-randomization assessments.

The NETT randomized study is essentially divides patients into two groups pursuant to the Protocol. One group will receive medical therapy, which consists of two parts: medical management and pulmonary rehabilitation. The overall responsibility for medical management of NETT patients will remain with the patient's regular primary care physician. However, NETT patients will be evaluated by a NETT physician to insure that NETT treatment standards are met. The NETT physicians will make recommendations for medical management to the primary care physicians. The pulmonary rehabilitation program, which is divided into three phases, spans the duration of the NETT trial (approximately fifty-four months). Certain portions of the pulmonary rehabilitation program must take place at NETT centers; to accommodate patients who may not live near a NETT center, other portions may occur at "satellite" rehabilitation centers certified for participation in NETT.

The second group will receive the surgical treatment. LVRS will be performed by NETT center surgeons at a NETT center. LVRS patients will be managed post-operatively in a manner similar to other patients undergoing major thoracic surgery. The Protocol describes in detail required post-operative care procedures and management of complications.

²"Randomization" is the process of randomly assigning patients to the surgical and non-surgical study groups. An undetermined number of patients not ultimately selected for randomization will participate in NETT for screening and evaluation purposes.

³To be eligible for the NETT study, patients must satisfy specific selection and exclusion criteria set forth in the Protocol.

All NETT patients will be seen at NETT clinics for follow-up visits and data collection at six month intervals for two years after randomization and annually thereafter. These follow-up visits are expected to last one to two days, depending on the patient's condition and the procedures scheduled. Patients will also be required to complete questionnaires at home. NETT centers will maintain telephone contact with patients in accordance with a schedule set forth in the Protocol.

B. The Proposed Arrangement

1. HCFA Reimbursement for NETT Items and Services

Currently, LVRS is not a Medicare covered service, unless it is performed as part of the NETT study.⁴ See Coverage Issues Manual ("CIM") (HCFA-Pub 6) at 35-93.⁵ HCFA has agreed to provide reimbursement directly to NETT clinical center contractors and other designated providers for patient care services, including inpatient hospital services, physician and other professional services, and laboratory, diagnostic, and other therapeutic services for Medicare beneficiaries participating in NETT. HCFA will cover these services if NHLBI certifies that the provider is in compliance with the Protocol and the NETT manual of operations. NETT providers will not be reimbursed for items and services not allowable under Medicare, such as oral prescriptions. HCFA will continue to pay for services for Medicare beneficiaries recruited into NETT until the contracts with the NETT centers expire or are terminated by NHLBI or until a patient is no longer eligible to participate in NETT. HCFA may withhold payments if documentation is

⁴HCFA adopted a nonreimbursement policy for LVRS in 1995 because of the dearth of medical evidence supporting the surgery's effectiveness and the potential for high morbidity and mortality among Medicare beneficiaries who might receive LVRS. That same year, HCFA requested a technology assessment of LVRS by the Center for Health Care Technology (CHCT) within the Agency for Health Care Policy Research. The resulting CHCT report concluded that the objective data available did not permit a logical and scientifically defensible conclusion about the risks and benefits of LVRS. The report further concluded that some proportion of patients may have realized some benefits from the procedure and that a prospective trial of LVRS was both ethically and scientifically essential. Based on the CHCT assessment, HCFA approached NHLBI about collaborating on the evaluation of LVRS.

⁵CIM § 35-93 states, "HCFA has determined that LVRS is reasonable and necessary when it is provided under the conditions detailed by the protocol of the HCFA/NHLBI clinical study. Therefore, Medicare will cover LVRS in those limited circumstances when it is provided to a Medicare beneficiary under the protocols established for the study."

missing, incomplete, or inaccurate. NHLBI will be required to provide HCFA with lists of participating NETT patients and providers. Claims will be processed using normal Medicare reimbursement procedures. However, claims for NETT items and services will indicate, through special codes, whether the patient is a NETT patient, whether the provider is a NETT provider, and whether the patient has been randomized into the surgical group.

2. Proposal to Waive Copayments and Deductibles

Under section 1833 of the Social Security 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. §1395; 42 C.F.R. Part 410. The Requestors seek to waive these copayments and deductibles for items and services within the scope of the NETT Protocol and covered under Medicare Part B. The Requestors assert that waiving these copayment amounts 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. The Requestors further assert that requiring payment of 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. The Requestors assert that patients typically do not pay to participate in research projects.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute, 42 U.S.C. §1320a-7b(b), 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.

42 U.S.C. § 1320a-7b(b). 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.⁶

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

⁶Because 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.

coinsurance and deductible amounts (or any part thereof).⁷

We have said previously in a Special Fraud Alert that providers who routinely waive Medicare copayments and deductibles may be held liable under the anti-kickback statute. See OIG Special Fraud Alert, 59 Fed. Reg. 242 (1994).⁸ We explained that when providers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing the patient to purchase items or services in violation of the anti-kickback statute's proscription against offering or paying something of value as an inducement to generate business payable by Medicare. We further stated that except in cases of financial hardship, a good faith effort to collect deductibles and copayments must be made. Finally, we noted in our Special Fraud Alert that one indicator of a potentially prohibited waiver is the failure to collect copayments or deductibles for a specific group of Medicare patients for reasons unrelated to indigency.

B. Analysis

The Proposed Arrangement, which would waive deductible and coinsurance amounts routinely and without regard to financial hardship,⁹ 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 elaborated below, we conclude that in the particular circumstances presented

⁷The 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. The statute contains further exceptions for certain differentials in coinsurance and deductible amounts as part of a benefit plan and for certain incentives to individuals to promote the delivery of preventive care. Because we find that the Proposed Arrangement would not be subject to sanction under the statutory prohibition, we do not reach the issue of whether any of the statutory exceptions would apply.

⁸Although the Special Fraud Alert primarily addressed charge-based providers, we expressly stated that the Special Fraud Alert should not be interpreted to legitimize routine waiver of copayments and deductibles with respect to providers paid under prospective payment or cost-based systems.

⁹With respect to NETT's economically disadvantaged patients, individualized determinations of indigency might suffice to exempt NETT providers from their obligation to collect copayments for those specific patients.

here, the Proposed Arrangement would not be subject to sanction under the anti-kickback statute. We further conclude that the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 231(h) of HIPAA, 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.

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 NETT providers. Where remuneration is paid by a provider to a beneficiary, the inquiry under the anti-kickback statute is whether such remuneration is paid to induce Federal health program business, whereas under section 231(h) of HIPAA, the test for a violation is whether such remuneration is something that the donor knows or should know is likely to induce the beneficiary's selection of a provider of Federal program services. The Proposed Arrangement is unlikely to have either of these prohibited effects. Simply put, Medicare patients will enroll in NETT because enrollment in NETT is the only means of obtaining Medicare coverage of LVRS, not because copayments are waived. As a practical matter, Medicare beneficiaries have no choice of LVRS providers outside of NETT. Nor is the Proposed Arrangement likely to influence the choice of providers within NETT; NETT anticipates that all providers will waive deductibles and copayments. In short, the purpose of the waivers of NETT cost-sharing amounts is to induce participation in a scientific study, not to induce utilization of Medicare covered services.
- The Proposed Arrangement will not increase the risk of overutilization of Medicare covered services. One adverse consequence of routine waivers of coinsurance obligations is the increased risk of overutilization of services payable by Medicare. Here, the Protocol controls utilization of services. The Proposed Arrangement would not apply to health care services that are not included in the Protocol. Nor would it apply for any period of time during which a Medicare beneficiary ceases to be a NETT patient.¹⁰ Thus, the Proposed

¹⁰It 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

Arrangement is unlikely to result in an increased risk of overutilization of Medicare covered services.¹¹ 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 4,700 over a fifty-four month period.¹² This number may be even smaller, because some NETT patients may be privately insured.

- The Proposed Arrangement is a reasonable means of enhancing the likelihood of success of the NETT study. Patient compliance with all aspects of the study, including visits to NETT clinics when required and cooperation with follow-up data collection efforts, is essential to producing valid study results. HCFA has determined that it needs a thorough and accurate study of LVRS in order to evaluate the surgery's efficacy and cost-effectiveness for the purpose of deciding whether to cover LVRS as a "reasonable and necessary" service under the Medicare program. 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. In these circumstances, waiving copayments is a reasonable means of enhancing patient compliance with study requirements and retaining patients for the entire study period. Waiving copayments will also ensure that economically disadvantaged patients are not precluded from the study.

In sum, the Proposed Arrangement reasonably accommodates the needs of an

ineligibility determination and the reapplication.

¹¹Nothing 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.

¹²We recognize that an indeterminate number of patients who do not ultimately qualify for NETT may obtain some copayment waivers during the screening process. The numbers of these patients will be limited by the initial screening criteria. HCFA has agreed to reimburse 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.

important, government-sponsored scientific study, without posing a significant risk of fraud and abuse of the Medicare program.

C. Conclusion

For the above-stated reasons, and based on the information provided by the Requesters and subject to certain conditions described below, we conclude that the Proposed Arrangement would not constitute grounds for the imposition of sanctions under 42 U.S.C. §§ 1320a-7a(a)(5) or 1320a-7b(b).

III. 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 [redacted], which are the Requesters 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.

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 Requesters 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 requesters 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.

Sincerely,

/s/

D. McCarty Thornton
Chief Counsel to the Inspector
General

[Attached Distribution List redacted]