PUBLICATION

OIG Approves Another Patient Assistance Program in Advisory Opinion 15-16 [Ober|Kaler]

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On December 28, 2015, the Office of Inspector General (OIG) approved another patient assistance program in Advisory Opinion 15-16 [PDF]. The OIG analyzed contributions to a private charitable organization under the anti-kickback statute and assistance to patients under the civil monetary penalty prohibition against inducements to beneficiaries (Beneficiary Inducement CMP). The OIG focused on the charitable organization's extensive safeguards in concluding that the program posed low risks under both laws.

The charitable organization requesting the opinion proposed to create two Disease Funds to provide assistance to financially needy patients with specified diseases. The requestor would rely on "widely recognized clinical standards" to define qualifying diseases, and any donors to the Funds would have no role in identifying or defining covered diseases. The Funds would cover out-of-pocket costs for outpatient drugs used to treat the covered diseases. Only insured patients meeting specific, consistently applied financial criteria based on federal poverty guidelines would be eligible. Eligibility would be verified by the requestor. Available assistance would range from full coverage of out-of-pocket outpatient drug expenses for the neediest patients and coverage of some portion of such expenses based on a fixed sliding scale for less-needy patients. Patients would be required to have selected a provider and a treatment plan before becoming eligible for assistance, though they would be free to change providers and treatment plans at any time. The requestor would not provide for or arrange for referrals to any provider, supplier, or treatment regimen.

Donors, which would include individuals, foundations, and corporations, would be free to earmark their donations for either Fund. However, under the requestor's strict conflict-of-interest policies, donors and their affiliates (including family members) would not be eligible to serve in a leadership capacity for the requestor. Further, donors could not direct donations to be used for specific patients, treatment regimens, or providers, and would have no role in determining or influencing eligibility for assistance. Donors could receive aggregate information regarding the number of qualifying patients and the amount disbursed from each Fund, but no patient-level information would be available to donors.

With regard to the anti-kickback statute, the OIG cited four factors that minimized the risk that referrals would be influenced by donor contributions. First, the OIG noted that the requestor had sufficient measures in place to ensure that it would remain autonomous of any donor's influence. For example, the requestor would have full discretion to determine how donations were used and would implement steps to prevent donors from exercising influence over the requestor's organization. Second, the OIG determined that requiring patients to have selected providers and a treatment regimen before becoming eligible for assistance reduced the likelihood of inappropriate referrals. Third, the OIG noted that because only aggregate data would be available to donors, a donor would not be able to determine the extent to which its donations led to increased utilization of its own services or products. Finally, the OIG determined that because donors would not be able to influence the definition of covered diseases, allowing earmarked donations would not increase the risk of indirect referrals.

With respect to the Beneficiary Inducement CMP, the OIG determined that federal health care program beneficiaries would not be unduly influenced because of the strict financial criteria used to determine eligibility. It also noted that patients would be eligible for assistance on a first-come, first-served basis only, and then only when a treatment plan was already in place. Eligibility would not be based on provider contributions, and the requestor would not refer patients to or recommend any particular provider.

Advisory Opinion 15-16 is one in a series of opinions approving nonprofit, tax-exempt, charitable organizations providing assistance with out-of-pocket expenses for prescription drugs to financially needy patients. The opinion is consistent with the OIG's November 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees [PDF] and the OIG's May 2014 Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs [PDF].