



[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: January 21, 2004

Posted: February 9, 2004

[name and address redacted]

Re: OIG Advisory Opinion No. 04-01

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 Bypass Angioplasty Revascularization Investigation 2 Diabetes clinical trial (“BARI 2D”) sponsored by the National Heart, Lung, and Blood Institute (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 penalties provision for illegal remuneration to beneficiaries at section 1128A(a)(5) of the Act.

You have certified that all of the information provided in your request, including all supplemental submissions, 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 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 [name of requestor redacted] 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 [name of requestor redacted] 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. BARI 2D Clinical Trial and Treatment Protocol

BARI 2D 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 Institute of Diabetes and Digestive and Kidney Diseases (“NIDDK”) and the Centers for Disease Control and Prevention are also involved in the clinical trial.

BARI 2D will be conducted over a seven-year period at approximately forty clinical centers (“Clinical Centers”)¹ and will involve approximately 2,800 patients.² All participating patients must have Type II diabetes and coronary artery disease that is documented to be stable; their median age at entry will be approximately forty-six. The primary focus of the BARI 2D trial is to investigate the best medical approaches for addressing coronary artery disease in people with Type II diabetes. The trial will compare the effectiveness of two different drug therapy approaches.³ It will also compare the effectiveness of drug therapy combined with early surgery (bypass or angioplasty) to drug therapy alone.

BARI 2D is neither a commercial study nor a product-oriented or product specific study; it is, 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

¹ The Clinical Centers, their various clinical units, and the study’s central facilities have been selected in accordance with NHLBI specifications.

² Approximately 500 BARI 2D patients will be patients at Canadian clinical sites and will not be subject to Medicare or other Federal health care program coverage. Of the remaining patients, the Requestor has estimated that approximately 45% will be covered by Medicare or other Federal health care programs, 35% will have private health care insurance, and 20% will be without health coverage of any sort.

³ No opinion is expressed herein regarding the contributions, purchase, or distribution of drugs by any party collaborating in BARI 2D.

questions to be resolved, the type of drugs and supplies to be used, and the detailed treatment protocol to be applied in BARI 2D were developed collaboratively by investigators in the Clinical Centers, in conjunction with NHLBI scientists, and reviewed by an independent protocol review committee reporting to the NHLBI Director. In addition, the NHLBI has appointed a Data and Safety Monitoring Board for BARI 2D, to provide independent advice concerning scientific issues pertaining to human subject safety and data quality.

B. The Proposed Arrangement

All BARI 2D 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, and lancets are provided to BARI 2D patients in the United States through an agreement between NHLBI and a specified manufacturer of the SMBG supplies. Neither the Requestor, nor the manufacturer, was involved in the planning of the BARI 2D protocol or the determination of the frequency of SMBG testing. The Requestor and manufacturer are not, and will not be, involved in the governance of the trial or selection of the participants.

[name of requestor redacted] (the "Requestor"), a nationwide supplier of blood glucose testing products, will purchase SMBG supplies from the manufacturer and distribute such supplies to BARI 2D patients in the United States throughout the term of the study. The clinical units in the Clinical Centers will transmit to the Requestor copies of all prescriptions for SMBG supplies being used by BARI 2D patients. The Requestor will provide SMBG supplies to BARI 2D patients and seek reimbursement from the Medicare and Medicaid programs or other private or public health insurance programs. BARI 2D patients who are not insured will receive SMBG supplies free of charge throughout the term of the study.

Glucose monitoring is vital to diabetes management, and it is the goal of BARI 2D to have SMBG supplies available to all participants. Moreover, in accordance with its historical practice, and to encourage adequate enrollment in the study, NHLBI wants patients to receive care under the BARI 2D 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 BARI 2D 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, BARI 2D patients, or any other party with respect to SMBG supplies being used by BARI

4

The Requestor has certified that SMBG frequency of 75 times per month is a reasonable estimate for an average BARI 2D patient over the average term of the study.

2D patients.⁵

II. LEGAL ANALYSIS

A. Law

Section 1128A(a)(5) of the Act prohibits any person from giving remuneration 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(i)(6) of the Act defines "remuneration" for purposes of section 1128A(a)(5) 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.

⁵ 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.

⁶ The statute contains an exception to the definition of remuneration, not applicable here, 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. Section 1128A(i)(6) 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 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 obligations, 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 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 potentially present a risk of fraud and abuse.

Notwithstanding, we conclude that, in the particular circumstances presented here, we would not impose 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.

⁷ HCFA National Coverage Determination (Sept. 19, 2000) posted on the CMS website at <http://www.cms.hhs.gov/coverage/8d2.asp>. See also Medicare National Coverage Determinations Manual (NDC) § 310.1, formerly Medicare Issues Manual (CMS Pub. 6), § 30-1.

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

First, BARI 2D is an NIH-sponsored scientific study that has been initiated, organized, funded, and managed by NHLBI with participation by the NIDDK. NHLBI controls the determination of the 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 selected all of the study's Clinical Centers in accordance with its own specifications.

Second, BARI 2D is neither a commercial study nor a product-oriented or product-specific study. Unlike many privately sponsored clinical trials, BARI 2D 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 BARI 2D is likely to have significant consequences for the professional medical treatment of all affected patients, including Medicare beneficiaries.

In contrast to BARI 2D, 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, routine 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 [name of requestor redacted] 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 [name of requestor redacted], 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, and 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 that 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 [name of requestor redacted] 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 [name of requestor redacted] 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