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. 15-17

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a non-profit, tax-exempt, charitable organization's proposal to provide financial assistance with copayment obligations, health insurance premiums, and insurance deductibles to patients, including Medicare and Medicaid beneficiaries, receiving treatment for [disease state redacted] (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 non-profit, tax-exempt, charitable organization dedicated to reducing the onset of [disease stated redacted] (the "Specified Disease"), improving outcomes for patients with the Specified Disease, and offering support to patients with the Specified Disease and their families. Under the Proposed Arrangement, Requestor would establish and administer a program to help financially needy patients with their copayment[1] obligations, health insurance premiums, and deductibles for outpatient prescription drugs used to treat the Specified Disease.

Patients would learn about the Proposed Arrangement through a variety of sources, including their treating physicians, Requestor's outreach via its website and social media, and written materials distributed by Requestor for placement in physicians' offices. Before applying for financial assistance, a patient must have selected his health care provider, practitioner, or supplier, and must have a treatment regimen in place. While receiving Requestor's assistance, patients would remain free to change their providers, practitioners, suppliers, drugs, and insurance plans.

Requestor would assess a patient's eligibility for financial assistance based on the Federal poverty guidelines. 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 the fund's designated financial eligibility criteria prior to enrolling applicants in the fund or within a reasonable time thereafter. Such screening process would be applied uniformly across the fund and would involve: verifying an applicant's financial

[1] For purposes of this advisory opinion, we use the term "copayment" to refer to copayments of set amounts and percentage-based coinsurance amounts.

resources through information provided by a third party service, collecting documentation of financial need from the applicant, or some combination thereof. Based on a showing of financial need, assistance would be awarded on a first-come, first-served basis, to the extent funding is available. Requestor certified that it would not make eligibility determinations based in whole or in part on: the interest of any person or entity who contributes to Requestor's support program ("Donor") or affiliate(s) of Donors,[2] including the amount of contributions made by any Donor whose drugs 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 entity (including whether the referring person or entity is a Donor).

If a patient meets the eligibility criteria, he would receive financial assistance under the Proposed Arrangement for an initial term of one year. To continue receiving financial assistance for a subsequent one-year period, Requestor would re-verify a patient's financial need and the patient would be required to submit documentation from his physician that he continues to need treatment for the Specified Disease. A patient would be required to notify Requestor if his financial circumstances changed during the financial assistance period.

For the Proposed Arrangement, Requestor would maintain only one disease fund. Such fund would be limited to patients diagnosed with Stage 3 or Stage 4 of the Specified Disease. Requestor certified that, except as specifically provided in this paragraph, the Specified Disease fund would be established for a broadly defined disease state based on widely recognized clinical standards, without reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of the Specified Disease, type of drug treatment, or any other way of narrowing the definition of the widely recognized underlying disease state. Requestor certified that no Donor or affiliate of any Donor directly or indirectly influenced the identification or delineation of the proposed Specified Disease fund.

According to Requestor, multiple drugs made or marketed by a number of different pharmaceutical manufacturers are available for treatment of both of the stages of the Specified Disease covered under the Proposed Arrangement. Requestor would not limit its assistance to high-cost or specialty drugs. Requestor certified that it would make financial assistance available for all drugs (including generic or bioequivalent drugs) approved by the Food and Drug Administration to treat the Specified Disease, and would not limit financial assistance to drugs expressly approved for advanced stages of the Specified Disease. Requestor would not maintain a disease fund that would provide

[2] 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.

financial assistance for only one drug, or only the drugs made or marketed by one manufacturer or its affiliates.

Requestor certified that it would not refer patients to, recommend, or arrange for the use of any particular provider, practitioner, supplier, drug, or insurance plan and that patients would have complete freedom of choice in such matters. Requestor would disburse the financial assistance directly to the patient's pharmacy, physician, third-party payor, physician practice, or hospital, as applicable. If the individual or entity does not accept third-party payment, or if the patient otherwise paid his copayment obligation, health insurance premium, or deductible out of pocket, the patient could submit proof to Requestor that he incurred the cost and Requestor would pay the patient directly.

Charitable contributions to the patient assistance program would come, in large part, from Donors that are pharmaceutical manufacturers. All donations would be in the form of cash or cash equivalents. A Donor would be able to change or discontinue its contributions to Requestor at any time, as specified in the written donation agreement between Requestor and the Donor. Requestor would not permit Donors to earmark their donations to support any particular drug or type of cost-sharing obligation. Requestor's discretion to use the donations would be absolute, independent, and autonomous.

Requestor is governed by an independent Board of Directors ("Board"). No Donor, or affiliate of a Donor, exerts any direct or indirect influence over Requestor or would exert any direct or indirect influence over the Proposed Arrangement. No person who is a Donor, or immediate family member, director, officer, employee, or person otherwise affiliated with a Donor, currently serves on or 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 member of such former director, officer, or employee of a Donor, currently serves on or would be eligible to serve on the Board. Requestor maintains a conflict of interest policy to ensure independence in the Board's decision-making.

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. Instead, Requestor would provide Donors with the aggregate number of applicants, the aggregate number of patients served, and the total amount of funds used for financial assistance under the Proposed Arrangement. Requestor's reports to Donors would not contain any data 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 under the Proposed Arrangement. Requestor certified that patients would not receive any information about 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 aspects of the Proposed Arrangement require scrutiny: the Donors' contributions to Requestor and Requestor's assistance to patients. We address them in turn.

1. Donors' Contributions to Requestor

Long-standing 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 Donors' contributions influencing direct or indirect referrals by Requestor.

First, no Donor or affiliate of any Donor exerts direct or indirect control over Requestor, and would not exert direct or indirect control over its patient assistance program. Requestor is a non-profit, tax-exempt, charitable organization that operates with absolute, independent, and autonomous discretion as to the use of Donors' contributions. No Donor, or immediate family member, director, officer, employee, or person otherwise affiliated with a Donor (including any former director, officer, or employee who maintains an ongoing relationship with a Donor or his or her immediate family members), currently serves on, or would be eligible to serve on, the Board.

Second, before applying for assistance, a patient already would have selected his health care provider, practitioner, or supplier, and already would have a treatment regimen in place. Patients would remain free, while receiving Requestor's assistance, to change their health care providers, practitioners, suppliers, drugs, and insurance plans. 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. No individual patient information would be conveyed to any Donor. Further, Requestor would not provide Donors with any data related to the identity, amount, or nature of drugs 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 financial assistance, the aggregate number of patients served, and the total amount of funds used for financial assistance under the Proposed Arrangement. 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, 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)) directly or

indirectly influenced the identification or delineation of the proposed Specified Disease fund. To mitigate the risk that Donors could direct funds to their own drugs, Requestor further certified that: (1) it would establish the Specified Disease fund for a broadly defined disease state based on widely recognized clinical standards and in a manner that would cover a broad spectrum of available drugs; and (2) except to the extent Requestor would limit the grant funds to patients in Stage 3 or Stage 4 of the Specified Disease, the Specified Disease fund would not be defined by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of the Specified Disease, type of drug treatment, or any other way of narrowing the definition of the widely recognized underlying disease state. Moreover, Requestor would make financial assistance available for all drugs, including generic or bioequivalent drugs, approved by the Food and Drug Administration to treat the Specified Disease (and would not limit financial assistance to drugs expressly approved for advanced stages of the Specified Disease).[3] Requestor would not maintain a disease fund that would provide financial assistance for only one drug, or only the drugs made or marketed by one manufacturer or its affiliates. Requestor would not permit Donors to earmark their donations to support any particular drug or type of cost-sharing obligation. For the combination of reasons described above, it is unlikely that the Proposed Arrangement would serve as a disguised conduit for financial assistance from a pharmaceutical manufacturer Donor to induce patients to use its drugs.

In sum, Requestor is a 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 could reasonably be construed as payments to Requestor to arrange for referrals.[4]

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[3] We note that some charities implement systems that require a minimum claim amount, in part to avoid the administrative burdens of reimbursing numerous claims for small amounts of money. Such a system would be consistent with Requestor's certification that it would offer financial assistance for all drugs approved by the Food and Drug Administration to treat the Specified Disease, so long as it does not have the effect of denying reimbursement for lower copayments while paying higher copayments in full. For example, a charity may require a recipient of assistance to accumulate receipts for claims up to a certain threshold (e.g., $50) and then submit them together for reimbursement. A charity may also require a recipient to pay a certain amount of the cost-sharing on all claims (e.g., the first $20 on any claim). However, any system that would result in patients paying more for an inexpensive drug than they would for a high-cost drug would be inconsistent with Requestor's certification that it would not limit its assistance to high-cost drugs.

[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; Nov.

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

In the circumstances presented by the Proposed Arrangement, Requestor's proposed provision of financial assistance with copayment obligations, health insurance premiums, and deductibles for certain eligible, financially needy patients, including Federal and State 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 financial need, without considering the identity of any of his health care providers, practitioners, suppliers, drugs, or insurance plan; the identity of any referring party; or the identity of any Donor that may have contributed to the Specified Disease fund or the amount of the donation. In addition, Requestor would determine eligibility 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 and would have a treatment regimen in place at the time of applying for assistance, and they would remain free to change their providers, practitioners, suppliers, drugs, and insurance plans. Eligibility determinations would not be based, in whole or in part, on whether a patient's provider, practitioner, or supplier has made contributions to Requestor's support program. Requestor would not refer patients to, recommend, or arrange for the use of any particular practitioner, provider, supplier, drug, or insurance plan. Patients would not be informed of the identity of Donors.

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 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.

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 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 that is part of the Proposed Arrangement 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