[*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 11, 2009

Posted: May 18, 2009

[Name and address redacted]

Re: OIG Advisory Opinion No. 09-04

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a nonprofit, tax-exempt, charitable organization's arrangement to provide financial assistance with cost-sharing obligations associated with certain advanced diagnostic testing owed by financially needy patients, including Medicare and Medicaid beneficiaries (the "Arrangement"). Specifically, you have inquired whether the existing Arrangement constitutes 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 does not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, the Office of Inspector General ("OIG") 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 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 an independent, non-profit, tax-exempt, charitable organization dedicated to providing financial assistance and certain therapy management services to financially needy patients nationwide, including Medicare beneficiaries enrolled in Medicare Part D, undergoing medical treatment for certain chronic diseases that may require costly specialty therapeutics.[1]

Requestor also operates the Arrangement, which is a patient assistance program that provides financial assistance to financially needy patients, including Medicare and Medicaid beneficiaries, who are HIV-positive or have colorectal cancer and require certain costly diagnostic tests related to their medical care. Specifically, Requestor assists patients suffering from HIV who need phenotype and tropism testing and colorectal cancer patients who need KRAS and Epidermal Growth Factor Receptor testing ("Advanced Diagnostics for HIV" and "Advanced Diagnostics for Colorectal Cancer," respectively, and collectively referred to as "Advanced Diagnostics").[2] The Advanced Diagnostics are ordered by

[1] We previously issued an advisory opinion to Requestor approving its program to support financially needy patients through cost-sharing assistance for certain specialty therapeutics. See OIG Advisory Opinion No. 06-10.

[2] Requestor provides assistance to Federal health care beneficiaries and private pay patients under the Arrangement. According to Requestor, certain tests covered by the Arrangement may not be covered services under a patient's insurance. For diagnostic testing services not covered by insurance, Requestor assists the patient with up to 100% of the testing costs. If the tests are covered by the patient's insurance, Requestor may assist the patient with his or her cost-sharing obligation, if any, to obtain the test. Federal health care program

physicians to help them accurately prescribe the appropriate drug therapies to treat an individual's disease.

Requestor's funding is provided by individual donors, corporations, and foundations and includes donations from manufacturers of drug products, pharmacies that dispense drugs, and suppliers of types of services used by patients assisted by Requestor. All donations are either cash or cash equivalents. Donors may change or discontinue their contributions at any time. Requestor has two separate funds dedicated to Advanced Diagnostics for HIV and Advanced Diagnostics for Colorectal Cancer (collectively, referred to as the "Funds"). The Funds cover all available Advanced Diagnostics for HIV and all available Advanced Diagnostics for Colorectal Cancer, as well as available suppliers of those tests.[3] Each Fund includes multiple types of tests used in the diagnosis of HIV or colorectal cancer, and each Fund covers tests conducted by multiple testing providers. Requestor certified that the tests in each Fund comply with widely recognized clinical standards. Donors may provide unrestricted donations or donors may earmark contributions for the support of patients assisted through either of the Funds; however, donations may not be earmarked for patients using a specific Advanced Diagnostics testing provider or a specific test. No donor or affiliate of any donor (including, without limitation, any employee, agent, officer, shareholder, or contractor) exerts any direct or indirect influence or control over Requestor or the Arrangement and Requestor maintains absolute, independent, and autonomous discretion as to the use of donor contributions in the Funds.

Requestor has certified that no donor or affiliate of any donor (including, without limitation, any employee, agent, officer, shareholder, or contractor) directly or indirectly influences Requestor's selection of Advanced Diagnostics covered by the Funds.

Requestor does not provide donors with any individual patient information. Requestor informs donors of the aggregate number of applicants for assistance within a particular Fund and the aggregate number of patients qualifying for assistance for a particular Fund. Requestor's reports to donors do not contain any information that enable a donor to correlate the amount or frequency of its donations with the amount or frequency of the use of its products or services. Requestor does not convey any data to donors related to the identity, amount or nature of services subsidized under the Arrangement. Requestor does not inform a patient 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

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beneficiaries are treated in the same manner as other insured patients under the Arrangement.

[3] Currently, one of the Advanced Diagnostics for HIV has only one supplier in the United States. Requestor certified that any new supplier of the test will also be covered.

Revenue Service ("IRS") regulations, Requestor's annual report and list of donations are publicly available upon request.

Requestor operates the Arrangement as follows. Requestor has established objective financial need criteria based on certain national standards of indigence to determine patient eligibility. Patients qualify for help from the Requestor if they meet the financial need criteria, are diagnosed with HIV or colorectal cancer, and have a physician's order for an Advanced Diagnostics test. Prior to enrollment, the patient's physician also has selected a laboratory to provide the test on the patient's behalf.

All prospective patient participants complete an application. Requestor processes applications in order of receipt on a first-come, first-served basis, and accepts an eligible patient to the extent funding is available. Assistance with cost-sharing obligations for Advanced Diagnostics is available without regard to the provider, practitioner, supplier, service, or product used by the patient. When administratively feasible, Requestor pays the patient's cost-sharing obligations directly, reducing the out-of-pocket costs incurred by the patient. When direct payment is not administratively feasible, the patient pays the cost-sharing obligations, and then submits receipts to the Requestor for reimbursement.

Potential patient applicants learn about Requestor's program from a variety of sources, including physicians, pharmacies, health care providers, patient advocacy groups, pharmaceutical manufacturers, Requestor, and others. Requestor assesses patient applications and makes eligibility determinations without regard to: (i) the interests of any donor (or any donor affiliates); (ii) the applicant's choice of provider, practitioner, supplier, service, or product; or (iii) the identity of the referring person or organization, including whether the referring person or organization is a donor.

Requestor's enrollees are under the care of a physician at the time they apply to Requestor for assistance. Requestor certified that its staff does not refer applicants to, recommend, or arrange for the use of any particular provider, practitioner, supplier, service, or product. Patients have complete freedom of choice regarding their providers, practitioners, suppliers, and products. Requestor notifies all enrolled patients that they are free at any time to switch providers, practitioners, suppliers, services, or products without affecting their eligibility for assistance.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services

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

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

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

B. Analysis

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

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.

1. Donor Contributions to Requestor

Because the design and administration of Requestor's Arrangement interposes an independent, *bona fide* charitable organization between donors and patients in a manner that effectively insulates beneficiary decision-making from information attributing the funding of their benefit to any donor, it is unlikely that donor contributions influence any patient's selection of a particular provider, practitioner, supplier, service, or product. Similarly, there appears to be a minimal risk that donor contributions improperly influence referrals to any provider, practitioner, supplier, service, or product by Requestor. We reach this conclusion based on a combination of the following factors.

First, no donor or affiliate of any donor exerts direct or indirect control over Requestor or its Funds. Requestor certified that it is a national, independent, nonprofit, tax-exempt charitable organization that maintains absolute, independent, and autonomous discretion as to the use of donor contributions to the Funds.

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. Requestor considers applications 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 and each patient's treating physician has ordered one of the Advanced Diagnostics. While receiving Requestor's financial assistance, all participating patients are free to change their health care providers, practitioners, suppliers, or products. Requestor does not refer any participating patient to any donor or to any provider, practitioner, supplier, service, or product.

Third, Requestor awards assistance without regard to any donor's interests and without regard to the applicant's choice of product, provider, practitioner, service, or supplier. When determining an applicant's eligibility for the Arrangement, Requestor assesses patient applications and makes eligibility determinations without regard to: (i) the interests of any donor (or any donor affiliates); (ii) the applicant's choice of provider, practitioner, supplier, service, or product; or (iii) the identity of the referring person or organization, including whether the referring person or organization is a donor.

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

Fifth, Requestor does not provide donors with any data that allows a donor to correlate the amount or frequency of its donations with the amount or frequency of the use of its products or services. Requestor does not convey individual patient information to any donor, nor

does it convey any data related to the identity, amount, or nature of services subsidized under the Arrangement. Some aggregate data may be provided to donors as a courtesy, but is limited to the aggregate number of applicants and the aggregate number of applicants qualifying for assistance. 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 the Funds should not, on the facts presented, raise the risk of abuse. In this case, Requestor certified that no donor or affiliate of any donor (including, without limitation, any employee, agent, officer, shareholder, or contractor) directly or indirectly influences the Requestor's selection of Advanced Diagnostics covered by the Funds. Moreover, to ensure that Requestor's Funds are appropriately delineated and operate in a manner that minimizes the ability of a donor to direct its donation to a particular patient, test, or supplier, Requestor has further certified that the tests covered by the Funds are consistent with widely recognized clinical standards; each Fund covers multiple tests and suppliers used in the diagnosis of HIV or colorectal cancer; and all available suppliers are covered. In these circumstances, it is unlikely that the earmarking will result in the Arrangement serving as a disguised conduit for financial assistance from a donor to patients using particular products, suppliers, or services.

In sum, Requestor's interposition as an independent charitable organization between donors and patients and the design and administration of the Arrangement provide sufficient insulation so Requestor's assistance to patients should not be attributed to any of its donors. Donors are not assured that the amount of financial assistance their patients, clients, or customers receive bears any relationship to the amount of their donations. Indeed, donors are not guaranteed that any of their patients, clients, or customers receive any financial assistance whatsoever from Requestor. In these circumstances, we do not believe that the contributions made by donors to Requestor can reasonably be construed as payments to eligible beneficiaries of the Medicare or Medicaid programs or to Requestor to arrange for referrals.

2. Requestor's Grants to Patients

In the circumstances presented by the Arrangement, Requestor's provision of assistance with Medicare and Medicaid cost-sharing obligations for certain eligible, financially needy Medicare and Medicaid beneficiaries is not likely to influence improperly any beneficiary's selection of a particular provider, practitioner, supplier, service, or product.

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 patients are already under the care of a physician at the time of application. Requestor makes no referrals or recommendations regarding specific providers, practitioners, suppliers, services, or products. 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 financial need, without considering the identity of any of his or her health care providers, practitioners, suppliers, services, or products; the identity of any referring party; or the identity of any donor that may have contributed for the support of the Funds or the amount of the donation. 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, services, or products without affecting their continued eligibility for assistance.

Third, Requestor's assistance in no way limits beneficiaries' freedom of choice. Beneficiaries already have an order for an Advanced Diagnostics test before they enroll in the Arrangement, and they remain free to select any testing supplier, regardless of whether the supplier (or any other donor) has made contributions to Requestor's Funds. Beneficiaries are free to switch suppliers or types of Advanced Diagnostics test without losing their subsidy.

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 Requestor has a significant incentive to monitor utilization so as to keep expenditures to a minimum.

In light of all of the foregoing considerations, we would not subject Requestor to administrative sanctions in connection with the Arrangement under sections 1128A(a)(5), 1128A(a)(7), or 1128B(7) of the Act.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement does not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG 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.

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 [name redacted] 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 [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