



[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: September 27, 2002

Posted: October 4, 2002

[name and address redacted]

Re: OIG Advisory Opinion No. 02-13

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding financial assistance to be provided by a non-profit foundation that a pharmaceutical company proposes to establish and fund to subsidize cost-sharing amounts incurred by financially needy patients using its drug (the "Proposed Arrangement"). Specifically, you have inquired whether 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.

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 could potentially generate prohibited remuneration under the anti-kickback statute and that the Office of Inspector General (“OIG”) could potentially impose administrative sanctions on [N Company] 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 Proposed Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties’ intent, which determination is beyond the scope of the advisory opinion process.

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

[N Company] (the “Requestor”) is a pharmaceutical company that manufactures and markets biologicals, including a drug for the treatment of anemia (low red blood cell count) associated with chronic renal failure (“Drug A”). Drug A is administered in a physician’s office at a charge to the patient of several thousand dollars a year. There is at least one competing drug for each of Drug A’s approved uses.

The Requestor proposes to establish and fund, initially for a three-year period, a non-profit, tax-exempt corporation (the “Foundation”). The Requestor would be solely and exclusively responsible for providing all contributions to the Foundation. All contributions to the Foundation would be earmarked for the support of patients using Drug A. The Foundation would pay all or part of the cost-sharing amounts incurred by privately insured and Medicare patients using Drug A who are deemed to be financially needy.

The Foundation would be directed by a Board of Directors responsible for all its operating protocols. No employee of the Requestor would serve on the Foundation’s Board of Directors. No Foundation employee, officer, or Board member would have any financial relationship with the Requestor.

Potential applicants might learn about the Foundation's financial assistance program from a variety of sources, including physicians, health care providers, and the Requestor's own patient assistance program. The Requestor would also advertise the availability of the Foundation's financial assistance program to physicians who could prescribe, or influence the prescription of, Drug A.

Only patients who are using or intend to use Drug A would be eligible for financial assistance. The Foundation would review requests for financial assistance by examining an applicant's medical condition, verifying the medical necessity of the applicant's use of Drug A, and confirming the applicant's private insurance or Medicare coverage. The Foundation would then examine the patient's available financial resources, including both income and assets, in relation to its established financial standards and would then compare those resources to the applicant's expected Drug A cost-sharing obligations under the patient's insurance coverage.

The Foundation would determine the patient's eligibility for assistance and, depending on need, provide partial or full subsidization of the patient's cost-sharing amounts. The Foundation, operating through a distributor selected for this purpose, would authorize a purchase credit to an eligible patient's physician for Drug A in the amount of the patient's subsidy. The distributor selected by the Foundation would inform the physician in a manner reasonably calculated to give notice to the physician of the physician's obligations to report the purchase credit and to provide information as required in 42 C.F.R. § 1001.952(h). The Foundation would provide such financial assistance to the patient for a specific period of time (initially, up to three years), after which the patient would be able to reapply.

Finally, the Foundation's staff would not take the identity of the referring person, physician, or organization into consideration when assessing patient applications or in making determinations of financial assistance. The Requestor would play no role in the selection or determination of patients eligible for assistance and would receive no data identifying either patients who received assistance from the Foundation or physicians whose patients applied for or received assistance from the Foundation.

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. 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 State health care programs. 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

The Proposed Arrangement, by which the Requestor would subsidize all or part of certain Medicare beneficiaries’ Part B cost-sharing amounts through the Foundation, would clearly implicate the anti-kickback statute.

As a threshold matter, we would consider the grants by the Foundation to be payments by the Requestor. Neither the Foundation’s interposition between the Requestor and eligible Medicare beneficiaries, nor the design and administration of the Proposed Arrangement, provide sufficient insulation so that the Foundation’s subsidy of Medicare Part B cost-sharing amounts for Drug A could not be attributed to the Requestor. Most importantly, the Foundation’s financial assistance would be funded by the Requestor and would be available only to patients receiving, or willing to receive, the Requestor’s Drug A.

The question becomes whether we should permit a manufacturer of a drug or device that is covered under a Federal health care program to subsidize copayments incurred by financially needy beneficiaries for using the manufacturer’s product. For the reasons set out below, we believe such arrangements implicate the anti-kickback statute and pose a substantial risk of program and patient fraud and abuse.

First, the Proposed Arrangement is squarely prohibited by the statute. The Requestor proposes, in effect, to subsidize copayments for patients who use Drug A, thereby shifting all or part of the cost for the drug to the Medicare program. The Proposed Arrangement differs in two important respects from a provider's unadvertised, non-routine waiver of copayments based upon a patient's financial need, which has long been permitted. The Proposed Arrangement would result in a patient's physician receiving full payment for prescribing Drug A (i.e., payment from Medicare for 80% of the Medicare allowable amount and the 20% copayment from the Foundation).¹ In addition, the availability of financial assistance would be advertised to physicians and patient advocacy groups.

Second, the Proposed Arrangement poses all the usual risks of fraud and abuse associated with kickbacks. The Proposed Arrangement would provide Drug A with an obvious financial advantage over competing drugs in the market. Since the Requestor is subsidizing copayments for Drug A, rational beneficiaries will prefer treatment with Drug A to one for which they must pay the entire copayment. Moreover, physicians will prefer to prescribe a drug for which they will receive full reimbursement, rather than one for which they bear the risk of collection of cost-sharing obligations.

Moreover, the Proposed Arrangement may easily result in increased costs to the Medicare program. Since beneficiaries are insulated from their full financial liability for Drug A and since prescribing physicians receive full reimbursement, there is no incentive to use competing products, even if they are less expensive. More importantly, Medicare reimbursement for Drug A is calculated based on a drug's average wholesale price -- a price substantially controlled by the manufacturer. Accordingly, the Requestor can readily recoup some or all of the cost of the Proposed Arrangement from the Medicare program simply by increasing its sales price for Drug A and reporting a corresponding increase in the average wholesale price -- thereby keeping its profits and those of its physician-customers at a consistent level at the expense of the Medicare program.

Third, patient assistance programs that subsidize Medicare cost-sharing can be very profitable to manufacturers. So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the copayment, the manufacturer makes a profit.

¹ We note that the Foundation's authorization of purchase credit for Drug A to an eligible patient's physician in the amount of the patient's subsidy would not constitute a "discount" within the terms of the safe harbor at 42 C.F.R. § 1001.952(h).

Given that the marginal variable cost of a drug can be quite low, the profit can be considerable, especially for an expensive drug for a chronic condition.

Fourth, there are non-abusive, albeit less profitable, alternatives. For example, manufacturers may provide free drugs to financially needy beneficiaries so long as no federal health care program is billed for all or part of the drugs. Many pharmaceutical manufacturers operate such patient assistance programs. Alternatively, the Requestor's desire to help financially needy patients can be achieved without directly subsidizing patients who use its product. For example, in OIG Advisory Opinion No. 02-1, we approved an arrangement for drug manufacturers to pool contributions in an independent foundation that awards grants based on need, without reference to any specific contributing drug manufacturer. A similar approach could be used here.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially impose administrative sanctions on [N Company] 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 Proposed Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [N 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.

- 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 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.

Sincerely,

Lewis Morris
Assistant Inspector General for Legal Affairs