PUBLICATION

Charity's Patient Assistance Program Passes OIG Muster in Advisory Opinion 15-17 [Ober|Kaler]

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On December 28, 2015, the Department of Health and Human Services, Office of Inspector General (OIG) issued OIG Advisory Opinion 15-17 [PDF], approving a charity's proposal to unveil a new patient assistance program dedicated to supporting patients with a specified disease state (Specified Disease). In light of the numerous safeguards proposed by the charity, the OIG concluded the arrangement would likely pose a low risk under both the federal anti-kickback statute and the civil monetary penalty provision prohibiting inducements to beneficiaries (Beneficiary Inducement CMP).

Overview of the Proposed Patient Assistance Program

Under the proposed patient assistance program, the charity will assist financially needy patients, including Medicare and Medicaid beneficiaries, with their copayment and coinsurance obligations, health insurance premiums, and deductibles for outpatient prescription drugs used to treat the Specified Disease. The Specified Disease is, as represented by the charity, a "broadly defined" disease state based on "widely recognized clinical standards," without reference to specific symptoms, severity of symptoms, method of administration of drugs, or type of drug treatment.

The charity intends to disseminate information regarding the proposed patient assistance program via patients' treating physicians, written material to be placed in physicians' offices, and direct online outreach by the charity itself. Participation in the proposed program will be limited in accordance with the following parameters:

- *Patients diagnosed with Stage 3 or Stage 4 of the Specified Disease*: Eligibility in the program will be limited to patients diagnosed with Stage 3 or Stage 4 of the Specified Disease. That said, financial assistance will not be limited to only those drugs expressly approved for Stage 3 or Stage 4 of the Specified Disease.
- *Patients must already have a treating provider*: To participate in the proposed program, patients must have already selected a health care provider, practitioner, or supplier, with a treatment regimen in place. While enrolled in the proposed program, patients will remain free to change their providers, practitioners, suppliers, drugs, and insurance plans.
- *Financial need, in accordance with federal poverty guidelines*: In line with the charity's stated intent to apply a "reasonable, verifiable, and uniform measure of financial need," patient eligibility will be based on financial need, in accordance with the federal poverty level guidelines. The charity will employ a screening process to verify applicants' representations, relying on either a third-party vendor and/or directly collecting documentation of financial resources from the patient.

The charity certified that under no circumstances would patient eligibility be determined based in whole or in part on (a) the interest of a donor; (b) the patient's choice of provider, practitioner, supplier, drug, or insurance plan; or (c) the identity of the referring person or entity. In further support of patient choice, the charity certified that it "would not refer patients to, recommend, or arrange for the use of any particular provider, practitioner, supplier, drug, or insurance plan…."

Upon meeting the eligibility criteria, patients would be approved to participate in the charity's patient assistance program on a first-come, first-served basis, for a term of one year. Patients could participate for a second year upon the charity re-verifying the patient's financial need, and the patient submitting documentation from his or her physician indicating treatment for the Specified Disease remains ongoing.

Charitable contributions to the proposed patient assistance program would come largely from pharmaceutical manufacturers. However, the charity certified that no donor to the charity or affiliate of any donor directly or indirectly influenced the identification of the proposed Specified Disease fund. In support of this certification, the charity stated that (a) the charity prohibits all donors from earmarking their donations to support a particular drug or type of cost-sharing obligation; (b) donors are able to change or discontinue their contributions to the charity at any time; and (c) multiple drugs, marketed by different pharmaceutical manufactures, are available to treat the Specified Disease, each of which the charity would provide financial assistance for. In addition, the charity is governed by an independent board of directors, in which no donor or affiliate of a donor (including former directors, officers, or employees of a donor who maintain an ongoing relationship with a donor), exerts direct or indirect influence.

The charity would provide donors to the Specified Disease fund with data outlining the aggregate number of applicants, patients served, and the amount of funds used. The data provided would not allow for a donor to assess the impact of its donation on the use of its drugs. Patients would not receive any information about donors and donors would not receive any information about other donors.

Anti-kickback Statute

The OIG concluded the charity's proposed patient assistance program would pose a "minimal risk" under the anti-kickback statute – that is, given the program safeguards proposed by the charity, it was unlikely that any donors' contribution to the charity would be construed as payments to arrange for referrals to the donor. In reaching its conclusion, the OIG highlighted the following factors:

- *The charity's independence from donors*: No donor (or affiliate of any donor) exerts control over the charity, as evidenced by the fact that (a) the charity retains independence in how it may use a donor's contribution; (b) no donor exerted influence in selecting the Specified Disease fund; and (c) the charity's board remains independent of any donor's or donor affiliate's influence.
- *Participating patients will already have a treatment regimen in place*: In order to participate in the charity's proposed program, patients must have selected a health care provider, practitioner, or supplier. Accordingly, the patient will already have a treatment regimen in place. In addition, the charity itself may not refer patients to, recommend, or arrange for, the use of a particular practitioner, provider, supplier, drug, or insurance plan. Also, participating patients remain free to change their health care provider, supplier, drug, or insurance plan. As such, participation in the charity's proposed program will not influence a patient's selection of a particular practitioner, provider, supplier, drug, or insurance plan.
- *Donors receive limited data*: Under the proposed program, the data provided by the charity to donors will be limited to the aggregate number of applicants for financial assistance, the number of patients served, and the total amount of funds used for financial assistance. Donors will not receive data that would allow them to specifically correlate their donations with the use of their respective drug(s). Likewise, patients will not receive any information regarding donors.
- *Donors' lack of involvement in selecting the disease state*: The charity certified that no donor, or affiliate of any donor, directly or indirectly, influenced the identification of the Specified Disease and corresponding disease fund. In support of this certification, the OIG looked to the fact that the disease fund is broadly defined and is based on "widely recognized clinical standards" for a "broad spectrum

of available drugs." While the disease fund would be limited to patients in stage 3 or stage 4 of the Specified Disease, it would not otherwise be limited by specific symptoms, etc., and financial assistance would be available for all drugs, including generic or bioequivalent drugs used to treat any stage of the Specified Disease.

The above factors, the OIG concluded, would provide "sufficient insulation," such that it would be unlikely the charity's proposed arrangement would serve as a "disguised conduit" in which a pharmaceutical manufacturer would seek to induce patients to use its drugs.

Beneficiary Inducement CMP

Similar to the anti-kickback statute analysis, the OIG concluded that the charity's proposed arrangement presents a low risk under the Beneficiary Inducement CMP.

In doing so, the OIG first emphasized that patient eligibility would be based solely on financial need, to be verified by the charity using a screening process. Eligibility would be in no way linked to (a) the identity of a patient's health care provider, supplier, drug, or insurance plan; (b) the identity of any referring party; or (c) the identity of any donor to the Specified Disease fund. Rather, participating patients must have already selected a provider, practitioner, or supplier, prior to enrolling in the proposed arrangement. Consequently, the charity's proposed arrangement would be unlikely to influence a participating patient's selection of a provider, practitioner, or supplier for items or services paid by Medicare or a state health care program.

Second, the OIG highlighted the fact that the charity itself would remain wholly removed from any decisions related to participating patient's medical treatment, and would not refer patients to, recommend, or arrange for the use of any particular practitioner, provider, supplier, drug, or insurance plan. Participation in the program would remain on a first-come, first-served basis, to the extent a patient met the charity's financial need criteria and funding remained available. This too, the OIG concluded, would safeguard against the charity's proposed program from influencing a participating patient's selection of a provider, practitioner, or supplier for items or services paid by Medicare or s state health care program.

Ober|Kaler's Comments

Advisory Opinion 15-17 is consistent with the OIG's long-standing approval of nonprofit, tax-exempt, charitable organizations providing assistance with out-of-pocket expenses for prescription drugs to financially needy patients that meet certain criterias. While the OIG continues to emphasize the importance of the patient assistance program being focused on a broadly defined disease state, in Advisory Opinion 15-17 the OIG approved a program that was limited to Stage 3 and Stage 4 of the specified disease state.