DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

MAR - 3 2017

Dana A. Kuhn, Ph.D.
President and Founder
Patient Services, Inc.
P.O. Box 5930
Midlothian, VA 23112

Re: Notice of Modification of OIG Advisory Opinion No. 02-1

Dear Dr. Kuhn:

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 4, 2002, the OIG issued to Patient Services, Inc. (the "Charity") OIG Advisory Opinion No. 02-1, which is a favorable opinion regarding the Charity's operation of a PAP to provide grants to defray medical expenses (including cost-sharing obligations for drug treatments and health insurance premiums) for patients who meet certain financial need criteria and suffer from specific chronic illnesses or rare disorders. In that opinion, we did not address 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.

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[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 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 has requested the following three exceptions to this general principle:

> (a) 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 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).
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> (b) The Charity will have a fund that provides, at a minimum, copayment support for all prescription drugs used to manage (but not treat) any cancer. For example, the fund will cover anti-nausea medications, opioid and non-opioid pain medications, antidepressants prescribed for depression secondary to a patient's cancer diagnosis, medications that treat opioid-induced constipation, and any other drug that manages an issue related to cancer.
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> (c) The Charity also will have a fund for patients with Pseudobulbar Affect ("PBA"), a condition affecting certain patients with neurological disorders. While limited to patients with PBA, this fund will cover, at a minimum, copayment support for all prescription drugs that are used to treat either PBA or the neurological disorders that underlie a patient's PBA, such as Alzheimer's disease, multiple sclerosis, and amyotrophic lateral sclerosis. Patients who qualify for the fund may receive cost-sharing assistance or premium assistance. Patients who receive cost-sharing assistance may apply it toward drugs addressing PBA or the underlying neurological condition, and they will be informed of this fact. The Charity may impose an across-the-board cap on this particular fund that would limit the total assistance provided to individual patients.

We find that these three proposed exceptions, as set out by the Charity, do not materially raise the risk of this arrangement. The funds for patients with certain metastatic cancers will cover all drugs approved by the FDA for the type of cancer in question, which should ensure the support of a broad range of drugs by each such fund. The cancer management fund and the fund for patients with PBA will each be broadly defined in a manner that covers a wide spectrum of products. Neither fund will limit assistance to a subset of available products. The two funds will be subject to all of the safeguards applicable to any other disease fund described in OIG Advisory Opinion 02-1, as further

modified herein. The cancer management fund and the fund for patients with PBA therefore will be unlikely to support exclusively or primarily the products of their donors and will be unlikely to otherwise be operated to induce the purchase of those products.

(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 (including one drug and a therapeutic device used to administer that drug), 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. (This includes one fund for patients with a disease for which there is only one FDA-approved stand-alone treatment, although there is an additional drug approved by the FDA for use in combination with the single stand-alone treatment.) At a minimum, the Charity will provide copayment support for all prescription drugs used by a patient in connection with managing the disease, including, but not limited to, prescription 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 products, including generic or bioequivalent drugs, covered by the applicable payor, including Medicare, when prescribed for the treatment 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 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

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[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.

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 proposed the following additional modifications to Advisory Opinion 02-1.

(1) Some of the Charity's disease funds provide forms of assistance in addition to cost-sharing assistance for drugs. Such additional assistance may include cost-sharing assistance with infusion services, office visits, health care counseling, diagnostic testing, nursing services and therapy services; support for medical devices and equipment; and reasonable transportation (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 forms of assistance are covered, they are and will be covered in the same disease fund as the drug therapies to treat the underlying disease that is the subject of the fund. The Charity certified that the same safeguards applicable to drug cost-sharing assistance described in OIG Advisory Opinion 02-1, as modified herein, apply to the Charity's administration of these forms of assistance. Extending one or more of these additional forms of assistance to patients qualified for a given disease fund, in this context, should not raise the risk to Federal health care programs.

(2) The Charity proposes to establish disease funds that would provide financial assistance only to qualified Federal health care program beneficiaries. Such funds would operate in accordance with all of the safeguards and parameters set forth in OIG Advisory Opinion 02-1, as modified herein. Consistent with our existing guidance, we will not impose sanctions in connection with the Charity's establishment of disease funds that provide assistance only to qualified Federal health care program beneficiaries, provided that the operation of these disease funds is otherwise consistent with the certifications set forth in Advisory Opinion 02-1 and herein.

(3) In addition to (or in lieu of) cost-sharing assistance for drug therapies and therapeutic devices (if applicable) used to treat or manage, as applicable, the underlying disease state, some of the Charity's disease state funds would provide premium assistance to all qualifying enrollees. We do not believe adding premium support to a disease fund that meets the criteria set forth in OIG Advisory Opinion 02-1, as modified herein, or maintaining a fund that provides only premium support, increases the risk.

(4) The Charity proposes to provide cost-sharing assistance for qualified applicants for therapeutic devices that treat underlying diseases, in addition to drug therapy. 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.

More recent favorable advisory opinions issued to independent charity PAPs incorporated safeguards that did not appear in OIG Advisory Opinion 02-1. We therefore asked the Charity to make certain additional certifications, to ensure compliance with our long-standing guidance regarding independence from donors:

(1) The Charity certified that donors may earmark their contributions to a specific disease fund, but the donations are and will be otherwise unrestricted. The Charity's discretion to use the donations otherwise is and will be absolute, independent, and autonomous.

(2) The Charity certified that it is and will be governed by an independent board of directors (the "Board"). No donor, or affiliate of a donor, exerts or will exert any direct or indirect influence over the Charity or its PAP. No donor, or immediate family member, director, officer, employee, or person otherwise affiliated with a donor is or will be eligible to serve on the Board. No former director, officer, or employee of a donor who maintains an ongoing relationship with the donor (via consulting or otherwise), or immediate family members of such former director, officer, or employee of a donor is or will be eligible to serve on the Board. Finally, no Board member or employee of the Charity receives or will receive, directly or indirectly, any form of compensation from any donor.

(3) The Charity certified that it, in its sole discretion, determines, and will determine, the diseases it supports through its funds. Such funds are, and will be, defined by the Board based on its independent assessment of whether a new fund will best serve patient needs. The Charity defines and will define its disease funds in accordance with widely recognized clinical standards. The Charity's disease funds are, and will be, defined in a manner that covers within each a broad spectrum of products. The Charity does not, and will not, solicit suggestions from donors regarding the identification or delineation of disease funds. No donor or affiliate of any donor (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) directly or indirectly influences or will influence the identification or delineation of any of the Charity's disease funds. The Charity certified, more specifically, that it will not establish or modify funds for specific diseases at the request or suggestion of donors or prospective donors (or affiliates of donors or prospective donors) that manufacture drugs or devices for the treatment of such diseases or that otherwise have a financial interest in the establishment or modification of such funds.

(4) The Charity certified that it assesses and will assess patient applications and makes grant determinations without regard to: (i) the interests of any donor or any donor affiliates; (ii) the applicant's choice of product, provider, practitioner, supplier, or insurance company; (iii) the identity of the referring person or organization, including whether the referring entity is a donor; or (iv) the amount of contributions made by any donor whose services or products are used or may be used by the patient. The Charity certified that it does not, through its staff or otherwise, refer applicants or potential applicants to or recommend any items or services, or any providers, practitioners, or suppliers of items or services. For example, if the Charity provides information regarding a donor's PAP, the Charity also will provide, in the same place or at the same time, and with the same prominence, information about all manufacturer-sponsored PAPs for drugs that treat or manage the same condition; if the Charity provides a link on its website to a PAP offered by a donor to a fund, the Charity also will provide links to all manufacturer PAPs that support drugs covered by the fund. These certifications help ensure that the Charity's PAP will not steer patients to the products of its donors.

(5) The Charity proposes to provide donors with quarterly or monthly projected estimates of when a particular fund is likely to be exhausted, based on current donations and assistance provided to fund enrollees. However, the Charity will not provide donors with any individual patient information or any data related to the identity, amount, or nature of drugs, devices, or services subsidized by the PAP. The Charity's reports to donors will not contain any information that would enable a donor to correlate the amount or frequency of its donations with the number or medical condition of patients who use its products or services or the volume of those products or services. The Charity does not and will not inform applicants of the identities of donors or when a particular manufacturer donates to the Charity. Finally, patients do not and will not receive any information about donors, and donors do not receive any information regarding other donors, except that the Charity's annual report and list of donations may be publicly available to the extent required by the Internal Revenue Service, or as otherwise required by law.

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. 02-1 remain accurate.[3] Accordingly, the Charity's PAP, as modified herein:

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[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 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. 02-1 up until the date of this modification,

(i) would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Social Security Act (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. 02-1. The modification of OIG Advisory Opinion No. 02-1 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
Chief Counsel to the Inspector General

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as long as the material facts were fully, completely, and accurately presented, and the arrangement in practice comported with that information at all times.