



[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: October 27, 2010

Posted: November 3, 2010

Re: Notice of Modification of OIG Advisory Opinion No. 08-17

Dear [Name redacted]:

We are writing in response to your request to modify Office of Inspector General (“OIG”) Advisory Opinion No. 08-17, which we issued to [name redacted] (the “Requestor”) on October 14, 2008. In OIG Advisory Opinion 08-17, we concluded that the Requestor’s proposal to provide financial assistance to certain financially needy patients (the “Existing Arrangement”): (i) 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. Specifically, the Existing Arrangement provides assistance to financially needy patients with a *bona fide* diagnosis of cystic fibrosis with pulmonary complications who have insurance coverage, including coverage under Medicare and Medicaid, but who cannot afford the costs associated with their prescription drug coverage. The Requestor is a nonprofit, tax-exempt, charitable organization.

The Requestor proposes to modify its Existing Arrangement in three ways. First, the Requestor would expand its Existing Arrangement to provide financial assistance to patients with a *bona fide* diagnosis of cystic fibrosis, even if they do not have pulmonary complications. The Requestor would continue to focus the expanded program primarily on increasing access to high-cost, medically necessary drug treatment options that are often skipped by cystic fibrosis patients who cannot afford to pay. Second, the Requestor would expand its financial eligibility standards to cover more patients. Lastly, the Requestor

would replace its current requirement that a patient provide an explanation of benefits in order to enroll in the Existing Arrangement with a new requirement of a written certification and proof of certain drug costs incurred by the enrollee.

The Requestor has certified that all of the information provided in the request for modification of OIG Advisory Opinion 08-17, 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 above, 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 08-17.

First, the Requestor desires to expand its Existing Arrangement to include all patients diagnosed with cystic fibrosis, rather than limit assistance only to cystic fibrosis patients with pulmonary complications. The Requestor would continue to provide patients with financial assistance for cost-sharing obligations associated with certain high cost, medically necessary drug treatment options. Donations would continue to be unrestricted and combined in a single fund, available for use by the Requestor to carry out its charitable mission. The Requestor would award assistance without regard to any donor's interests and without regard to the applicant's choice of product, provider, practitioner, supplier, or insurance plan and has certified that all of the information provided in the original request and all supplementary information, other than the proposed modifications, remain correct. Therefore, the proposed modification to broaden the Requestor's sole disease fund 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 modify its patient eligibility standards to expand eligibility to families with higher household incomes than in the Existing Arrangement. The modified financial need criteria (and any future revisions to the financial need criteria) would continue to be based on national standards of indigence and would be uniformly applied. The Requestor would continue to use objective criteria for determining eligibility for assistance based upon the enrollee's medical condition and financial need. All other aspects of the Existing Arrangement related to an enrollee's income eligibility would remain the same, including the fact that the Requestor's pharmacy would not participate directly or indirectly in setting program eligibility criteria. Given this, our original determination is not altered by the revised income eligibility standards.

Third, the Requestor would no longer require proof from an enrollee that the Requestor is the payor of last resort by requiring an enrollee to provide the Requestor with a written explanation of benefits from an enrollee's insurer, denying coverage. In lieu of this

requirement, enrollees would provide proof of costs incurred for treatments or drug products obtained by the enrollee for treatment of cystic fibrosis and a written certification to the Requestor that the enrollee has not obtained and will not obtain the same financial assistance provided by the Requestor from another source.

Based on the totality of facts and circumstances and, for the reasons set forth in OIG Advisory Opinion No. 08-17 and herein, we conclude that the three modifications would not affect our conclusion in OIG Advisory Opinion 08-17. 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) 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. 08-17. The modification of OIG Advisory Opinion No. 08-17 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