[*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: October 11, 2011

Posted: October 18, 2011

[Name and address redacted]

Re: Notice of Modification of OIG Advisory Opinion No. 07-18

Dear [Name redacted]:

We are writing in response to your request to modify Office of Inspector General ("OIG") Advisory Opinion No. 07-18, which we issued to [name redacted] (the "Requestor" or the "Foundation") on December 19, 2007. In OIG Advisory Opinion 07-18, we concluded that: (i) the Foundation's then-existing arrangement to provide assistance with cost-sharing obligations to certain financially needy individuals diagnosed with specified serious diseases, and its then-proposed arrangement to assist with premium obligations for similarly situated patients, (collectively, the "Existing Arrangement") would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of 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.

Under the Existing Arrangement, the Foundation provides annual individual patient grants to help insured patients, including, but not limited to, Federal health care program beneficiaries, cover copayments, deductibles, and co-insurance associated with certain high-cost drugs used to treat specified diseases. In order to be eligible for co-pay assistance, a patient must have health insurance coverage for the relevant disease, the patient's insurance must cover the medication for which he or she seeks assistance, and the medication must

treat the disease itself or conditions precipitated by medication used to treat the disease. The patient must meet certain minimum income qualifications that are based on a designated percentage of the Federal Poverty Level.

The Foundation proposes to modify its Existing Arrangement in two ways, as described in greater detail below. In brief, the Foundation proposes to: (1) move towards a specialty therapeutics model such that its disease funds would only offer assistance to patients prescribed treatment with specialty therapeutics (as defined below); and (2) enroll certain pharmacies as "Participating Pharmacies" through which claims could be processed more efficiently.

The Foundation has certified that all of the information provided in the request for modification of OIG Advisory Opinion 07-18 is true and correct and constitutes a complete description of the relevant facts and agreements among the parties. In particular, the Requestor has certified that, apart from the two modifications described herein, the Existing Arrangement would continue to operate in accordance with the facts certified in the Foundation's original request (and supplemental submissions) in connection with OIG Advisory Opinion 07-18. We find that the proposed modifications described below do not increase the risk to Federal health care programs.

First, the Foundation proposes to implement a specialty therapeutics model for establishing new disease funds such that the Foundation would only offer assistance to patients prescribed specialty therapeutics for a particular chronic or life-threatening disease. Specialty therapeutics are costly medications with particular features that complicate their use (e.g., the medications may require physician administration, the medications may be self-administrable but require injection or infusion, the medications may require special handling or storage, or their effective use may require significant patient education). According to the Foundation, limiting its assistance to patients requiring these particularly expensive medications will help the charity maximize efficiency, minimize cost, and prioritize providing assistance to patients who are the most in need. Therefore, in addition to limiting new disease funds to specialty therapeutics, the Foundation would also review existing funds to determine whether to convert those funds to the new model.

Over the past several years, we have received numerous requests from charities seeking to establish or modify patient assistance programs with a focus on high-cost drugs. We understand that charities have limited resources and seek to focus those resources on patients with the greatest need. However, we are concerned that narrowly defined disease categories, particularly in combination with a focus on high-cost drugs, can effectively result in patients being steered to particular products based on the availability of a subsidy and increase the likelihood that the charity would serve as an improper conduit for donors to provide funds to patients who use their specific products. With that said, and as we have

recognized in the past, properly structured programs that define their disease funds in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products—even when many or most of those products are specialty therapeutics—can present a sufficiently low level of risk to Federal health care programs. Here, disease funds would continue to be designated and defined at the Foundation's sole discretion through an internal decision-making process. Decisions about disease funds would be based on an independent assessment by the Foundation's Board of Directors (its "Board")[1] of whether a new fund would best serve patient needs. Each disease fund would be defined in accordance with widely recognized clinical standards, and would cover at least two specialty therapeutics marketed by different manufacturers, assuming more than one specialty therapeutic is available for the particular disease state or diagnosis that is the subject of the fund. In all cases, the Foundation would continue to make every effort to include new specialty therapeutics as they become available. In circumstances where there is only one specialty therapeutic to treat a particular disease state or diagnosis that is the subject of the fund, or only one pharmaceutical manufacturer that makes all of the specialty therapeutics for the disease state or diagnosis, the Foundation would not limit the fund for that disease state or diagnosis to specialty therapeutics; in those circumstances, the Foundation would cover other drugs for the disease state or diagnosis, if, in the Foundation's understanding, such drugs exist.[2] The Foundation provided a list of specialty therapeutics that would be covered under existing funds and under the initial new funds that the Foundation is considering pursuing. All funds on this list include at least two specialty therapeutics, marketed by different manufacturers. In fact, the majority of funds on the list include at least four specialty therapeutics.

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[1] Board members (or their spouses or domestic partners) may receive compensation, including honoraria and reimbursement for travel and related expenses from, or hold stock or other investment interest in, a donor that is involved in the research, manufacture, or sale of pharmaceutical products, but at no time may a majority of the Board, its officers, or its committees be composed of members having such financial or employment relationships with any donors or affiliates of donors. In OIG Advisory Opinion 07-18, the Foundation had stated that no future Board members would receive compensation from, or have direct stock or investment interests in, a donor. However, the Foundation stated in this request for modification that Board members may continue to have financial or employment interests in a donor entity as long as the requirements relating to Board composition and recusal set forth in OIG Advisory Opinion 07-18 are met.

[2] The Foundation has certified that only in rare circumstances would there be only one product or one manufacturer (including its affiliates) that makes all of the products relevant to an otherwise properly delineated fund (including specialty therapeutics and non-specialty therapeutics). In such rare circumstances, the Foundation would use its best efforts to cover additional products and manufacturers as they become available.

The Foundation is a charity with limited resources, and it already focuses its assistance program on patients who need high-cost medications. All safeguards that led us to determine that the Existing Arrangement entailed minimal risk that donor contributions would improperly influence referrals by the Foundation, and that beneficiaries would not likely be improperly influenced in their selection of a particular provider, practitioner, supplier, or product, would remain in place. Therefore, we do not view the Foundation's proposal to specifically cover specialty therapeutics as increasing risk to Federal health care programs.

Under the second proposed modification, the Foundation would enroll certain pharmacies as "Participating Pharmacies" through which claims could be processed more efficiently. Any duly licensed pharmacy capable of dispensing specialty therapeutics and equipped to appropriately exchange information with the Foundation for claims processing would be permitted to enroll as a Participating Pharmacy. Participating Pharmacies would have access to a streamlined process for approving patient eligibility, while other pharmacies would be required to use the existing online or telephone application process, which can take longer. Under the Existing Arrangement, review of an applicant's eligibility is typically completed in two days, although additional time may be required in order to obtain income documentation. If an application is approved, the patient receives a pharmacy benefit card that allows the patient to avoid up-front out-of-pocket obligations for his or her medications and facilitates providers billing to the Foundation directly on the patient's behalf.

Patients would not be required to use a Participating Pharmacy to obtain their medications; the benefit card the patient uses to avoid up-front costs would continue to be valid at any duly licensed pharmacy, and that pharmacy provider would still be able to bill the Foundation directly. Moreover, under the Existing Arrangement, the Foundation has in place two programs that would continue after this modification, which would lessen the effect of any delay a patient might experience by choosing not to use a Participating Pharmacy. First, the Foundation has a temporary approval program that allows it to grant financial assistance to cover the out-of-pocket obligation for a 30-day supply of medication while a patient's application is pending. In addition, after a patient's application is approved, the patient can submit claims for pharmaceutical out-of-pocket obligations incurred in the period back to 90 days prior to approval. Because patients would continue to be free to use any duly licensed pharmacy, and the patient's choice of pharmacy would have only a temporary and minimal impact on the timing of receiving benefits, enrollment of Participating Pharmacies would not increase risk to Federal health care programs or have a detrimental effect on beneficiaries.

Based on the totality of facts and circumstances and, for the reasons set forth in OIG Advisory Opinion No. 07-18 and herein, we conclude that the two modifications would not affect our conclusion in OIG Advisory Opinion 07-18. Accordingly, the Foundation's Existing Arrangement, as modified by the proposed modifications described herein, (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 Requestor 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. 07-18. The modification of OIG Advisory Opinion No. 07-18 means that the advisory opinion continues in full force and effect in modified form. See 42 C.F.R. § 1008.45(b)(3).

Sincerely,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General