



[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 26, 2010

Posted: June 3, 2010

[Name and address redacted]

Re: OIG Advisory Opinion No. 10-07

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a nonprofit, tax-exempt, charitable organization's proposal to provide assistance with cost-sharing obligations to financially needy individuals, including Medicare and Medicaid beneficiaries, diagnosed with Multiple Sclerosis, cancer, or rheumatoid arthritis (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed 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 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 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, charitable organization organized to establish grant programs to provide aid to financially needy patients, including Medicare and Medicaid beneficiaries, who have been diagnosed with Multiple Sclerosis, cancer, or rheumatoid arthritis (“Specified Diseases”).¹ Requestor would establish a separate fund for each of the three Specified Diseases and a fourth fund for genetic testing, which would be available for genetic testing associated with any of the Specified Diseases. The grants would be used to assist patients with cost-sharing amounts related to certain prescribed medications (“Specialty Medications”²), or to cover up to 100% of the cost of a genetic test that a physician orders to determine an effective course of treatment for a

¹ In the future, Requestor may expand the Proposed Arrangement to provide assistance to patients diagnosed with other diseases. The expanded program would include the same features and safeguards as the Proposed Arrangement. We express no opinion about the potential expansion of the Proposed Arrangement.

² For purposes of the Proposed Arrangement, Specialty Medications are costly medications for the Specified Diseases with particular features that complicate their use (*i.e.*, 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 provided us with a listing of currently available Specialty Medications.

Specified Disease. Requestor would also provide free therapy management information on its web site to assist patients in complying with their medication regimens.

Requestor would publicize the availability of the grant program on its web site and to medical providers and pharmacies that typically treat patients with the Specified Diseases. Patients would apply for assistance by completing a grant application that would include the patient's diagnosis, proof of income, and other financial disclosures. Patients must be under the care of a physician and already undergoing treatment for a Specified Disease at the time of application to be eligible for assistance, but patients would be free to change providers, suppliers, or Specialty Medications without losing eligibility for aid. Requestor would employ counselors to assist patients both in completing the grant application and in understanding other forms of financial assistance that might be available to them (e.g., Low Income Subsidy assistance available through the Social Security Administration). Requestor would process applications on a first-come, first-served basis, to the extent funding is available.

Grants would be awarded on a uniform sliding scale, based on Requestor's assessment of the patient's financial need. Requestor would not make eligibility determinations based in whole or in part on: the interest of any person or entity who contributes to Requestor's grant program funds ("Donor") or affiliate(s) of Donors³; the applicant's choice of provider, practitioner, insurer, insurance plan, supplier, test, or product; or the identity of the referring person or organization (including whether the referring person is a Donor). Requestor would assess an applicant's financial eligibility for a grant based on the Federal poverty guidelines. Patients would have to reapply for aid annually and would be required to notify Requestor if their financial situation changed during the grant period. Further, patients could be disenrolled from the grant program upon proof of continued non-compliance with their medication regimens.

Requestor has certified that it would define the Specified Diseases in accordance with widely recognized clinical standards and would not define the Specified Diseases by reference to specific symptoms, severity of symptoms, the method of administration of drugs, or the availability of associated genetic testing. As defined, the Specified Diseases cover a broad spectrum of available products. Requestor has further certified that no Donor or affiliate of any Donor directly or indirectly influences the identification or delineation of the Specified Diseases.

³ The term "affiliate" of any Donor includes, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager) of a Donor.

There are currently several different Specialty Medications, manufactured by a variety of different companies, available to treat each of the three Specified Diseases. Requestor has further certified that it would cover all new Specialty Medications as they become FDA-approved and available. Although Specialty Medications are often dispensed by specialty pharmacies, thousands of other pharmacies are also capable of dispensing the Specialty Medications. For a patient to qualify for assistance under the Proposed Arrangement, the Specialty Medication must have been prescribed as part of an approved course of treatment for a Specified Disease, and must not be for an off-label use. Patients may receive assistance with the cost of genetic testing if the test is ordered by a physician to determine an effective course of treatment for a Specified Disease. Requestor has certified that it would not refer applicants to, recommend, or arrange for the use of any particular medication, test, practitioner, provider, or supplier, and that patients would have complete freedom of choice in such matters. Requestor would provide the cost-sharing grants directly to the pharmacy, laboratory, or other health care provider or supplier whenever possible. However, if the patient's chosen provider or supplier does not accept third party payment, the patient may submit proof to Requestor that he or she incurred the cost, and then Requestor would make the grant payable to the patient.

Requestor intends to solicit donations from the general public, such as individuals, foundations, and corporations, including pharmaceutical manufacturers. All donations would be in the form of cash or cash equivalents. Donors would be able to change or discontinue their contributions to Requestor at any time. Donors could provide unrestricted donations, or could earmark their contributions either: (1) for the support of patients with a particular Specified Disease; or (2) for the support of patients requiring a genetic test. However, donations could not be earmarked for patients using a specific Specialty Medication, requiring a specific genetic test, or for genetic tests associated with a particular Specified Disease. Requestor's discretion to use the donations would be absolute, independent, and autonomous.

Requestor has certified that no health plan, affiliate of a health plan, Donor, or affiliate of any Donor, would exert any direct or indirect influence or control over Requestor or Requestor's program. No Donor, or immediate family members, directors, officers, employees, or persons otherwise affiliated with Donors, would be eligible to serve on Requestor's Board. Upon request, Requestor would inform Donors on a monthly basis of the aggregate number of all applicants qualifying for assistance for particular Specified Diseases, as well as the aggregate number of applicants qualifying for assistance for genetic testing. Requestor would not provide Donors with any individual patient information. Requestor's reports to Donors would not contain any information that would enable a Donor to correlate the amount or frequency of its donations with the number of patients that use its Specialty Medications or genetic tests, or the volume of those products or services. Requestor would not inform patients or Donors 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 would be 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. 1985), 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 aspects of the Proposed 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 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 proposed design and administration of the Proposed Arrangement would interpose an independent, bona fide charitable organization between Donors and patients in a manner that would effectively insulate beneficiary decision-making from information attributing the funding of their benefit to any Donor. Thus, it appears unlikely that Donor contributions would influence any beneficiary's selection of a particular provider, practitioner, supplier, test, or product. Similarly, there appears to be a minimal risk that the Donor contributions would improperly influence referrals by Requestor. We reach this conclusion based on a combination of the following factors.

First, no Donor or affiliate of any Donor would exert 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. No Donor, or immediate family members, directors, officers, employees, or persons otherwise affiliated with Donors, would be eligible to serve on Requestor's Board.

Second, Requestor would award assistance in a truly independent manner that would sever any link between Donors and beneficiaries. Requestor would make all financial eligibility determinations using its own objective criteria. Applications would be considered on a first-come, first-served basis, to the extent of available funding. Before applying for assistance, each patient will have already selected his or her health care providers, practitioners, suppliers, and products and will already have a treatment regimen in place. All patients would remain free, while receiving Requestor's assistance, to change their health care providers, practitioners, suppliers, or Specialty Medications. Requestor would not refer any patient to any Donor or affiliate of a Donor, or to any provider, practitioner, supplier, medication, or test.

Third, Requestor would award assistance without regard to any Donor's interests and without regard to the applicant's choice of provider, practitioner, supplier, test, or product. When determining patient eligibility for the Proposed Arrangement, Requestor would not take into account the identity of any provider, practitioner, insurer, health plan, supplier of items or services, test, 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 would provide assistance based on a reasonable, verifiable, and uniform measure of financial need that would be applied in a consistent manner.

Fifth, Requestor would 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 would be conveyed to any Donor, nor would be 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 this would be limited to aggregate numbers of qualifying patients for each Specified Disease or aggregate numbers of patients qualifying for assistance with genetic testing. Patients would not receive any information regarding Donors, and Donors would 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 Specified Diseases or for genetic testing, generally, 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)) would directly or indirectly influence the identification of the Specified Diseases. To ensure that Requestor's Specified Diseases are appropriately defined, Requestor has further certified that: (i) it would define its Specified Diseases in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products; and (ii) its Specified Diseases would not be defined by reference to specific symptoms, severity of symptoms, the method of administration of drugs, or the availability of associated genetic testing. Moreover, several different Specialty Medications are currently available to treat each Specified Disease, and Requestor has certified that it will cover all new Specialty Medications as they become FDA-approved and available. Donors would not be permitted to earmark contributions for specific Specialty Medications or genetic tests, nor could they earmark contributions for genetic tests

applicable to a particular Specified Disease. Under these circumstances, it is unlikely that the earmarking would result in the Proposed 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 Proposed Arrangement provide sufficient insulation so that Requestor's assistance to patients should not be attributed to any of its Donors. Donors would not be assured that the amount of financial assistance their patients, clients, or customers receive would bear any relationship to the amount of their donations. Indeed, Donors would not be guaranteed that any of their patients, clients, or customers would receive any financial assistance whatsoever from Requestor. In these circumstances, we do not believe that the contributions Donors would make to Requestor can reasonably be construed as payments to eligible beneficiaries of the Medicare or Medicaid programs or to Requestor to arrange for referrals.⁴

2. Requestor's Assistance to Medicare and Medicaid Beneficiaries

In the circumstances presented by the Proposed Arrangement, Requestor's proposed provision of financial assistance with cost-sharing obligations for certain eligible, financially needy beneficiaries is not likely to influence improperly any beneficiary's selection of a particular provider, practitioner, supplier, product, or test.⁵ We reach this conclusion based on the following factors.

First, Requestor would assist all eligible, financially needy patients on a first-come, first-served basis, to the extent funding is available. Patients would not be eligible for assistance unless they meet Requestor's financial need eligibility criteria. In all cases, the patients would already be under the care of a physician with a treatment regimen in place at the time of application. Requestor would make no referrals or recommendations regarding specific

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 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.

⁵ Given this conclusion here—that the Proposed 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.

providers, practitioners, suppliers, tests, or products. Patients would not be informed of the identity of Donors.

Second, Requestor's determination of an applicant's qualification for assistance would 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 tests; the identity of any referring party; or the identity of any Donor that may have contributed for the support of the applicant's Specified Disease or the amount of the donation. Requestor would provide assistance based on a reasonable, verifiable, and uniform measure of financial need that would be applied in a consistent manner.

Third, Requestor's assistance would in no way limit beneficiaries' freedom of choice. Beneficiaries will have already selected a provider, practitioner, or supplier of items or services—and Specialty Medications or a genetic test will have already been ordered for them—prior to their application for Requestor's assistance. Beneficiaries would remain free to select any provider, practitioner, supplier, product, or test, regardless of whether that provider, practitioner, supplier, or product or test manufacturer has made contributions to Requestor's support program. Similarly, beneficiaries would be free at any time to switch providers, practitioners, suppliers, or products without affecting their continued eligibility for assistance.

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.

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 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 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