



[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.]

Issued: May 19, 2011

Posted: May 26, 2011

[Name and address redacted]

Re: Notice of Modification of OIG Advisory Opinion No. 10-07

Dear [Name redacted]:

We are writing in response to your request to modify Office of Inspector General (“OIG”) Advisory Opinion No. 10-07, which we issued to [name redacted] (the “Requestor”) on May 26, 2010. In OIG Advisory Opinion No. 10-07, we concluded that: (i) the Requestor’s proposal to provide assistance with cost-sharing obligations to certain financially needy individuals diagnosed with any of three specified diseases (the “Original Arrangement”) would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the Original 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 Original Arrangement.

Pursuant to the Original Arrangement, the Requestor may provide assistance, and will market its grant programs, to financially needy patients, including both Federal health care program beneficiaries and privately insured patients, who have been diagnosed with Multiple Sclerosis, cancer, or rheumatoid arthritis. The Requestor may establish assistance funds for each of these diseases and a fourth fund to provide assistance with genetic testing associated with any of the three specified diseases.¹ The Requestor proposes to modify its Original Arrangement in two ways, as described in greater detail below. In brief, the Requestor would: (i) establish a process to create new assistance funds for additional diseases; and (ii) provide assistance not just with cost-sharing obligations and genetic testing, but also with health insurance premiums.

¹ To date, only the fund for Multiple Sclerosis is operational.

The Requestor has certified that all of the information provided in the request for modification of OIG Advisory Opinion No. 10-07 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 two modifications described herein, the Original Arrangement would continue to operate in accordance with all material facts certified in the Requestor's original request (and supplemental submissions) in connection with OIG Advisory Opinion No. 10-07. We find that the proposed modifications described below do not increase the risk to the Federal health care programs.

First, the Requestor seeks the flexibility to add new disease funds to its assistance program. Any additional disease funds would be defined by the Requestor's board, based on an independent assessment of whether a new fund arrangement would serve patient needs. Like the disease funds established under the Original Arrangement, any new funds would be defined in accordance with widely recognized clinical standards and would not be defined by reference to specific symptoms, the severity of symptoms, the method of administration of drugs, or the availability of associated genetic testing. When defining new disease funds, the Requestor would ensure that each fund would cover a broad spectrum of available products, and the Requestor would not solicit suggestions from any donors regarding the identification or delineation of any funds. Because the Requestor would include the same safeguards used in developing the originally approved disease funds when establishing additional funds—and the additional funds, when established, would operate in accordance with all other material facts certified in the original request—the proposed modification does not change our original determination that the Requestor's program would not be construed as payments to Federal health care program beneficiaries or to the Requestor to arrange for referrals.

Second, the Requestor proposes to expand the assistance programs that we approved in OIG Advisory Opinion No. 10-07 to include not just cost-sharing and the cost of genetic testing, but also assistance with health insurance premiums. The grant application and approval process and standards would be the same as the process and standards outlined in OIG Advisory Opinion No. 10-07. The Requestor would continue to establish and uniformly apply objective criteria based on the Federal poverty guidelines to determine eligibility for assistance. Restrictions on donations would be the same under the proposed arrangement as those under the Original Arrangement, including the ability to earmark donations for a specific disease fund, but not to earmark funds for patients using a specific medication or requiring a specific genetic test. The Requestor would publicize the availability of this new form of assistance and would provide information to individuals who may qualify for it. The Requestor would provide the premium assistance grants directly to the insurance provider on behalf of approved applicants, whenever possible. In cases in which the insurance provider will not accept third-party payment,

grants would be made payable to the recipient upon proof that the recipient incurred such costs. The new category of assistance proposed by the Requestor would be subject to the same or equivalent safeguards that we approved in connection with the Requestor's original request that resulted in the issuance of OIG Advisory Opinion No. 10-07, including the fact that neither the Requestor nor its staff would refer applicants to, recommend, or arrange for the use of any particular insurer; patients would have complete freedom of choice in that regard.

Based on the totality of facts and circumstances, and for the reasons set forth in OIG Advisory Opinion No. 10-07 and herein, we conclude that the two modifications would not affect our conclusion in OIG Advisory Opinion No. 10-07. Accordingly, the Requestor's Original 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) while 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 Original 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. 10-07. The modification of OIG Advisory Opinion No. 10-07 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/

Lewis Morris
Chief Counsel to the Inspector General