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: October 26, 2015

Posted: November 2, 2015

[Name and address redacted]

Re: Modification of OIG Advisory Opinion No. 07-18

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 December 19, 2007, the OIG issued to [name redacted] (the "Charity") OIG Advisory Opinion No. 07-18, which is a favorable opinion regarding the Charity's operation of a PAP that provides cost-sharing assistance primarily for high-cost medications to patients who have been diagnosed with one of the disease states for which the Charity maintains a disease fund and who meet certain financial need criteria. On October 11, 2011, OIG issued a modification to that opinion to permit the charity to, among other things, move towards a specialty therapeutics model such that its disease funds would offer assistance only to

[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).

patients prescribed specialty therapeutics. In that opinion, as modified, we approved certain features that we have since determined are problematic.

In accordance 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 the concerns we described in the Supplemental Bulletin 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 develop and 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 Food and Drug Administration ("FDA") for 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 drugs 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, drugs to treat symptoms of the disease, such as pain medications, and prescription drugs 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 all prescription medications, including generic or bioequivalent drugs, so long as the drugs are FDA-approved or indicated in compendia, evidence-based guidelines, or clinical guidelines for a diagnosis that qualifies the patient for assistance from the fund.[2]

[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

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.

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. 07-18 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 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.

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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 also may 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.

[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. 07-18, as modified, 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.

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. 07-18, as modified. The further modification of OIG Advisory Opinion No. 07-18 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