



[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: September 23, 2011

Posted: September 30, 2011

[Names and addresses redacted]

Re: Notice of Modification of OIG Advisory Opinion No. 07-06

Gentlemen:

We are writing in response to your request to modify Office of Inspector General (“OIG”) Advisory Opinion No. 07-06, which we issued on July 23, 2007 to [name redacted] (the “Foundation”) and to [name redacted] (collectively, the “Requestors”). In OIG Advisory Opinion No. 07-06, we concluded that: (i) the arrangement to provide assistance with cost-sharing obligations and premium obligations to certain financially needy individuals with specified chronic diseases (the “Original Arrangement”) did not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the Original 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 Requestors 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 Original Arrangement.

Pursuant to the Original Arrangement, the Foundation provides assistance from a series of individual charitable funds (the “Open Funds”) to financially needy patients, including both Federal health care program beneficiaries and privately insured patients, who have been diagnosed with specified disease states.¹ Through the Open Funds, the Foundation

¹ Presently, the Open Funds cover the following disease states: acute porphyrias; age-related macular degeneration; anemia associated with chronic renal insufficiency/chronic renal failure; ankylosing spondylitis; asthma, moderate to severe; bone metastases; breast cancer; carcinoid tumors and symptoms related to carcinoid tumors; chemotherapy

may provide financial assistance for specific, documented out-of-pocket expenses associated with outpatient prescription drug treatment, including insurance premiums and cost-sharing amounts. As described in greater detail below, the Foundation proposes to modify its Original Arrangement by establishing a process to create new charitable funds to direct assistance solely to qualified Medicare beneficiaries with specified disease states.

The Requestors certified that all of the information provided in the request for modification of OIG Advisory Opinion No. 07-06 is true and correct and constitutes a complete description of the relevant facts and agreements among the parties. In particular, the Requestors certified that, apart from the modifications described herein, the Original Arrangement would continue to operate in accordance with all material facts certified in the Requestors' original request (and supplemental submissions) in connection with OIG Advisory Opinion No. 07-06. We find that the proposed modification described below does not increase the risk to the Federal health care programs.

The Requestors seek the flexibility to expand the Original Arrangement by establishing funds (individually, a "Medicare Access Fund" and collectively, the "Medicare Access Funds") that would provide assistance only to qualified Medicare beneficiaries with specified disease states (the "Proposed Arrangement").² Donors interested in supporting a particular disease state would be presented the option of earmarking assistance to that disease state in the context of the Open Funds, the Medicare Access Funds, or both.³ In

induced anemia; chemotherapy induced neutropenia; colorectal carcinoma; cytomegalovirus; cutaneous t-cell lymphoma; Dupuytren's disease; glioblastoma multiforme and anaplastic astrocytoma; head and neck cancer; hepatitis B and C; idiopathic thrombocytopenic purpura; iron overload as a result of blood transfusions; immunosuppressive treatment for solid organ transplant recipients; non-Hodgkin's lymphoma; non-small cell lung cancer; post menopausal osteoporosis; psoriasis, psoriatic arthritis; rheumatoid arthritis; secondary hyperparathyroidism; and Wilm's tumor.

² The Foundation states that it plans to implement a pilot Medicare Access Fund for autoimmune diseases. The pilot fund would cover a number of disease states, each of which is currently covered by a separate Open Fund, that share common characteristics, including rheumatoid arthritis, psoriasis, psoriatic arthritis, and several other disease states. According to the Foundation, aggregation in this manner would produce administrative and economic benefits. Subsequent funds might also aggregate disease states.

³ According to the Requestors, to the extent funding is available, Medicare beneficiaries would first receive benefits from the Medicare Access Funds. In the event that the Medicare Access Funds were exhausted, Medicare beneficiaries would continue to be

OIG Advisory Opinion 07-06, the Requestors certified that the Foundation defines its disease funds in accordance with widely recognized clinical standards and in a manner that covers within each disease fund a broad spectrum of available products. The Requestors further certified that, in rare circumstances where there may be only one product relevant to an otherwise properly delineated fund or only one manufacturer (including its affiliates) that makes all of the products relevant to an otherwise properly delineated fund, the Foundation uses its best efforts to cover additional products and manufacturers as they become available. In their request for modification of OIG Advisory Opinion 07-06, however, the Requestors certified that the Medicare Access Funds would extend financial assistance only in connection with disease states for which at least two different products from two different manufacturers are supported by the funds. This safeguard would ensure that Medicare Access Funds would not be established for single-product or single-manufacturer disease states, even in rare instances, and thus reduces the likelihood that earmarked donations would effectively steer Medicare beneficiaries to particular products based on the availability of a subsidy. In all other respects, the Requestors certified that the same safeguards would be employed in connection with the Medicare Access Funds as under the Original Arrangement. The Foundation would award assistance without regard to any donor's interests and without regard to the applicant's choice of product, provider, practitioner, supplier, or insurance plan, as long as he or she meets eligibility criteria.

Therefore, the proposed modification does not change our original determination that the Foundation's program would not be construed as payments to Federal health care program beneficiaries or to the Foundation to arrange for referrals. Our conclusion might differ if the Medicare Access Funds included single-product or single-manufacturer disease states.

The Proposed Arrangement represents a departure from patient assistance programs we have addressed in the past in that the Requestors would expressly limit the aid provided by the proposed funds to qualified Medicare beneficiaries. However, based on the totality of facts and circumstances, and for the reasons set forth in OIG Advisory Opinion No. 07-06 and herein, we conclude that the modification would not affect our conclusion in OIG Advisory Opinion No. 07-06. Accordingly, the Requestors' Original Arrangement, as modified by the proposed modification described herein, (i) would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while 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 Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate

eligible for available benefits from the Open Funds on the same basis as non-Medicare patients.

to the commission of acts described in section 1128B(b) of the Act) in connection with the Original 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. 07-06. The modification of OIG Advisory Opinion No. 07-06 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