



Washington, D.C. 20201

[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: August 18, 2006

Posted: August 25, 2006

[Name and address redacted]

Re: OIG Advisory Opinion No. 06-09

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a nonprofit, tax-exempt, charitable organization's proposals to subsidize Medicare Part D premium and cost-sharing obligations owed by financially needy patients with end-stage renal disease and chronic kidney disease (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) 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 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 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.

I. FACTUAL BACKGROUND

[Name redacted] (the “Requestor”) is a nonprofit, tax-exempt, charitable organization, which operates a publicly supported charity that provides direct financial assistance, comprehensive education, clinical research, and community service programs to individuals at risk for, and suffering from, kidney disease. Among its programs, the Requestor operates a scheme that assists patients with costs associated with Medicare Part B and Medigap insurance premiums.¹ Under the Proposed Arrangement, the Requestor intends to implement two additional programs to assist financially needy Medicare beneficiaries suffering from chronic kidney disease and end stage renal disease. The first program would subsidize: (i) premiums for Medicare Part D plans offering enhanced alternative coverage in the form of expanded formulary coverage for prescription medications for kidney diseases and conditions;² and (ii) beneficiary cost-sharing obligations under Medicare Part D. The second program would subsidize Part D cost-sharing obligations for products that prevent and manage abnormalities, debilities, and health risks (“conditions specific”) associated with kidney disease. The Requestor plans to begin with a program to assist patients with bone disease related to kidney failure; it may later initiate other conditions specific programs to

¹The Requestor previously received a favorable OIG Advisory Opinion to use charitable donations from renal dialysis providers and others to fund the program, known as the Health Insurance Premium Program. See Advisory Opinion No. 97-1. The Requestor has certified that the Proposed Arrangement is substantially similar in all operational aspects to the program approved by the OIG in Advisory Opinion 97-1.

²Enhanced alternative coverage refers to Part D plans that provide extra benefits beyond the basic benefit by: (i) covering drugs that are not part of the standard Part D coverage; and/or (ii) making certain types of changes to cost-sharing and deductible obligations that result in enrollees receiving benefits that have a higher actuarial value than the benefits available under standard Part D coverage. See 42 C.F.R. § 423.104(f). It is the first form of enhanced coverage that is of special importance to the Requestor and grant recipients.

assist kidney patients (we refer to these programs collectively as the “Conditions Specific Programs”).

All programs under the Proposed Arrangement will operate as follows. All applicants will complete a grant application (typically with assistance from a social worker). The Requestor will process grant applications in order of receipt on a first-come, first-served basis, to the extent funding is available.

The Requestor has established objective criteria for determining eligibility for assistance that are based upon the applicant’s medical condition and financial need. The Requestor will provide financial assistance for a specific period of time (up to one year), after which a recipient may reapply. Patients will be required to notify the Requestor if their financial circumstances change during the grant period. Grants will be awarded pursuant to a sliding scale based on the Requestor’s assessment of applicants’ individual needs.

In most cases, premium assistance grants will be made directly by the Requestor to the recipient’s insurance company. Cost-sharing assistance grants will be paid directly by Requestor to physicians, providers and suppliers of items and services (including drugs). In cases where the insurance company or provider will not accept third-party payment, grants will be made payable to the recipient in care of his or her social worker, upon proof that the recipient incurred costs.

Potential applicants will learn about the Requestor’s programs from a variety of sources, including Requestor and other support organizations, physician offices, dialysis providers and suppliers, 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, supplier, or insurance company (except that, in the case of premium assistance, the applicant’s selected Part D plan must be an enhanced alternative coverage plan); or (iii) the identity of the referring person or organization, including whether the referring person or organization is a donor. The Requestor also certifies grant determinations will be made without regard to the amount of contributions made by any pharmaceutical company or other donor whose services or products are used or may be used by the patient.

Applicants will 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, supplier, or insurance company (except that the Requestor’s staff may assist patients in identifying those Part D plans that offer qualifying enhanced alternative coverage). Grant recipients will have complete freedom regarding their choice of products, practitioners, providers, suppliers, insurance companies, and treatment regimens. The Requestor will notify all patients that they are free at any time to switch products, practitioners, providers, suppliers, or insurance companies without affecting their continued eligibility for financial assistance (except that, in the case of premium assistance, the patient’s selected Part D plan must be an enhanced alternative coverage plan).

The Requestor will receive substantial funding for the Proposed Arrangement from dialysis providers and suppliers, as well as pharmaceutical manufacturers. It may also receive funding from insurance companies and other individuals and entities. All donations will be either cash or cash equivalents. Donors will be permitted to change or discontinue their contributions to the Requestor at any time. Donors may either provide unrestricted donations or designate funds for a particular Conditions Specific Program. The Requestor has certified that its discretion as to the use of contributions will be absolute, independent, and autonomous. 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.

Upon request, donors will be informed monthly of the aggregate number of all applicants for assistance. No individual patient's information will be conveyed to donors. The Requestor has certified that reports to donors will not contain any information that would enable a donor to correlate the amount or frequency of its donations with the number or medical condition of patients that use its products or services, or the volume of those products or 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.

With respect to the Conditions Specific Programs, the Requestor, in its sole discretion, will determine the conditions it will support through its programs. The Requestor has certified that: (i) it will define its condition categories in accordance with widely recognized clinical standards and in a manner that covers within each Conditions Specific Program a spectrum of available products;³ and (ii) its condition categories will not be defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs or other products. 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 a Conditions Specific Program.⁴

³For example, with respect to the bone disease pilot program at least four manufacturers offer medications that are prescribed by physicians to protect the bones of patients with kidney disease. In rare circumstances where there may only be one product covered by Part D relevant to an otherwise properly delineated condition or only one manufacturer (including its affiliates) that makes all of the Part D covered products relevant to an otherwise properly delineated condition, the Requestor has certified that it will use its best efforts to cover additional products and manufacturers as they become available.

⁴Donors may provide the Requestor with educational materials that the donors generally make

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.”

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 patients. We address them in turn.

available to practitioners or the general public (e.g., clinical information about drug products).

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 Medicare 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, or the selection of any particular Part D plan. 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 will have absolute, independent, and autonomous discretion as to the use of donor contributions.

Second, the Requestor awards assistance in a truly independent manner that severs any link between donors and patients. The Requestor will make all financial eligibility determinations using its own objective 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, practitioner, or supplier 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. Patients will also remain free to change Part D plans, although premium assistance, if any, will be contingent on selecting a plan that offers qualifying enhanced alternative coverage. The Requestor will not refer any patient to any provider, practitioner, supplier, product or plan (except that the Requestor's staff may assist patients in identifying those Part D plans that offer qualifying enhanced coverage).

Third, the Requestor awards assistance without regard to any donor's interests and without regard to the applicant's choice of product, provider, practitioner, supplier, or insurance plan. When determining an applicant's 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 applicant 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 applicant. The Requestor will also not take into account the identity of the insurer or Part D plan selected by the applicant, although the Requestor will determine whether the selected plan offers

qualifying enhanced alternative coverage.⁵ If it does not, the applicant will not qualify for premium support, but may still qualify for cost-sharing assistance.

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 allow a donor to correlate the amount or frequency of its donations with the amount or frequency of the use of its products or services. No individual patient's 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. 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 donor and patient data to donors and patients.

Finally, the fact that the Requestor will permit donors to earmark donations for the Conditions Specific Programs 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 designation of the condition categories. Moreover, to ensure that the Requestor's condition categories are appropriately defined, the Requestor has further certified that: (i) it will define its condition categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products; and (ii) its condition 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.

⁵In light of the totality of circumstances presented, the fact that Requestor limits its premium assistance to enhanced alternative coverage plans that offer additional drug coverage for kidney disease reasonably relates to, and furthers, the Requestor's specific charitable mission. The limitation represents a reasonable approach to marshaling scarce charitable resources in a manner that precludes a donor from using its contribution to influence a beneficiary to enroll in a specific plan or with a specific insurance company.

Donors have no assurance 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.⁶

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 Part D 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.

First, the Requestor will assist all eligible, financially needy applicants on a first-come, first-served basis to the extent funding is available. Applicants will not be eligible for assistance unless they meet Requestor's financial need eligibility criteria. 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, products, or plans (except that the Requestor's staff may assist patients in identifying those Part D plans that offer qualifying enhanced alternative coverage). Patients will not be informed of the identity of donors.

Second, the Requestor's determination of an applicant's financial qualification for assistance will be based solely on his or her financial need, without considering the identity of any of his or her health care providers, practitioners, suppliers, products, or plans; the identity of any referring party; or the identity of any donor that may have contributed for the treatment of the beneficiary's condition. 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 patients that they are free at any time to switch providers, practitioners, suppliers, or products without affecting their continued eligibility for financial assistance. The Requestor will also notify them that they are free to switch insurance plans when permitted by the Medicare program, without affecting their eligibility for assistance (except that, in the case of premium assistance, the patient selected Part D plan must be an enhanced alternative coverage plan).

⁶This 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, cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with donors should not raise anti-kickback concerns, even if the charities receive charitable contributions from those donors.

Third, the Requestor's subsidies for the patient populations it serves will expand, rather than limit, patient 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 his or her application for the Requestor's financial assistance. Most importantly, once in possession of Medicare Part D coverage, a patient 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). By subsidizing enhanced alternative coverage premiums, the Requestor further expands the range of available options for financially needy Medicare beneficiaries suffering from kidney diseases and conditions.

Finally, the Requestor's own interest as a charitable, tax-exempt entity that must maximize use of its scarce resources to fulfill its charitable mission ensures that the Requestor will have a significant incentive to monitor utilization so as to keep subsidies to a minimum.

In light of all of the foregoing considerations, we would not subject the Requestor to administrative sanctions in connection with the Proposed Arrangement under sections 1128A(a)(5), 1128A(a)(7), or 1128B(7) of the Act.

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 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, 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General