DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

MAY 21 2014

Patrick McKercher, President
Patient Access Network Foundation
900 19th Street, NW, Suite 200
Washington DC 20006

Re: OIG Advisory Opinion 07-18, as modified

Dear Mr. McKercher:

The Office of Inspector General (OIG) issued Advisory Opinion 07-18 to Patient Access Network Foundation (Requestor) on December 19, 2007 and modified it on October 11, 2011. This advisory opinion is among a number of similar opinions that we issued regarding patient assistance programs (PAPs) operated by independent charities since we published the "OIG Special Advisory Bulletin on Patient Assistance Programs for Part D Enrollees"[1] in 2005 (2005 SAB). In that guidance, we explained that we could only speculate on fraud and abuse risk areas, because the Part D benefit had not yet begun.

Since the issuance of the 2005 SAB and Advisory Opinion 07-18, we have gained experience with the Part D program and with the operations of independent charity PAPs. That experience has taught us that these types of PAPs have not always operated as we expected. As a result, we are issuing additional guidance to the public regarding independent charity PAPs. A copy of our "Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs" (Supplemental Bulletin) is enclosed with this letter.

Through the advisory opinion process, we approve only those arrangements or proposed arrangements that we conclude pose a minimal risk of fraud and abuse. Pursuant to 42 CFR 1008.45, advisory opinions are issued without prejudice to the right of the OIG to reconsider the questions involved and, where the public interest requires, to rescind, terminate or modify the advisory opinions. Because we no longer believe that certain aspects of Advisory Opinion 07-18, as modified, pose a sufficiently low risk of fraud and abuse, we will require certain changes going forward for Requestor to retain its favorable advisory opinion.

(1) Requestor certified that it would define its disease funds: (i) in accordance with widely recognized clinical standards; (ii) in a manner that covers within each disease fund a broad spectrum of available products; and (iii) without reference to specific symptoms, severity of symptoms, or the method of administration of drugs or other products. We are concerned that some organizations are defining disease funds too narrowly. Going forward, we will expressly require that disease funds not be defined with reference to the stages of the disease or the drugs or treatments to be included in the fund. Although we believed these criteria to be implicit, we

[1] 70 Fed. Reg. 70623 (Nov. 22, 2005).

want to be clear in the opinion. Thus, with this more explicit explanation, we ask Requestor to certify that its disease funds will not be defined 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.

(2) Like many of the opinions we have issued, Requestor's opinion includes a caveat that there may be "rare instances" of single-drug funds. We intend to remove this or similar language from any opinion in which it appears. We ask Requestor to certify that it does not maintain any disease funds that provide copayment assistance for only one drug covered by Medicare for the disease(s) in a particular disease fund or only one pharmaceutical manufacturer (including its affiliates) that makes or markets all of the Medicare-covered drugs for the disease(s) in a particular disease fund. Alternatively, if Requestor maintains, and proposes to continue to maintain, a particular disease fund, which is legitimately defined, that covers only a single drug or the drugs of a single manufacturer, we ask that Requestor provide specific information about that fund, and we would consider each such fund on a case-by-case basis. Before submitting information regarding a single-drug fund for our consideration, please consider alternatives to single-drug coverage. Such alternatives include, but are not limited to: combining two or more related disease funds; expanding the definition of a disease fund; covering any drugs needed by financially qualified patients with the particular disease that is the subject of the fund; or covering copayments for all items and services needed by such patients.

(3) We also have issued a number of advisory opinions that allow PAPs to include only high-cost or specialty drugs. For the reasons articulated in the attached Supplemental Bulletin, we no longer believe, as a general matter, that disease funds that cover copayments only for expensive or specialty drugs pose a sufficiently low risk of fraud and abuse to permit us to continue to grant PAPs prospective immunity in connection with those disease funds. Thus, to maintain a favorable opinion, we ask that Requestor's disease funds include all products, including generic or bioequivalent drugs, that are covered by Medicare when prescribed for the treatment of the disease state(s) covered by the fund. Alternatively, Requestor may certify that its disease funds include all products, including generic or bioequivalent drugs, approved by the Food and Drug Administration for treatment of the disease state(s) covered by the fund. If Requestor desires to maintain a particular fund that does not support all drugs approved for the relevant disease state, please provide evidence that the fund poses a minimal risk of fraud and abuse and therefore warrants a favorable opinion.

Enclosed is a draft document including proposed certifications to address the points described above. You may propose new certifications or modifications to these proposed certifications to update Advisory Opinion 07-18, as modified, consistent with OIG guidance.

As stated in Advisory Opinion 07-18, as modified, the OIG will not proceed against Requestor with respect to any action that is part of the arrangement described in the opinion, taken in good faith reliance on the opinion, as long as all of the material facts were fully, completely, and accurately presented, and the arrangement in practice has comported with the information provided. Requestor's favorable advisory opinion will continue to protect the arrangement

described in the opinion until such time as we issue a final notice of modification or termination to Requestor.

We would like to work with you to achieve a further modification of Advisory Opinion 07-18 that will permit Requestor to continue to meet the needs of patients, while reducing the risk of fraud and abuse. As part of this process, this letter constitutes preliminary notice to you, pursuant to 42 CFR 1008.45, of our intent to terminate or modify Advisory Opinion 07-18 as described above, subject to your right to respond. You have 30 days from the date of this letter to provide the information solicited above, and any other information you want the OIG to consider in evaluating the need to modify or terminate this opinion.

Please send such information to the following address:

Chief, Industry Guidance Branch
United States Department of Health and Human Services
Office of Counsel to the Inspector General
Cohen Building - Room 5527
330 Independence Avenue, SW
Washington, DC 20201

If you have any questions regarding this letter or the Supplemental Bulletin or anticipate that you will be unable to submit a complete response within 30 days despite a good faith effort, please contact the Industry Guidance Branch attorney assigned to your opinion, Heather Westphal, within 14 days. Ms. Westphal can be reached at (202) 205-8877 or Heather.Westphal@oig.hhs.gov. If you do not submit a response or contact the assigned attorney within the relevant time period, the OIG will make its decision based on currently available information. You will be informed of the decision.

Sincerely,

Gregory E. Demske
Chief Counsel to the Inspector General

Enclosures

Draft
Proposed Certifications

Patient Access Network Foundation (Requestor) certifies as follows, in connection with the proposed further modification of Advisory Opinion 07-18, as previously modified on October 11, 2011:

(1) Requestor 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.

(2) Requestor 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.

(3) Requestor will not limit its assistance to high-cost or specialty drugs. Instead, Requestor will make assistance available for all products, including generic or bioequivalent drugs, covered by Medicare when prescribed for the treatment of the disease state(s) covered by the fund. [Alternate: Requestor will make assistance available for all products, including generic or bioequivalent drugs, approved by the Food and Drug Administration for treatment of the disease state(s) covered by the fund.

(4) [Reserved: to be added by Requestor, if necessary.]

Except as expressly provided above, all other facts to which Requestor certified in its submissions in connection with Advisory Opinion 07-18 and its modification remain accurate.