



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



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June 21, 2013

Mr. John Walter
The Leukemia & Lymphoma Society, Inc.
1311 Mamronc Ave., Suite 310
White Plains, NY 10605

Re: Modification of Advisory Opinion 06-13 (Request No. R882)

Dear Mr. Walter:

Enclosed is a Modification of Advisory Opinion No. 06-13, in response to the above-captioned advisory opinion request. I also emailed the opinion to Mr. Nangle in your office.

Sincerely,

Meredith Williams
Senior Counsel
Industry Guidance Branch

Enclosure



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John E. Walter
The Leukemia & Lymphoma Society, Inc.
1311 Mamronck Ave., Suite 310
White Plains, NY 10605

Re: Notice of Modification of OIG Advisory Opinion No. 06-13

Dear Mr. Walter:

We are writing in response to your request to modify Office of Inspector General ("OIG") Advisory Opinion No. 06-13, which we issued to The Leukemia & Lymphoma Society, Inc. (the "Requestor") on September 18, 2006. In OIG Advisory Opinion No. 06-13, we concluded that: (i) the Requestor's then-existing arrangement to provide grants to assist with costs of premiums and cost-sharing obligations to certain financially needy individuals diagnosed with specific blood-related cancers (collectively, the "Existing Arrangement") would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the Existing Arrangement 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 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.

Under the Existing Arrangement, the Requestor provides annual individual grants to help patients with blood-related cancers, including but not limited to Federal health care program beneficiaries, to pay for their health insurance premiums and medical cost-sharing obligations. The Requestor helps only those patients who demonstrate significant financial need. It generally pays premium assistance grants directly to the patient's insurance company and pays cost-sharing assistance grants directly to physicians, providers, and suppliers of items and services (including drugs).

The Requestor currently pools donations into five disease funds. All of these funds provide and would continue to provide financial grants consisting of premium and cost-sharing assistance. Disease funds would continue to be designated and defined at the Requestor's sole discretion through an internal decision-making process. Donors may provide unrestricted donations or may earmark their contributions for the financial support of patients within a specific disease fund; however, donations must be unrestricted within that fund. Each disease fund would continue to be defined in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products; no disease fund would be defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs. Each of the Requestor's funds covers and would continue to cover cost-sharing for many categories of drugs prescribed for treatment of the disease designated within the disease fund. These include, among others: chemotherapy; antibiotics; anti-fungal, anti-nausea, and anti-depressant drugs; pain medication; and sleep aids. The Requestor's disease funds have not covered and would not cover only one drug or the drugs of only one pharmaceutical manufacturer (including its affiliates).¹

The Requestor certified that all of the information provided in the request to modify OIG Advisory Opinion No. 06-13 (and supplemental submissions) is true and correct and constitutes a complete description of the relevant facts and agreements among the parties. In particular, the Requestor certified that, apart from the modifications described herein, the Existing Arrangement would 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. 06-13. We find that the proposed modifications described below do not materially increase the risk to Federal health care programs.

First, the Requestor proposes to stagger its patient grant application renewal process based on the date the Requestor initially approves a patient's application. Financial assistance would continue for 12 consecutive months following approval of the application. Currently

¹ In OIG Advisory Opinion No. 06-13, footnote 1, we stated: "In rare circumstances, where there may be only one drug covered by Part D for the disease in a particular category or only one pharmaceutical manufacturer (including its affiliates) that makes all of the Part D covered drugs for the diseases in a particular category, the Requestor will use its best efforts to cover additional products and manufacturers as they become available." The Requestor's certification that disease funds have not covered and would not cover only one drug or the drugs of only one pharmaceutical manufacturer (including its affiliates) supercedes footnote 1 of Advisory Opinion No. 06-13.

the coverage period for all enrollees begins July 1 and continues to June 30 each year, which results in a large volume of enrollment applications in July. Under the proposed modification, each enrollee's coverage year would begin on the first day of the month in which the enrollee's application was initially approved.

Second, the Requestor proposes to modify its current practice of awarding assistance on a first-come, first-served basis for some of its disease funds. Currently, a patient may be enrolled for assistance in a certain disease fund, but funding for that category may be exhausted before the enrollee receives financial assistance for which he or she received approval at enrollment. To preserve the availability of funding for all patients enrolled in the disease fund, the Requestor would reserve the maximum annual funding allowed for each enrollee within the disease category upon approval of the enrollee's initial claim submission. If an enrollee does not file an additional claim within 90 days, the remaining unspent funds reserved for that enrollee would be released. Once all available funding for a disease fund is reserved for current enrollees, no additional enrollees would be accepted for the disease fund. The Requestor would use this reserve system for disease categories that the Requestor anticipates would not have sufficient funding to meet patient requests for assistance.

Third, the Requestor proposes to establish a cap for some of its disease funds on the amount of financial assistance provided by the Requestor to each enrollee for premium assistance. Decisions about disease fund premium assistance caps would be based on an assessment by the Requestor's senior management of whether limiting the amount of premium assistance within a disease fund would best serve patient needs.

Fourth, the Requestor proposes to use a pharmacy benefit manager ("PBM") to administer copayment assistance at the enrollee's pharmacy point of sale through the use of a membership card. The PBM would adjudicate the claim, determining the enrollee's copayment assistance amount owed, and would distribute the funds to the enrollee's pharmacy on behalf of the Requestor. The proposed fees payable to the PBM include a fixed administrative services fee and a per-transaction fee that may decrease based on the volume of transactions processed by the PBM. The Requestor would also pay an administrative fee to the PBM for each membership card printed and mailed to a program enrollee. The fees paid by the Requestor to the PBM would be equal to fair market value in an arm's-length transaction for each claim processed.² The Requestor would select a PBM

² We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). For purposes of

through a competitive bidding process. The Requestor would include in the PBM contract a prohibition on the PBM influencing an enrollee's selection of a particular product, practitioner, provider, supplier, or insurance plan, as well as a requirement that the PBM not disclose any information obtained from administering the membership card to any party other than the Requestor.

The membership card would include the Requestor's logo but it would not contain any drug product, manufacturer, or donor names. Patients would be able to use the card at any retail or specialty pharmacy within the PBM's network. To preserve an enrollee's right to use the pharmacy of his or her choice, enrollees that elect to use a pharmacy outside the PBM's network would pay the coinsurance at the pharmacy and submit a claim for reimbursement to the Requestor. The Requestor makes no referrals or recommendations regarding specific providers, practitioners, suppliers, products, or plans, and the membership card would not contain branding information that would imply an endorsement or referral to any specific providers, practitioners, suppliers, products, or plans.

The Requestor is a charity with limited resources, and it focuses its assistance program on financially needy patients who need assistance paying for insurance premiums and cost-sharing obligations. These modifications are largely administrative in nature. All safeguards that led us to determine that the Existing Arrangement entailed minimal risk that donor contributions would improperly influence referrals by the Requestor, and beneficiaries would not likely be improperly influenced in their selection of a particular provider, practitioner, supplier, or product, would remain in place.³ Therefore, we do not view the Requestor's proposal to modify its programs as described above as materially increasing risk to Federal health care programs.

this advisory opinion, we rely on the Requestor's certification of fair market value for each of the fees.

³ Indeed, the safeguards described in Advisory Opinion No. 06-13 have been strengthened on one respect. In OIG Advisory Opinion No. 06-13, footnote 1, we stated: "In rare circumstances, where there may be only one drug covered by Part D for the disease in a particular category or only one pharmaceutical manufacturer (including its affiliates) that makes all of the Part D covered drugs for the diseases in a particular category, the Requestor will use its best efforts to cover additional products and manufacturers as they become available." In support of its request for this Modification, however, the Requestor certified that each of its disease funds covers cost-sharing for many categories of drugs, and that none of these funds have covered, nor would any cover, only one drug or the drugs of only one pharmaceutical manufacturer (including its affiliates).

Based on the totality of facts and circumstances and, for the reasons set forth in OIG Advisory Opinion No. 06-13 and herein, we conclude that these modifications would not affect our conclusion in OIG Advisory Opinion No. 06-13. Accordingly, the Requestor's Existing Arrangement, as modified by the proposed modifications described herein, (i) would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although it 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 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.

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. 06-13. The modification of OIG Advisory Opinion No. 06-13 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