



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:** January 13, 2016

**Posted:** January 20, 2016

[Name and address redacted]

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

Dear [Name redacted]:

We are writing regarding Office of Inspector General (“OIG”) Advisory Opinion No. 08-17, which we issued to [name redacted] (the “Foundation”) on October 14, 2008, and subsequently modified on October 27, 2010 and April 4, 2012. In OIG Advisory Opinion No. 08-17, as modified, we concluded that: (i) the Foundation’s then-proposed arrangement to provide financial assistance to financially needy patients with cystic fibrosis who have insurance coverage, including coverage under Medicare and Medicaid, but who cannot afford the costs associated with their prescription drug coverage (the “Arrangement”), 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) although the Arrangement could potentially generate prohibited remuneration under the Federal 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 Arrangement.

As of October 12, 2015, the Foundation ceased enrolling new patients in the Arrangement and began helping patients who had been receiving assistance under the Arrangement to enroll in a patient assistance program operated by [name redacted] (the “PAP”), a non-profit, charitable organization.

The Foundation will not provide financial assistance for any claims enrolled patients submit after December 31, 2015 (the “Last Claim Date”). After the Last Claim Date, the Foundation will provide financial assistance only to patients who enrolled in the Arrangement prior to October 12, 2015, and only for claims the patients submitted prior to the Last Claim Date for which the PAP cannot provide financial assistance because the patients incurred the costs before enrolling in the PAP. The Foundation will make the last payment for financial assistance under the Arrangement before December 31, 2016. The Foundation certified that the Arrangement will terminate by December 31, 2016 (the “Termination Date”).

The OIG informed the Foundation that, because the Foundation will cease operations, the OIG would modify OIG Advisory Opinion 08-17 to reflect the Foundation’s winding down of the Arrangement and would terminate OIG Advisory Opinion No. 08-17 as of the Termination Date.<sup>1</sup> Pursuant to 42 C.F.R. § 1008.45(a), this letter serves as final notice of the OIG’s modification and termination of OIG Advisory Opinion No. 08-17. The modification of Advisory Opinion No. 08-17 means that: (i) the Arrangement, as modified as described herein, does not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Arrangement, as modified, 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 will 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 Arrangement, as modified. The termination of OIG Advisory Opinion No. 08-17 means that the advisory opinion is no longer in force and effect after the Termination Date. See 42 C.F.R. § 1008.45(b)(2). This modification and termination is without prejudice to the Foundation’s right to submit an advisory opinion request with respect to

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<sup>1</sup> On May 21, 2014, the OIG issued a Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs (the “Supplemental Bulletin”). The Supplemental Bulletin is available at: <http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf> and was subsequently published in the Federal Register at 79 Fed. Reg. 31120 (May 30, 2014). The Supplemental Bulletin provides additional guidance on patient assistance programs operated by independent charities to address certain risks about these programs that have come to our attention in recent years. We sent the Supplemental Bulletin, together with targeted letters, to all independent charities that have received favorable advisory opinions from us to request certain clarifications and modifications to those opinions. Because the Foundation will cease operations, we determined that we would not require the Foundation to implement the modifications referenced in our letter; instead, the OIG would modify OIG Advisory Opinion No. 08-17 to reflect the wind-down arrangement described herein and terminate the opinion as of the Termination Date.

any other existing arrangement or arrangement that the Foundation in good faith plans to undertake.

Sincerely,

/Gregory E. Demske/

Gregory E. Demske  
Chief Counsel to the Inspector General