



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 30, 2015

Posted: January 6, 2016

[Name and address redacted]

Re: Notice of Modification of OIG Advisory Opinion No. 04-15

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 October 29, 2004, the OIG issued to [name redacted] (the “Charity”) OIG Advisory Opinion No. 04-15, which is a favorable opinion regarding the Charity’s proposal to operate a PAP to provide grants to defray costs of prescription drug therapies for patients who meet certain financial need criteria and are suffering from specific chronic or life-threatening diseases. On August 29, 2008, OIG issued a modification to that opinion to permit the Charity to: (i) provide donors with monthly aggregate applicant data; (ii) modify its standard donation agreement to permit donors to terminate participation; and (iii) expand

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).

the Charity's operations to provide assistance with additional disease categories. 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 proposed additional certifications that would have to be executed for the Charity to retain its favorable advisory opinion.

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). In addition, the Charity intends to maintain a disease fund [disease fund name redacted]. Although this fund would be defined based on a symptom of cancer, we find this particular fund to be low risk because of additional certifications provided by the Charity. First, the Charity certified that there are currently 62 different drugs from 26 different manufacturers available to treat [symptom redacted]. Therefore, defining the fund based on a symptom is not a way to create a narrow fund in this instance. Second, and crucial to the analysis, the Charity will not limit the assistance provided through this fund to drugs to treat [symptom redacted]. This is consistent with the operation of the Charity's other funds, which are not limited to drugs that treat the disease that is the subject of the fund. Patients who qualify for assistance from the [disease fund name redacted] fund would be able to receive assistance not just with their copayments for the medications prescribed for the [symptom redacted], but also with all other medications prescribed for the management and treatment of the patient's underlying 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 and therapeutic devices (if applicable) used by a patient for an FDA-approved indication related to managing the disease, including, but not limited to, prescription drugs and devices 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 products, including generic or bioequivalent drugs, covered by the applicable payor, including Medicare, when prescribed for the treatment or management of the disease state(s) covered by the fund.²

In addition, we asked the Charity to certify, and it did certify, that it determines eligibility according to 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. Beginning January 1, 2016, such screening process will be applied uniformly across funds, and will involve: 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 establish disease funds that would provide assistance only to qualifying 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 04-15, as modified on August 29, 2008, 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) In addition to (or in lieu of) cost-sharing assistance for drug therapies and therapeutic devices (if applicable) used to treat and manage the underlying disease state, some of the Charity's funds would provide premium assistance to all qualifying enrollees, including

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.

Federal health care program beneficiaries. We do not view adding premium support to a disease fund that meets the criteria set forth in the Charity’s advisory opinion, as modified herein, or maintaining a fund that provides only premium support, increases the risk.

(3) The Charity proposes to provide cost-sharing assistance for qualified applicants for therapeutic devices that treat underlying diseases. To the extent that both therapeutic devices and drugs are available to treat the underlying disease, any such devices would be covered in the same disease-state fund as the drugs that treat the disease. With this request for modification, the Charity would be expanding the items covered within a disease fund. All of the same safeguards would apply, and thus we do not believe adding therapeutic devices to a disease fund increases the risk.

(4) The Charity would provide assistance with the cost of genetic testing in two separate ways. First, the Charity may establish one or more broad funds to provide assistance with diagnostic and prognostic genetic tests and assays (*e.g.*, a fund for cancer-related testing). Any such fund would include multiple tests offered by multiple manufacturers or laboratories, and the fund(s) may also include assistance with insurance premiums. These tests would not be included in a disease-specific fund, because they are performed before the patient has a diagnosis of a particular disease. The second type of assistance that the Charity would provide for genetic testing would be through its disease funds. The Charity would provide assistance for genetic tests used for therapeutic management of certain diseases for which it has disease funds. In such cases, a single disease fund would offer cost-sharing assistance for prescription drugs, therapeutic devices (if applicable), premium support (if applicable), and for genetic tests used for therapeutic management of the same underlying disease. We do not believe the fact that the cost-sharing assistance would be provided for diagnostic or other tests rather than (or in addition to) prescription drugs would increase the risk, when the same safeguards, such as including multiple tests by multiple manufacturers or laboratories for broad disease categories, would apply.

(5) The Charity seeks to update the financial need criteria that it included in OIG Advisory Opinion 04-15. Pursuant to this modification, a patient with a household income of 400% or less of the Federal poverty guidelines, considering family size and adjusting for the cost of living index, where appropriate, could be eligible for financial assistance. The income limits could vary from disease fund to disease fund, but would not exceed the level specified above. We have not mandated any particular income level that would constitute “financial need.” We require only that charities determine eligibility according to reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner. If the Charity’s disease funds are established and maintained in accordance with our guidance, and patient eligibility criteria does not vary within the fund, we do not view this particular household income level proposal as increasing the risk to Federal health care programs.

(6) The Charity previously required pharmaceutical manufacturers that donate to one or more of the Charity's funds to make a commitment of at least three years, provided that the donor could change or discontinue its contributions to a fund without cause upon 120 days prior written notice. In this modification, the Charity seeks to update its opinion to reflect that donors now sign one-year agreements, and still may change or discontinue its contributions to a fund without cause upon 120 days' prior written notice. We do not believe that the Charity's reducing the length of such an agreement with its donors increases risk.

(7) Some of the Charity's disease funds would provide cost-sharing assistance with infusion services, including the office visit (if applicable) associated with the administration of certain medication therapies, such as chemotherapy treatment, utilized to treat the underlying disease covered by the fund. When these additional services are covered, they would be covered in the same disease fund as the drug therapies to treat the underlying disease that is the subject of the fund. We do not believe that covering cost-sharing assistance associated with infusion services (in addition to the drugs themselves) raises the risk, particularly given the structure of this particular charity's operations. Specifically, the Charity has certified that it covers not only the primary treatment drug(s) for its patients, but it also covers other drugs needed by the patients to help manage the disease. Through this modification, many funds also will cover therapeutic devices, genetic tests used for therapeutic management of a disease, and premium support. Adding cost-sharing assistance associated with administering the drugs to funds that already support other needs of patients qualified for the fund beyond the treatment drugs should not raise the 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. 04-15 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. 04-15 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. 04-15. The modification of OIG Advisory Opinion No. 04-15 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