



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 23, 2015

Posted: December 30, 2015

[Name and address redacted]

Re: Notice of Modification of OIG Advisory Opinion No. 06-04

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 April 20, 2006, the OIG issued to [name redacted] (the “Charity”) OIG Advisory Opinion No. 06-04, which is a favorable opinion regarding the Charity’s then-proposal to provide financially needy Medicare beneficiaries with assistance with premiums and cost-sharing obligations under Medicare Part B, Medicare Part D, Medigap, and Medicare Advantage. In that opinion, 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

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).

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 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 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 therapeutic device, or only the drugs or therapeutic devices made or marketed by one manufacturer or its affiliates. If the Charity sponsors a fund for a disease for which the FDA has approved only one drug or therapeutic device, 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, including, but not limited to, prescription drugs to treat symptoms of the disease, such as pain medications, and 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, which are approved by the FDA for treatment of the disease state(s) covered by 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 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

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 proposes to allow its Executive Committee to modify limits on the financial need criteria for patient eligibility to participate in its programs. The modified financial need criteria (and any future revisions to the financial need criteria) would continue to be objective, based on national standards of indigence, and applied uniformly within a disease fund. In addition, the Charity proposes to eliminate the requirement that, in order to qualify for premium assistance and assistance with cost-sharing obligations, patients must pay a set percentage of their gross monthly income toward these expenses. All other aspects related to an enrollee's income eligibility would remain the same. We do not believe that the Charity's action of modifying the financial need criteria or ceasing to require a financially needy patient to share in certain costs before receiving assistance would increase the risk to Federal health care programs. The Charity certified herein that it determines eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner. This safeguard, in combination with the objective method described above for determining financial need criteria, make the proposed modification to the financial need criteria low risk. With respect to eliminating a patient's cost-sharing obligation, the Charity assists patients only after a good-faith determination of financial need. Under these circumstances, together with the other safeguards described in Advisory Opinion 06-04, we do not believe the Charity's elimination of a cost-sharing obligation increases risk.

(2) The Charity proposes to allow its Executive Committee to modify the maximum caps set on premium assistance, copayment assistance, and emergency assistance available under its programs. Any modified cap amount would be applied uniformly within a disease fund. Imposing or modifying caps on the amount of financial assistance available does not increase risk, as long as the cap is applied uniformly within the fund.

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 currently provides forms of assistance in addition to copayment assistance for drugs in some of its disease funds. Such additional assistance may include, but is not limited to, assistance with disease fund-related FDA Risk Evaluation and Mitigation Strategies testing requirements; copayment assistance for related physician office visits; expenses for medical supplies, equipment, and testing as determined by the prescribing physician; and transportation to and from medical appointments. Such supplemental assistance is (or would be) provided on a case-by-case basis, depending on the need of the individual patient and the funding available. When these additional services are covered, they are (or would be) covered in the same disease fund as the drug therapies to treat the underlying disease that is the subject of the fund; the same safeguards applicable to drug copayment assistance described in Advisory Opinion 06-04, as modified herein, apply to this supplemental assistance. We do not believe that covering additional patient expenses in the same fund as the covered drugs increases the risk to Federal health care programs. The types of additional assistance that the Charity provides are related to the patient's treatment and would not inappropriately benefit any particular donor, provider, or supplier.

(4) The Charity intends to establish a disease fund that would provide assistance only to Federal health care program beneficiaries. Any such fund would be subject to all of the safeguards applicable to any other disease fund described in Advisory Opinion 06-04, as 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.”

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. 06-04 remain accurate.³ Accordingly, the Charity's PAP, as 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

³ 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; 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. 06-04 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.

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(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. 06-04. The modification of OIG Advisory Opinion No. 06-04 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