PUBLICATION

OIG Approves Charitable Organization's Patient Assistance Program [Ober|Kaler]

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On May 28, 2015, the U.S. Department of Health & Human Services, Office of Inspector General (OIG) issued an advisory opinion approving a charitable organization's proposal to provide financial assistance to individuals with chronic diseases by assisting with the costs of health insurance and drug and device therapies. In Advisory Opinion 15-06, the OIG drew upon its past guidance regarding patient assistance programs (PAPs) to approve an arrangement operated by a charity that involves disease funds under certain carefully defined parameters.

Past OIG Guidance Regarding PAPs

Prior to Advisory Opinion 15-06, and as referenced therein as support for its conclusion that the requestor's donor structure presented low risk, the OIG has previously opined on the structure of charitable PAPs. A 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees [PDF] (2005 SAB), which was released prior to the implementation of the Medicare Part D prescription drug program, set forth a list of factors that may be used to assess the propriety of PAPs operated by independent charities. The 2005 SAB confirmed that bona fide independent charities may focus on particular diseases, and pharmaceutical manufacturers may donate to such disease funds if they have a broad focus. Of particular concern to the OIG in the 2005 SAB, with regard to disease funds, was the potential for fraud and abuse if pharmaceutical manufacturers and their affiliates are able to exert direct or indirect influence or control over the fund, or if donors are able to influence the diseases covered by the fund, or if the fund is defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs.

Meanwhile, in its 2014 Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs [PDF] (Supplemental SAB), the OIG expanded its concerns to include situations in which a disease fund is defined by the stages of a particular disease or the type of drug treatment used for the disease, or where the fund otherwise narrows the treatment of widely recognized disease states or focuses on the products of donors. Also problematic are situations in which the fund is limited to a subset of available products rather than all available products approved by the FDA for treatment of the disease state. Similarly, the PAP eligibility determinations were considered more critical to the OIG in the Supplemental SAB. According to the Supplemental SAB, eligibility must be determined using reasonable, verifiable, and uniform measures of financial need, applied consistently. Finally, the OIG warned that PAPs should be configured to ensure that they operate independently from their donors, which includes safeguards so that donors are not given information that would enable them to correlate the amount or frequency of donations with the number of aid recipients who use their products, or the volume of such products supported by the PAP.

Advisory Opinion 15-06 Proposed Arrangement

The Advisory Opinion requestor is a nonprofit, tax-exempt, 501(c)(3) charitable organization that proposed to establish a program to provide financial assistance to individuals with cost-sharing obligations for prescription drugs or devices, health insurance premiums, and incidental expenses (such as travel and ongoing testing), associated with treatment of chronic diseases (Program). The requestor would be governed by an independent

board of directors, with specific controls in place to maintain its independence and freedom from conflict, such as prohibiting board members who are affiliated with or related to a donor, those who were former directors and officers of a donor and maintain relationships with the donor, and those who are affiliated with the third-party vendor performing patient eligibility verification for the requestor.

The requestor would solicit cash or cash-equivalent donations from many sources, including pharmaceutical and device companies, specialty pharmacies, distributors, individuals, and corporations (Donors). Except for certain limited aggregate data, Donors would not receive data beyond minimal information found in the requestor's annual report.

This charitable organization would establish various disease funds, under each of which the requestor would assess patient eligibility for assistance based on the federal poverty guidelines. Each fund would apply the criteria uniformly, and assistance would be offered on a first-come, first-served basis. The requestor would not make eligibility determinations based on the interests of any Donors or affiliates thereof, and would subcontract benefit verification to an unaffiliated vendor. While Donors would be permitted to earmark their donations for a specific disease fund, donations would be otherwise unrestricted.

The requestor would make copayment assistance available for all drugs and devices covered by Medicare or the primary insurer for the treatment of that disease. With the exception of disease funds limited to the metastatic stage of certain types of cancer, disease funds would be established for broadly defined disease states according to widely recognized clinical standards, without reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, or type of drug or device treatment. No disease fund would provide assistance for only one drug or device, or only those drugs or devices manufactured by one manufacturer or its affiliates (except where only one exists, in which case the requestor would provide assistance for the other medical needs of those patients, including drugs used to manage the disease and to manage the side effects of the disease).

Importantly, before applying for assistance, a patient must have selected a health provider, practitioner, or supplier, and have a treatment regimen in place, and the patient would remain free to change such providers, practitioners, or suppliers, or drug or device therapies, or insurance plans, at any time. Candidates would annually reapply for assistance and undergo an eligibility reassessment.

The requestor would not refer patients or recommend or arrange for the use of any practitioner, provider, supplier, drug or device. Patients would use a benefit card at the patients' preferred pharmacy or device distributer if treatment is self-administered. Where treatment is physician-administered, the requestor would provide assistance directly to the patient's physician or hospital, or directly to the patient (upon verification) if the physician or hospital does not accept third-party payments or the benefit card.

Analysis Under Civil Monetary Penalty Law Against Inducements to Beneficiaries and Antikickback Statute

As discussed below, the OIG considered two main aspects of the proposed arrangement: (1) Donor contributions to the requestor; and (2) the requestor's assistance to patients.

Donor Contributions to Requestor

As to Donor contributions to the requestor, the OIG concluded that the design and administration of the Program presented minimal risk and would provide sufficient insulation to prevent assistance decisions being influenced by the Donors. The OIG based its analysis on four aspects of the arrangement that provide protection.

First, the OIG highlighted the autonomy of the charitable organization, the non-affiliation with any Donor, and the inability of any Donor to exert direct or indirect control or influence over the charitable organization or the Program. The requestor's independent discretion to use donations was apparent in the facts discussed above, and the inability of Donors or their affiliates to influence the board of directors was adequately protected. Second, the OIG highlighted that under the requestor's PAP, patients must have selected their provider, practitioner, or supplier and have a treatment regimen in place prior to applying for benefits, and remain free to change them while receiving assistance. Further protection is found in the requestor certifying that it would not make referrals or recommendations to patients.

Third, other than certain aggregate application and Program use data described above, no data would be shared with Donors to allow them to correlate the amount or frequency of donations with the use of their drugs, devices, or services. Individual patient information would not be conveyed to Donors, nor would information related to the identity, amount, or nature of the drugs, devices and services subsidized under the Program. Finally, that Donors may earmark donations for certain disease funds does not significantly raise the risk of abuse according to the OIG. The disease funds were broadly defined without reference to stages, symptoms, severity, or type or method of administration of drugs (other than for metastatic stages of certain cancers), which appropriately limits the risk of Donor influence, as does the requirement that the requestor make assistance available for all drugs and devices approved for treatment of a disease by Medicare or the primary insurer, including generic and bioequivalent drugs. The requestor's Program cannot make assistance available for only one drug or device, or those made by only one manufacturer or its affiliates (without additional protections outlined above). The OIG found that for a combination of these reasons, "it is unlikely that the earmarking would result in the [Program] serving as a disguised conduit for financial assistance from a Donor to patients using its drugs or devices."

Requestor's Assistance to Patients

As to the requestor's assistance to patients, the OIG focused on the protections afforded by two characteristics of the Program. First, eligibility decisions would be based solely on financial need, according to uniform standards applied consistently, without regard for the identity of the provider, practitioner, supplier, drug, device, referring party, or any Donor. Second, patients must have their provider, practitioner, or supplier, and their treatment plan, in place prior to applying for assistance (which the patient remains free to change while receiving assistance), and would receive support on a first-come, first-served basis. Eligibility decisions would not be based on whether the provider, practitioner, or supplier is a Donor, and the requestor would not make any referrals or recommendations or share Donor identities with patients. For these reasons, the OIG found the Program presented a low risk of fraud and abuse.

Ober|Kaler Comments

In Advisory Opinion 15-06, the OIG drew upon its past guidance regarding PAPs to approve an arrangement that is operated by a charity and permits disease funds under certain carefully defined parameters. The OIG has previously expressed concern about disease funds. Here, the disease funds were broadly defined according to accepted standards, without regard to the symptoms, treatment, or stage of the disease. The one narrow exception was for disease funds that relate to the metastatic stage of certain cancers, where the PAP covers all drugs approved by the FDA for treatment of that type of cancer (not just drugs limited to treatment of the metastatic stage).

In approving these disease funds, the OIG stressed the importance of the protection built into the arrangement, including the board of director independence from donors, strict limits on the involvement of donors and anyone related to them, the patients' freedom of choice to switch providers and suppliers, and the requirement that patients select their providers and suppliers and have a treatment plan in place before applying to the PAP

for assistance. Advisory Opinion 15-06 thus provides another concrete example of the type of PAP arrangement that the OIG is willing to approve.