



[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: April 20, 2006

Posted: April 27, 2006

[Name and address redacted]

Re: OIG Advisory Opinion No. 06-04

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a nonprofit, tax-exempt, charitable corporation's proposal to provide financially needy Medicare beneficiaries with assistance with premiums and cost-sharing obligations under Medicare Part B, Medicare Part D, Medigap (as hereinafter defined), and Medicare Advantage (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, 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, the anti-kickback statute.

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: (i) [Requestor's name redacted's] Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while [Requestor's name redacted's] 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 [Requestor's 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 Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

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"), a nonprofit, tax-exempt, charitable corporation, aids individuals and families through assistance with funding for treatment of two specific chronic diseases: [disease names redacted]. The Requestor's current programs for patients with [disease names redacted] include: (i) premium support (*i.e.*, financial assistance to subsidize premiums for private insurance for financially needy patients); (ii) emergency relief (*i.e.*, one-time grants of up to \$500 to address urgent needs and lack of financial resources); and (iii) non-financial assistance, such as assisting families with locating insurance, appealing insurance payment denials, providing personal support services, and acting as a liaison between the patient community and legislators regarding critical issues of importance to patient communities.

Under the Proposed Arrangement, the Requestor will expand its premium support program to offer financial assistance for premiums and cost-sharing obligations to financially needy Medicare beneficiaries under Medicare Part B, Medicare Part D, Medicare Supplementary Health Insurance ("Medigap"), and Medicare Advantage. With respect to Medicare beneficiaries enrolled in a Part D plan, the financial assistance could include assistance with any premiums and cost sharing obligations (including during any deductible, coverage gap, and catastrophic coverage periods).

The Requestor will operate its programs under the Proposed Arrangement as follows. All prospective grant recipients must complete an application. The Requestor will process grant applications in order of receipt on a first-come, first-served basis. The Requestor will

establish objective criteria for determining eligibility for assistance, which will be based upon the applicant's medical condition and financial need. Under those criteria, the Requestor will consider for assistance those applicants whose gross monthly income is below 250% of the Federal poverty level. For premium assistance and assistance with cost-sharing obligations, qualifying patients will be responsible for paying a portion of the monthly expense equal to at least four percent (4%) of the applicant's gross monthly income.¹ The Requestor will provide a grant for the remainder of the monthly premium or cost-sharing obligation, up to a maximum of \$350 per month.² Whenever possible, the Requestor will not make cash grants directly to patients; rather, checks will be made out to a patient's insurance company, practitioner, provider, or supplier.³ The Requestor will provide financial assistance for a specific period of time (up to one year), after which a patient may reapply. Grant recipients will be required to notify the Requestor if their financial circumstances change during the grant period.

Potential applicants will learn about the Requestor's programs from a variety of sources, including self-referrals, other support organizations, physician offices, pharmaceutical manufacturers, and others. The Requestor will assess patient applications and make grant determinations without regard to: (i) the interests of any donor (or any donor affiliates); (ii) the applicant's choice of product, provider, practitioner, or supplier; or (iii) the identity of the referring person or organization, including whether the referring person or organization is a donor.

Applicants must be under the care of a physician with a treatment regimen in place at the time of application. The Requestor has certified that its staff will not refer applicants to, recommend, or arrange for the use of any particular product, practitioner, provider, or supplier. At all times, patients will have complete freedom of choice regarding their physicians, providers, suppliers, and treatment regimens. The Requestor will notify all grant recipients that they are free at any time to switch products, practitioners, providers, or suppliers without affecting their continued eligibility for financial assistance.

¹In some cases, patients may receive subsidies if they demonstrate to the satisfaction of the Requestor that they cannot afford the four percent amount.

²The amount of assistance can exceed \$350 only in extraordinary circumstances and only based upon the review and approval of the Requestor's grant review committee.

³In cases where an insurance company, practitioner, provider, or supplier will not accept the Requestor's third-party payments (such as, for example, some pharmacies), the Requestor will make the checks payable to the patient as reimbursement only upon proof of payment.

Most of the Requestor's funding is (and will continue to be) provided by non-profit organizations, home health agencies, manufacturers of drugs used to treat the chronic diseases covered by the Requestor's programs, and suppliers that provide services to patients receiving assistance from the Requestor. The remainder of the Requestor's funding is (and will continue to be) provided by individual donors, foundation grants, and [charity name redacted], an annual workplace giving campaign for employees of [state name redacted]. All donations are either cash or cash equivalents. Donors can change or discontinue their contributions to the Requestor at any time. Under the Proposed Arrangement, the Requestor will permit donors to provide unrestricted donations or to designate that their funds be used in one of two ways. First, donors can designate that their funds be used to support patients in a specific disease category; however, use of the donations must be unrestricted within that disease category (*i.e.*, donations can be used for qualifying applicants suffering from any disease within the specified disease category in connection with premium/cost-sharing assistance, emergency relief, or non-financial assistance). Second, donors can designate that their funds be used to support patients through a specific program (*i.e.*, either premium/cost-sharing assistance, emergency relief, or non-financial assistance); however, use of the donations cannot be limited to a specific disease or disease category within the specified program.

The Requestor has certified that no donor or affiliate of any donor (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) has exerted or will exert any direct or indirect influence or control over the Requestor or any of the Requestor's programs.⁴ Upon request, donors will be informed monthly, as a courtesy, of the aggregate number of all applicants for assistance in a particular disease category and the aggregate number of patients qualifying for assistance in the disease category. No individual patient information will be conveyed to donors. The Requestor has certified that the monthly data will not contain any information that would enable a donor to correlate the amount or frequency of its donations with the number of subsidized prescriptions or orders for its products or the volume or medical condition of patients choosing its services. Patients will not be informed of the identity of specific donors. Neither patients nor donors will be informed of the donations made to the Requestor by others, although, as required by Internal Revenue Service regulations, the Requestor's annual report and list of donors will be publicly available upon request.

⁴The Requestor has further certified that no health plan or affiliate of any health plan has exerted or will exert any direct or indirect influence or control over the Requestor or any of the Requestor's programs.

The Requestor is continuing to work to obtain additional funding to broaden the scope of its programs. To the extent funding is limited, the Requestor, in its sole discretion, will determine the disease categories it will support through its programs and the diseases it will include within each disease category. ([Disease names redacted] will be integrated into one or more broader disease categories.) The Requestor has certified that: (i) it will define its disease categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products; and (ii) its disease categories will not be defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs.⁵ The Requestor has further certified that no donor or affiliate of any donor (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) will directly or indirectly influence the identification or delineation of the disease categories.⁶ (The Requestor notes that its current plans to expand its programs to cover additional diseases stem from requests made by patient advocate groups unconnected to any pharmaceutical manufacturer or other donor.)

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 (“remuneration”) 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 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.”

⁵In rare circumstances where there may only be one drug covered by Part D for the disease in a particular category or only one pharmaceutical manufacturer (including its affiliates) that makes all of the Part D covered drugs for the diseases in a particular disease category, the Requestor has certified that it will use its best efforts to cover additional products and manufacturers as they become available.

⁶Donors may provide the Requestor with educational materials that the donors generally make available to practitioners or the general public (e.g., clinical information about drug products).

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

Two remunerative aspects of the Proposed Arrangement require scrutiny under section 1128A(a)(5) of the Act and the anti-kickback statute: the donor contributions to the Requestor and the Requestor’s grants to beneficiaries. We address them in turn.

1. Donor Contributions to the Requestor

Long-standing OIG guidance makes clear that industry stakeholders can effectively contribute to the health care safety net for financially needy beneficiaries by contributing to independent, *bona fide* charitable assistance programs. Under a properly structured program, such donations should raise few, if any, concerns about improper beneficiary inducements.

In the instant case, the Requestor’s particular design and administration of the Proposed Arrangement will interpose an independent, *bona fide* charitable organization between donors and patients in a manner that effectively insulates beneficiary decision-making from information attributing the funding of their benefit to any donor. Thus, it appears unlikely that donor contributions would influence any Medicare beneficiary’s selection of a particular provider, practitioner, supplier, or product. Similarly, there would appear to be a minimal risk that donor contributions would improperly influence referrals by the Requestor. We reach this conclusion based on the combination of the following factors.

First, no donor or affiliate of any donor exerts direct or indirect control over the Requestor or its programs. The Requestor is an independent, nonprofit, tax-exempt charitable organization that is not affiliated with any donor. The Requestor receives funding from a broad cross-section of health care industry donors (including, for example, drug manufacturers and suppliers of services), as well as non-profit organizations, individuals, and [charity name redacted].

Second, the Requestor awards assistance in a truly independent manner that severs any link between donors and beneficiaries. The Requestor will make all financial eligibility determinations using its own criteria. Applications will be considered on a first-come, first served basis, to the extent of available funding. Before applying for financial assistance, each patient will have selected his or her health care provider and will have a treatment regimen in place. All patients will remain free, while receiving the Requestor's financial assistance, to change their health care providers, practitioners, suppliers, or products. The Requestor will not refer patients to any donor or to any provider, practitioner, supplier, or product.

Third, the Requestor awards assistance without regard to any donor's interests and without regard to the beneficiary's choice of provider, practitioner, supplier, or product. When determining patient eligibility for the Proposed Arrangement, the Requestor will not take into account the identity of any provider, practitioner, supplier of items or services, or drug or other product the patient may use; the identity of any referring person or organization; or the amount of any contributions made by a donor whose services or products are used or may be used by the patient.

Fourth, based on the Requestor's certifications, the Requestor will provide assistance based upon a reasonable, verifiable, and uniform measure of financial need that will be applied in a consistent manner.

Fifth, the Requestor will not provide donors with any data that would facilitate the donor in correlating the amount or frequency of its donations with the amount or frequency of the use of its products or services. No individual patient information will be conveyed to any donor, nor will any data related to the identity, amount, or nature of products or services subsidized under the Proposed Arrangement. Some aggregate data may be provided to donors as a courtesy, but will be limited to aggregate numbers of applicants and aggregate numbers of qualifying patients in specific disease categories. Patients will not receive any information regarding donors, and donors will not receive any information regarding other donors, except that the Requestor's annual report may be publicly available, as required by the IRS. In the instant case, we believe these safeguards appropriately minimize the potential risk otherwise presented by reporting of patient and donor data to donors and patients.

Finally, the fact that the Requestor will permit donors to earmark donations for specific disease categories should not, on the facts presented, significantly raise the risk of abuse. In this case, the Requestor has certified that no donor or affiliate of any donor (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) will directly or indirectly influence the identification of the disease categories. Moreover, to ensure that the Requestor's disease categories are appropriately defined, the Requestor has further certified that: (i) it will define its disease categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products; and (ii) its disease categories will not be defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs. In these circumstances, it is unlikely that the earmarking will result in the Proposed Arrangement serving as a disguised conduit for financial assistance from a donor to patients using its products.

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 proposed subsidies should not be attributed to any of its donors. Donors will not be 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 will not be 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 or to the Requestor to arrange for referrals.⁷

2. The Requestor's Grants to Medicare Beneficiaries

In the circumstances presented by the Proposed Arrangement, the Requestor's subsidy, in whole or in part, of premiums and cost-sharing obligations for certain eligible, financially needy Medicare beneficiaries is not likely to influence improperly any beneficiary's selection of a particular provider, practitioner, supplier, or product.

⁷This conclusion is consistent with the OIG's November 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (70 Fed. Reg. 70623; November 22, 2005), in which the OIG made it clear that, in the circumstances described in the Bulletin, (i) cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, even if the charities receive manufacturer contributions, and that, (ii) in general, the fact that a pharmaceutical manufacturer's donations are earmarked for one or more broad disease categories should not significantly raise the risk of abuse.

First, the Requestor will assist all eligible, financially needy patients on a first-come, first-served basis, to the extent funding is available. Patients will not be eligible for assistance if their gross monthly income exceeds 250% of the poverty line. In all cases, the patient will already be under the care of a physician with a treatment regimen in place at the time of application. The Requestor will make no referrals or recommendations regarding specific providers, practitioners, suppliers, or products. Patients will not be informed of the identity of donors.

Second, the Requestor's determination of a patient's financial qualification for assistance will be based solely on the patient's financial need, without considering the identity of any of the patient's health care providers, suppliers, or products; the identity of any referring party; or the identity of any donor that may have contributed for the support of the patient's specific disease category. The Requestor will provide assistance based upon a reasonable, verifiable, and uniform measure of financial need that will be applied in a consistent manner. The Requestor will notify all grant recipients that they are free at any time to switch providers, practitioners, suppliers, or products without affecting their continued eligibility for financial assistance.

Third, the Requestor's subsidies for the patient populations it serves will expand, rather than limit, beneficiaries' freedom of choice. Patients will have already selected a provider, practitioner, or supplier of items or services – and drugs or other products will likely have been prescribed for the patient – prior to the patient's application for the Requestor's financial assistance. Most importantly, once in possession of Medicare Part B, Medicare Part D, Medigap, or Medicare Advantage coverage, a beneficiary will be able to select any provider, practitioner, or supplier of items or services (and have any product prescribed or ordered), regardless of whether that provider, practitioner, or supplier (or product manufacturer) has made contributions to the Requestor's support programs (subject to plan network and formulary restrictions).

In light of all of the foregoing considerations, we would not subject the Requestor to administrative sanctions under section 1128A(a)(5) of the Act or 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: (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) 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 [Requestor's 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 Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Requestor's 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 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 will not proceed against the Requestor 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 the Requestor 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,

Lewis Morris
Chief Counsel to the Inspector General