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: November 25, 2013

Posted: December 2, 2013

[Name and address redacted]

Re: OIG Advisory Opinion No. 13-19

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding patient assistance programs that provide funding for premium assistance and certain other medical expenses to [disease redacted] patients in financial need (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes 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 Arrangement does not constitute grounds for the

imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the 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") will 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 Arrangement. This opinion is limited to the 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

[Disease redacted] is a rare, genetic disorder that causes an enzyme deficiency with a variable disease course, ranging from no outward symptoms to severe disability and death. It is incurable, but treatments are available for some variants of the disease.

[Name redacted] (the "Foundation") is a non-profit, tax-exempt charitable organization that serves the [disease redacted] community by, among other things, providing funding for research into the cause, treatment, and cure for [disease redacted]. [Name redacted] (the "Requestor") is a supporting organization[1] of the Foundation. The Requestor operates patient assistance programs for patients with [disease redacted].

The Requestor provides financial assistance to [disease redacted] patients through two programs: (1) [program redacted], which helps [disease redacted] patients pay insurance premiums for themselves and their families[2] (the "Premium Assistance Program"), and (2) [program redacted], which covers the cost of certain items and services not covered by insurance that are necessary for [disease redacted] patients to receive needed care (the "Basic Services Program") (collectively, the "Programs"). The Premium Assistance Program provides funding for primary and/or secondary insurance premiums, which may include medical, dental, and vision premiums, Medicare Part B premiums, Medicare Part D premiums, and premiums related to catastrophic policies. The Basic Services Program covers travel expenses to and from a physician office or a hospital for [drug treatment

[1] Specifically, the Requestor is a Type I supporting organization under section 509(a)(3) of the Internal Revenue Code.

[2] The Requestor certified that family members are eligible for funding because the families of [disease redacted] patients also bear a financial burden due to the disease.

redacted] ("Therapy") up to $100 per month; over-the-counter medications prescribed for [disease redacted] up to $100 per month; travel expenses for one [disease redacted] evaluation per year; alternative therapy charges (such as massage therapy, acupuncture, or yoga) that are not covered by insurance and are prescribed for [disease redacted] up to $500 per month; and infusion charges for Therapy for uninsured patients up to $1,000 per month. Insurance copayments, deductibles, and coinsurance are not eligible expenses under either of the Programs.

Both the Foundation and the Requestor are led by the same board of directors and corporate officers (the "Board of Directors") and have similar articles of incorporation and bylaws. With the exception of the Chief Executive Officer (the "CEO"), who receives a salary from the Foundation, members of the Board of Directors are not compensated for their role in the Foundation or the Requestor.[3] The Requestor also has an advisory group (the "Advisory Group"), consisting of three voting members, who determine patient eligibility to participate in the Programs, and one facilitator (the "Facilitator"), who processes the patient applications. Two of the voting members of the Advisory Group review applications for financial eligibility, and the other voting member, who is a physician, reviews the applications with respect to the diagnosis of [disease redacted]. The Advisory Group meets eight times a year, and the Requestor compensates the voting members $800 per meeting; the Facilitator is a full-time employee of the Requestor and receives a salary. The Facilitator's salary and the Advisory Group members' compensation come from the Requestor's general funds. Such compensation does not vary with, and is in no way influenced by, the grant or denial of funds to any particular applicant to the Programs.[4] No donor or immediate family member, director, officer, or employee of a donor, or persons otherwise affiliated with donors (other than in a capacity as a [disease redacted] patient or as the family member of a [disease redacted] patient), serve on the Board of Directors or the Advisory Group. No member or immediate family member of the Board of Directors or the Advisory Group has a financial relationship with any donor.

The Requestor operates the Programs as follows. All prospective participants complete an application. The Requestor processes applications in order of receipt, on a first-come, first-served basis, to the extent funding is available. The Requestor has established objective criteria for determining eligibility for assistance that are based

[3] The members of the Board of Directors are entitled to receive reimbursement for travel expenses incurred in attending meetings, but most meetings occur through teleconferencing and/or in [state redacted], where all current members are located.

[4] Similarly, any reimbursement by the Foundation or the Requestor to cover expenses that members of the Board of Directors may incur comes from the companies' general funds and has no relationship to how the Requestor awards funds under the Programs.

upon the applicant's diagnosis of [disease redacted] and financial need. The financial need criteria are based on national standards of indigence. In addition, all patients eligible for the Premium Assistance Program must have access to insurance, and all patients eligible for the Basic Services Program must have at least one eligible expense. Assistance generally is provided for the calendar year, depending on the Requestor's financial resources. Participants are required to notify the Requestor if their financial circumstances change during that time.

Potential applicants learn about the Requestor from a variety of sources, including physicians, health care providers, pharmaceutical manufacturers, the Foundation, and others. The Advisory Group assesses patient applications without regard to: (i) the interests of any donor or any donor affiliates; (ii) the applicant's choice of product, provider, practitioner, supplier, or insurance company; (iii) the identity of the referring person or organization, including whether the referring entity is a donor; or (iv) the amount of contributions made by any donor whose services or products are used or may be used by the patient.

The Requestor has certified that it does not refer applicants to, recommend, or arrange for the use of any particular product, practitioner, provider, supplier, or insurance company. Patients have complete freedom of choice regarding their products, practitioners, providers, suppliers, insurance companies, and treatment regimens.

The Requestor receives some funding from individual donors, corporations, and foundations, but its main source of funding comes from the Foundation. All of the funds coming through the Foundation to the Requestor are donations that have been earmarked for either the Premium Assistance Program or the Basic Services Program from pharmaceutical manufacturers that produce drugs to treat [disease redacted]; no additional restrictions are placed on the funds. Neither the Foundation nor the Requestor receives non-cash donations. The Requestor has absolute, independent, and autonomous discretion as to the use of contributions for the Programs. 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)) exerts any direct or indirect influence or control over the Foundation, the Requestor, or the Programs, including the selection of [disease redacted] as the Programs' focus or the selection of eligible expenses for which the Programs provide assistance.[5]

No individual patient information, nor information related to the identity, amount or nature of items or services subsidized under the Programs, is provided to donors.

[5] Donors may provide the Requestor or the Foundation with educational materials that the donors generally make available to practitioners or the general public (e.g., clinical information about drug products).

Aggregate information is provided to donors upon request, but the data includes information for patients on all drug treatments, as well as for those patients who are not on any drug treatment. Any data provided is limited to aggregate numbers of applicants and aggregate numbers of qualifying applicants in the Programs and, as a result, does not contain any information that enables a donor to correlate the amount or frequency of its donations with the number of patients who use its products or services, or the volume of those products.

Drug treatments for [disease redacted] include multiple products from more than one manufacturer. All of these products have been designated and approved as orphan drugs as related to [disease redacted] due to the disease's low incidence. The Requestor certified that patients need not receive or seek any particular treatment or any treatment at all to receive funds under the Programs. Although some of the eligible expenses under the Basic Services Program are related to Therapy drug treatments (e.g., travel expenses up to $100 per month to a physician office or a hospital for Therapy), patients can choose any Therapy drug treatment or any other treatment or product by any manufacturer that is currently available or will become available in the future.

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 (the "CMP") 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

Long-standing OIG guidance makes clear that industry stakeholders can contribute to the health care safety net for financially needy patients, including beneficiaries of Federal health care programs, by contributing to independent, bona fide charitable assistance programs. Under a properly structured program, such donations should raise few, if any, concerns about improper beneficiary inducements. To ensure such independence, a charitable assistance program should not exert any direct or indirect influence over its donors, nor should donors have links to the charity that could directly or indirectly influence the operations of the charity or its subsidy programs. Moreover, the charitable assistance program must not function as a conduit for payments or other benefits from donors to patients and must not impermissibly influence beneficiaries' choices. The program must avoid engaging in practices that effectively result in the subsidization of a donor's particular products.

At issue here are independent, charitable assistance programs designed to aid patients with [disease redacted], a rare disease for which only orphan drug treatments are available. Earmarking donations for a rare disease with a relatively limited number of treatments increases the risk that the charity would serve as an improper conduit for donors to provide funds to patients who use their specific products. In this case, however, certain factors decrease this risk. Although [disease redacted] is a rare disease, multiple products from more than one manufacturer are available to treat the disease. Moreover, the Requestor does not provide assistance for insurance copayments, deductibles, and coinsurance under either of the Programs; instead, the Requestor provides grants to patients to pay for insurance premiums and certain expenses not covered by insurance. Patients need not receive or seek any particular treatment or any treatment at all to receive funds under the Programs. By providing grants to pay for insurance premiums and certain expenses not covered by insurance, the Requestor's ability to influence how patients ultimately choose items and services payable by

Federal health care programs is minimized. Once patients have insurance coverage, they are able to select among the providers, practitioners, and suppliers of their choice. In this particular context, grants for payment of insurance premiums expand, rather than limit, beneficiaries' freedom of choice.

In combination with the type of assistance provided under the Arrangement (i.e., assistance for payment of insurance premiums and certain medical expenses not covered by insurance), other features of the Requestor's particular design and administration of the Programs also reduce the risk of improper beneficiary inducements.

First, no donor or affiliate of any donor exerts direct or indirect control over the Requestor. The Requestor is a non-profit, tax-exempt, independent, charitable corporation that has absolute, independent, and autonomous discretion as to the use of donor contributions for the Programs.

Second, the Requestor awards assistance in a truly independent manner that severs any link between donors and beneficiaries. The Requestor makes all financial eligibility determinations using its own objective criteria. Patients are not eligible for assistance unless they meet the Requestor's financial need eligibility criteria. Applications are considered on a first-come, first-served basis, to the extent of available funding. While receiving the Requestor's financial assistance, all patients remain free to change their health care providers, practitioners, suppliers, or products. Patients also remain free to change insurance plans. The Requestor does not refer any patient to any donor or to any provider, practitioner, supplier, product, or plan.

Third, the Requestor awards assistance without regard to any donor's interests and without regard to the patient's choice of product, provider, practitioner, supplier, or insurance plan. When determining patient eligibility for the Programs under the Arrangement, the Requestor does not take into account the identity of any provider, practitioner, supplier of items or services, or drug or other product the patient may use; the identity of any referring person or organization; or the amount of any contributions made by a donor whose services or products are used or may be used by the patient. The Requestor also does not take into account the identity of the insurer or insurance plan selected by the patient.

Fourth, based on the Requestor's certifications, assistance is provided based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.

Fifth, donors are not provided with any data that would facilitate the correlation of the amount or frequency of their donations with the amount or frequency of the use of their products or services. No individual patient information is conveyed to any donor, nor is any data related to the identity, amount, or nature of items or services subsidized under

the Arrangement. Some aggregate data may be provided to donors as a courtesy upon request, but the data provided includes information for all patients, including patients not receiving any treatment. Accordingly, such aggregate data is limited to numbers of applicants and numbers of patients entering and leaving the Programs.

In light of the totality of the facts and circumstance presented, we will not subject the Requestor to administrative sanctions under the CMP in connection with the Arrangement. For the same reasons, we find the Arrangement presents a sufficiently low risk of fraud and abuse under the anti-kickback statute.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement does not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the 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 will 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 Arrangement. This opinion is limited to the 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 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 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 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 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