



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



MAY 21 2014

Louis J. DeGennaro, Ph.D.
Interim President & CEO
The Leukemia & Lymphoma Society, Inc.
1311 Mamaroneck Avenue
White Plains, NY 10605

Re: OIG Advisory Opinion 06-13, as modified

Dear Dr. DeGennaro:

The Office of Inspector General (OIG) issued Advisory Opinion 06-13 to The Leukemia & Lymphoma Society, Inc. (Requestor) on September 18, 2006 and modified it on June 21, 2013. 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, 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. It appears that Advisory Opinion 06-13, as modified, substantially complies with our guidance. However, we ask that Requestor confirm the following certifications:

(1) Requestor certified that it would define its disease funds: (a) in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products; and (b) without reference to specific symptoms, severity of symptoms, or the method of administration of drugs. Because 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 stages of a disease or the drugs or treatments to be included in the fund. Although we believed these criteria to be implicit, we want to be clear in the advisory opinions. Thus, to ensure

¹ 70 Fed. Reg. 70623 (Nov. 22, 2005).

that Advisory Opinion 06-13, as modified, includes the same certification as other opinions, 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 original opinion includes a caveat that there may be "rare instances" of single-drug funds. However, Requestor retracted this caveat in the modification we issued on June 21, 2013. We intend to remove this or similar language from any opinion in which it appears. Thus, we ask Requestor to confirm that it does not maintain any disease funds that cover 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.

(3) We also have issued a number of advisory opinions that allow PAPs to provide copayment assistance for 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. The arrangement approved in Requestor's opinion, as modified, is not limited to high-cost or specialty drugs. In fact, Requestor's modification indicates that each disease fund covers cost-sharing for many categories of drugs prescribed for treatment of the disease designated within the disease fund, not just for drugs that treat the disease itself (e.g., instead of covering only chemotherapy, Requestor also covers antibiotics; anti-fungal, anti-nausea, and anti-depressant drugs; pain medication; and sleep aids). However, for consistency across similar opinions, we ask that Requestor certify that its disease funds cover 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 particular 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 No. 06-14, consistent with OIG guidance.

Requestor's favorable advisory opinion will continue to protect the arrangement described in the opinion until such time as we may issue a final notice of modification.

We would appreciate it if you would provide the information solicited above, and any other information you want the OIG to consider in connection with this request, within 30 days from the date of this letter.

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.

Sincerely,



Gregory E. Demske
Chief Counsel to the Inspector General

Enclosures

DRAFT
PROPOSED CERTIFICATIONS

The Leukemia & Lymphoma Society, Inc. (Requestor) certifies as follows, in connection with the proposed further modification of Advisory Opinion 06-13, as previously modified on June 21, 2013:

(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 provide 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 at least 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 06-13 and its modification remain accurate.