



[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: December 23, 2002

Posted: January 3, 2003

[name and address redacted]

Re: OIG Advisory Opinion No. 02-16

Dear [name redacted]:

We are writing in response to your request for an advisory opinion, in which you ask whether waiving cost-sharing obligations under Part B of the Medicare program for self-monitored blood glucose equipment and supplies used by Medicare beneficiaries who participate in the Action to Control Cardiovascular Risk clinical trial (“ACCORD”) sponsored by the National Heart, Lung, and Blood Institute (the “Proposed Arrangement”) would constitute grounds for sanctions 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 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 [Q Company] 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 [Q Company], the requestor 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

A. ACCORD Clinical Trial and Treatment Protocol

ACCORD is a randomized clinical trial initiated, organized, funded, and managed by the National Heart, Lung, and Blood Institute (“NHLBI”), an institute of the National Institutes of Health (“NIH”). The National Institutes of Diabetes and Digestive and Kidney Diseases and the Centers for Disease Control and Prevention are also involved in the clinical trial.

ACCORD will be conducted over a sixty-month period by seven clinical networks (the “Clinical Networks”)¹ and will involve approximately 10,000 patients.² All participating patients must have Type II diabetes and either diagnosed coronary heart disease or two further major risk factors for the development of coronary heart disease; their median age at entry into ACCORD will be approximately 65. ACCORD specifically addresses whether the treatment of Type II diabetes patients is improved by (1) lowering their blood glucose and systolic blood pressure to levels below those currently recommended and (2) administering drugs³ that modify their serum HDL cholesterol and triglyceride levels.

ACCORD is neither a commercial study nor a product-oriented or product-specific study, but rather a scientific study of emerging public health and clinical issues pertaining to the treatment of patients with Type II diabetes and coronary heart disease. The clinical questions to be resolved, the type of drugs and supplies to be used, and the detailed

¹NHLBI has competitively selected the Clinical Networks, their various clinical units, and the study’s central facilities in accordance with NHLBI specifications.

²Approximately 1,500 ACCORD patients will be patients in clinical units in a Clinical Network in Canada and will not be subject to Medicare or other Federal health care program coverage. An additional 2,000 ACCORD patients will be patients in Department of Veterans Affairs clinics and will receive supplies and equipment independently of the Proposed Arrangement. Of the remaining 6,500 ACCORD patients, the Requestor has estimated that approximately 60% will be covered by Medicare or other Federal health care programs, 20% will have private health insurance coverage, and 20% will be without health care coverage of any sort.

³No opinion is expressed herein regarding the contribution, purchase, or distribution of drugs by any party collaborating in ACCORD.

treatment protocol to be applied in ACCORD were developed collaboratively by investigators in the Clinical Networks in conjunction with NHLBI scientists, followed by a review by an independent protocol review committee reporting to the NHLBI Director.

B. The Proposed Arrangement

All ACCORD patients will be required to self-monitor their blood glucose levels in accordance with the study's treatment protocol.⁴ Self-monitored blood glucose ("SMBG") supplies, consisting of blood glucose monitors, blood-testing strips, lancets, and syringes, are provided to ACCORD patients in the United States through an agreement between NHLBI and a specified manufacturer of the SMBG supplies.

The manufacturer proposes to enter into an agreement with [Q Company] (the "Requestor"), a nationwide supplier of blood glucose testing products, by which the Requestor will purchase SMBG supplies from the manufacturer and distribute such supplies to ACCORD patients in the United States throughout the term of the study. The clinical units in the Clinical Networks will transmit to the Requestor copies of all prescriptions for SMBG supplies being used by ACCORD patients. The Requestor will provide SMBG supplies to ACCORD patients and will seek reimbursement from the Medicare and Medicaid programs or other private or public health insurance programs. ACCORD patients who are not insured will receive SMBG supplies free of charge throughout the term of the study.

In accordance with its historical practice and to encourage adequate enrollment in the study, NHLBI wants patients to receive care under the ACCORD clinical trial without charge. For Medicare patients, the Requestor will waive Part B cost-sharing obligations for SMBG supplies. NHLBI believes that waiving cost-sharing obligations for ACCORD enrollees will promote and enhance patient participation throughout the term of the study.

The Requestor has 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 Requestor, the manufacturer, NHLBI, ACCORD patients, or any other party with respect to SMBG supplies being used by ACCORD patients.⁵

⁴For ACCORD patients not yet on insulin, the protocol specifies self-monitoring of blood glucose from one to four times a day, depending on the patient's glycemic goal. For patients on insulin, the protocol specifies an SMBG frequency ranging from three to eight times a day. The Requestor has certified that an SMBG frequency of 75 times per month is a reasonable estimate for an average ACCORD patient over the average term of the study.

⁵The 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

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 Medicare or Medicaid beneficiary that the donor 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 the Medicare or Medicaid programs. Where a party commits an act described in section 1128A(a)(5) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties of not more than \$10,000 for each item or service and to exclude such party from the Federal health care programs. Section 1128A(a)(5) of the Act defines "remuneration" as including, inter alia, the waiver of cost-sharing obligations (or any part thereof).⁶

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. 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 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

On September 19, 2000, the Health Care Financing Administration ("HCFA") [now known as the Centers for Medicare & Medicaid Services ("CMS")] issued a National Coverage

circumstances, this advisory opinion is without force and effect.

⁶The statute contains an exception, not applicable here, to the definition of remuneration for certain waivers of cost-sharing obligations that are not advertised, that are not routine, and that are either granted to financially needy patients or waived after making reasonable collection efforts.

Determination (“NCD”)⁷ that extended Medicare coverage to the “routine costs of qualifying clinical trials” as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in such clinical trials. The NCD pertains to coverage for, among other things, the items being studied.⁸

The NCD was designed to permit Medicare beneficiaries to receive treatment in a qualifying clinical trial on the same basis as they receive other Medicare-covered items and services. Accordingly, the NCD makes clear that all Medicare program requirements, including all applicable cost-sharing obligation requirements, apply to items and services provided through qualifying clinical trials. Likewise, all Medicare fraud and abuse authorities apply.

The Proposed Arrangement, under which the Requestor will waive cost-sharing obligations without regard to financial hardship, implicates (1) the proscription of section 1128A(a)(5) of the Act against giving something of value to a Medicare beneficiary that the donor knows or should know is likely to influence the beneficiary’s choice of a particular supplier and (2) 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.

NHLBI and other trial sponsors waive cost-sharing obligations for enrollees in clinical trials to encourage them to participate in studies. However, many clinical trials, including trials qualifying for Medicare coverage under the NCD, 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 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 potentially present a risk of fraud and abuse.

Notwithstanding, we conclude that, in the particular circumstances presented here, the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under sections 1128A(a)(5), 1128(b)(7), or 1128A(a)(7) of the Act, since 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.

First, ACCORD is an NIH-sponsored scientific study that has been initiated, organized, funded, and managed exclusively by NHLBI. NHLBI controls the determination of the

⁷HCFA National Coverage Determination (Sept. 19, 2000) posted on the CMS web site at <http://www.cms.hhs.gov/coverage/8d2.asp>. See also Medicare Coverage Issues Manual (CMS Pub. 6), § 30-1.

⁸We express no opinion as to whether SMBG supplies constitute the routine costs of a qualifying clinical trial under the NCD.

strategic clinical questions to be resolved through the study, the types of drugs and supplies to be used in the study, and the detailed treatment protocol to be followed by the study. Moreover, NHLBI has competitively selected all of the study's clinical components and central facilities in accordance with its own specifications.

Second, ACCORD is neither a commercial study nor a product-oriented or product-specific study. Unlike many privately sponsored clinical trials, ACCORD is not intended to develop, study, or benefit any specific commercial product.

Third, NHLBI believes that the resolution of the public health and clinical issues addressed by ACCORD is likely to have significant consequences for the professional medical treatment of all affected patients, including Medicare beneficiaries.

In contrast to ACCORD, 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 NCD and the Medicare fraud and abuse authorities, waivers of cost-sharing obligations to 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.

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 [Q Company] 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 [Q Company], which is the requestor 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, or the National Coverage Determination.

- 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 [Q Company] 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 [Q Company] 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