

PUBLICATION

OIG Approves Nonprofit Foundation's Proposed Copayment Assistance Program [Ober|Kaler]

2015: Issue 1

On January 5, 2015, the OIG posted a favorable advisory opinion, OIG Advisory Opinion 14-11, regarding a 501(c)(3) charitable foundation's (Foundation) proposal to establish a patient assistance program that would provide copayment assistance based on financial need to patients with Crohn's disease and ulcerative colitis (Specified Diseases), including patients covered by federal health care programs. The advisory opinion is consistent with the OIG's past guidance approving cost-sharing subsidies provided by bona fide, charitable organizations that receive donations from donors whose products are supported by the cost-sharing subsidies.

Under the proposed arrangement, the Foundation would maintain two disease funds, one for each of the Specified Diseases, as defined by widely recognized clinical standards. The Foundation certified that a patient would be permitted to apply for the assistance only after the patient has selected his or her health care provider or practitioner, and the patient's treatment regimen is already established, and the patient would remain free to change providers, practitioners, suppliers, drugs and insurance plans at any time. The Foundation will use a preset sliding scale to determine the patient's assistance amount (full or partial) on a first come, first served basis, and grant the patient award for one year, at which time the patient may reapply. The Foundation certified that multiple drugs are available to treat each of the Specified Diseases, and that the Foundation would make assistance available for all drugs, including generics and bioequivalents, that are covered by the patient's insurance to treat the Specified Disease. The Foundation would provide the financial assistance directly to the patient's pharmacy, or other health care provider or supplier whenever possible, unless the provider or supplier does not accept third-party payment and the patient can submit for reimbursement.

The Foundation would receive donations from a number of sources, including pharmaceutical manufacturers. A donor can provide unrestricted donations or earmark donations to support patients with particular Specified Diseases. No donor or individual affiliated with a donor may serve on the Foundation's Board. Moreover, while the Foundation may give the donors aggregate data regarding the number of claims or the average amount of grants, the Foundation will not provide any individual patient information or data related to the identity, amount or nature of drugs subsidized under the proposed arrangement.

The OIG analyzed two aspects of the proposed arrangement — the donor contributions to the Foundation and the Foundation's assistance to the patients — and found minimal risk of fraud and abuse under the antikickback statute and civil monetary provision regarding beneficiary inducements.

With respect to the donor contributions, the OIG identified the following factors as minimizing risk that the donor contributions would directly or indirectly influence referrals:

- Foundation operates as an independent, tax-exempt, charitable organization, and no donor, immediate family member, or persons otherwise affiliated with the donor are eligible to sit on the Foundation's board or otherwise exert control over the Foundation or its program.
- The Foundation will not refer any patient to a particular provider, supplier, drug or plan, since the patient must have selected his or her health care providers and suppliers and have an established

treatment regimen prior to applying for assistance. The patient would maintain freedom of choice throughout the program.

- While the Foundation may make certain aggregate data available, it will not provide any data that would facilitate a donor in correlating the amount or frequency of its donations with the amount or frequency of the use of its drugs or services.
- The Foundation will permit a donor to earmark donations to a particular Specified Disease, but such diseases are defined based on widely recognized clinical standards without regard to the type of treatment or specific symptoms. Donors would not be permitted to earmark donations for particular treatment or drugs.

In addition, the OIG concluded that the provision of assistance to federal health care program beneficiaries presents a low risk of fraud and abuse and is not likely to influence a beneficiary's selection of a particular provider, practitioner or supplier for the following reasons:

- The Foundation would determine eligibility for assistance solely based on financial need without considering the identity of the patient's health care providers, practitioners, suppliers or drugs, or the identity of any donor that has contributed to the Specified Disease fund.
- The Foundation will assist patients on a first come, first serve basis, and will not recommend, or arrange for the patient's use of any particular practitioner, provider or supplier. The patients would not be informed of the identity of any donors.