DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of Inspector General
330 Independence Ave., S.W.
Washington, D.C. 20201

FACSIMILE TRANSMITTAL SHEET

DATE: 9/28/2007

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REMARKS:

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

SEP 28 2007

Diane Blum
CancerCare
275 Seventh Avenue
22nd Floor
New York, NY 10001

Re: OIG Advisory Opinion No. 07-11

Dear Ms. Blum:

We are writing in response to your request for an advisory opinion regarding a nonprofit, tax-exempt, charitable organization's proposal to establish a foundation to provide financially needy cancer patients with grants to defray their out-of-pocket treatment costs (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 CancerCare 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 CancerCare, 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

CancerCare (the "Requestor") is a non-profit, tax-exempt charitable organization dedicated to helping cancer patients, their families, and care givers. The Requestor offers counseling and educational services to people affected by cancer, as well as limited financial assistance to financially needy cancer patients. Although the Requestor has provided financial assistance to numerous patients, to date, the Requestor's main focus has been the counseling and education aspects of the Requestor's mission.

Under the Proposed Arrangement, the Requestor will establish a foundation (the "Foundation") to help financially needy cancer patients pay for their drugs to treat certain types of cancer as well as certain conditions incident to cancer therapy. The Foundation will offer patients help with their cost-sharing obligations for drugs, and might also offer help with insurance premium payments. Through this program, the Foundation will offer financial help with out-of-pocket costs to financially needy cancer patients, including Medicaid beneficiaries and 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 may include assistance with any premiums and cost-sharing obligations (including during any deductible, coverage gap, and catastrophic coverage periods).

The Foundation will operate 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 will establish objective criteria for determining eligibility for assistance, which will be based upon the applicant's medical condition and financial need. The

financial need criteria will be based on certain national standards of indigence. Grants will be awarded based on the Foundation's assessment of applicants' individual needs. The Foundation will provide financial assistance for a specific period of time (up to 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.

In most cases, premium assistance grants will be made directly by the Foundation to the patient's insurance company. Cost-sharing grants will be paid directly by the Foundation 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 patient, upon proof that the patient incurred costs.

Potential applicants will learn about the Foundation's programs from a variety of sources, including physicians, health care providers, patient advocacy groups, pharmaceutical manufacturers, the Foundation, the Requestor, 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 person or organization is a donor. The Requestor also has certified that grant determinations will be made without regard to the amount of contributions made by any pharmaceutical company 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 the Foundation will not refer applicants to, recommend, or arrange for the use of any particular product, practitioner, provider, supplier, or plan. Patients will have complete freedom of choice regarding their products, practitioners, providers, suppliers, insurance companies, and treatment regimens. The Foundation 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. The Foundation will also notify grant recipients who are Medicare beneficiaries that they are free to switch insurance plans when permitted by the Medicare program, without affecting their eligibility for assistance from the Foundation.

Requestor anticipates that much of the Foundation's funding under the Proposed Arrangement will be provided by manufacturers of drugs used to treat the cancers and conditions incident to cancer therapy that will be covered by the Foundation's programs, and by suppliers of the types of services used by patients that the Foundation will assist. Requestor 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 product. Donors may change or discontinue their contributions to the Foundation at any time. Donors may provide unrestricted donations. Alternatively, donors may earmark their contributions for the support of patients within a specific disease category; however, donations must be unrestricted within that disease category. 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.

Upon request, donors will be informed monthly of the aggregate number of applicants for assistance in particular disease categories 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 Foundation's 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 who 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 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 will assist patients whose illnesses fall into set disease categories. The Foundation will define some of the disease categories based on particular types of cancer (e.g., breast cancer, lung cancer, pancreatic cancer, etc.), and other disease categories based on common sequelae of cancer therapy (e.g., chemotherapy-induced nausea, chemotherapy-induced anemia, chemotherapy-induced neutropenia, etc.). The Requestor has certified that the Foundation will define its disease categories: (i) in accordance with widely recognized clinical standards and (ii) in a manner that covers a broad spectrum of available products.[1] The Requestor has further certified that, for disease categories based on cancer type, the categories will be defined without subdividing or otherwise more narrowly defining the types of cancer by reference to specific symptoms, severity of symptoms, or the method of

[1]Requestor anticipates that all disease categories will include multiple products from more than one manufacturer. In the unlikely event that a situation would arise such that there would be only one drug covered by Federal health care programs for a particular disease category or only one pharmaceutical manufacturer (including its affiliates) that makes all of the covered drugs for the particular disease category, the Foundation will use its best efforts to cover additional products and manufacturers as they become available.

administration of drugs. The Requestor has further certified that, for disease categories based on sequelae of cancer therapy, the categories will be defined such that the sequelae will be conditions that commonly occur incident to numerous types of chemotherapy used to treat numerous types of cancers and without subdividing or otherwise more narrowly defining the condition such that it would be likely only to result from treatment with a particular pharmacologic agent or particular method of administration of drugs. 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 Foundation's disease categories.

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.), 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 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 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 Requestor or 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 programs. 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. 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 Requestor'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 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 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.

Finally, the fact that the Foundation will permit donors to earmark donations for particular disease categories should not, on the facts presented, significantly raise the risk of abuse. In some cases, earmarking donations for narrowly defined disease categories would effectively result in patients being steered to particular products based on the availability of the subsidy, and increase the likelihood that the charity would serve as an improper conduit for donors to provide funds to patients who use their specific products. 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 Foundation's identification of the disease categories. The disease categories will include some categories defined to cover particular types of cancer as well as some categories defined to cover conditions that are common sequelae of cancer therapy. To ensure that the disease categories that are based on diagnoses of particular types of cancer are appropriately defined, the Requestor has further certified that: (i) the Foundation will define its disease categories in accordance with widely recognized clinical standards; (ii) in a manner that covers a broad spectrum of available products; and (iii) without subdividing or otherwise more narrowly defining the types of cancer by reference to specific symptoms, severity of symptoms, or the method of administration of drugs. To ensure that the disease categories that are based on sequelae of cancer therapy are appropriately defined, the Requestor has further certified that the Foundation will define its disease categories: (i) in accordance with widely recognized clinical standards; (ii) in a manner that covers a broad spectrum of available products; and (iii) such that the sequelae will be conditions that commonly occur incident to numerous types of chemotherapy used to treat numerous types of cancers and without subdividing or otherwise more narrowly defining the condition such that it would be likely only to result from treatment with a particular pharmacologic agent or particular 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 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 Requestor or to the Foundation to arrange for referrals.[2]

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[2] 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 subsides 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.

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 premiums and 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, or product.

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 providers, practitioners, suppliers, or products without affecting their continued eligibility for financial assistance. The Foundation will also notify patients who are Medicare beneficiaries that they are free to switch insurance plans when permitted by the Medicare program, without affecting their eligibility for 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 likely have been prescribed for the patient – prior to his or her application for the Foundation's financial assistance. Also, to the extent that the Foundation will provide premium assistance to help patients secure insurance coverage, such as Medicare Part B, Medicare Part D, Medigap, or Medicare Advantage coverage, once in possession of such insurance 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 Foundation's support programs (subject to plan network and formulary restrictions).

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.

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 the 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 CancerCare, 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 CancerCare 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 CancerCare 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