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 21, 2015

Posted: December 29, 2015

[Name and address redacted]

Re: Notice of Modification of OIG Advisory Opinion No. 11-05

Dear [Name redacted]:

On May 21, 2014, the Office of Inspector General ("OIG") issued a Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs (the "Supplemental Bulletin").[1] The Supplemental Bulletin provides additional guidance on patient assistance programs ("PAPs") operated by independent charities to address certain risks about these programs that have come to our attention in recent years. We sent the Supplemental Bulletin, together with targeted letters, to all independent charities that have received favorable advisory opinions from us to request certain clarifications and modifications to those opinions.

On May 13, 2011, the OIG issued to [name redacted] (the "Charity") OIG Advisory Opinion No. 11-05, a favorable opinion regarding the Charity's operation of a PAP that provided vouchers for free genetic tests to certain eligible individuals, and its then-proposed arrangement to provide financial assistance with cost-sharing obligations for certain genetic tests to financially needy individuals, including but not limited to Medicare and Medicaid beneficiaries. On June 7, 2013, the OIG issued a modification to that opinion to permit the Charity to expand its support program to offer cost-sharing assistance for prescription drugs for cancer treatment to financially needy individuals, through specific disease funds. In accordance with our authority at 42 C.F.R. § 1008.45, we sent the Charity a letter on May

[1] The Supplemental Bulletin is available at: http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf and was subsequently published in the Federal Register at 79 Fed. Reg. 31120 (May 30, 2014).

21, 2014, requesting confirmation that the Charity operates in compliance with our guidance and proposing certifications to address the risks identified in the Supplemental Bulletin.

The Charity has responded to our inquiry with the following three certifications:

(1) Except as specifically provided in this paragraph, the Charity will not define its disease funds 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. The Charity intends to maintain disease funds that would be limited to patients with certain metastatic cancers. In those disease funds, the Charity will cover, at a minimum, all drugs that are approved by the U.S. Food and Drug Administration ("FDA") for treatment of the type of cancer (not limited to drugs expressly approved for the metastatic stage of the cancer).

(2) The Charity will not maintain any disease fund that provides copayment assistance for only one drug, or only the drugs made or marketed by one manufacturer or its affiliates. If the Charity establishes a fund for a disease for which the FDA has approved only one drug or only drugs made or marketed by one manufacturer or its affiliates, the Charity will 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, the Charity will provide copayment support for all prescription medications used by a patient for an FDA-approved indication related to managing the disease that is the subject of the fund, including, but not limited to, prescription medications to treat symptoms of the disease, such as pain medications, and prescription medications to treat side effects of treatments, such as anti-nausea medications.

(3) The Charity will not limit its assistance to high-cost or specialty drugs. Instead, the Charity will make assistance available for, at a minimum, all prescription medications, including generic or bioequivalent drugs, approved by the FDA for treatment of the disease state(s) covered by the fund.[2]

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[2] 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 this certification as 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 the Charity's certification that it would not limit its assistance to high-cost drugs.

In addition, we asked the Charity to certify, and it did certify, that it determines eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner. The Charity employs a process for screening all applicants for compliance with a fund's designated financial eligibility criteria prior to the applicant's receipt of assistance, or within a reasonable period of time after assistance is initiated. Such screening process involves collection of documentation of financial need from each applicant.

In addition to the certifications above related to the Supplemental Bulletin, the Charity proposes to modify its current operations to allow donors and their affiliates to earmark donations to support a particular disease fund, but the donations would otherwise be unrestricted. The same safeguards that apply to donor contributions to the Charity described in OIG Advisory Opinion 11-05, as modified on June 7, 2013, and as further modified herein, would apply to any earmarked contributions. Based on the Charity's certifications, the fact that donors would be permitted to earmark donations for a particular disease fund should not significantly increase the risk of abuse. The Charity certified that its funds meet all of the safeguards laid out in our guidance. In particular, the Charity certified that the disease funds: are broadly defined in accordance with widely accepted clinical standards and in a manner that covers a broad spectrum of products; are not defined for the purpose of limiting the drugs for which the Charity's PAP provides assistance; and assist not only with all drugs that treat the cancer that is the subject of the fund, but also with all drugs that treat particular diseases that affect the patient's cancer treatment, such as diabetes mellitus and hypertension. These features, among others certified to by the Charity, make it 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.

The Charity certified that, except as expressly provided above, all other material facts to which the Charity certified in its submissions in connection with OIG Advisory Opinion No. 11-05 and its modification remain accurate.[3] Accordingly, the Charity's PAP, as further modified herein: (i) would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the PAP could potentially generate prohibited remuneration under the anti-kickback statute if the requisite

[3] The Charity has not sought an opinion on, and we express no opinion regarding, any of the Charity's operations (past or future) that may fall outside of the facts presented to us; any operations that deviate from the express certifications provided in connection with an advisory opinion are not protected by the advisory opinion. However, the OIG will not proceed against the Charity with respect to any action taken in good faith reliance on OIG Advisory Opinion No. 11-05 and its modification up until the date of this modification, as long as the material facts were fully, completely, and accurately presented, and the arrangement in practice comported with that information.

intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on the Charity 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 PAP, as modified previously and herein.

Pursuant to 42 C.F.R. § 1008.45(a), this letter serves as final notice of the OIG's modification of OIG Advisory Opinion No. 11-05. The modification of OIG Advisory Opinion No. 11-05 means that the advisory opinion continues in full force and effect in modified form. See 42 C.F.R. § 1008.45(b)(3).

Sincerely,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General