



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: May 28, 2015

Posted: June 4, 2015

[Name and address redacted]

Re: OIG Advisory Opinion No. 15-06

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 financial assistance to individuals with chronic diseases, including cancer, to assist with the costs of health insurance and drug and device therapies (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 entity that proposes to establish a patient assistance program to provide financial assistance to individuals with cost-sharing obligations for prescription drugs or devices, health insurance premiums, incidental expenses (e.g., travel expenses, ongoing testing), or a combination thereof, associated with the treatment of various chronic diseases.

Patients would learn about the Proposed Arrangement through a variety of sources including their treating physicians, dispensing pharmacies (including specialty pharmacies), durable medical equipment distributors, patient support groups, and product manufacturers. 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, drug or device therapies, or insurance plans.

Requestor would establish multiple disease funds under the Proposed Arrangement. For each disease fund, Requestor would assess a patient’s eligibility for financial assistance based on the Federal poverty guidelines. Each fund’s eligibility criteria would be uniformly applied to all applicants; financial assistance would be awarded on a first-come, first-served basis to any financially qualified patient, to the extent funding is available. 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 any Donors,¹ including the amount of contributions made by any Donor whose drugs or devices may be used by the patient; the patient's choice of provider, practitioner, supplier, drug, device, or plan; or the identity of the referring person or entity (including whether the referring person or entity is a Donor). Requestor may establish disease funds that provide financial assistance exclusively to patients covered under Medicare, Medicaid, or other Federal health care programs, as defined by 42 U.S.C. § 1320a-7b(f). Any such funds would be subject to all of the same safeguards as other disease funds described herein.

Financial assistance initially would be awarded through the end of the calendar year. To continue receiving assistance in subsequent years, a patient would need to reapply and would be subject to an eligibility re-determination. Patients would be required to notify Requestor if their financial situations changed during the financial assistance period. Requestor intends to subcontract out the benefits verification² function to an unaffiliated vendor. Requestor certified that no personnel or agents of such vendor would determine (or assist in determining) the structure of any disease fund or the criteria used to determine eligibility for assistance for a particular fund. Further, personnel and agents of the vendor would be prohibited from bringing any proposals for disease funds or eligibility criteria to Requestor's Board of Directors for review and from soliciting donations for or on behalf of Requestor. In the event the vendor is a pharmacy, the pharmacy would be permitted to dispense drugs to program enrollees, but Requestor would not prefer such pharmacy or refer enrollees to it. The vendor would be contractually prohibited from using any patient information that Requestor would provide to the vendor for any purpose other than benefits verification, including contacting the patient directly or, if the vendor is a pharmacy, promoting its pharmacy services. The vendor also would be contractually required to comply with all applicable laws, including the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the regulations thereunder. The vendor would be required to enter into an agreement similar to the HIPAA-compliant Business Associate Agreement with Requestor, which would require the vendor to limit use and disclosure 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.

² The vendor would verify a patient's applicable deductibles, co-payments, or co-insurance and, for a Medicare Part D beneficiary, the beneficiary's maximum coverage gap liability associated with a given drug therapy. Requestor certified that its arrangement with the vendor would be set forth in writing and that compensation would be fair market value. We are not authorized to opine on whether fair market value shall be, or was, paid for any goods, services, or property. See section 1128D(b)(3) of the Act.

patient information to the minimum necessary to perform the benefits verification services for Requestor.

Requestor certified that, except as specifically provided in this paragraph, disease funds would be established for broadly defined disease states based on widely recognized clinical standards, without reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug or device treatment, or any other way of narrowing the definition of widely recognized disease states. Requestor would make copayment assistance³ available for all drugs (including generic or bioequivalent drugs) and devices (if applicable for a particular fund) that are covered by Medicare or the patient's primary insurer for treatment of the disease that is the subject of the fund. Requestor may develop disease funds that would be limited to the metastatic stage of certain types of cancer. In those disease funds, Requestor would cover, at a minimum, all drugs that are approved by the U.S. Food and Drug Administration ("FDA") for the type of cancer (not limited to drugs expressly approved for the metastatic stage of the cancer).

Requestor certified that it would not maintain any disease fund that provides copayment assistance for only one drug or device, or only the drugs or devices made or marketed by one manufacturer or its affiliates. If Requestor sponsors a fund for a disease for which the FDA has approved only one drug, or there is only one device available to treat the disease (or there are only drugs or devices made or marketed by one manufacturer or its affiliates), Requestor would provide support for other medical needs of patients with the disease, in addition to copayment support for the FDA-approved treatment of the disease. At a minimum, Requestor would provide copayment support for all drugs used by a patient for an FDA-approved indication relating to managing the disease, including, but not limited to, drugs to treat symptoms of the disease, such as pain medications, and drugs to treat side effects of treatments, such as anti-nausea medications. Requestor further certified that no Donor or affiliate of any Donor would directly or indirectly influence the identification or delineation of a disease fund.

Requestor certified that it would not refer patients to, recommend, or arrange for the use of any particular practitioner, provider, supplier, drug, device, or plan and that patients would have complete freedom of choice in such matters. Requestor would give each patient a benefit card to use at the patient's preferred pharmacy or durable medical equipment distributor, if the patient is receiving assistance for a drug or device that is self-administered. If a patient is receiving assistance for a drug or device that is physician-administered, Requestor would provide the financial assistance directly to the patient's

³ Although Requestor intends to provide assistance for patients' insurance premiums, incidental expenses, or both, in addition to copayment assistance in some disease funds, all disease funds would include copayment assistance.

physician or hospital, whenever possible. However, if the patient's chosen provider or supplier does not accept third party payment or the benefit card, the patient could submit proof to Requestor that he or she incurred the cost, and then Requestor would make the payment directly to the patient. Requestor intends to subcontract with an unaffiliated claims processing vendor or pharmacy benefits manager to: adjudicate claims electronically; pay dispensing pharmacies, durable medical equipment distributors and administering physicians; and process and pay enrollees for claims submitted directly by enrollees, if their physicians, pharmacies, or durable medical equipment distributors do not accept third party payment.

Requestor would solicit donations from a variety of sources, including pharmaceutical and device companies, specialty pharmacies, distributors, individuals, and corporations. 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, subject to prior written notice to Requestor, as specified in the written donation agreement between Requestor and the Donor. Donors may earmark their contributions to a specific disease fund, but the donations would otherwise be unrestricted. Requestor's discretion to use the donations would be absolute, independent, and autonomous.

Requestor would be governed by an independent Board of Directors (the "Board"). No Donor, or affiliate of a Donor, would exert any direct or indirect influence over Requestor or Requestor's patient assistance program. No Donor, or immediate family member, director, officer, employee, or person otherwise affiliated with a Donor would be eligible to serve on the Board. Requestor further certified that no former director, officer or employee of a Donor who maintains an ongoing relationship with the Donor (via consulting or otherwise), or immediate family members of such former director, officer, or employee of a Donor would be eligible to serve on the Board. In addition, no Board member or senior manager would be a director, officer, or employee of or the immediate family member of a director, officer, or employee of the unaffiliated third party vendor performing benefits verification for Requestor or the unaffiliated third party claims-processing vendor. Notwithstanding the foregoing, an individual who owns a de minimis number of shares of publicly traded stock of a Donor or its affiliates, and has disclosed such ownership to Requestor, or who owns an indirect interest in a Donor or its affiliates by way of ownership of publicly traded stock through a broadly diversified mutual fund, may serve on the Board. Requestor may require recusal of a Board member from consideration of any matter involving an entity in which a Board member has any ownership interest, in accordance with Requestor's conflict of interest policy. Requestor's conflict of interest policy would require Board members to disclose potential conflicts of interest annually in writing, and orally throughout the year if any new potential conflict of interest arises, and would have a process for resolving any potential conflicts of interest.

Requestor would inform Donors of the aggregate number of applicants for assistance, the aggregate number of applicants qualifying for assistance, the amount of assistance distributed, and projections for additional funding needs related solely to disease funds to which the Donors contributed. Requestor would not provide Donors with any individual patient information or any data related to the identity, amount, or nature of drugs, devices, or services 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 number or medical condition of patients who use its products or services or the volume of those products or services. Requestor would not inform applicants of the identities of Donors or when a particular manufacturer donates to Requestor. Finally, patients would not receive any information about 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 to the extent required by the Internal Revenue Service ("IRS").

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: the Donor contributions to Requestor and Requestor's assistance to patients. We address them in turn.

1. Donor Contributions to Requestor

Longstanding OIG guidance makes clear that industry stakeholders can contribute effectively 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 combination of the following reasons, we believe that the Proposed Arrangement entails minimal risk of Donor contributions influencing direct or indirect referrals by Requestor.

First, no Donor or affiliate of any Donor would exert direct or indirect control over Requestor or its patient assistance 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 (including former directors, officers, or employees who maintain ongoing relationships with Donors or their immediate family members), would be eligible to serve on Requestor's Board.

Second, before applying for assistance, each patient already would have selected his or her health care provider, practitioner, or supplier, and already would have a treatment regimen in place. All patients would remain free, while receiving Requestor's assistance, to change their physicians, pharmacies, treatment regimens, and health insurance. Requestor would not refer patients to, recommend, or arrange for the use of any particular practitioner, provider, supplier, drug, device, or 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, devices, 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, devices, or services subsidized under the Proposed Arrangement. Some aggregated data

may be provided to Donors as a courtesy, but such data would be limited to the aggregate number of applicants for assistance, the aggregate number of applicants qualifying for assistance, the amount of assistance distributed, and projections for additional funding needs related solely to disease funds to which the Donors contributed. 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 would permit Donors to earmark donations to particular 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 directly or indirectly influence the identification or delineation of disease funds. Further limiting the risk that Donors could direct funds to their own products, Requestor certified that: (i) it would define its disease funds in accordance with broadly defined disease states based on widely recognized clinical standards; and (ii) except to the extent that Requestor limits certain disease funds to the metastatic stage of certain cancers, its disease funds 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 or device treatment, or any other way of narrowing the definition of widely recognized disease states. Moreover, Requestor would make assistance available for all drugs, including generic or bioequivalent drugs, and devices (if applicable to the disease fund) that are covered by Medicare or the patient's primary insurer for treatment of the disease that is the subject of the fund, and certain disease funds might also include assistance with insurance premiums and incidental expenses. Requestor would not maintain any disease fund that provides financial assistance for only one drug or device, or only the drugs or devices made or marketed by one manufacturer or its affiliates. In the case of funds limited to patients who have metastatic cancer, Requestor would cover, at a minimum, all drugs that are approved by the FDA for the type of cancer (not limited to drugs expressly approved for the metastatic stage of the cancer). Donors would be permitted to earmark contributions to a particular disease fund, but not with any greater specificity (e.g., not for patients requiring certain treatments). For the combination of the reasons set forth in this paragraph, 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 drugs or devices.

In sum, Requestor is a 501(c)(3) charitable entity that must use its donated funds in a manner that maximizes its charitable mission. Requestor's design and administration of the Proposed Arrangement as described herein would provide sufficient insulation so that

Requestor's assistance to patients should not be attributed to, or influenced by, any of its Donors. In these circumstances, for the combination of reasons described above, we do not believe that the contributions Donors would make to Requestor can reasonably be construed as payments to Requestor to arrange for referrals.⁴

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 copayment obligations, and in some disease funds, with insurance premiums and incidental expenses, 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, supplier, product, or service. We reach this conclusion based on the following factors.

First, Requestor's determination of a patient's qualification for financial 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 devices; the identity of any referring party; or the identity of any Donor that may have contributed for the support of the patient's 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.

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, and have a treatment regimen in place at the time they apply for assistance, and would remain free to

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) 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 Bulletin, 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. In addition, as we also explain in the May 2014 Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs, we do not believe the mere fact that a disease fund may serve only Federal health care program beneficiaries would increase risk to the Federal health care programs. 79 Fed. Reg. at 31122.

change their provider, practitioner, supplier, drug or device therapy, or insurance plan. Eligibility determinations would be made in a consistent, uniform manner and would not be based, in whole or in part, on whether a patient's provider, practitioner, or supplier has made contributions to Requestor's patient assistance program. Requestor would not refer patients to, recommend, or arrange for the use of any particular practitioner, provider, supplier, drug, device, or plan. 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 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General