[*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: May 20, 2010

Posted: May 27, 2010

[Name and address redacted]

Re: OIG Advisory Opinion No. 10-06

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a patient assistance program (the "Arrangement"). Specifically, you have inquired whether the Arrangement would constitute grounds for the imposition of 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 Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, 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 would 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") will 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 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 for an advisory opinion 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] ("Requestor") is a non-profit, tax-exempt, independent, charitable corporation whose mission is to assist underinsured patients with their prescription drug co-payment obligations. Under the Arrangement, Requestor operates a patient assistance program ("PAP") that offers financial help with co-payments to patients, including Medicare beneficiaries covered by Medicare Part B, Medicare Part D, Medicare Supplementary Health Insurance ("Medigap"),[1] and Medicare Advantage. With respect to Medicare beneficiaries enrolled in a Part D plan, the financial assistance may include assistance with any premium and cost-sharing obligations (including deductible, coverage gap, and catastrophic coverage periods).

An independent board of directors governs Requestor. The board oversees all policy-making functions for Requestor, such as patient eligibility requirements, categories of diseases addressed, and program requirements for funds established for each disease addressed ("disease funds"). Except as noted below, no board member has any financial or employment relationship with Requestor and no board member receives any form of compensation from any donor organization; if at any time a conflict arises, the conflicted board member will disclose the relationship and recuse himself or herself from any matters

[1] In general, Medigap helps pay for health care costs such as co-insurance, co-payments, and deductibles; however, there are twelve different Medigap plans, which offer different benefits, and it is possible for a patient to have one of the Medigap plans and still not have full prescription coverage. In these specific cases, Requestor assists with prescription co-payments.

involving that donor, including fundraising, decisions made about disease funds, and grant recipient eligibility.[2]

Requestor operates its PAP as follows. All prospective grant recipients complete an application. Requestor processes grant applications in order of receipt, on a first-come, first-served basis, to the extent funding is available. Requestor has established objective criteria for determining grant eligibility that is based on medical condition and financial need. Grants provide assistance for the calendar year. Grant recipients are required to notify Requestor if their financial circumstances change during the grant period.

Grants are distributed to recipients by means of a MasterCard debit card (the "Debit Card") issued by [name redacted], a third-party vendor (the "Vendor").[3] No Debit Card carries any direct funds; the funds are stored virtually against each account number and are applied only when the prescription is processed. At the point of sale, pharmacy staff transmits primary insurance information and the Debit Card number to the Vendor's pharmacy benefits manager. The pharmacy benefits manager adjudicates the patient's grant and allows that amount of money to be released from the Debit Card. The Vendor's pharmacy benefits manager technology prevents grant recipients from using the Debit Card to purchase any item that does not have a national drug code that accords with the disease for which the grant recipient's grant was made. The Debit Card will only have Requestor's and MasterCard's logo on it; it will not have any drug product, manufacturer, or donor names on it. The Vendor's systems for administering the Debit Card are HIPAA-compliant.

Prospective grant recipients learn about the PAP from a variety of sources, including Requestor's website, physician offices, and patient advocacy organizations. Requestor certifies that it assesses applications and makes grant determinations without regard to: (i) the interests of any donor or donor affiliates; (ii) the applicant's choice of product, provider, practitioner, supplier, or insurance company; (iii) the identity of the referring person or organization, including whether the referring entity is a donor; or (iv) the amount of contributions made by any pharmaceutical company or other donor whose services or products are or may be used by the grant recipient

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[2] Requestor has disclosed one physician on the board who has compensation arrangements with potential donors. Requestor has certified that this physician will follow the recusal rules. We express no opinion about this physician's relationship with donors.

[3] The Debit Card can be used anywhere that MasterCard is accepted. In rare instances where MasterCard is not accepted where the grant recipient chooses to fill his or her prescription, grants are made payable to the provider or supplier of the medication upon proof of cost.

Applicants must be under the care of a physician with a current prescription in place to apply for a grant. Neither Requestor nor its vendors refer, recommend or arrange for grant recipients to use any particular product, provider, practitioner, supplier, or insurance company. Patients will have complete freedom of choice regarding their products, practitioners, providers, suppliers, insurance companies, and treatment regimens. Requestor provides written notification to all grant recipients that they may switch products, providers, practitioners, suppliers, or insurance companies at any time without affecting their continued eligibility for financial assistance from Requestor.

Requestor has solicited funding from individual donors, corporations, foundations, and pharmaceutical manufacturers. Donations to Requestor are cash or cash equivalents, and do not include drug product. Donors may make unrestricted donations or earmark their donation for the support of a specific disease fund. Requestor has absolute, independent, and autonomous discretion as to the use of the contributions within a disease fund. 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 Requestor.

At present, Requestor's board has not established any specific disease funds, but Requestor certifies that it, in its sole discretion, will determine the diseases it will support through its funds. Disease funds will be defined by Requestor's board based on its independent assessment of whether a new fund arrangement will best serve patient needs. Requestor will define 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. Disease funds will not be defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs or other products. Requestor has not and will not solicit suggestions from donors regarding the identification or delineation of disease funds. 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 of Requestor's disease funds.

Donors are informed periodically of the aggregate number of applicants for assistance in particular disease funds, the aggregate number of applicants qualifying for assistance in the disease fund, and the number of patients who withdrew from or restarted the PAP. No individual patient information is conveyed to donors. Requestor's 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 who 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 Requestor by others, although, as required by Internal Revenue Service ("IRS") regulations, Requestor's annual report is publicly available upon request.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

Section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or state health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state health care program (including Medicaid). The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of section 1128A(a)(5) as including "transfers of items or services for free or for other than fair market value." 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).

B. Analysis

Two aspects of the Arrangement require scrutiny under section 1128A(a)(5) of the Act and the anti-kickback statute: donor contributions to Requestor and Requestor's grants to patients. We address them in turn.

1. Donor Contributions to Requestor

Long-standing OIG guidance makes clear that industry stakeholders can effectively contribute to the health care safety net for financially needy patients, including beneficiaries of Federal health care programs, by contributing to independent, bona fide charitable assistance programs. Under a properly structured program, such donations should raise few, if any, concerns about improper beneficiary inducements.

In the instant case, Requestor's particular design and administration of the Arrangement interpose an independent, bona fide charitable organization between donors and patients in a manner that effectively insulates beneficiary decision-making from information attributing the funding of their benefit to any donor. Thus, it appears unlikely that donor contributions influence any Federal health care program beneficiary's selection of a particular provider, practitioner, supplier, or product, or the selection of any particular insurance plan. Similarly, there would appear to be a minimal risk that donor contributions improperly influence referrals by Requestor. 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 Requestor. Requestor is a non-profit, tax-exempt, independent, charitable corporation that has absolute, independent, and autonomous discretion as to the use of donor contributions.

Second, Requestor awards assistance in a truly independent manner that severs any link between donors and beneficiaries. Requestor makes all financial eligibility determinations using its own objective criteria. Applications will be considered on a first-come, first-served basis, to the extent of available funding. Before applying for financial assistance, each patient has selected his or her health care provider, practitioner, or supplier and has a prescription in place. While receiving Requestor'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. Requestor does not refer any patient to any donor or to any provider, practitioner, supplier, product, or plan.

Third, Requestor 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 patient eligibility for the Arrangement, Requestor does not take

into account the identity of any provider, practitioner, supplier of items or services, or drug or other product the patient may use; the identity of any referring person or organization; or the amount of any contributions made by a donor whose services or products are used or may be used by the patient. Requestor also does not take into account the identity of the insurer or insurance plan selected by the patient.

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

Fifth, Requestor does not provide donors with any data that would facilitate the donor in correlating the amount or frequency of its donations with the amount or frequency of the use of its products or services. No individual patient information is conveyed to any donor, nor is any data related to the identity, amount, or nature of products or services subsidized under the Arrangement. Some aggregate data may be provided to donors as a courtesy, but are limited to aggregate numbers of applicants, numbers of patients entering and leaving the PAP, and aggregate numbers of patients in specific disease categories. Patients do not receive any information regarding donors, and donors do not receive any information regarding other donors, except that Requestor's annual report may be publicly available, as required by the IRS. In the instant case, we believe these safeguards appropriately minimize the potential risk otherwise presented by reporting donor and patient data to donors and patients.

Finally, the fact that Requestor permits donors to earmark donations for particular disease categories should not, on the facts presented, significantly raise the risk of abuse. In some cases, earmarking donations for narrowly defined disease categories would effectively result in patients being steered to particular products based on the availability of the subsidy, and increase the likelihood that the charity would serve as an improper conduit for donors to provide funds to patients who use their specific products. In this case, Requestor has certified that no donor or affiliate of any donor (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) directly or indirectly influences Requestor's identification of the disease categories.

In sum, Requestor's interposition as an independent charitable organization between donors and patients and the design and administration of the Arrangement provides sufficient insulation so that Requestor's proposed grants should not be attributed to any of its donors. Donors receive 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 will receive any financial assistance whatsoever from Requestor. In these circumstances, we do not believe that the

contributions made by donors to Requestor can reasonably be construed as payments to beneficiaries of Federal health care programs or to Requestor to arrange for referrals.[4]

2. Requestor's Grants to Federal Health Care Program Beneficiaries

In the circumstances presented by the Arrangement, Requestor's grants, in whole or in part, of cost-sharing obligations and premiums for certain eligible, financially needy Federal health care program beneficiaries are not likely to influence improperly any beneficiary's selection of a particular provider, practitioner, supplier, or product.[5]

First, Requestor assists all eligible, financially needy patients on a first-come, first-served basis, to the extent funding is available. Patients are not eligible for assistance unless they meet Requestor's financial need eligibility criteria. In all cases, the patient is already under the care of a physician with a treatment regimen in place at the time of application. Requestor makes no referrals or recommendations regarding specific providers, practitioners, suppliers, products, or plans, and the Debit Card is free of any branding that would imply an endorsement or referral to any specific providers, practitioners, suppliers, products, or plans. Finally, patients are not informed of the identity of donors.

Second, Requestor's determination of an applicant's financial qualification for assistance is based solely on his or her medical condition and financial need, without considering the identity of any of his or her health care providers, practitioners, suppliers, products, or insurance plan; the identity of any referring party; or the identity of any donor that may have contributed for the support of the applicant's condition. Requestor provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner. Requestor 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. Requestor also notifies patients who are Medicare beneficiaries

[4] This conclusion is consistent with the OIG's November 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (70 Fed. Reg. 70623; November 22, 2005), in which the OIG made it clear that, in the circumstances described in the Bulletin, cost-sharing subsides provided by bona fide, independent charities unaffiliated with donors should not raise anti-kickback concerns, even if the charities receive charitable contributions from those donors.

[5] Given this conclusion here—that the Arrangement is not likely to influence improperly beneficiary choice—we need not reach the issue of whether the new exception at section 1128A(i)(6)(F) of the Act, as added by the Patient Protection and Affordable Care Act (P.L. 111-148, 124 Stat. 119), might also apply.

that they are free to switch insurance plans when permitted by the Medicare program, without affecting their continued eligibility for assistance from Requestor.

Third, Requestor's grants for the patient populations it serves does not limit beneficiaries' freedom of choice. Patients have already selected a provider, practitioner, or supplier of items or services—and drugs or other products will likely have been prescribed for the patient—prior to his or her application for Requestor's financial assistance. In addition, Requestor provides written notification to all grant recipients that they may switch products, providers, practitioners, suppliers, or insurance companies at any time without affecting the their continued eligibility for financial assistance from Requestor.

Finally, Requestor's own interest as a charitable, tax-exempt entity that must maximize use of its scarce resources to fulfill its charitable mission ensures that it 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 the Arrangement would 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 will 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 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 for an advisory opinion 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 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 Requestor 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 Requestor 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