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: June 7, 2013

Posted: June 14, 2013

[Name and address redacted]

Re: Modification of OIG Advisory Opinion No. 11-05

Dear [Name redacted]:

We are writing in response to your request to modify Office of Inspector General ("OIG") Advisory Opinion No. 11-05, which we issued to [name redacted] (the "Foundation") on May 13, 2011. In OIG Advisory Opinion No. 11-05, we concluded that the Foundation's proposal to provide financial assistance with cost-sharing obligations for certain genetic tests to financially needy individuals, including but not limited to Medicare and Medicaid beneficiaries (the "Existing Arrangement"), (i) 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) while 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.[1]

[1] OIG Advisory Opinion No. 11-05 also analyzed the Foundation's practice of providing vouchers for free genetic tests to individuals who are uninsured or whose insurance does not cover genetic tests (the "Voucher Arrangement") and found that the Voucher Arrangement did not constitute remuneration under section 1128A(a)(5) and did not implicate the anti-kickback statute.

Under the Existing Arrangement, the Foundation provides support for uninsured and underinsured patients to help them access genetic testing used to screen for cancer. For patients with insurance, including Federal health care program beneficiaries, the Foundation provides individual patient grants that can be used to cover copayments, deductibles, and coinsurance payments associated with genetic testing. To be eligible for copayment assistance, the patient must meet certain income qualifications that are based on a designated percentage of the poverty guidelines.[2] In addition, the genetic test must meet medical criteria to be included in the program. The Foundation would continue to operate the Existing Arrangement in accordance with the facts certified in the Foundation's original request (and supplemental submissions) in connection with OIG Advisory Opinion No. 11-05.

The Foundation proposes to expand its support program by also providing cost-sharing assistance for prescription drugs related to the treatment of cancer (the "Proposed Arrangement"). The Foundation intends to develop and maintain specific disease funds to provide this assistance. The disease funds would be defined by the Foundation's board, in the board's sole discretion, based on the board's independent assessment of whether a new fund arrangement will best serve patients' needs. Each disease fund would support a range of disease states and would include all drugs available to treat those disease states. The Foundation would not define a disease fund in a manner such that it would include only one drug or only drugs made by a single manufacturer. In addition, the Foundation intends to provide cost-sharing assistance with medications that treat particular diseases associated with the treatment of cancer, such as diabetes mellitus and hypertension. Thus, a diabetic patient with a specific form of cancer would apply to the disease fund for that form of cancer, but would be eligible to receive assistance for both the cancer medication and the diabetes medication from that fund.

The Foundation has certified that the Proposed Arrangement would operate in a manner substantially similar to the Existing Arrangement with respect to donor contributions and patient eligibility determinations. The Foundation would award assistance to all eligible patients on a first-come, first-served basis to the extent funding is available. Insured patients who have an income below a designated percentage of the poverty guidelines and who are under the care of a physician and undergoing treatment for cancer at the time of application would be eligible for assistance. Participating patients could change providers,

[2] Pursuant to section 673(2) of the Omnibus Budget Reconciliation Act of 1981, the Secretary of the Department of Health and Human Services is required to update the poverty guidelines annually.

practitioners, suppliers, products, or insurance plans without losing eligibility for aid.[3] Under the Proposed Arrangement, the Foundation would cap the amount of copayment assistance at a certain level per beneficiary, per drug, per year. In addition, under the Proposed Arrangement, pharmaceutical manufacturer donors and their affiliates would not be permitted to earmark donations to support specific disease states.

The Foundation has certified that all of the information provided in the request for modification of OIG Advisory Opinion No. 11-05 is true and correct and constitutes a complete description of the relevant facts and agreements among the parties. We find that the proposed modifications described herein do not materially increase the risk to Federal health care programs.

First, the Proposed Arrangement does not pose a risk of steering patients to particular medications. The disease funds would not be limited to a subset of available drugs to treat the patient's condition. Instead, the Foundation would provide assistance to eligible patients for all drugs available to treat the patient's cancer, as well as for drugs related to certain conditions that affect a patient's cancer treatment.

Second, patient eligibility would continue to be determined using objective criteria that can be applied in a consistent manner and would not take into consideration any of the following: an interest of a person or entity who contributes to the Foundation's grant program funds or their affiliates; the applicant's choice of provider, practitioner, insurer, insurance plan, supplier, test, or product; or the identity of the referring person or organization.

Third, the Proposed Arrangement presents a low risk of improper influence by donors. The Foundation certified that no health plan, affiliate of a health plan, donor, or affiliate of any donor would exert any direct or indirect influence or control over the Foundation or the Foundation's programs. Further, pharmaceutical manufacturer donors and their affiliates would not be permitted to earmark their donations to particular funds or disease states.

In sum, the Foundation's Proposed Arrangement would not raise the same concerns about the potential for improper donor influence presented in some patient assistance programs.

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[3] The Foundation indicated that it plans to maintain a network of participating pharmacies that have made arrangements with the Foundation for the efficient processing of claims. However, eligible patients would not be required to use these pharmacies to receive assistance. Further, the Foundation has no ownership interests or affiliations with any pharmacy, and the board of directors and staff of the Foundation would sign conflict of interest forms that prohibit them (and their family members) from affiliating with a facility that provides services that will be reimbursed in part through the copayment assistance program.

Here, a patient with a type of cancer covered by the disease funds would be eligible for assistance with any drug that the patient's doctor prescribes related to the cancer treatment rather than being limited to only specialty drugs. Further, pharmaceutical manufacturers and their affiliates would be unable to earmark their donations, thus decreasing the chance that the manufacturer is supporting its own drugs. Based on the totality of the facts and circumstances and for the reasons set forth in OIG Advisory Opinion No. 11-05 and herein, we conclude that the Proposed Arrangement would not affect our conclusion in OIG Advisory Opinion No. 11-05. Accordingly, the Existing Arrangement, as supplemented by the Proposed Arrangement, (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. 11-05. The modification of OIG Advisory Opinion No. 11-05 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