



DEPARTMENT OF HEALTH AND HUMAN SERVICES

**OFFICE OF INSPECTOR GENERAL**

WASHINGTON, DC 20201



*[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:** April 4, 2012

**Posted:** April 11, 2012

[Name and address redacted]

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

Dear [Name redacted]:

We are writing in response to your request to further modify Office of Inspector General (“OIG”) Advisory Opinion No. 08-17, which we issued to [name redacted] (the “Foundation”) on October 14, 2008, and modified on October 27, 2010. In OIG Advisory Opinion 08-17, we concluded that: (i) the Foundation’s then-proposed arrangement to provide financial 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 “Original Arrangement”) would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although 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 Foundation 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.

In the Notice of Modification of OIG Advisory Opinion No. 08-17, we concluded that: (i) the Foundation’s then-proposed arrangement to: (a) expand the Original Arrangement to provide financial assistance to patients with a bona fide diagnosis of cystic fibrosis, even if they do not have pulmonary complications, (b) expand its financial eligibility standards to cover more patients, and (c) replace its requirement that a patient provide an explanation of benefits from the patient’s insurer denying coverage in order to enroll in

the Original Arrangement with a new requirement that the patient provide a written certification and proof of certain drug costs incurred by the patient, (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) although 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 Foundation 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 Foundation may give patients who are seeking financial assistance from the Foundation (“Prospective Recipients”) general contact information regarding publicly funded coverage options (such as Medicare or state-funded health care programs, such as Medicaid) or other patient assistance programs (such as state programs or other charitable assistance programs). The Foundation proposes to modify the Existing Arrangement by expanding the services it offers to Prospective Recipients to include counseling from a law firm regarding the Prospective Recipients’ eligibility for Federal and state-funded benefits programs and, for Prospective Recipients who appear to be eligible, assistance from the law firm in applying for benefits.

The Foundation certified that all of the information provided in the request for further modification of OIG Advisory Opinion 08-17 is true and correct and constitutes a complete description of the relevant facts and agreements among the parties. In particular, the Foundation certified that, apart from the modification described herein, the Existing Arrangement would continue to operate in accordance with the facts certified in the Foundation’s original request and prior request for modification (and supplemental submissions) in connection with OIG Advisory Opinion 08-17. We find that the proposed modification described below does not increase the risk to Federal health care programs.

The Foundation has entered into an agreement with a law firm that is familiar with the needs of cystic fibrosis patients. Pursuant to that agreement, the law firm would provide counseling services to Prospective Recipients regarding their eligibility for publicly funded benefits and, if appropriate, assist the Prospective Recipients with their initial benefits applications. The Foundation certified that it would compensate the law firm on a per-task basis set at fair market value.<sup>1</sup> The Foundation certified that neither it nor the law firm would refer or otherwise influence Prospective Recipients to use any particular

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<sup>1</sup> 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).

product, practitioner, provider, supplier, or insurance plan, or act in any way that would frustrate a Prospective Recipient's freedom of choice in selecting an insurance plan.<sup>2</sup>

Based on the totality of facts and circumstances and, for the reasons set forth in OIG Advisory Opinion No. 08-17, as previously modified, and herein, we conclude that the modification would not affect our conclusion in OIG Advisory Opinion 08-17, as previously modified. Accordingly, the Foundation's Existing Arrangement, as modified by the proposed modification 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 Foundation 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,

/Gregory E. Demske/

Gregory E. Demske  
Chief Counsel to the Inspector General

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<sup>2</sup> Although the law firm is not a requestor of this modification, the Foundation certified as to these facts by providing a letter from the law firm in which the law firm certified that it would not engage in this conduct. For purposes of this modification, we rely on the Foundation's certification regarding the law firm's conduct. If the law firm engages in conduct that is contrary to, or inconsistent with, this certification, this modification is without force and effect.