



[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: December 19, 2007

Posted: January 3, 2007

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 07-18

[Salutation redacted]:

We are writing in response to your request for an advisory opinion regarding a nonprofit, tax-exempt, charitable organization's existing arrangement to subsidize cost-sharing (the "Existing Arrangement"), as well as its proposed arrangement to subsidize premium obligations (the "Proposed Arrangement"), associated with out-patient drug treatment owed by financially needy Medicare or Medicaid patients with certain chronic diseases. Specifically, you have inquired whether the Existing Arrangement or the Proposed Arrangement (separately or in combination) 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) neither the Existing Arrangement nor the Proposed

Arrangement (separately or in combination) would constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the Existing Arrangement or the Proposed Arrangement (separately or in combination) 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 Existing Arrangement or the Proposed Arrangement. This opinion is limited to the Existing Arrangement and 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 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

[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. 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 cost-sharing amounts under the Existing Arrangement. The Foundation would provide comparable assistance with premium obligations under the Proposed Arrangement. The Foundation offers (and would continue to offer, were the Proposed Arrangement implemented) financial assistance to financially needy Medicare and Medicaid beneficiaries under any Medicare or Medicaid program.² The Foundation’s support is focused primarily on high-cost medications, since those typically present the greatest financial burden for patients.

¹ The Foundation’s funds include the following: Age-Related Macular Degeneration, Anemia, Ankylosing Spondylitis, Breast Cancer, Colorectal Cancer, Crohn’s Disease, Cutaneous T-Cell Lymphoma, Cystic Fibrosis, Gaucher Disease, Growth Hormone Deficiency, Multiple Myeloma, Multiple Sclerosis, Myelodysplastic Syndrome, Non-Hodgkin’s Lymphoma, Non-Small Cell Lung Cancer, Oncology Cytoprotection, Pancreatic Cancer, Plaque Psoriasis, Respiratory Syncytial Virus and Rheumatoid Arthritis.

² The Foundation makes identical benefits available to privately insured 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.³ The Administrator played a key role in coordinating and funding the establishment of the Foundation. The Administrator provides staff, as well as 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 Administrator is a subsidiary of [name redacted] (the “Distributor Parent Company”), which, among other things, is a leading pharmaceutical distributor.⁴ For the purposes of this advisory opinion, references to affiliates of the Administrator include the Distributor Parent Company.

The Foundation is governed by an independent Board of Directors, which handles all policy-making functions for the Foundation, such as the determination of patient eligibility requirements, disease funds served, and program requirements for each disease fund. Some existing Board members may receive compensation from or have direct stock ownership in a donor; however, those members will disclose the relationship and recuse themselves from any conversations or decisions about that donor. Future Board members will not receive any compensation from, or hold any stock or investment interest in, a donor or its affiliates. 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.

None of the Foundation’s Board Members or officers will have any financial or employment relationship with the Administrator or any affiliate of the Administrator. Administrator’s

³However, the Foundation provides assistance with medications without regard to whether the manufacturer of the medication is a commercial client of the Administrator.

⁴The Distributor Parent Company is one of several competitive wholesale drug distributor operations available for use by drug manufacturers. Neither the Administrator nor the Foundation has any influence or input on manufacturer selection of distribution companies. The Administrator and the Foundation have no knowledge or involvement in tracking or monitoring the products that the Distributor Parent Company distributes on behalf of its manufacturer clients. Under no circumstances are there incentives or other favorable treatment provided for the Distributor Parent Company, or its subsidiaries, in the administration of the Foundation’s assistance programs. The Foundation does not make payments to the Distributor Parent Company and no drug shipments are made from the Distributor Parent Company to the Foundation. Under no circumstances will any patient, fund, donor, or product information be shared between the Distributor Parent Company and the Foundation.

employees or agents performing staff work for the Foundation are compensated by the Administrator in a manner consistent with fair market value in an arm's-length transaction. Their compensation is not determined in any manner that takes into account the volume or value of any referrals or business otherwise generated for donors, or for the Administrator or any Administrator affiliates. Administrator's employees or agents performing staff work for the Foundation receive no compensation from the Foundation or any Foundation donors in addition to compensation they receive from the Administrator.

The compensation paid by the Foundation to its employees, officers and Board Members is consistent with fair market value in an arm's-length transaction. Their compensation is not determined in any manner that takes into account the volume or value of any referrals or business otherwise generated for donors, or for the Administrator or any Administrator affiliates.

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 the Foundation's assessment of applicants' individual financial needs and available funds. 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.

Under the Existing Arrangement, 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. Under the Proposed Arrangement, premium assistance grants would be made directly by the Foundation to the patient's insurance company. 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 Foundation staff does not refer recipients to, recommend, or arrange for the use of any particular product, practitioner, provider, supplier, or insurance plan (although the Foundation may provide general contact information regarding publicly funded coverage options (such as Medicare or Medicaid) or other patient assistance programs (such as state programs or other charitable assistance programs)). 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. Donations will not include drug product. 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 is 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 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;⁵ 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 the Foundation does not solicit suggestions from donors regarding the identification or delineation of disease funds. They 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 Foundation disease fund.⁶

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.⁷ The Administrator receives fees for its services on behalf of the Arrangement that are, according to the Requestors, fair market value in an arm's-length transaction. We express no opinion with respect to the arrangement between the Foundation and the Administrator.

The Administrator does not engage in any fundraising activities for the Foundation within the health care industry, nor does it participate in the selection of disease states eligible for Foundation subsidies. Only Foundation employees or contractors who have no financial or employment ties with the Administrator or any of its affiliates, may solicit donations from potential health care industry donors, including pharmaceutical manufacturers, or bring fund

⁵For each fund, at least two drug treatments (manufactured by different companies) are available to treat or prevent the subject disease. In rare circumstances where there may be only one product relevant, or only one manufacturer (including its affiliates) that makes all of the products relevant to, an otherwise properly delineated fund, the Foundation will use its best efforts to cover additional products and manufacturers as they become available.

⁶Donors 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).

⁷Administrator's staff and contractors that work with the Administrator's other clients do not produce reports on Foundation marketing or fundraising opportunities.

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 independent 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 staff 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) separate electronic databases and directories to collect and maintain data for the Foundation; (v) regular and comprehensive training for the Administrator's and the Foundation's staffs 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, manufacturers or their affiliates, or vice-versa.

The Requestors have further certified 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 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 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 Foundation's programs. Should the Requestors fail to maintain compliance with any aspect of the Existing Arrangement or the Proposed Arrangement as certified, including, without limitation, the safeguards, the "ethical wall," and the complete independence 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 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." 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 Existing Arrangement and 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 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 its programs 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 Existing Arrangement and the Proposed Arrangement are, and would 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 its programs, 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. No individual patient's information is conveyed to any donor, nor any data related to the identity, amount, or nature of products or services subsidized under the Existing Arrangement or the Proposed Arrangement. 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 create significant risks that the Existing Arrangement and the Proposed Arrangement could be misused as conduits 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 independent 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 Foundation and do not work for any of the Administrator's other clients;
- separate physical space for personnel assigned to the Foundation;
- separate electronic directories to collect and maintain data for the Foundation;
- regular and comprehensive training for the Administrator's and Foundation's staffs 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 or their solicitation of suggestions from donors regarding the use of funds or delineation of drug categories;
- 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 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 Foundation's programs.

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 or affiliate interests. Should the Foundation's programs fail to operate independently in any manner from the Administrator's commercial operations, or client or affiliate interests, or should any aspect of the programs be influenced directly or indirectly by the Administrator's commercial clients or affiliates, 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 Requestors have 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 Requestors have further certified that: (i) the Foundation 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) 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. 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 Foundation's programs 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 independence from the Administrator's commercial business), its interposition between donors and patients, and the design and administration of the Existing Arrangement and the Proposed Arrangement (including safeguards implemented, or to be 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 receives 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.⁸

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

In the circumstances presented by the Existing Arrangement and the Proposed Arrangement, the Foundation's subsidy, in whole or in part, of cost-sharing obligations, insurance premiums, or both for certain eligible, financially needy Medicare and Medicaid

⁸This 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.

beneficiaries is not (and would not be) 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 Foundation'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 expands, rather than limits, 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 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 Existing Arrangement and the Proposed Arrangement

(separately or in combination) would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the Existing Arrangement and the Proposed Arrangement (separately or in combination) 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 Foundation under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Existing and the Proposed Arrangement separately or in combination. This opinion is limited to the Existing Arrangement and the Proposed Arrangement, 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 [names redacted] with respect to any action that is part of the Existing Arrangement or 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 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 that this advisory opinion is modified or terminated, the OIG will not proceed against [names 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General