



[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 20, 2010

Posted: August 30, 2010

[Name and address redacted]

Re: OIG Advisory Opinion No. 10-12

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a nonprofit, tax-exempt, charitable organization's proposal to provide financially-needy brain tumor patients with grants to defray their cost-sharing obligations for drugs and/or devices (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 “Foundation”) is a non-profit, tax-exempt charitable organization dedicated to funding brain tumor research, education, and patient services. It offers a comprehensive array of services to brain tumor patients and their families and care givers, including the provision of educational materials and the organization of support groups and fundraisers. The Foundation is governed by an executive board (the “Executive Board”). The Foundation also has a medical advisory board (the “Medical Advisory Board”), which participates in some programs and services provided by the Foundation.

Under the Proposed Arrangement, the Foundation will establish a patient assistance program to help financially-needy brain tumor patients pay for their drugs and/or devices to treat brain tumors as well as conditions incident to brain tumor treatment (e.g., chemotherapy-induced nausea, chemotherapy-induced anemia, chemotherapy-induced neutropenia, etc.) (the “PAP”). Through this PAP, the Foundation will offer financial help with cost-sharing obligations to insured, financially-needy brain tumor patients, including, but not limited to, Medicare beneficiaries under Medicare Part B, Medicare Part D, Medicare Supplementary Health Insurance (“Medigap”),¹ and Medicare Advantage. With

¹ In general, Medigap helps pay for health care costs such as co-insurance, copayments, and deductibles; however, it is possible for a patient to have a Medigap plan and still not have full prescription coverage. In these specific cases, the Foundation will assist with prescription copayments.

respect to Medicare beneficiaries enrolled in a Part D plan, the financial assistance may include assistance with any cost-sharing obligations (including during any deductible, coverage gap, and catastrophic coverage periods).

The Executive Board will oversee all policy-making and operational functions for the PAP. One member of the Executive Board is an employee of the Foundation; the other three members are independent volunteers who receive no compensation in any form from the Foundation or anticipated donors. No donor or immediate family member, director, officer, or employee of a donor, or persons otherwise affiliated with donors, will be eligible to serve on the Executive Board.

The Foundation will operate the PAP as follows. All prospective grant recipients will complete an application. The Foundation will process grant applications in order of receipt on a first-come, first-served basis, to the extent funding is available.

The Foundation has established objective criteria for determining eligibility for assistance that are based upon the applicant's medical condition and financial need; in addition, all eligible patients must have insurance that pays for drugs and/or devices. Financial need is determined with reference to the Federal poverty level, as well as special circumstances such as the loss of a patient's or caregiver's job or exceptionally high out-of-pocket medical expenses proportionate to income. The amount granted per patient is expected to be the full amount for which the patient is responsible out-of-pocket. The Foundation will closely monitor utilization and may have to adjust the financial criteria up or down, as well as the maximum per patient grant amounts to better serve patients based on the PAP's supply and demand. If necessary, the Foundation may have to impose a yearly limit, which may be based on a sliding scale based on family income. Grants will be awarded based on the Foundation's assessment of applicants' individual needs. The Foundation will provide financial assistance for one year, after which a recipient may reapply. Recipients will be required to notify the Foundation if their financial circumstances change during the grant period.

The Foundation will require the following documentation: financial data, a letter from the patient's physician stating that the patient has a brain tumor and the prescribed treatment; bills from the suppliers showing prescribed drug and/or device costs, the amount paid by insurance, and the patient's cost-sharing obligations.² Grants will be paid directly by the Foundation to suppliers, if possible; otherwise, grants will be made payable to the patient, subject to proof that the patient incurred the cost-sharing expense.

² All private information will be stored securely, in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Potential applicants will learn about the Foundation's PAP from a variety of sources, including physicians, health care providers, patient advocacy groups, pharmaceutical and device manufacturers, the Foundation, and others. The Foundation 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; or (iii) the identity of the referring person or organization, including whether the referring entity is a donor; or (iv) the amount of contributions made by any donor whose services or products are used or may be used by the patient.

Applicants must be under the care of a physician with a treatment regimen and supplier of drugs and/or devices in place at the time of application. The Foundation has certified that it will not refer applicants to, recommend, or arrange for the use of any particular product, practitioner, provider, supplier, or insurance company. Patients will have complete freedom of choice regarding their products, practitioners, providers, suppliers, insurance companies, and treatment regimens. The Foundation will provide written notification to all grant recipients that they may switch products, practitioners, providers, suppliers, or insurance companies without affecting their continued eligibility for financial assistance from the Foundation.

The Foundation anticipates that much of its funding under the Proposed Arrangement will be provided by manufacturers of drugs and devices used to treat brain tumors as well as conditions incident to brain tumor treatment that will be covered by the Foundation's PAP. The Foundation anticipates that the remainder of the Foundation's funding will be provided by individual donors, corporations, and foundations. All donations to fund the Proposed Arrangement will be either cash or cash equivalents. Donations will not include drug or device products. Donors will provide unrestricted donations. The Foundation has absolute, independent, and autonomous discretion as to the use of contributions for the PAP. Donors will be asked to commit to a three-year donation cycle, but they may withdraw at any time upon 120-days written notice. 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 exert any direct or indirect influence or control over the Foundation or any of the Foundation's programs.

Donors will receive a report periodically including the following information: the aggregate number of applicants for assistance; the aggregate number of patients qualifying for assistance; the aggregate amount disbursed from the fund during that reporting period; and the current balance of the fund. No individual patient information will be conveyed to donors. The Foundation has certified that its 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 of patients who use its products or services, or the volume of those products. Patients will not be informed of the identity of specific donors. Neither patients

nor donors will be informed of the donations made to the Foundation by others, although, as required by Internal Revenue Service regulations, the Foundation's annual report and list of donors will be publicly available upon request.

The Foundation has defined patients qualified for the PAP in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of products to treat brain tumors and conditions incident to brain tumor treatment for which patients will receive assistance with out-of-pocket expenses under the PAP.³ The Foundation 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 of the products covered by the PAP.

Some of the members of the Foundation's Medical Advisory Board may have financial ties with potential PAP donors; however, none of the members of the Medical Advisory Board will participate in any manner in the oversight or operation of the PAP. The Foundation has certified that it will separate its non-PAP programs and services⁴ from the work it performs for the PAP by means of an ethical wall that combines various elements, including: (i) a separate web site for the PAP that is not linked to and makes no reference to the web site for the Foundation's other programs and services; (ii) a separate project team for the PAP, including personnel who are dedicated solely to perform work for the PAP and no other Foundation programs or services; (iii) a separate data intake and storage system, including a phone line designated specifically for the PAP and unique computer software and separate electronic directories for the PAP; (iv) closed board meetings for Executive Board members only to discuss PAP policies and operations; (v) regular training for the PAP personnel, non-PAP personnel, and Medical Advisory Board members on the implementation and maintenance of this ethical wall; and (vi) a prohibition on tying, conditioning, or connecting donations to the PAP with the Foundation's other programs or services and vice versa. Should the Foundation fail to maintain compliance with any aspect of the Proposed Arrangement, including, without limitation, the safeguards, the ethical wall, and the

³ The Foundation anticipates that drugs and/or devices to treat brain tumors and conditions incident to brain tumor treatment will include multiple products from more than one manufacturer.

⁴ Non-PAP Foundation programs and services include helping patients in the following ways: finding and participating in clinical trials; obtaining second opinions at major medical centers; locating and utilizing in-person and online support groups; education through web site, video, live conferences, and telephone support; fundraising events; and funding of medical research.

complete separation of the PAP from the Foundation’s other programs and services, this opinion would be without force and effect.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. 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. 1985), 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.

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 state health care program, including Medicaid, 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 a state health care program, including 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 “transfers of items or services for free or for other than fair market value.”

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 Foundation and the Foundation's grants to patients. We address them in turn.

1. Donor Contributions to the Foundation

Long-standing OIG guidance makes clear that industry stakeholders can effectively contribute to the health care safety net for financially needy patients, including beneficiaries of Federal health care programs, 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 Foundation'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 Federal health care program beneficiary's selection of a particular provider, practitioner, supplier, or product, or the selection of any particular insurance plan. Similarly, there would appear to be a minimal risk that donor contributions would improperly influence referrals by the Foundation. We reach this conclusion based on the combination of the following factors.

First, no donor or affiliate of any donor will exert direct or indirect control over the Foundation or its PAP. The Foundation will be an independent, nonprofit, tax-exempt charitable organization that will have absolute, independent, and autonomous discretion as to the use of donor contributions.

Second, the Foundation will award assistance in a truly independent manner that severs any link between donors and beneficiaries. The Foundation 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. While receiving the Foundation's financial assistance, all patients will remain free to change their health care providers, practitioners, suppliers, or products. Patients will also remain free to change insurance plans. Under the Proposed Arrangement, the Foundation will not refer any patient to any donor or to any provider, practitioner, supplier, product or plan.

Third, the Foundation will award 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 patient eligibility for the Proposed Arrangement, the Foundation 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. The Foundation also will not take into account the identity of the insurer or insurance plan selected by the patient.

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

Fifth, the Foundation 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; aggregate numbers of qualifying patients; aggregate funds disbursed during that reporting period; and the current balance of the fund. Patients will not receive any information regarding donors, and donors will not receive any information regarding other donors, except that the Foundation'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.

Sixth, the financial ties of some members of the Medical Advisory Board with pharmaceutical and/or device manufacturers and other similar entities potentially create risks that the Proposed Arrangement could be misused as a conduit for pharmaceutical and/or device manufacturers to provide remuneration to Medicare or Medicaid beneficiaries who use their products. However, the Foundation has certified that none of the members of the Medical Advisory Board will participate in any manner in the oversight or operation of the PAP. The PAP will be set up and operated completely independently from the Foundation's other programs and services.

The Foundation has certified that it will implement and maintain the following safeguards to separate its non-PAP programs and services from the work it performs for the PAP:

- a separate web site for the PAP that is not linked to and makes no reference to the web site for the Foundation's other programs and services;

- a separate project team for the PAP, including personnel who are dedicated solely to perform work for the PAP and no other Foundation programs or services;
- a separate data intake and storage system, including a phone line designated specifically for the PAP and unique computer software and separate electronic directories for the PAP;
- closed board meetings for Executive Board members only to discuss PAP policies and operations;
- regular training for the PAP personnel, non-PAP personnel, and Medical Advisory Board members on the implementation and maintenance of this ethical wall; and
- a prohibition on tying, conditioning, or connecting donations to the PAP with the Foundation's other programs or services and vice versa.

These safeguards, when combined with the totality of facts presented, sufficiently mitigate the risk that the Foundation's assistance decisions might be improperly influenced by pharmaceutical and/or device companies, or interests of any member of the Medical Advisory Board. Should the PAP fail to operate independently in any manner from the Foundation's other programs and services, or should any aspect of the PAP be influenced directly or indirectly by the other programs and services, this opinion would be without force and effect.

Finally, the PAP under the Proposed Arrangement is defined to cover a broad spectrum of products; it is not narrowly defined in such a way that it would effectively result in patients being steered to particular products based on the availability of the subsidy, thereby increasing the likelihood that the charity would serve as an improper conduit for donors to provide funds to patients who use their specific products. Moreover, in this case, the Foundation 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 Foundation's identification of covered drugs and devices.

In sum, the Foundation's interposition as an independent charitable organization between donors and patients and the design and administration of the Proposed Arrangement will provide sufficient insulation so that the Foundation'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 Foundation. In these circumstances, we do not believe that the contributions made by donors to the

Foundation can reasonably be construed as payments to beneficiaries of Federal health care programs or to the Foundation to arrange for referrals.⁵

2. The Foundation's Grants to Federal Health Care Program Beneficiaries

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

First, the Foundation 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 unless they meet the Foundation'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 Foundation will make no referrals or recommendations regarding specific providers, practitioners, suppliers, products, or plans. Patients will not be informed of the identity of donors.

Second, the Foundation'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 insurance plan; the identity of any referring party; or the identity of any donor that may have contributed for the support of the applicant's condition. The Foundation will provide assistance based upon a reasonable, verifiable, and uniform measure of financial need that will be applied in a consistent manner. The Foundation will notify all patients that they are free at any time to switch products, providers, practitioners, suppliers, or insurance plans without affecting their continued eligibility for financial assistance.

Third, the Foundation's subsidies for the patient populations it will serve 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 have been prescribed for the patient—prior to his or her application for the Foundation's financial assistance. In addition, the Foundation provides written notification to all grant recipients

⁵ This 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.

that they may switch products, providers, suppliers, or insurance plans at any time without affecting their continued eligibility for financial assistance from the Foundation.

Finally, the Foundation'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 Foundation will have a significant incentive to monitor utilization so as to keep subsidies to a minimum.

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 [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 [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 [name redacted] 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 [name redacted] 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/

Lewis Morris
Chief Counsel to the Inspector General