



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 Termination of OIG Advisory Opinion No. 10-06

Dear [Name redacted]:

We are writing in reference to the Office of Inspector General (the “OIG”) Advisory Opinion No. 10-06, which was issued to [name redacted] (the “Corporation”) on May 20, 2010. In OIG Advisory Opinion No. 10-06, we concluded (i) the Corporation’s arrangement to provide financial assistance to financially needy patients in connection with premium and cost-sharing obligations 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 Corporation 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.

On October 27, 2015, you informed us that the Corporation never implemented the Arrangement and does not intend to do so in the future. As a consequence, by letter dated October 28, 2015, the OIG provided you with a notice of intent to terminate

Advisory Opinion No. 10-06 (the “Notice”).¹ Pursuant to 42 C.F.R. § 1008.45, the OIG also provided you with a reasonable opportunity to respond to the Notice.

Pursuant to 42 C.F.R. § 1008.45(a), this letter serves as final notice of the OIG’s termination of OIG Advisory Opinion No. 10-06. The termination of OIG Advisory Opinion No. 10-06 means that the advisory opinion is revoked as of the termination date and is no longer in force and effect after the termination date. See 42 C.F.R. § 1008.45(b)(2).

This termination is without prejudice to the Corporation’s right to submit an advisory opinion request with respect to any other existing arrangement or arrangement that the Corporation in good faith plans to undertake.

Sincerely,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General

¹ 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 Corporation did not implement the Arrangement and does not intend to do so, we determined that no modification of the opinion would be required; instead the OIG would terminate the opinion.