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 29, 2014

Posted: January 5, 2015

[Name and address redacted]

Re: OIG Advisory Opinion No. 14-11

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 copayment[1] obligations to financially needy patients, including Medicare and Medicaid beneficiaries, diagnosed with Crohn's disease or ulcerative colitis (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.

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

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 501(c)(3) charitable foundation dedicated to finding cures for, and improving the quality of life of individuals affected by, Crohn's disease and ulcerative colitis (the "Specified Diseases"). Requestor proposes to establish a patient assistance program to provide copayment assistance to patients with a demonstrated financial need for such assistance. Requestor intends to work with another 501(c)(3) charitable organization (the "Administrator") to administer the Proposed Arrangement.[2]

Patients would learn about the Proposed Arrangement through a variety of sources, including their existing relationships with Requestor or the Administrator, physicians, health care entities, and patient support groups. 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.

[2] Requestor certified that any role played by the Administrator in the Proposed Arrangement would be performed in accordance with all of Requestor's certifications herein.

Requestor would assess a patient'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 patient diagnosed with one of the Specified Diseases, to the extent funding is available. Requestor would use a preset sliding scale, which could result in financial assistance that would partially or fully subsidize the patient's copayment 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,[3] 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 is a Donor). Financial assistance would be awarded for a specified period of time (up to one year), after which patients could reapply. Patients would be required to notify Requestor if their financial situation changed during the grant period.

Consistent with its mission, Requestor would maintain two disease funds—one for each Specified Disease. Requestor certified that the Specified Diseases are 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 each Specified Disease, and Requestor would make assistance available for all drugs (including generic or bioequivalent drugs) covered by the patient's primary insurance when prescribed for the treatment of a Specified Disease; 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 directly or indirectly influenced the identification or delineation of the Specified Diseases.

Requestor certified that it would not refer patients to, recommend, or arrange for the use of any particular practitioner, provider, supplier, drug, or plan and that patients would have complete freedom of choice in such matters. Requestor would provide the financial assistance directly to the patient's pharmacy, or other health care provider or supplier whenever possible. However, if the patient's chosen provider or supplier does not accept

[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.

third party payment, or if the patient otherwise paid his or her copayment amount out-of-pocket, 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.[4]

Requestor would solicit donations from its regular donor sources, which include 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 either provide unrestricted donations or earmark their contributions for the support of patients with a particular Specified Disease; Requestor's discretion to use the donations would be absolute, independent, and autonomous.

Requestor 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 member, director, officer, employee, or person otherwise affiliated with a Donor, would be eligible to serve on Requestor's Board. Requestor certified that it maintains a conflicts of interest policy for its Board to ensure independence in the Board's decision-making.

As a courtesy, Requestor may give Donors aggregate data, such as the number of claims submitted or the average amount of patient grants, but any data provided would be limited to aggregate numbers of qualifying patients for each fund or the aggregate amount disbursed from the 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 or services. Requestor certified that 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 to the extent required by the Internal Revenue Service ("IRS").

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[4] Requestor intends to have a minimum out-of-pocket threshold for claims, which would not exceed $50 per claim. If an individual copayment amount fell below the threshold, patients would be permitted to aggregate claims and submit them to Requestor as a single claim. According to Requestor, having a threshold amount gives Requestor the ability to effectively manage all claims from an administrative point of view (by avoiding the burden of numerous claims for small amounts of money) while still allowing patients to obtain assistance for copayments associated with any and all drugs for the Specified Diseases at whatever cost.

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

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 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, 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 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 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 the aggregate amount disbursed from each fund. 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 each Specified Disease 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)) directly or indirectly influenced the identification of the Specified Diseases. Requestor further certified that:

(i) it defined its Specified Diseases in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available drugs; and (ii) its Specified Diseases are not 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 make assistance available for all drugs, including generic or bioequivalent drugs, covered by the patient's primary insurance for treatment of the Specified Disease covered by the fund, 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 Specified Disease, but not with any greater specificity (e.g., not for patients requiring certain treatments). 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 drugs.

In sum, Requestor is an existing charity, dedicated to finding cures for, and improving the quality of life of individuals affected by, the Specified Diseases that is now seeking to expand its charitable work to help patients with their copayment costs. 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 Requestor to arrange for referrals.[5]

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 for certain eligible, financially needy patients, including Federal health care program beneficiaries, presents a low risk of

[5] 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 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.

fraud and abuse and is not likely to influence any beneficiary's selection of a particular provider, practitioner, or supplier. 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, or drugs; the identity of any referring party; or the identity of any Donor that may have contributed for the support of the patient'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.

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 of application, and would remain free to change provider, practitioner, or supplier. 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, 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) 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General