

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Office of Inspector General****Washington, D.C. 20201****OCT 29 2004**

Ms. Nancy Davenport-Ennis
CEO, President
Patient Advocate Foundation
700 Thimble Shoals Blvd.
Suite 200
Newport News, Virginia 23606

Re: OIG Advisory Opinion No. 04-15

Dear Ms. Davenport-Ennis:

We are writing in response to your request for an advisory opinion regarding grants provided by a nonprofit, charitable organization to financially-needy patients suffering from specific chronic or life-threatening diseases to defray the costs of prescription drug therapies (the "Proposed Program"). Specifically, you have inquired whether the Proposed Program 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 Program would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the Proposed Program could potentially generate prohibited remuneration under the

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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 Patient Advocate Foundation 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 Program. This opinion is limited to the Proposed Program 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 Patient Advocate Foundation, 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

Patient Advocate Foundation (the "Requestor"), a nonprofit, tax-exempt, charitable corporation formed in 1996, serves as a liaison between patients and their insurers, employers, and creditors to resolve insurance, job retention, and debt crisis matters relative to their diagnoses. The Requestor provides professional case managers who negotiate with patients' insurers to resolve coverage and benefits issues, patients' employers to mediate job discrimination issues, and patients' creditors to facilitate resolution of debt crisis matters. It provides services to individuals who are insured, uninsured, or underinsured, and some of the insured individuals are Medicare beneficiaries. The Requestor receives donations from a variety of sources, including, but not limited to, providers and suppliers of health care services, pharmaceutical companies, and individuals. The Requestor has certified that it is not subject to control, directly or indirectly, by any donor that is affiliated in any way with any pharmaceutical company.

The Requestor proposes to establish and operate a patient assistance program to defray the costs of expensive prescription drug therapies incurred by financially-needy patients suffering from specific chronic or life-threatening diseases.¹ Under the Proposed Program,

¹The Proposed Program is limited to the following specific disease or illness categories: ovarian cancer; uterine cancer; kidney cancer; prostate cancer; breast cancer; colon cancer; lung cancer; brain cancer; myeloma; lymphoma; leukemia; sarcomas; pancreatic cancer; HIV/AIDS; mental health diseases; diabetes; noncancerous kidney disease; multiple sclerosis; Hepatitis A, B, or C; autoimmune disorders (e.g., arthritis, Crohn's disease, arthritic psoriasis, etc.); cervical cancer; testicular cancer; and macular degeneration.

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for eligible privately-insured patients and Medicare beneficiaries, the Requestor would pay all or part of the patient's cost-sharing obligations for prescription drugs.²

Requests for financial assistance will be reviewed on a first-come, first-served basis. The Requestor has established criteria for determining eligibility for assistance, which are based upon the applicant's disease or illness category and the applicant's financial need. Under those criteria, the Requestor will typically consider for assistance those applicants whose net income is 250% or less of the poverty line set annually by the Department of Health and Human Services' Health Resources and Services Administration.³ The Requestor will use a preset sliding scale to determine a patient's eligibility for assistance, which can range from full subsidization to significant cost-sharing with the patient. In most cases, the Requestor will not make cash grants directly to patients;⁴ rather, checks will be made out to a patient's insurance company, provider, or supplier. Subject to the availability of funds, the Requestor will provide financial assistance for a specific period of time (up to one year), after which the patient may reapply. Beneficiaries of the Requestor's grants will be required to notify the Requestor if their financial circumstances change during the grant period.

Potential applicants will learn about the Proposed Program from a variety of sources. The Requestor anticipates that many prospective grant recipients will learn of the Proposed Program through their existing relationship with the Requestor, while others will probably learn about the Proposed Program from physicians, health care facilities or agencies, patient support groups, nonprofit organizations that support research about their particular diseases, or drug manufacturers' patient assistance programs. 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.

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 does not refer applicants to, recommend, or arrange for the use of any particular product, physician, provider, or supplier.

²For eligible privately-insured patients only, the Requestor may, within its sole discretion, offer to pay all or part of the patient's health insurance premium, instead of offering assistance with cost-sharing obligations.

³The Requestor determines net income using a formula that takes into account family income and expenses, including medical expenses.

⁴In a small number of cases where third-party payments are refused, checks will be made payable to the patient as reimbursement only upon proof of payment.

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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 providers, practitioners, or suppliers without affecting their continued eligibility for financial assistance.

The Proposed Program will be funded through donations made to the Requestor from a variety of sources, including manufacturers of drugs used to treat the chronic illnesses and diseases that are covered by the Proposed Program. The Requestor will require that each pharmaceutical manufacturer that participates in the Proposed Program make a commitment of at least three years. Donors may earmark their contributions for the support of patients with a particular illness or disease. No individual or aggregate patient information will be conveyed to any donor. 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.⁵

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 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

⁵In the past, the Requestor has thanked major donors in its annual report, and the Requestor plans to continue this practice.

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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

The Proposed Program, by which the Requestor would subsidize, in whole or in part, certain Medicare beneficiaries' Part B cost-sharing obligations, 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 Program 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 Program.

1. Donor Contributions to the Requestor

Because the Requestor's particular design and administration of the Proposed Program will interpose 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 to any donor, it appears unlikely that donor contributions would influence any Medicare 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, nonprofit, tax-exempt charitable organization that is not subject to control, directly or indirectly, by any donor that is affiliated in any way with any pharmaceutical company. Patients will learn about the Proposed Program from a variety of sources, including their preexisting relationships with the Requestor and their contacts with other individuals and entities, many of which are not affiliated with any of the Requestor's donors.

Eligibility for the Requestor's financial assistance will be available to any financially-qualified patient suffering from the specific chronic illnesses and diseases targeted by the

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Proposed Program, regardless of the particular physicians, providers, suppliers of items or services, or drugs that the patient may use. The Requestor will make all financial eligibility determinations using its own criteria and will 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. No individual or aggregate patient information will be conveyed to any donor.

Moreover, before applying for financial assistance, all patients will have selected their health care providers (and, where appropriate, the providers will have prescribed drugs for the patient) based on their best medical interests. All patients will remain free, while receiving the Requestor's financial assistance, to change their health care providers, suppliers, or products. The Requestor will not refer patients to any donor or other provider, supplier, or product.

In sum, the Requestor's interposition as an independent charitable organization between donors and patients and the design and administration of the Proposed Program provide sufficient insulation so that the Requestor's subsidy of Medicare Part B cost-sharing obligations 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.

2. The Requestor's Subsidy of Medicare Part B Cost-Sharing Obligations

In the circumstances presented by the Proposed Program, we believe that the Requestor's subsidy, in whole or in part, of Medicare Part B cost-sharing obligations 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 will assist all financially-qualified patients on a first-come, first-served basis, to the extent funding is available. In virtually all cases, the patient will already be receiving treatment for his or her condition. Thus, the patient will have already selected providers, practitioners, and suppliers, 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 cost-sharing obligations. Even if asked, the

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Requestor will make no referrals or recommendations regarding specific providers, practitioners, or suppliers.

Second, the Requestor's determination of a patient's financial qualification for assistance will be 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 patient's specific medical condition. The Requestor will notify all grant recipients that they are free at any time to switch providers, practitioners, or suppliers without affecting their continued eligibility for financial assistance.

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

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Program would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the Proposed Program 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 Patient Advocate Foundation 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 Program. This opinion is limited to the Proposed Program 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 Patient Advocate Foundation, 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.

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- 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 Program, 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 Program 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 Program 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