



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: July 15, 2016

Posted: July 22, 2016

[Name and address redacted]

Re: Notice of Modification of OIG Advisory Opinion No. 10-12

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 August 20, 2010, the OIG issued to [name redacted] (the “Charity”) OIG Advisory Opinion No. 10-12, which is a favorable opinion regarding the Charity’s then-proposal to operate a PAP to provide cost-sharing assistance for drugs and devices to treat brain tumors as well as conditions incident to brain tumor treatment (e.g., chemotherapy-induced nausea, chemotherapy-induced anemia, chemotherapy-induced neutropenia, etc.). In accordance with our authority at 42 C.F.R. § 1008.45, we sent the Charity a letter on May 21, 2014, requesting confirmation that the Charity operates in compliance with our guidance and, to that end, proposed certifications concerning risks identified in the Supplemental Bulletin.

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 FR 31120 (May 30, 2014).

The Charity has responded to our request and has addressed the concerns we described in the Supplemental Bulletin through the following three certifications:

- (1) The Charity will not define its disease fund 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 a widely recognized disease state.
- (2) The Charity will not maintain a disease fund that includes only one drug, or only the drugs made or marketed by one manufacturer or its affiliates.
- (3) The Charity will not limit its assistance to high-cost or specialty drugs. Instead, the Charity will make assistance available for all products approved by the U.S. Food and Drug Administration to treat a primary malignant brain tumor.²

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.

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

(1) The Charity proposes to modify the definition of its disease fund to cover drugs and devices to treat primary malignant brain tumors. While the definition of the Charity's disease fund that we originally approved in OIG Advisory Opinion No. 10-12 included all brain tumors as well as conditions incident to brain tumor treatment, the proposed modified definition of drugs and devices to treat primary malignant brain tumors would continue to cover a widely recognized disease state and would remain consistent with the other safeguards we outlined in the Supplemental Bulletin, including those regarding the definition of an independent charity's disease fund. Accordingly, the Charity's proposed modified definition does not significantly raise the risk of fraud or abuse.

(2) The Charity requests a modification involving information that it may post on its websites. In requesting OIG Advisory Opinion No. 10-12, the Charity certified that it offers non-PAP programs and services that include helping patients in the following ways: finding and participating in clinical trials; obtaining second opinions at major medical centers; locating and utilizing in-person and online support groups; education through website, video, live conferences, and telephone support; fundraising events; and funding of medical research. Due to the fact that some of the board members who oversee the Charity's non-PAP programs and services may have ties to potential donors to the PAP, the Charity certified that it would separate its non-PAP programs and services from the work it performs for the PAP by means of an ethical wall that combines various elements, including, among others: a separate website for the PAP (the "PAP Website") that is not linked to and makes no reference to the website for the Charity's other programs and services (the "Charity Website"). OIG Advisory Opinion 10-12 relies upon these certifications. The Charity seeks a modification that would enable it to add a page of general resources on each website that would include contact information for numerous programs and foundations to assist patients with primary malignant brain tumors, including contact information for the PAP on the Charity Website and contact information for the Charity's non-PAP programs and services on the PAP Website.

The purpose for implementing the ethical wall is to safeguard against the risk that the Charity's assistance decisions might be improperly influenced by pharmaceutical and device companies, or the interests of any of the Charity's non-PAP board members with ties to such donors. We do not believe the mere inclusion of contact information for the Charity's own programs on a general list of resources on each website would significantly increase the risk of this abuse occurring. As all of the other elements comprising the ethical wall to maintain the independence of the PAP from the Charity's non-PAP programs and services remain intact, we find that this proposed modification does not raise significant risk to 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. 10-12 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 (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the PAP, as modified 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. 10-12. The modification of OIG Advisory Opinion No. 10-12 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

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. 10-12 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.