



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



[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: December 28, 2015

Posted: January 4, 2016

[Name and address redacted]

Re: OIG Advisory Opinion No. 15-16

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 out-of-pocket expenses for outpatient prescription drugs to financially needy insured patients, including, but not limited to, Medicare and Medicaid beneficiaries (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) although 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 501(c)(3) charitable foundation that proposes to establish a patient assistance program to provide assistance with out-of-pocket expenses for outpatient prescription drugs to certain patients who demonstrate financial need. Requestor would maintain two disease funds, which would be entitled [disease fund redacted] and [disease fund redacted] (the “Disease Funds”). The [disease fund redacted] would provide assistance to patients with numerous types of cancer, while the [disease fund redacted] would provide assistance to patients with chronic kidney disease (not on dialysis) or iron deficiency anemia.

Patients would learn about the Proposed Arrangement through a variety of sources, including physicians, patient support groups, and Requestor’s marketing activities. Before applying for assistance, a patient must have selected his or her health care provider, practitioner, or supplier, and have a treatment regimen in place. While receiving Requestor’s financial assistance, patients would remain free to change their providers, practitioners, suppliers, drugs, or insurance plans.

Requestor would assess an applicant’s financial eligibility for copayment assistance based on the Federal poverty guidelines. Financial assistance would be awarded on a first-come, first-served basis to any financially qualified applicant diagnosed with one of the diseases covered by a Disease Fund, to the extent funding is available. Requestor would determine eligibility according to a reasonable, verifiable, and uniform measure of financial need that would be applied in a consistent manner. Requestor would employ a process for screening all applicants for compliance with a Disease Fund’s designated financial eligibility criteria prior to enrolling applicants in a Disease Fund or within a reasonable time thereafter. Such screening process would be applied uniformly across both Disease Funds, and would involve: verifying an applicant’s financial resources

through information provided by a third party service, collecting documentation of financial need from the applicant, or some combination thereof. Requestor would use a preset sliding scale to award a percentage of financial assistance based on the applicant's income level, which could result in financial assistance that would fully subsidize the patient's out-of-pocket costs or, for higher-income applicants, subsidize only a portion of those costs.

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 Donors,¹ including the amount of contributions made by any Donor whose drugs or services may be used by the patient; the patient's choice of provider, practitioner, supplier, drug, or insurance plan; or the identity of the referring person or organization (including whether the referring person or organization is a Donor). Financial assistance would be awarded for a specified period of time (up to one year), after which applicants could reapply. A patient would be required to notify Requestor if his or her financial situation changed during the grant period.

Requestor certified that the specified diseases covered by the Disease Funds would be defined in accordance with widely recognized clinical standards, and not by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states. Requestor certified that multiple drugs made or marketed by a number of different manufacturers are available to treat the diseases covered by each of the Disease Funds. Requestor certified that, at a minimum, it would make financial assistance available for all drugs (including generic or bioequivalent drugs) approved by the Food and Drug Administration ("FDA") to treat the diseases covered by the Disease Funds. Requestor would not maintain a disease fund that would provide copayment assistance for only one drug, or the drugs made or marketed by only one manufacturer or its affiliates. Requestor has further certified that no Donor or affiliate of any Donor would directly or indirectly influence the identification or delineation of the diseases covered by the Disease Funds.

Requestor certified that it would not refer patients to, recommend, or arrange for the use of any particular practitioner, provider, supplier, drug, or insurance plan and that patients would have complete freedom of choice in such matters. Requestor would provide the financial assistance directly to the patient's health care provider or supplier whenever possible. However, if the patient's chosen provider or supplier does not accept third-party payment, or if the patient otherwise paid his or her copayment amount out-of-

¹ 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.

pocket, the patient could submit proof to Requestor that he or she incurred the cost, and then Requestor would pay the patient directly.

Requestor would solicit donations from individuals, foundations, and corporations (including pharmaceutical manufacturers). All donations would be in the form of cash or cash equivalents. Donors would be asked to commit to donating to Requestor for a period of time (e.g., three years); however, Donors would be able to discontinue donations to Requestor upon 120 days written notice. Donors could either provide unrestricted donations or earmark their contributions to support either the [disease fund redacted] or the [disease fund redacted]. Donors would not be permitted to earmark contributions for treatment of a specific disease covered by a Disease Fund. Requestor's discretion to use the donations within each Disease Fund would be absolute, independent, and autonomous. Requestor certified that no Donor would be guaranteed that any of its patients, clients, or customers would receive any financial assistance whatsoever from Requestor nor would the amount of financial assistance its patients, clients, or customers receive bear any relationship to the amount of its donations.

Requestor is governed by an independent Board of Directors ("Board"). Requestor certified that no physician, health care provider, 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 Proposed Arrangement. No Donor, or immediate family member, director, officer, employee, or person otherwise affiliated with a Donor, would be eligible to serve on Requestor's Board (including any former director, officer, or employee who maintains an ongoing relationship with a Donor or his or her immediate family member). Requestor certified that it maintains a conflicts of interest policy for its Board to ensure independence in the Board's decision-making. Except for charitable donations made by Donors under the Proposed Arrangement, Requestor does not have any financial relationship with any manufacturer of any drug or product, including, but not limited to, drugs or products subsidized by the Proposed Arrangement. Additionally, Requestor certified that it has no financial relationship with any physician or other health care provider that treats patients eligible to receive assistance from Requestor.

As a courtesy, Requestor may give Donors aggregate data regarding the Disease Funds, but any data provided would be limited to the aggregate numbers of qualifying patients for each Disease Fund or the aggregate amount disbursed from the Disease Fund. Requestor would not provide Donors with any individual patient information or any data related to the identity, amount, or nature of drugs subsidized by the patient assistance program. 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 amount or frequency of the use of its drugs. Requestor certified that patients would not receive any information regarding Donors, and Donors would not receive any information regarding other Donors, except through public disclosures that may be required by law.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully 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. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); 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 offers or transfers remuneration 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 primary aspects of the Proposed Arrangement require scrutiny: 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 patients, including Federal health care program beneficiaries, by contributing to independent, bona fide charitable assistance programs. For the following reasons, in combination, we believe that the Proposed Arrangement entails minimal risk of Donor contributions influencing direct or indirect referrals by Requestor.

First, no Donor, affiliate of any Donor, physician, or health care provider would exert direct or indirect control over Requestor or its program. Requestor is a 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 (including any former director, officer, or employee who maintains an ongoing relationship with a Donor or his or her immediate family member), would be eligible to serve on Requestor's Board. Additionally, Requestor certified that it has no financial relationship with any physician or other health care provider that treats patients eligible to receive assistance from Requestor.

Second, before applying for assistance, each patient already would have selected his or her health care providers, practitioners, or suppliers, and already would have a treatment regimen in place. All patients would remain free, while receiving Requestor's assistance, to change their health care providers, practitioners, suppliers, drugs or insurance plan. Requestor would not refer patients to, recommend, or arrange for the use of any particular practitioner, provider, supplier, drug, or insurance plan.

Third, Requestor would not provide Donors with any data that would facilitate a Donor in correlating the amount or frequency of its donations with the amount or frequency of the use of its drugs 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 drugs or services subsidized under the Proposed Arrangement. Some aggregated data may be provided to Donors as a courtesy, but this would be limited to aggregate numbers of qualifying patients for each Disease Fund or the aggregate amount disbursed from each Disease Fund. Patients would not receive any information regarding Donors, and Donors would not receive any information regarding other Donors, except through public disclosures that may be required by law. 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 both of the Disease Funds generally should not, on the facts presented, significantly 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 (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) would influence directly or indirectly the identification or delineation of the diseases covered by its two Disease Funds. Requestor further certified that diseases covered by its Disease Funds: (i) would be defined in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available drugs; and (ii) would not be defined by reference to specific symptoms, severity of symptoms, the method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states. Moreover, Requestor would, at a minimum, make assistance available for all drugs approved by the FDA for treatment of each disease covered by a Disease Fund, including generic or bioequivalent drugs, and several different drugs made or marketed by various manufacturers are currently available to treat each specified disease. Donors would be permitted to earmark contributions only for a particular Disease Fund, but not with any greater specificity (e.g., not for patients requiring certain treatments or for a specified disease covered by one of the Disease Funds). 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 pharmaceutical manufacturer Donor to induce patients to use its drugs.

In sum, Requestor is a charity dedicated to helping patients with their out-of-pocket costs for outpatient prescription drugs used to treat certain diseases. 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, or influenced by, 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 Requestor to arrange for referrals.²

² 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) and the OIG's May 2014 Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs (79 Fed. Reg. 31120; May 30, 2014), in which the OIG made it clear that, in the circumstances described in the

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

In the circumstances presented by the Proposed Arrangement, Requestor's proposed provision of financial assistance with out-of-pocket costs for certain eligible, financially needy patients, including Federal health care program beneficiaries, presents a low risk of fraud and abuse and is not likely to influence any beneficiary's selection of a particular provider, practitioner, or supplier for items or services for which payment may be made in whole or in part by Medicare or a State health care program. We reach this conclusion based on the following factors.

First, Requestor's determination of a patient'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, drugs, or insurance plans; the identity of any referring party; or the identity of any Donor that may have contributed to one of Requestor's Disease Funds or the amount of the donation. In addition, Requestor would provide assistance based on a reasonable, verifiable, and uniform measure of financial need that would be applied in a consistent manner, and would employ a process for screening all applicants for compliance with the fund's designated financial eligibility criteria prior to enrolling applicants in the fund or within a reasonable time thereafter.

Second, 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. As explained above, all patients already would have selected a provider, practitioner, or supplier, would have a treatment regimen in place at the time of application, and would remain free to change their provider, practitioner, supplier, drug, or insurance plan. Eligibility determinations would not be based, in whole or in part, on whether a patient's provider, practitioner, or supplier has made contributions to the Proposed Arrangement. Requestor would not refer patients to, recommend, or arrange for the use of any particular practitioner, provider, or supplier. Patients would not be informed of the identity of Donors.

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) although the Proposed Arrangement could potentially generate prohibited

bulletins, cost-sharing subsidies provided by bona fide, independent charities should not raise anti-kickback concerns, even if the charities receive charitable contributions from donors whose products are supported by the cost-sharing subsidies.

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 by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- 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 (or that provision's application to the Medicaid program at section 1903(s) 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General