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 5, 2016

Posted: May 12, 2016

[Name and address redacted]

Re: Notice of Modification of OIG Advisory Opinion No. 10-07, as modified

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 to 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 26, 2010, the OIG issued to [name redacted] (the "Charity") OIG Advisory Opinion No. 10-07, which is a favorable opinion regarding the Charity's then-proposal to operate a PAP to provide cost-sharing assistance for specialty medications to patients who had been diagnosed with one of three specific disease states and to maintain a separate fund for genetic testing costs. On May 19, 2011, the OIG issued a modification to that opinion to permit the Charity to add new disease funds to its PAP, provided that the same safeguards used for developing the original funds were maintained. In that opinion, as modified, we approved certain features that we have since determined are problematic. In accordance

[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).

with our authority at 42 C.F.R. § 1008.45, we sent the Charity a letter on May 21, 2014 that highlighted our areas of concern, explained that certain aspects of the PAP would have to be modified for the Charity to retain its favorable advisory opinion, and proposed certifications to address these points.

The Charity has responded to our request and has addressed our concerns through 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 the metastatic stage of certain types of cancer. In those disease funds, the Charity will cover, at a minimum, all drugs that are approved by the 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 the 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, 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 burden 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

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 enrolling applicants in a fund or within a reasonable time thereafter. Such screening process is applied uniformly across funds, and involves: verifying each applicant's financial resources through information provided by a third party service, collecting documentation of financial need from the applicant, or some combination thereof.

In addition to the certifications above, the Charity proposes the following additional modifications to its current operations:

(1) The Charity intends to establish funds that would serve only Federal health care program beneficiaries. Any such funds would be subject to all of the safeguards applicable to any other disease fund described in Advisory Opinion 10-07, as modified on May 19, 2011, and as further modified herein. As we explained in the Supplemental Bulletin, "[w]e do not believe that the mere fact that a fund serves only Federal health care program beneficiaries increases the risk to the Federal health care programs."

(2) The Charity intends to establish new funds that cover multiple disease states. These funds may include certain disease states for which the FDA has approved only one drug or more than one drug made or marketed by the same manufacturer; collectively, however, the fund would include multiple drugs from multiple manufacturers approved by the FDA to treat the disease states covered by the fund. Specifically, for example, the Charity intends to expand the definition of one of its current disease state funds (which currently covers more than one drug made by more than one manufacturer) to encompass a second disease state that has only two drugs made or marketed by one manufacturer that are indicated to treat the second disease state. The Charity would make assistance available for, at a minimum, all prescription medications, including generic or bioequivalent drugs, approved by the FDA for treatment of the disease states covered by the fund, and all of the same safeguards applicable to other funds would apply to these funds. In particular, donors would be permitted to earmark their donations for any properly defined fund (whether the fund includes one or more disease states), but they would not be able to earmark for any drug or disease state (if a fund covers more than one) within the fund.[3] Because the fund

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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.

[3] The Charity would not be required to provide assistance with all prescription drugs used by a patient for an FDA-approved indication related to managing the diseases, as required

would include multiple drugs made or marketed by multiple manufacturers, and all other safeguards would apply, we do not believe these combined funds present an unacceptable risk of fraud and abuse.

(3) The Charity certified that it currently provides forms of assistance in addition to copayment and premium assistance in some funds, and intends to provide similar additional assistance for other existing or new funds in the future. Such additional assistance may include, but is not limited to, premium assistance; cost-sharing assistance for related physician office visits, home visits, medical devices, and genetic tests (including diagnostic genetic tests[4]); and incidental expenses related to receiving such treatment, such as child care, travel/transportation, lodging and meals. Such supplemental assistance is (or would be) provided on a case-by-case basis upon the request of a qualified patient. The same safeguards applicable to drug copayment assistance described in OIG Advisory Opinion 10-07, as modified on May 19, 2011, and as further modified herein, would apply to this supplemental assistance.

(4) The Charity certified that donors may earmark their donations to any fund that is established and defined in accordance with the principles set forth in its original advisory opinion and subsequent modifications and complies with all of the safeguards (including, but not limited to, those prohibiting donor influence in establishing or operating the fund) set forth in those opinions. The Charity characterizes this as a clarification of a previous certification.

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. 10-07 and its May 19, 2011 modification remain accurate.[5] Accordingly, the Charity's

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for funds for disease states for which the FDA has approved only one drug or only the drugs made or marketed by one manufacturer or its affiliates.

[4] Because diagnostic genetic tests are, by definition, pre-diagnosis, the Charity certified that the eligibility criteria would require a physician's order for the test, rather than the patient being "under the care of a physician and already undergoing treatment" for the disease at the time of application, as certified in connection with OIG Advisory Opinion 10-07. All other eligibility criteria would be the same as in OIG Advisory Opinion 10-07, as modified on May 19, 2011, and as further modified herein.

[5] The Charity has not sought an opinion on, and we express no opinion regarding, any of the Charity's operations that may have fallen outside of the facts presented to us. As we reference in the Supplemental Bulletin, to the extent that any material facts were not fully, completely, and accurately presented, or the arrangement in practice has not comported with

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 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. 10-07. The modification of OIG Advisory Opinion No. 10-07 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

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the information provided in connection with the advisory opinion, then the arrangement would not be protected. However, the OIG will not proceed against the Charity with respect to any action taken in good faith reliance on OIG Advisory Opinion No. 10-07 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 at all times.