DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of Inspector General
Washington, D.C. 20201

Issued: April 4, 2002

Posted: April 11, 2002

Dana Kuhn, Ph.D.

Re: OIG Advisory Opinion No. 02-1

Dear Dr. Kuhn:

We are writing in response to your request for an advisory opinion, in which you ask whether grants provided by a non-profit, charitable organization to financially needy Medicare beneficiaries in order to subsidize their costs of medical care (including cost-sharing amounts under Part B of the Medicare program and premium expenses for Medicare Supplementary Health Insurance ("Medigap") coverage) (the "Proposed Arrangement") would be grounds for the imposition of sanctions under section 1128A(a)(5) of the Social Security Act (the "Act") or under the exclusion authority at section 1128(b)(7) of 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 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 [S Organization] 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 [S Organization], 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

[S Organization] (the "Requestor") is a non-profit, tax-exempt, charitable corporation that is not subject to control, directly or indirectly, by any donor. The Requestor provides financial assistance to help defray the medical expenses of financially needy patients suffering from specific chronic illnesses or rare disorders.[1] The financial assistance includes paying all or part of a patient's health insurance premiums and copayments for privately insured and otherwise uninsured patients. The Requestor desires to provide similar financial assistance to financially needy Medicare beneficiaries, using the same eligibility criteria and grant procedures. That process is described below.

Requests for financial assistance are reviewed on a first-come, first-served basis, to the extent funding is available for the applicant's medical condition. The Requestor first examines an applicant's available financial resources in relation to certain established national standards of indigence and then compares those resources to the applicant's expected costs of treatment. The Requestor uses a pre-set sliding scale to determine a patient's eligibility for assistance, which can range from full subsidization of the patient's private health insurance premiums and copayments to significant cost-sharing with the patient. In most cases, the Requestor does not make cash grants directly to patients;[2] rather, checks are made out to the patients' insurance companies, physicians, providers,

---

[1]The Requestor currently supports treatment for the following conditions: [redacted].

[2]In a small number of cases where third-party payments are refused, checks are made payable to the patient as reimbursement only upon proof of payment.

and suppliers of items and services (including drugs).[3] The Requestor provides financial assistance for a specific period of time (up to two years), after which the patient may reapply.

Potential applicants learn about the Requestor's financial assistance programs from a variety of sources, including physicians, health care providers, patient advocacy groups, and drug manufacturers' patient assistance programs. However, approximately half of those who receive assistance annually from the Requestor are referred by donors who make contributions to the Requestor**.** The Requestor has certified that its staff does not take the identity of the referring person or organization or the amount of any donor's contribution into consideration when assessing patient applications or making grant determinations. The Requestor has further certified that its staff does not refer applicants to or recommend providers, practitioners, or suppliers of items or services.

A substantial portion of the Requestor's funding is provided by manufacturers of drugs used to treat the specific chronic illnesses or diseases that are covered by the Requestor's programs and by suppliers of services to patients that the Requestor is assisting, such as home care infusion companies and specialty pharmacies. Donors may change or discontinue their contributions at any time. Virtually all contributions are earmarked for the support of patients with a particular disease or condition. Donors that refer patients to the Requestor are informed quarterly or monthly, depending upon the specific disease category, of the aggregate number of all applicants for assistance in the disease category specified by the donor and the aggregate number of patients qualifying for assistance in that disease category. No individual patient information is conveyed to donors. Patients are not informed of the identity of specific donors of funds for specific disease categories.

In many cases, donors enter into Participation Agreements with the Requestor. Participation Agreements cover approximately half of the Requestor's total average annual donations. These agreements generally obligate the donor to make contributions to the Requestor under fixed conditions. Contributions made pursuant to these agreements are earmarked to assist patients with particular illnesses or diseases designated by the donor. Currently, the Participation Agreements obligate the Requestor to assess the eligibility of patients referred to it by the donor and to submit periodic reports to the donor listing the number of patient referrals made by donor; the number by donor of patient applications mailed, received, and accepted; and the number by donor of

---

[3]While the Requestor pays a patient's providers and insurers directly, the Requestor notifies patients that they are free at all times to switch to another provider. Of course, depending on the comparative costs of the new provider, the amount of financial assistance might change.

patients accepted and denied. Upon implementation of the Proposed Arrangement, this reporting requirement will be changed so that, as the Requestor has certified, patient information will be reported to donors on an aggregate basis only within specific disease categories.

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 program beneficiary that the benefactor 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. The OIG may also initiate administrative proceedings 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 "the waiver of coinsurance and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value."

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, in whole or in part, certain Medicare beneficiaries' Part B copayments and deductible amounts and Medigap premiums, implicates section 1128A(a)(5)of the Act, as well as the anti-kickback statute. Nevertheless, for the reasons set forth below, 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. We further conclude that, in the particular circumstances presented here, we would not seek to impose administrative sanctions under the anti-kickback statute in connection with the Proposed Arrangement.

1. Donor Contributions to the Requestor

Because the Requestor's particular design and administration of the Proposed Arrangement interposes an independent charitable organization between donors and patients in a manner that effectively insulates beneficiary decision-making from information attributing the funding of their benefit by any donor, it appears unlikely that donor contributions would influence any Medicare or Medicaid beneficiary's selection of a particular provider, practitioner, or supplier. Thus, donor contributions to the Requestor would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act.

The Requestor is an independent, non-profit, tax-exempt charitable organization that is not subject to control, directly or indirectly, by any donor. A variety of sources refer patients to the Requestor for financial assistance, many of which sources are not affiliated with any donor that contributes to the Requestor.

Eligibility for the Requestor's financial assistance is available to any financially qualified patient suffering from the specific chronic illnesses or diseases targeted by the Requestor's program, regardless of the particular physicians, providers, suppliers of items or services, or drugs that the patient may use. The Requestor makes all financial eligibility determinations using its own criteria and does not take into account the identity of any physician, provider, supplier of items or services, or drug that the patient may use or the amount of any contributions made by a donor whose services or products are used or may be used by the patient.

Moreover, before applying for financial assistance, all patients have selected their health care providers (and, where appropriate, the providers have prescribed drugs for the patient) freely based on their best medical interests after consultation with their physicians and other providers and remain free while receiving the Requestor's financial

assistance to change their health care providers. The Requestor does not refer patients to any donor or other provider.

In sum, the Requestor's interposition as an independent charitable organization between donors and patients and the design and administration of the Proposed Arrangement provide sufficient insulation so that the Requestor's subsidy of Medicare Part B copayments and deductibles and Medigap premiums should not be attributed to any of its donors. Donors are not assured that the amount of financial assistance their patients, clients, or customers receive will bear any relationship to the amount of their donations. Indeed, donors are not guaranteed that any of their patients, clients, or customers will receive any financial assistance whatsoever from the Requestor. In these circumstances, we do not believe that the contributions made by donors to the Requestor can reasonably be construed as payments to eligible beneficiaries of the Medicare program.

2. The Requestor's Subsidy of Medicare Part B Copayments and Deductibles and Medigap Premiums

In the circumstances presented by the Proposed Arrangement, we believe that the Requestor's subsidy, in whole or in part, of Medicare Part B copayments and deductible amounts and Medigap premiums for certain financially qualified Medicare beneficiaries is not likely to influence any beneficiary's selection of a particular provider, practitioner, or supplier.

First, the Requestor assists all financially qualified patients on a first-come, first-served basis, to the extent funding is available for the patient's medical condition. In virtually all cases, the patient is already being treated for his or her condition and has thus already selected providers. Even if asked, the Requestor makes no referrals or recommendations regarding specific providers, practitioners, or suppliers.

Second, the Requestor's determination of a patient's financial qualification for assistance is based solely on the patient's aggregate financial need, without considering the identity of any of the patient's health care providers or the identity of any donor that may have contributed for the support of the specific medical condition. The Requestor notifies all grant recipients that they are free at any time to switch providers, practitioners, or suppliers without affecting their continued eligibility for financial assistance. While we consider problematic the Requestor's reporting of certain patient data to donors, we consider that the Requestor has appropriately minimized the risks of fraud and abuse by ensuring that such reports contain aggregate patient data, rather than data relating to specific patients; this method precludes donors from tracking the specific patients utilizing their products or the amounts paid by the Requestor to such patients.

Finally, the Requestor's subsidy of Medicare Part B copayments and deductible amounts and Medigap premiums for the patient populations it serves will expand, rather than limit, beneficiaries' freedom of choice. As a practical matter, most patients will have already selected a provider, practitioner, or supplier of items or services, and drugs will have been prescribed for the patient, prior to the patient's application for the Requestor's financial assistance or prior to the Requestor's initial payment of Medicare Part B copayments and deductibles or Medigap premiums. Most importantly, once in possession of Medicare Part B or Medigap coverage, a beneficiary will be able to select any provider, practitioner, or supplier of items or services (and have any drug prescribed), regardless of whether that provider, practitioner, or supplier (or drug manufacturer) has made contributions to the Requestor's support programs.

In light of all of the foregoing considerations and for similar reasons, we would furthermore not subject the Requestor to sanctions under the anti-kickback statute in connection with the Proposed Arrangement.

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 [S Organization] 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 [S Organization], 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.

- 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 [S Organization] 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 [S Organization] 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/

D. McCarty Thornton
Chief Counsel to the Inspector General