



[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: May 21, 2004

Posted: June 1, 2004

[name and address redacted]

Re: OIG Advisory Opinion No. 04-03

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a marketing company's arrangement to design, develop, and implement physician surveys conducted on behalf of pharmaceutical firms (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes 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.

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 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, but that the Office of Inspector General ("OIG") would not impose administrative sanctions on [name redacted]

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) in connection with the Arrangement.

This opinion may not be relied on by any persons other than [name 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.

1. FACTUAL BACKGROUND

[name redacted] (the “Requestor”), is an independent marketing firm, specializing in direct mailings, that designs, develops, and implements physician surveys on behalf of pharmaceutical companies. The Requestor is not a provider or supplier of health care items or services, nor a manufacturer of health care products. The Requestor’s only association with the health care industry is through its survey program.

When hired by a pharmaceutical company, the Requestor prepares and distributes surveys containing product-specific questions designed to gather information regarding physician preferences on drug labeling and product information. The surveys set forth a small number of product-specific statements, for example, “product X reduces the potential for Y drug interactions,” and ask physicians to rate on a scale of one to five the importance of including the information in the product information. The surveys may also ask about the physician’s preferences as to the format of information (*e.g.*, cd-rom, internet, live seminars, sales representatives). There are typically only four to six survey questions. In addition, the surveys provide limited information on services and materials available from the pharmaceutical company, including information such as the pharmaceutical company’s web site address, links to news reports and professional associations, and available patient materials.

The Requestor utilizes a one dollar check as the vehicle for communication of the physician’s survey responses.¹ The survey responses are printed on the back of a one dollar check made out to the physician. The check, which contains the survey responses, must be endorsed by the physician in order to be deposited. Alternatively, the physician can elect to donate the dollar to one of several non-profit organizations listed on the check by returning the one dollar check and survey response in a self-addressed, stamped envelope provided by the Requestor.

¹The Requestor has certified that it has never used, and will not use, a check amount greater than one dollar.

The Requestor enters into one-year contracts with its pharmaceutical company clients for its survey services. Under the Arrangement, the pharmaceutical company provides the Requestor with a list of physicians it wishes to survey. The pharmaceutical company clients pay the Requestor for the costs associated with designing and producing each survey, such as artwork, copy, proof, and printing costs; postage for all mailings; bank fees; and redemption of the one dollar checks used as the survey response vehicle. The Requestor does not receive any payment related to the Arrangement from the pharmaceutical companies aside from the reimbursement set forth under the contract, nor does the Requestor have any other relationships with the pharmaceutical companies that are related in any way to the Arrangement. Further, the pharmaceutical companies do not provide any additional payments to the surveyed physicians through the Requestor. The Requestor is not aware of any direct or indirect financial relationships between the pharmaceutical companies and any surveyed physicians.

In a twelve-month period, the Requestor produces a total of six to twelve surveys on behalf of two to four different pharmaceutical companies. Thus, the maximum number of surveys and the corresponding maximum dollar amount one physician may receive in a twelve month period is twelve dollars. Most surveyed physicians will receive fewer than the maximum number of surveys. Distribution of the surveys is limited to relevant physician specialties. For example, an allergist would receive surveys only on behalf of a pharmaceutical company seeking information on products applicable to an allergist's practice, such as an antihistamine product. The Requestor's mailing facility monitors the physician lists received from the pharmaceutical companies to ensure that a physician does not receive more than the maximum of twelve surveys in a twelve-month period.

The Requestor provides the pharmaceutical companies with aggregate survey data only. Thus, the information provided is not physician-specific, nor can it be tied to an individual physician's survey response. If the physician requests additional product information or patient product materials, the physician's request, with no other information about the physician or the physician's specific survey responses, is forwarded to the pharmaceutical company's fulfillment mailing facility. The Requestor may also send a one-page summary of the survey results to the physicians who responded to the survey. The Requestor has no patient contact and no contact with physicians other than through the survey instrument and possible reporting of survey results.

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.

B. Analysis

Although styled as a research practice, the Arrangement arguably constitutes a marketing or promotional activity. The anti-kickback statute places constraints on the marketing and promotion of pharmaceutical products reimbursed by Federal health care programs. Marketing and promotional practices that may be common in other businesses are not necessarily acceptable when Federal health care business is involved. The OIG has long-standing concerns that improper marketing and promotion of pharmaceutical products could skew the clinical judgment of physicians; increase costs to Federal health care programs and beneficiaries; result in overutilization; and raise patient safety or quality of care concerns. See e.g., *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731 (May 5, 2003). The pharmaceutical industry, like some other health care sectors, has taken an aggressive approach to marketing and promotional activities, cloaking many such activities in the guise of other purportedly

bona fide activities. These activities include questionable research and marketing payments. Thus, arrangements whereby a pharmaceutical company provides any form of remuneration to a physician, either directly or indirectly through a conduit entity or arrangement, potentially implicate the anti-kickback statute and must be carefully scrutinized.

Under the Arrangement, physicians receive money in connection with an activity conducted on behalf of a pharmaceutical company. Thus, the question arises whether the Arrangement is a conduit for funds flowing from the pharmaceutical company to the physicians to induce referrals. Notwithstanding our significant concerns in this area, the unique facts and circumstances surrounding the Arrangement reflect a number of safeguards that mitigate the risk of fraud or abuse or otherwise merit consideration.

First, the amount of compensation that may be paid to a physician in a twelve-month period is limited to a maximum of twelve dollars, which may come from multiple pharmaceutical companies. The limited dollar amount, coupled with safeguards that ensure a physician does not receive more than the maximum twelve-dollar amount in a one-year period, reduces the risk that the survey response checks are intended to induce referrals. Importantly, the pharmaceutical companies are not providing any additional payments to the physicians through the Requestor and because the survey responses of individual physicians are not available to the pharmaceutical companies, the surveys would appear to be an unlikely vehicle for identifying physicians who might be willing to accept improper payments.

Second, the limited scope of the survey (approximately four to six questions) and the nature of the particular questions further reduce the likelihood that the survey, standing alone, is intended to influence physicians' prescribing practices.² Moreover, upon completion of the survey, the pharmaceutical companies only receive aggregate data from the Requestor. Thus, the pharmaceutical company is not able to trace the specific survey responses back to specific physicians.

Third, the Requestor has no discernible ability to influence referrals of business for its pharmaceutical company clients. The Requestor is not a health care provider or supplier, and, apart from its survey services, is not involved in the health care business. The

²We express no opinion with respect to pharmaceutical clients' use of any information obtained through the survey process or their use of the survey process in connection with other activities, including, but not limited to, marketing or promotional activities.

Requestor has no patient contact and no contact with physicians other than through the survey instrument and possible reporting of survey results. The Requestor is paid by the pharmaceutical companies based on the Requestor's actual costs of conducting the survey. The Requestor does not receive any payments from the pharmaceutical companies in connection with the Arrangement other than the compensation set forth under the contract.

Fourth, the survey responses are contained on the back of a standard check that must be endorsed by the physician for deposit. This feature enhances the integrity of the survey program by safeguarding against individuals other than the physician completing the survey. The surveys clearly state that the survey must be completed, and the checks must be endorsed, by the physician.

Based on a totality of the foregoing reasons, we conclude that, while many similarly structured arrangements pose a significant risk of fraud or abuse, the singular facts presented by the Requestor, including the limited financial relationships involved, make that risk sufficiently low and that we would not subject the Arrangement to administrative sanctions in connection with the anti-kickback statute.

We caution, however, that a similar arrangement involving different facts would likely produce a different result. For example, an arrangement involving more lucrative payments to physicians or marketing or promotional activity by health care providers, practitioners, or suppliers on behalf of pharmaceutical manufacturers (or other sellers of health care products) would raise substantial concerns, as would any practice involving payments to a marketer or physician where those payments are tied directly or indirectly to the volume or value of referrals.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the 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, but that the OIG would not impose administrative sanctions on [name redacted] 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) in connection with the Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], 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 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 [name redacted] with respect to any action that is part of the 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, 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 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

Page 8 -OIG Advisory Opinion No. 04-03

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