DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General
Office of Counsel to the Inspector General

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Washington, D C. 20201

AUG 2 9 2008

Ms. Nancy Davenport-Ennis
CEO/President
Patient Advocate Foundation
700 Thimble Shoals Blvd., Suite 200
Newport News, VA 23606

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

Dear Ms. Davenport-Ennis:

We are writing in response to a request from Patient Advocate Foundation (the "Requestor") to modify Office of Inspector General ("OIG") Advisory Opinion No. 04-15, which we issued to the Requestor on October 29, 2004. In OIG Advisory Opinion No. 04-15, we concluded that the proposal by Requestor, a non-profit charitable organization, to operate a patient assistance program to provide grants to financially-needy patients suffering from specific chronic or life-threatening diseases to defray costs of prescription drug therapies (the "Existing Arrangement"): (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) 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, but that the OIG would not impose administrative sanctions on the Requestor 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 Existing Arrangement.

The Requestor proposes to modify its Existing Arrangement in three ways: (i) to provide donors with monthly aggregate applicant data; (ii) to modify its standard donation agreement to permit donors to terminate participation; and (iii) to expand the Requestor's existing disease categories.[1]

[1]Subsequent to the issuance of OIG Advisory Opinion No. 04-15, we issued OIG's Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 FR 70623, 70626 (November 22, 2005). We note that the Requestor's modifications regarding data and disease categories are drawn directly from parameters for patient assistance programs set forth in OIG's Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees. Furthermore, we note that the Requestor's Existing Arrangement subsidizes both Part B and Part D drugs.

The Requestor has certified that all of the information provided in the request for modification of OIG Advisory Opinion No. 04-15, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties. In particular, the Requestor has certified that, apart from the three modifications described in the request for modification, the Existing Arrangement will continue to operate in accordance with the facts certified in the Requestor's original request (and supplemental submissions) in connection with OIG Advisory Opinion No. 04-15.

First, the Requestor desires to change the type of data that will be reported to its donors. Currently, no individual or aggregate patient data is conveyed by the Requestor to its donors. The Requestor proposes to provide donors with monthly data regarding the aggregate number of applicants and qualifying applicants for assistance in particular disease categories, upon request. No individual patient's information would be conveyed to donors. The Requestor has certified that reports to donors would 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 that use its products or services, or the volume of those products or services.

Second, the Requestor proposes to modify its standard donation agreement to allow donors to change or discontinue their contributions to Requestor's Existing Arrangement without cause upon 120 days prior written notice. Currently, the Requestor requires donors to commit to participate in its program for at least three years. Requestor will continue to provide financial assistance to patients, subject to availability of funds, for a specific period of time (up to one year). The Requestor has certified that the prior written notice requirement would give the Requestor time necessary to transfer patients it could no longer help to other patient assistance programs or to provide patients advance notice of Requestor's inability to continue to provide future assistance. The Requestor has further certified that any determination regarding which patients would no longer receive funding would be based solely on a patient's individual financial need and the date that a patient became eligible to participate in Requestor's program (i.e., generally a "last in, first out" approach). Requestor's decision to discontinue assistance to a patient because of insufficient funds would not be based on the patient's therapy regimen.

Third, the Requestor proposes to expand its Existing Arrangement to provide assistance to patients suffering from additional, specific chronic or life-threatening diseases.[2] The

[2]The new disease categories are: Alzheimer's Disease; Bone Cancer (and other Myelomas); Chronic Kidney Disease; Cardiac Disease; Chemotherapy Induced Anemia/Chemotherapy Induced Neutropenia; Head and Neck Cancer; Inflammatory Bowel Disease; Liver Cancer; Lupus; Melanoma (and other skin cancers); Osteoporosis; Myelodsyplastic Syndrome (and other Pre-Leukemia diseases); Pain and Nausea;

Requestor has certified that the additional disease categories fully comply with the parameters and procedures certified by the Requestor in its original request (and supplemental submissions) in connection with OIG Advisory Opinion No. 04-15. The Requestor has further certified that the Requestor, in its sole discretion, defined the new categories in accordance with widely recognized clinical standards; in a manner that covers, within each category, a broad spectrum of available products; and without reference to specific symptoms, severity of symptoms, or the method of administration of drugs or other products.[3] The Requestor also certified that it does not solicit suggestions from donors regarding the identification or delineation of disease categories. 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 influenced the identification or delineation of the new disease categories.[4]

Based on the totality of facts and circumstances of the Existing Arrangement and the proposed modifications, and for the reasons set forth in OIG Advisory Opinion No. 04-15, we conclude that the three modifications would not affect our conclusion in OIG Advisory Opinion No. 04-15. Accordingly, the Requestor's Existing Arrangement, as modified, (i) would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) 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, but the OIG would not impose administrative sanctions on the Requestor 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 Existing Arrangement, as modified.

Parkinson's Disease; Rectal and Anal Cancers; Retinoblastoma (and other eye diseases); Rheumatoid Arthritis; Stomach Cancers; and Ulcerative Colitis.

[3]According to the Requestor, all new and existing disease categories under the Requestor's Existing Arrangement, as modified, will contain at least two drugs. However, in the rare circumstances where there may only be one drug to treat an otherwise properly delineated disease category or only one manufacturer (including its affiliates) that makes all of the drugs for a particular disease category, the Requestor will use its best efforts to cover additional products and manufacturers as they become available.

[4]We anticipate that the Requestor may create additional disease categories in accordance with the parameters certified 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,

Lewis Morris
Chief Counsel to the Inspector General