



[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: October 14, 2008

Posted: October 21, 2008

[Name and address redacted]

Re: OIG Advisory Opinion No. 08-17

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a nonprofit, tax-exempt, charitable organization's proposed arrangement to provide financial assistance to cover cost-sharing obligations associated with outpatient drug treatment owed by financially needy Medicare or Medicaid patients with [disease state redacted] (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 submissions, is true and correct and constitutes a complete description of the relevant facts. In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would not constitute grounds

for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, the Office of Inspector General (“OIG”) would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] (the “Parent Organization”), a nonprofit, tax-exempt charitable entity, organized [name redacted] (the “Foundation”) as a nonprofit, tax-exempt, charitable organization to operate exclusively as a charitable prescription drug patient assistance program. Under the Proposed Arrangement, the Foundation will provide financial assistance to financially needy patients with a *bona fide* diagnosis of [disease state redacted] who have insurance coverage, including coverage under Medicare and Medicaid, but who cannot afford the costs associated with their prescription drug coverage.¹ The Foundation’s patient assistance program will focus primarily on increasing access to high-cost, medically necessary drug treatment options that are often skipped by [disease state redacted] patients who cannot afford to pay.

The Foundation anticipates entering into a contractual relationship with the Parent Organization’s affiliate, [name redacted] (the “Pharmacy”), a national internet-based specialty pharmacy dedicated to serving patients diagnosed with [disease state redacted], to administer the program.² The Pharmacy has experience and expertise in assisting patients

¹ The Foundation will also provide financial assistance to patients without any insurance coverage. This assistance does not implicate sections 1128A(a)(5) or 1128B(b) of the Social Security Act.

² The Pharmacy is operated pursuant to a contract between two entities affiliated with the Parent Organization: The [name redacted] (the “[Taxable Entity]”), a taxable entity, and the [name redacted] (the “[Non-profit Entity]”), a non-profit entity that, like the Foundation, has the Parent Organization as its sole member. [Taxable Entity]’s stock is wholly-owned by [Non-profit Entity]. [Non-profit Entity] has employees, offices, computers, communication equipment and similar services and equipment. [Taxable

with [disease state redacted] to obtain financial help to pay for their drug treatments through already existing patient assistance programs. Based on its contractual relationship with the Foundation, the Pharmacy will perform non-discretionary tasks related to eligibility determinations and program administration.

The Foundation will be governed by an independent Board of Directors, which will handle all policy-making functions for the Foundation, such as the determination of patient eligibility requirements. The Board will consist of seven members, four of whom also serve on the Parent Organization Board. The remaining Board members will consist of persons unaffiliated with the Parent Organization, such as patients, parents of persons with [disease state redacted], providers, or researchers. No person who is a Foundation donor, a member of a donor's family, or a director, officer or employee of a donor will be eligible to serve on the Foundation's Board. 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.

The Foundation will operate its program as follows. All prospective assistance recipients will be required to complete an application. The Foundation will process grant applications in order of receipt on a first-come, first-served basis, to the extent funding is available. The Foundation has established objective criteria for determining eligibility for assistance, 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 will be awarded pursuant to the Foundation's assessment of applicants' individual financial needs. The Foundation will provide financial assistance for so long as the participating patient continues to meet the program's eligibility criteria. Annual reviews of all participating patients will be conducted to ensure they continue to meet the program's eligibility criteria. Participating patients will be required to notify the Foundation if their financial circumstances or insurance coverage materially change during their participation in the program.

Under the Proposed Arrangement, each approved applicant will receive a benefit card to use at the participating patient's preferred pharmacy when obtaining drugs or an associated drug delivery device. The participating patient's pharmacy will contact the Foundation for payment of the patient's cost-sharing obligations associated with the pharmaceutical items or services provided. In cases where the benefit card is not accepted, grants will be made payable to the participating patient after the patient furnishes proof of incurred costs and an explanation of benefits from the participating patient's insurer. If the patient does not have

Entity] holds state-issued licenses to operate a pharmacy, buys [disease state redacted] products from manufacturers, and has contracts with payers, including Medicare and Medicaid, for reimbursement on sales of its products. Pursuant to the contract between the two entities, [Non-profit Entity] provides [Taxable Entity] with employees, offices, computers, and similar services and equipment for the operation of the Pharmacy.

a preferred pharmacy, the Pharmacy, on behalf of the Foundation, will provide the patient with a list of pharmacies that does not, in any way, steer the patient to choose the Pharmacy over the other pharmacy options. The Pharmacy, for example, will provide a list of pharmacies in an order that does not highlight, bold, or in any other way make its pharmacy stand out from the others on the list.

Potential applicants will learn about the Foundation's program from a variety of sources, including the Foundation and other support organizations, physician offices, and others. The Foundation will assess 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 Foundation has also certified that grant determinations will be 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 participating patient.

Prospective patients will be under the care of a physician with a treatment regimen in place at the time they apply to participate. The Foundation certified that it will not refer participating patients 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 State-funded health care program, such as Medicaid) or other patient assistance programs (such as state programs or other charitable assistance programs)). Participating patients will have complete freedom of choice regarding their products, practitioners, providers, suppliers, insurance companies, and treatment regimens. The Foundation will notify all participating patients 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 the participating patient's insurance program).

Most of the Foundation's funding for the Proposed Arrangement will be provided by manufacturers of drugs and drug delivery devices that are used to treat [disease state redacted] covered by the Foundation's program. The remainder of the Foundation's funding may be provided by individual donors and other [disease state redacted] supporters. All donations 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. Donations will have to be unrestricted and be available for use by the Foundation to carry out its charitable patient assistance program.

The Foundation has certified that its discretion as to the use of the contributions within the fund will be absolute, independent, and autonomous. The Foundation has further certified

that no donor or affiliate of any donor (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) will be able to exert any direct or indirect influence or control over the Foundation or any of the Foundation's funds.

Donors will be informed periodically of the aggregate number of applicants for assistance, the aggregate number of applicants qualifying for assistance, the amount of assistance distributed, and projections for additional funding needs. No individual patient's information will be conveyed to donors. The Foundation has certified that 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 that 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 is publicly available upon request.

Pursuant to its contractual obligations to the Foundation, the Pharmacy will perform several non-discretionary tasks in furtherance of the Foundation's patient assistance program, including administering the funds, processing applications for assistance, determining eligibility based on the Foundation's established criteria, and disbursing the financial assistance for documented cost-sharing needs. The Pharmacy will not decide program or eligibility criteria for the Foundation. The Pharmacy will be paid by the Foundation for the costs it incurs in administering the program, based on fair market value in an arm's-length transaction. Its compensation will not be determined in any manner that takes into account the volume or value of any referrals or business otherwise generated for donors, or for the Pharmacy. We have not been asked about, and do not express an opinion with respect to, the arrangement between the Foundation and the Pharmacy.

To ensure the integrity of its operation of the Foundation's patient assistance program, the Pharmacy will: (i) maintain separate staff that is dedicated to the administration of the Foundation's program; (ii) keep the Foundation's books, records and operational information separated from the books, records, and operational information of the other entities for which the Pharmacy provides services; and (iii) not solicit donations from potential health care industry donors, including pharmaceutical manufacturers, or bring fund proposals to the Foundation's Board for review and approval.

The Foundation has further certified that the Pharmacy's Compliance Officer will incorporate into the Pharmacy's overall compliance monitoring activities and responsibilities oversight of the Pharmacy's administration and eligibility determination operations related to the Foundation's program, which will include a compliance review of the program at least annually. The Pharmacy's Compliance Officer will have direct access

to the Foundation's Board to report findings resulting from compliance reviews or to report on other compliance-related matters concerning the Pharmacy's administration and eligibility determination operations on behalf of the Foundation.

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.

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 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, the proposed design and administration of the Foundation's program 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 is unlikely that donor contributions would 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 program. The Foundation has certified that it is an independent, nonprofit, tax-exempt charitable organization that has, and will continue to maintain 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, through the Pharmacy, will make all financial eligibility determinations using its own objective criteria. The Pharmacy will not participate directly or indirectly in setting program or eligibility 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 participating patients will remain free to change their health care providers, practitioners, suppliers, or products. Patients will also remain free to change insurance plans (subject to the participating patient's insurance program limitations). The Foundation will not refer any participating 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 an applicant's eligibility for its programs, the Foundation will 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.

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

Fifth, the Foundation will 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 information will be conveyed to any donor, nor 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, the aggregate number of applicants qualifying for assistance, the amount of assistance distributed, and projections for additional funding needs. Patients will 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 Pharmacy's regular commercial business relationships with pharmaceutical manufacturers and other similar entities potentially create significant risks that the Proposed Arrangement could be misused as conduits for pharmaceutical manufacturers to provide remuneration to Medicare or Medicaid beneficiaries who use their products. However, the Foundation has certified that the Pharmacy's role as administrator of the Proposed Arrangement is, and will remain, entirely independent from its other business operations.

The Foundation has also certified that the Pharmacy will implement and maintain the following operational safeguards against improper influence by any of Pharmacy's pharmaceutical or other health care clients:

- a separate staff dedicated to the administration of the Foundation's program;
- the Foundation's books, records and operational information will be separated from the books, records and operational information of the other entities for which the Pharmacy provides services;

- the Pharmacy will not solicit donations from potential health care industry donors, including pharmaceutical manufacturers, or bring fund proposals to the Foundation's Board for review and approval;
- compensation paid to the Pharmacy for Foundation program administration services will be consistent with fair market value in arms-length transactions and will not reflect in any manner the volume or value of referrals or other business generated for any donor or donor affiliate.

The Foundation has further certified that that the Pharmacy's Compliance Officer will incorporate into the Pharmacy's overall compliance monitoring activities and responsibilities oversight of the Pharmacy's administration and eligibility determination operations on behalf of the Foundation, which will include a compliance review of the program at least annually. The Pharmacy's Compliance Officer will have direct access to the Foundation's Board to report findings resulting from compliance reviews or to report on other compliance-related matters concerning the Pharmacy's administration of the Foundation's program.

These safeguards, when combined with the totality of facts presented, sufficiently mitigates the risk that the Foundation's assistance decisions might be improperly influenced by pharmaceutical companies, or other client or affiliate interests. Should the Foundation's programs fail to operate independently in any manner from the Pharmacy's commercial operations, or client or affiliate interests, or should any aspect of the program be influenced directly or indirectly by the Pharmacy's commercial clients or affiliates, this opinion would be without force and effect.

In sum, the Foundation's operation as an independent charitable organization, its interposition between donors and patients, and the design and administration of the Proposed Arrangement (including safeguards to be implemented by the Pharmacy) will, if implemented as certified by the Foundation, provide sufficient insulation so that the Foundation's proposed assistance 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.³

³ This conclusion is consistent with the OIG's Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees 70 Fed. Reg. 70623 (November 22,

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

In the circumstances presented by the Proposed Arrangement, the Foundation's assistance, in whole or in part, for cost-sharing obligations for certain eligible, financially needy Medicare and State health care program, including Medicaid, beneficiaries is not (and would not be) likely to influence improperly any beneficiary's selection of a particular provider, practitioner, supplier, or product. 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, the Foundation will assist all eligible, financially needy applicants on a first-come, first-served basis, to the extent funding is available. Applicants will not be eligible for assistance unless they meet the Foundation's financial need eligibility criteria. In all cases, the applicant 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. If an applicant or participating patient does not have a preferred pharmacy, the Pharmacy will provide a list of pharmacies that does not, in any way, steer the applicant or recipient to favor the Pharmacy over the other options (e.g., the Pharmacy will provide a list of pharmacies in an order that does not highlight, bold, or in any other way make its pharmacy stand out from the others on the list). Applicants 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 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 will provide assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner. The Foundation will notify all participating 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 them that they are free to switch insurance plans (when permitted by the participating patient's insurance program) without affecting their eligibility for assistance.

2005), in which the OIG made 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.

Third, the Foundation's assistance for the patient population it serves will expand, rather than limit, patient freedom of choice. Patients will 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 patient assistance program. Most importantly, once in possession of Federal health care coverage under Medicare, or coverage under a State health care program, including Medicaid, 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 Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor of this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [name redacted] with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [name redacted] with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General