



[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: July 23, 2007

Posted: July 30, 2007

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 07-06

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a nonprofit, tax-exempt, charitable organization's arrangement to subsidize cost-sharing and premium obligations owed by financially needy Medicare or Medicaid patients with certain chronic diseases (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes 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 Arrangement does not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the 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 [names 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 Arrangement. This opinion is limited to the 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 the [names redacted], the requestors 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

The [name redacted] (the “Foundation”) is a nonprofit, tax-exempt, charitable organization that provides financial support to patients with certain medical conditions, who have insurance coverage, but who cannot afford the costs associated with coverage. Under the Arrangement, the Foundation operates a series of individual charitable funds for patients with certain serious diseases.¹ Through these funds, the Foundation provides financial assistance for specific, documented out-of-pocket expenses associated with outpatient prescription drug treatment, including insurance premiums and cost-sharing amounts. The Foundation offers this financial assistance to financially needy beneficiaries under any Medicare or Medicaid program. The Foundation’s support is focused primarily on high-cost medications, since those typically present the greatest financial burden for patients.

[Name redacted] (the “Administrator”) is a health care consulting company, with commercial clients that include pharmaceutical manufacturers whose products are used, or might be used, by patients participating in the Arrangement.² The Foundation was

¹The Foundation’s funds include the following: Acute Porphyria, Anemia associated with Chronic Renal Insufficiency and Chronic Renal Failure, Chemotherapy Induced Anemia and Neutropenia, Colorectal Carcinoma, Cutaneous T-Cell Lymphoma, Head and Neck Cancer, Hodgkin’s Disease, Immunosuppression for Solid Organ Transplants, Iron Overload Associated with Multiple Transfusions, Moderate to Severe Asthma, Multiple Myeloma, Myelodysplastic Syndromes (MDS), Non-Hodgkin’s Lymphoma, Non-Small Cell Lung Cancer, Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Secondary Hyperparathyroidism, and Wilm’s Tumor.

²The Foundation provides assistance with medications without regard to whether the manufacturer of the medication is a commercial client of the Administrator.

conceived of, and established by, employees of the Administrator. The Administrator provides certain administrative services to the Foundation and its charitable funds, as described more fully below. The Foundation and the Administrator are herein collectively referred to as the “Requestors.”

The Foundation is governed by an independent Board of Directors, which handles all policy-making functions for the Foundation, such as patient eligibility requirements, disease funds served, and program requirements for each disease fund. None of the Foundation’s Board Members has any financial or employment relationship (including, but not limited to, stock ownership) with any donor or affiliate of any donor. The Foundation may recruit additional Board Members in the future. No future Foundation Board Members will have any financial or employment relationship with any pharmaceutical manufacturer (or any affiliate of any such entity). To the extent an entity with which a Board Member has a financial or employment relationship offers a donation to the Foundation, that Board Member will disclose the relationship and recuse him/herself from considering the fund for which the donation was proposed. At no time will the majority of the Board be composed of Members having financial or employment relationships with any donors or affiliates of any donors.³ Moreover, neither any of the Foundation’s Board Members, nor any of its officers has any financial or employment relationship with the Administrator or any affiliate of the Administrator.

Compensation paid to Foundation employees, officers and Board Members, including compensation that Administrator pays to its employees or agents assigned to the Foundation, is consistent with fair market value in an arm’s-length transaction. Compensation paid to Foundation employees, officers and Board Members, including compensation that Administrator pays to its employees or agents assigned to the Foundation, does not in any way reflect the volume or value of business generated for donors.

The Foundation operates its program as follows. All prospective grant recipients must complete an application. The Foundation processes 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, which are based upon the applicant’s medical condition and financial need. The financial need criteria are based on certain national standards of indigence. Grants are awarded pursuant to a sliding scale based on the Foundation’s assessment of applicants’ individual financial

³The Foundation has disclosed that it is contemplating the addition of a Board Member with a health plan affiliation and that such Board Member would be recused from decisions relating to the health plan’s interests. As the addition of this Board Member is speculative at this time, we express no opinion with respect to the addition of such Board Member.

needs. The Foundation provides financial assistance for a specific period of time (up to one year), after which a recipient may reapply. Recipients are required to notify the Foundation if their financial circumstances change during the grant period.

In most cases, premium assistance grants are made directly by the Foundation to the patient's insurance company. Cost-sharing grants are paid directly by the Foundation to physicians, providers, and suppliers of items and services (including drugs). In cases where third-party payment is not accepted, grants are made payable to the patient, upon proof that the patient incurred the costs.

Potential applicants learn about the Foundation's funds from a variety of sources, including the Foundation and other support organizations, physician offices, and others. The Foundation assesses patient applications and makes 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 Requestors have also certified that grant determinations are 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 recipient.

Grant recipients are under the care of a physician with a treatment regimen in place at the time of application. The Requestors have certified that their staffs do not refer recipients to, recommend, or arrange for the use of any particular product, practitioner, provider, supplier, or insurance plan. Recipients have complete freedom of choice regarding their products, practitioners, providers, suppliers, insurance companies, and treatment regimens. The Foundation notifies all grant recipients that they are free at any time to switch products, practitioners, providers, suppliers, or insurance companies without affecting their continued eligibility for financial assistance (subject to any limitations imposed by an insurance program).

Most of the Foundation's funding for the Arrangement is provided by manufacturers of drugs that are used to treat diseases covered by the Foundation's programs. The remainder of the Foundation's funding is provided by individual donors, corporations, and foundations. All donations are either cash or cash equivalents. Donors may change or discontinue their contributions to the Foundation at any time. Donors may provide unrestricted donations; however, donors typically earmark their contributions for the support of patients covered by one of the Foundation's disease funds. Donations must be unrestricted within the disease fund.

The Requestors have certified that the Foundation's discretion as to the use of the contributions within a disease fund is 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)) exerts any direct or indirect influence or control over the Foundation or any of the Foundation's funds.

Donors are informed periodically of the aggregate number of applicants for assistance in particular disease funds and the aggregate number of applicants qualifying for assistance in the disease fund. No individual patient's information is conveyed to donors. The Requestors have certified that reports to donors do 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 are not informed of the identity of specific donors. Neither patients nor donors are 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 are publicly available upon request.

The Foundation, in its sole discretion, determines the diseases it will support through its funds. Disease funds are defined through an internal decision-making process. Decisions are based on an independent assessment by the Foundation's Board whether a new fund arrangement will best serve patient needs. The Requestors have certified that: (i) the Foundation defines its disease funds in accordance with widely recognized clinical standards and in a manner that covers within each disease fund a broad spectrum of available products;⁴ and (ii) the Foundation's disease funds are not defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs or other products. The Requestors have certified that they do not solicit suggestions from donors regarding the identification or delineation of disease funds. The Requestors have 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)) directly or indirectly influences the identification or delineation of any disease fund.⁵

⁴In rare circumstances where there may only be one product relevant to an otherwise properly delineated fund or only one manufacturer (including its affiliates) that makes all of the products relevant to an otherwise properly delineated fund, the Requestors have certified that the Foundation uses its best efforts to cover additional products and manufacturers as they become available. The Foundation sometimes receives unsolicited suggestions about disease funds from Donors; such suggestions are subject to the independent assessment of the Foundation described here.

⁵Donors may provide the Foundation with educational materials that the donors generally make available to practitioners or the general public (e.g., clinical information about drug products).

Acting at the direction of the Foundation's Board of Directors, the Administrator provides many services for running the Foundation's daily operations, including administering the funds, staffing the phone lines for patients and physicians to contact the Foundation, processing applications for assistance, providing the financial assistance for documented cost-sharing needs, maintaining records, and preparing research reports for the Board, as requested.⁶ Only Foundation employees or contractors who are neither employees nor agents of the Administrator may solicit donations from potential health care industry donors, including pharmaceutical manufacturers. Administrator employees or agents assigned to the Foundation may solicit donations for the Foundation outside the health care industry. Administrator employees or agents can not bring fund proposals to the Foundation's Board for review and approval. The Administrator does not decide program or eligibility criteria for the Foundation.

The Requestors have certified that the Administrator's role as administrator of the Arrangement is, and will remain, entirely separate from the Administrator's commercial operations. The Administrator separates its commercial-oriented functions from the work that it performs for the Foundation by means of an ethical wall that combines various elements, including: (i) a confidentiality agreement that contractually obligates the Administrator to hold information developed for and through the Foundation's operations in strict confidence; (ii) a separate project team for the Foundation, including both management and personnel that are dedicated solely to the Foundation and do not work for any of the Administrator's other clients; (iii) separate physical space for personnel assigned to the Foundation; (iv) unique computer software and separate electronic directories to collect and maintain data for the Foundation; (v) regular and comprehensive training for the Administrator's and the Foundation's staff on the implementation and maintenance of this ethical wall; (vi) a ban on the Administrator's employees and agents soliciting donations from potential health care industry donors, including pharmaceutical manufacturers, or bringing fund proposals to the Foundation's Board for review and approval; and (vii) a prohibition on tying, conditioning, or connecting donations to the Foundation with the Administrator's consulting work for commercial clients and manufacturers or vice-versa.

The Requestors further certify that the Foundation and the Administrator will take steps to ensure that these safeguards are implemented and the ethical wall is maintained. A Foundation employee or contractor who is neither an employee nor an agent of the Administrator shall be designated a Compliance Auditor. The Compliance Auditor will

⁶Administrator's staff and contractors who work with the Administrator's other clients do not produce reports on Foundation marketing or fundraising opportunities.

be assigned the task of producing detailed reports to the Board reviewing operation of the safeguards and the ethical wall at least twice annually. To this end, the Foundation and the Administrator shall maintain up-to-date records with the Compliance Auditor pertaining to the operation of the safeguards and ethical wall, including, but not limited to: copies of confidentiality agreements, training certificates, relevant personnel files, office space diagrams, and organization charts. The Compliance Auditor may also conduct audits or inspections in order to obtain information for the reports to the Board. In addition, the Foundation has engaged an independent review organization to conduct an annual independent audit of the Arrangement. Should the Requestors fail to maintain compliance with any aspect of the Arrangement as certified by the Requestors, including, without limitation, the safeguards, the ethical wall, and the complete separation of the Foundation from the interests of the Administrator's commercial operations, this opinion would be without force and effect.

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 beneficiary of Medicare or a state health care program, including Medicaid, 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." The OIG has previously taken the position that "incentives that are only nominal in value are not prohibited by the statute," and has interpreted "nominal value to be no more than \$10 per item, or \$50 in the aggregate on an annual basis." 65 F.R. 24400, 24410 – 24411 (April 26, 2000) (preamble to the final rule on the CMP).

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 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 Requestor

Long-standing OIG guidance makes clear that industry stakeholders can effectively contribute to the health care safety net for financially needy Medicare and Medicaid patients 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 and based on the totality of the Requestors' certifications, the Foundation's particular design and administration of the Arrangement interposes 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 influence any patient'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 exerts direct or indirect control over the Foundation or its programs. The Requestors have certified that the Foundation is an independent, nonprofit, tax-exempt charitable organization that has absolute, independent, and autonomous discretion as to the use of donor contributions. The Requestors have further certified that the Foundation's Arrangement is and will remain

wholly independent from the Administrator's commercial consulting work for any existing or potential donors or donor affiliates.

Second, the Foundation awards assistance in a truly independent manner that severs any link between donors and beneficiaries. The Foundation makes all financial eligibility determinations using its own objective criteria. The Administrator does not participate directly or indirectly in setting program or eligibility criteria. Applications are considered on a first-come, first-served basis, to the extent of available funding. Before applying for financial assistance, each patient has selected his or her health care provider, practitioner, or supplier and has a treatment regimen in place. While receiving the Foundation's financial assistance, all patients remain free to change their health care providers, practitioners, suppliers, or products. Patients also remain free to change insurance plans (subject to any insurance program limitations). The Foundation does not refer any patient to any donor or to any provider, practitioner, supplier, product, or plan.

Third, the Foundation 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 Arrangement, the Foundation does 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 Foundation also does not take into account the identity of any insurer or insurance plan selected by the applicant.

Fourth, based on the Requestors' certifications, the Foundation provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.

Fifth, the Foundation does 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. Neither any individual patient's information, nor any data related to the identity, amount, or nature of products or services subsidized under the Arrangement is conveyed to any donor. Some aggregate data may be provided to donors as a courtesy, but is limited to aggregate numbers of applicants and aggregate numbers of qualifying applicants within specific disease funds. Patients do not receive any information regarding donors, and donors do 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 Administrator's commercial consulting relationship with its pharmaceutical clients potentially creates a significant risk that the Arrangement could be misused as a conduit for pharmaceutical clients to provide remuneration to Medicare or Medicaid beneficiaries who use the clients' products. However, the Requestors have certified that the Administrator's role as administrator of the Arrangement is, and will remain, entirely separate from its commercial operations.

The Requestors have also certified that they will implement and maintain the following safeguards against improper influence by any of Administrator's pharmaceutical or other health care clients:

- a confidentiality agreement that contractually obligates the Administrator to hold information developed for and through the Foundation's operations in strict confidence;
- a separate project team for the Foundation, including both management and personnel who are dedicated solely to Requestor and do not work for any of the Administrator's other clients;
- separate physical space for personnel assigned to the Foundation;
- unique computer software and separate electronic directories to collect and maintain data for the Foundation;
- regular and comprehensive training for the Administrator's and Foundation's staff on the implementation and maintenance of the ethical wall created by the safeguards;
- a ban on the Administrator's employees' or agents' involvement in any of the Foundation's fundraising operations with respect to health care industry donors or their solicitation of suggestions from donors regarding the use of funds or delineation of disease funds;
- a prohibition on tying, conditioning, or connecting donations to the Foundation with the Administrator's work for any commercial client or vice-versa;
- compensation paid to Foundation employees, officers and Board members, officers, including compensation that Administrator pays to its employees and agents assigned to the Foundation, is consistent with fair market value in arm's-length transactions and does not reflect in any manner the volume or value of business generated for any donor or donor affiliate.

The Requestors have further certified that the Foundation will take certain practical steps to ensure that the Administrator implements these safeguards, including the use of a designated Compliance Auditor and an independent review organization to monitor the ethical wall and the independence of the Arrangement.

These safeguards, when combined with the totality of facts presented, should sufficiently mitigate the risk that the Foundation's subsidy decisions might be improperly influenced by pharmaceutical company or other client interests. Should the Arrangement fail to operate independently in any manner from the Administrator's commercial operations or client interests, or should any aspect of the Arrangement be influenced improperly by the Administrator's commercial clients, this opinion would be without force and effect.

Finally, the fact that the Foundation permits donors to earmark donations for particular disease funds should not, on the facts presented, significantly raise the risk of abuse. 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)) directly or indirectly influences the identification of the disease funds. Moreover, to ensure that the Foundation's disease funds are appropriately defined, the Foundation has further certified that: (i) it defines its disease funds in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products; and (ii) its disease funds are not defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs or other products. In addition, the Foundation has certified that it does not solicit suggestions from donors regarding the identification or delineation of disease funds. Disease funds are defined through an internal decision-making process. Decisions are based on an independent assessment by the Foundation's Board whether a new fund arrangement will best serve patient needs. In these circumstances, it is unlikely that the earmarking results in the Arrangement are serving as a disguised conduit for financial assistance from a donor to patients using its products.

In sum, the Foundation's operation as an independent charitable organization (including its putative strict separation from the Administrator's commercial business), its interposition between donors and patients, and the design and administration of the Arrangement (including safeguards implemented by the Administrator) should, if implemented as certified by the Requestors, provide sufficient insulation so that the Foundation's proposed subsidies should not be attributed to any of its donors. Donors have no assurance that the amount of financial assistance their patients, clients, or customers receive bears any relationship to the amount of their donations. Indeed, donors are not guaranteed that any of their patients, clients, or customers 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 eligible beneficiaries of the Medicare or Medicaid programs or

to the Foundation to arrange for referrals.⁷

2. The Foundation's Grants to Medicare and Medicaid Beneficiaries

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

First, the Foundation assists all eligible, financially needy applicants on a first-come, first-served basis, to the extent funding is available. Applicants are not eligible for assistance unless they meet the Requestor's financial need eligibility criteria. In all cases, the applicant is already under the care of a physician with a treatment regimen in place at the time of application. The Foundation makes no referrals or recommendations regarding specific providers, practitioners, suppliers, products, or plans. Applicants are not informed of the identity of donors.

Second, the Foundation's determination of an applicant's financial qualification for assistance is 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 support of the applicant's condition. The Foundation provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner. The Foundation notifies 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 also notifies them that they are free to switch insurance plans (when permitted by their insurance program), without affecting their eligibility for assistance.

Third, the Foundation's subsidies for the patient populations it serves expand, rather than limit, patient freedom of choice. Patients have already selected a provider, practitioner, or supplier of items or services – and drugs or other products likely have been prescribed for the patient – prior to the patient's application for the Foundation's financial

⁷This conclusion is consistent with the OIG's November 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees 70 Fed. Reg. 70623 (November 22, 2005), in which the OIG made it clear that, in the circumstances described in the Bulletin, 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.

assistance. Most importantly, once in possession of Medicare or Medicaid coverage, a beneficiary is 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 has 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 Arrangement does not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the 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 Requestors 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 Arrangement. This opinion is limited to the 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 [names redacted], the requestors 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 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 Requestors with respect to any action that is part of the 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 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 Requestors 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