



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: November 28, 2017

Posted: November 28, 2017

[Name and address redacted]

We are writing in reference to Office of Inspector General (“OIG”) Advisory Opinion No. 06-04, issued to [name redacted] (“Requestor”), a nonprofit, tax-exempt, charitable patient assistance program, on April 20, 2006, and subsequently modified on December 23, 2015 (collectively, “06-04”).

In accordance with our right to reconsider the questions and issues raised in advisory opinions, described at 42 C.F.R. § 1008.45 and in 06-04, we have determined that the public interest requires us to rescind 06-04. We have made this determination based on Requestor’s failure to fully, completely, and accurately disclose all relevant and material facts to OIG in accordance with 42 C.F.R. § 1008.45. We determined that Requestor failed to comply with certain factual certifications it made to OIG pursuant to 42 C.F.R. § 1008.38. Requestor’s certifications were material to OIG’s conclusions in 06-04 that: (i) the arrangement was sufficiently low risk, and (ii) we would not subject Requestor to administrative sanctions under section 1128A(a)(5) of the Social Security Act (the “Act”) or for violations of the anti-kickback statute, section 1128B(b) of the Act. Specifically, we have determined that, in contravention of the certifications Requestor made, Requestor: (i) provided patient-specific data to one or more donors that would enable the donor(s) to correlate the amount and frequency of their donations with the number of subsidized prescriptions or orders for their products, and (ii) allowed donors to directly or indirectly influence the identification or delineation of Requestor’s disease categories.

By letter dated August 10, 2017, OIG provided Requestor with a Preliminary Notice of Rescission or Termination of OIG Advisory Opinion No. 06-04 (the “Notice”). Pursuant to 42 C.F.R. § 1008.45, OIG also provided Requestor with a reasonable opportunity to respond to the Notice.

Requestor submitted information in response to the Notice. Requestor did not dispute our preliminary determination, nor did Requestor attempt to refute our specific findings regarding the relevant and material facts that were not fully, completely, and accurately disclosed to OIG. Instead, Requestor proposed to further modify 06-04 to add provisions related to its new compliance program. Requestor also stated that if OIG were to rescind or terminate 06-04, Requestor likely would cease operations and no longer provide copayment assistance to patients.

The factual certifications with which Requestor failed to comply were material to our determination in 06-04 that the arrangement interposed an independent, *bona fide* charitable organization between donors and patients. Requestor's failure to comply with these certifications materially increased the risk that Requestor served as a conduit for financial assistance from a pharmaceutical manufacturer donor to a patient, and thus increased the risk that the patients who sought assistance from Requestor would be steered to federally reimbursable drugs that the manufacturer donor sold. This type of steering can harm patients and the Federal health care programs, because, for example, patients may be urged to seek, and physicians may be more likely to prescribe, a more expensive drug if copayment assistance is available for that drug but not for less expensive but therapeutically equivalent alternatives. In these circumstances, manufacturers may have greater ability to raise the prices of their drugs while insulating patients from the immediate out-of-pocket effects of price increases, leaving Federal health care programs like Medicare (and the taxpayers who fund those programs) to bear the cost.

OIG cannot agree to Requestor's proposal to further modify 06-04, because Requestor allowed donors to directly or indirectly influence the identification or delineation of its disease categories. This practice directly contravened the specific safeguards Requestor promised to follow and upon which OIG relied in issuing the advisory opinion.

Finally, when issuing advisory opinions, OIG relies on the facts and information the requesting parties present to us. We do not undertake an independent investigation of the information or the arrangement that is the subject of the opinion. When a requesting party misrepresents material facts to us, its advisory opinion has no force or effect. Given the specific facts and circumstances of this matter, including the scope of Requestor's conduct, OIG believes it is necessary to rescind 06-04 to maintain the integrity of the advisory opinion process.

In light of the information we have reviewed, including Requestor's submission, we have determined that the public interest requires rescission, and hereby rescind 06-04 effective immediately. Nothing in this letter limits the investigational or prosecutorial authority of OIG, the Department of Justice, or any other agency of the government.

Pursuant to 42 C.F.R. § 1008.45(a), this letter serves as final notice of OIG's rescission of 06-04; any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the party's intent, which determination is beyond the scope of the advisory opinion process and this final notice. The rescission of 06-04 means that the advisory opinion and its modification are revoked retroactively to the original date of issuance (April 20, 2006) and will be deemed to have been without force and effect at any time. See 42 C.F.R. § 1008.45(b)(1).

Although Requestor has represented it may cease operations, we note that OIG's rescission of 06-04 does not require Requestor to do so. Should Requestor continue operations, all relevant laws and regulations continue to apply, and any violations could trigger enforcement action. To the extent that Requestor ceases operations, we would expect it to act in accordance with its nonprofit, charitable, tax-exempt purposes and either operate or wind down in a manner that protects patients and their access to outpatient prescription drugs. In addition, should Requestor cease operations, pharmaceutical manufacturers that wish to provide free drugs to impacted patients for the remaining period during which the patients otherwise would have received copayment assistance from Requestor may contact OIG if they have fraud and abuse concerns.

Sincerely,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General