



*[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:** September 14, 2006

**Posted:** September 21, 2006

[Name and address redacted]

**Re: OIG Advisory Opinion No. 06-10**

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a nonprofit, tax-exempt, charitable organization's practice of providing certain therapy management services and assistance with Medicare cost-sharing obligations to financially needy Medicare beneficiaries undergoing medical treatment for certain diseases (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (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.

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 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, but that 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 Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

This opinion may not be relied on by any persons other than [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.

## **1. FACTUAL BACKGROUND**

[Name redacted] (“Requestor”) is a non-profit, tax-exempt charitable organization dedicated to providing financial assistance and certain therapy management services to financially needy patients undergoing medical treatment for certain diseases. For many years, Requestor had limited its assistance to patients with private health insurance. Under the Arrangement, Requestor expanded its program to include financially needy Medicare beneficiaries, including beneficiaries enrolled in a Part D plan.<sup>1</sup>

Requestor operates its program to assist financially needy patients with any of several diseases (the “Funded Diseases”) that require therapy with certain types of medications (the “Specialty Therapeutics”). The Specialty Therapeutics are costly medications with particular features that complicate their use (*e.g.*, the medications may require physician administration, the medications may be self-administrable but require injection or infusion, the medications may require special handling or storage, or effective use may require significant patient education). Requestor has established objective financial need criteria, based on certain national standards of indigence. Medicare beneficiaries qualify

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<sup>1</sup>For ease of reference, we use the term “Part D plan” to refer to any plan offering Medicare outpatient prescription drug coverage under Medicare Part D, including freestanding private prescription drug plans (often referred to as “PDPs”) and drug plans offered as part of a Medicare Advantage plan (often referred to as “MA-PDs”).

for help from Requestor if they meet the financial need criteria, are diagnosed with a Funded Disease, and are undergoing treatment with a Specialty Therapeutic.<sup>2</sup>

Requestor operates its program as follows. All prospective patient participants complete an application. Requestor processes applications in order of receipt on a first-come, first-served basis, and accepts eligible patients to the extent funding is available. Once patients are accepted into the program, Requestor provides both financial assistance and therapy management services.

Some uses of the Specialty Therapeutics, primarily those involving physician administration, are covered under Medicare Part B, while other uses, primarily those involving patient self-administration, are covered under Medicare Part D. Requestor's financial assistance includes help with patient cost-sharing obligations (i.e. deductibles and co-payments) for the Specialty Therapeutics under both Medicare Parts B and D. Assistance with these cost-sharing obligations is available without regard to the provider, practitioner, supplier, or product used by the patient.<sup>3</sup>

Efficacy of the Specialty Therapeutics may be severely compromised if patients fail to comply with their prescribed treatment regimen. Requestor's program promotes compliance

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<sup>2</sup>Requestor may, in the future, alter the Funded Diseases covered by its program, subject to the limitations described below. Requestor also anticipates that, as additional medications are approved by the Food and Drug Administration for treating the Funded Diseases, it would expand the list of Specialty Therapeutics.

<sup>3</sup>When a patient obtains Specialty Therapeutics directly from a pharmacy, the patient is free to use any duly licensed pharmacy of his or her choosing. Requestor has enrolled certain pharmacies as "Participating Pharmacies." When a patient obtains a Specialty Therapeutic from a Participating Pharmacy, Requestor pays the cost-sharing assistance directly to the pharmacy, reducing the out-of-pocket costs incurred by the patient. When a patient obtains a Specialty Therapeutic from a pharmacy that has not enrolled as a Participating Pharmacy, the patient pays the cost-sharing obligations to the pharmacy, and then submits receipts to Requestor for reimbursement. Requestor allows any duly licensed pharmacy that is capable of dispensing the Specialty Therapeutics and appropriately exchanging information with Requestor to enroll as a Participating Pharmacy. For uses of Specialty Therapeutics where the patient obtains the medication directly from a physician, the patient is free to use any duly licensed physician of his or her choosing. 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 Requestor for reimbursement.

with treatment regimens by providing financial assistance to help patients purchase the Specialty Therapeutics and by providing therapy management services to help patients use the Specialty Therapeutics as directed. Patients can access the therapy management services via the internet and use a program that helps them track their disease progression and adhere to their prescribed treatment regimen. The therapy management services are rendered by a vendor under contract with Requestor.<sup>4</sup> Patients are not required to use the therapy management services, but they may be disenrolled from Requestor's program based on evidence of continued noncompliance with their prescribed treatment regimen. The therapy management services are not billed to any Federal health care program.

Requestor provides assistance for a specific period of time (generally one year), after which a patient may reapply. Patients are required to notify Requestor if their financial circumstances change during the assistance period.

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, or product;<sup>5</sup> or (iii) the identity of the referring person or organization, including whether the referring person or organization is a donor. Requestor makes patient eligibility determinations without regard to the amount of contributions made by any donor whose services or products are used or may be used by the patient.

Medicare beneficiaries are under the care of a physician with a treatment regimen in place at the time they apply to Requestor for assistance. Requestor has certified that its staff does not refer applicants to, recommend, or arrange for the use of any particular provider, practitioner, supplier, 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, or products without affecting their continued eligibility for assistance.<sup>6</sup>

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<sup>4</sup>We have not been asked about, and express no opinion regarding, any arrangements between Requestor and the entity providing therapy management services.

<sup>5</sup>Although Requestor's assistance is only available to patients using a Specialty Therapeutic, assistance remains available regardless of which Specialty Therapeutic a patient uses.

<sup>6</sup>Patients must, however, use at least one Specialty Therapeutic and remain compliant with that treatment regimen.

Requestor's funding is provided by individual donors, corporations, and foundations and includes donations from manufacturers of the Specialty Therapeutics, pharmacies that dispense the Specialty Therapeutics, infusion companies that administer the Specialty Therapeutics, and by suppliers of the types of services used by patients that Requestor assists. All donations are either cash or cash equivalents. Donors may change or discontinue their contributions to Requestor at any time. Donors may provide unrestricted donations. Alternatively, donors may earmark their contributions for the support of patients with a specific Funded Disease; however, donations must be unrestricted for those patients and may not be earmarked for patients using a specific Specialty Therapeutic. 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 or Requestor's program.

Upon request, Requestor informs donors of the aggregate number of all applicants for assistance for particular Funded Diseases and the aggregate number of patients qualifying for assistance for particular Funded Diseases. Requestor does not provide donors with any individual patient information. 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 that use its products or services, or the volume of those products or services. Requestor does not inform patients 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 and list of donations are publicly available upon request.

Requestor has certified that: (i) it defines (and will continue to define) its Funded Diseases in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products;<sup>7</sup> and (ii) its Funded Diseases are not (and will not be) defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs. Requestor 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)) directly or indirectly influences the identification or delineation of the Funded Diseases.

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<sup>7</sup>In rare circumstances, where there may be only one Specialty Therapeutic to treat a particular Funded Disease or only one pharmaceutical manufacturer (including its affiliates) that makes all of the Specialty Therapeutics for the Funded Disease, Requestor will use its best efforts to cover additional products and manufacturers as they become available.

## 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.

### 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 assistance 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 Medicare beneficiaries 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 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 would influence any Medicare beneficiary's selection of a particular provider, practitioner, supplier, or product. Similarly, there appears to be a minimal risk that donor contributions would 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 or its program. Requestor is an independent, nonprofit, tax-exempt charitable organization that operates with 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 are considered on a first-come, first-served basis, to the extent of available funding. Before applying for assistance, each patient has already selected his or her health care providers, practitioners, suppliers, and products and has a treatment regimen in place. All patients remain free, while receiving Requestor's assistance, to change their health care providers, practitioners, suppliers, or products (except that patients must use at least one Specialty Therapeutic in compliance with a prescribed treatment regimen to remain eligible for assistance). Requestor does not refer any patient to any donor or to any provider, practitioner, supplier, or product.

Third, Requestor awards assistance without regard to any donor's interests and without regard to the applicant's choice of provider, practitioner, supplier, or product. 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.

Fourth, based on Requestor's certifications, Requestor provides assistance 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 are 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 this is limited to aggregate numbers of applicants and aggregate numbers of qualifying patients with specific Funded Diseases. Patients do not receive any information regarding donors, and donors do not receive any information regarding other donors, except that

Requestor's annual report and list of donations 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 Funded Diseases should not, on the facts presented, significantly raise the risk of abuse. 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 the identification of the Funded Diseases. Moreover, to ensure that Requestor's Funded Diseases are appropriately defined, Requestor has further certified that: (I) it defines its Funded Diseases in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products; and (ii) its Funded Diseases are not defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs. 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 its products.

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 that 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 will bear 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 eligible beneficiaries of the Medicare program or to Requestor to arrange for referrals.<sup>8</sup>

## **2. Requestor's Assistance to Medicare Beneficiaries**

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

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<sup>8</sup>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 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.



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 with a treatment regimen in place at the time of application. Requestor makes no referrals or recommendations regarding specific providers, practitioners, suppliers, 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, or products; the identity of any referring party; or the identity of any donor that may have contributed for the support of the applicant's Funded Disease 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, or products (except that patients must use at least one Specialty Therapeutic in compliance with a prescribed treatment regimen to remain eligible for assistance) without affecting their continued eligibility for assistance.

Third, Requestor's assistance in no way limits beneficiaries' freedom of choice. Beneficiaries have already selected a provider, practitioner, or supplier of items or services – and drugs or other products have already been prescribed for them – prior to their application for Requestor's assistance. Beneficiaries remain free to select any provider, practitioner, supplier, or product, regardless of whether that provider, practitioner, supplier, or product manufacturer has made contributions to Requestor's support program.

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 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, but that 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 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 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,

/s/

Lewis Morris  
Chief Counsel to the Inspector General