



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: March 30, 2016

Posted: April 6, 2016

[Name and address redacted]

Re: Final Notice of Termination of OIG Advisory Opinion No. 06-09

Dear [Name redacted]:

We are writing regarding Office of Inspector General (“OIG”) Advisory Opinion No. 06-09, which we issued to [name redacted] (the “Fund”) on August 18, 2006. In OIG Advisory Opinion No. 06-09, we concluded that: (i) the Fund’s proposed arrangement to subsidize Medicare Part D premium and cost-sharing obligations owed by financially needy patients with end-stage renal disease and chronic kidney disease (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 Fund 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.

In October 2015, your counsel informed the OIG that the Fund currently has no program to subsidize Medicare Part D premium and cost-sharing obligations, and on December 18, 2015, he confirmed that the Fund has no plans to resume or implement such a program in the future. As a consequence, on December 22, 2015, the OIG provided you with a notice of intent to terminate Advisory Opinion No. 06-09 (the “Notice”).¹

¹ On May 21, 2014, the Office of Inspector General (“OIG”) issued a Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs

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. 06-09. The termination of OIG Advisory Opinion No. 06-09 means that the advisory opinion is no longer in force and effect. See 42 C.F.R. § 1008.45(b)(2).

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

Sincerely,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General

(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 (“PAPs”) 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 Arrangement is not currently in effect and the Fund does not intend to resume or implement the Arrangement in the future, we determined that no modification of the opinion would be required; instead OIG would terminate the opinion.