PUBLICATION

OIG Approves Charitable Program Providing Financial Assistance for MRIs in Advisory Opinion 15-14 [Ober|Kaler]

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On November 13, 2015, the U.S. Department of Health & Human Services, Office of Inspector General (OIG) issued Advisory Opinion 15-14 [PDF]. The Arrangement at issue is a charitable program designed to assist financially needy patients, including Medicare and Medicaid beneficiaries, obtain MRIs for diagnosis or evaluation of a particular disease state (Disease State).

The OIG separately analyzed (i) the contributions to the charitable program under the anti-kickback statute and (ii) the charitable program assistance to patients under the civil monetary penalty prohibition against inducements to beneficiaries. The OIG ultimately concluded that it would not impose administrative sanctions under either aspect of the program.

Under the program, financially needy patients with a particular Disease State could receive assistance to obtain an MRI for diagnosis or evaluation of the Disease State. Patients must already have a physician's order for an MRI, either for diagnosis or ongoing evaluation of the Disease State, to qualify for the program. Patients' financial eligibility would be determined based on federal poverty guidelines as a "reasonable, verifiable and uniform measure of financial need." Patients who have not received assistance in the previous 24 months would be eligible to receive financial assistance on a first-come, first-served basis.

After verifying patients' eligibility, the requestor categorizes patients as either "Co-Pay" or "Full-Pay" based on insurance status and terms. Full-Pay patients are patients who are either (i) uninsured or (ii) insured but their combined deductible balance and cost-sharing obligation exceeds the average charge for an MRI that the requestor has been able to negotiate in the geographic region. The requestor matches Full-Pay patients with a contracted MRI provider and pays for the cost of the MRI at the negotiated, discount rate. The requestor pays the MRI provider directly. On the other hand, Co-Pay patients are insured patients whose respective combined deductible balance and cost-sharing obligation does not exceed the average charge for an MRI that the requestor has been able to negotiate in the geographic region. Co-Pay patients choose an MRI provider in their insurance network, and the requestor pays the patients' applicable deductibles and cost-sharing obligations directly to the MRO provider.

The requestor funds the arrangement through donations from individuals, foundations, and corporations, including pharmaceutical manufacturers. The requestor certified that contracted MRI providers are not donors or affiliates of donors. The requestor may provide donors with aggregated data related to the program and patients' use of Disease State treatments. The requestor is governed by an independent Board of Directors and its discretion to use the donations is "absolute, independent, and autonomous."

The OIG first analyzed the donors' contributions to the requestor under the anti-kickback statute. Relying on its long-standing guidance which allows industry stakeholders to help health care safety net programs "by contributing to independent, *bona fide* charitable assistance programs," the OIG concluded that there was minimal risk of the contributions influencing referrals. The OIG based its decision on the following four factors:

1. Donors do not exert any direct or indirect influence over the requestor or the program. As an "independent, non-profit, tax-exempt charitable organization" it has total discretion with regards to use

of contributions. Donors do not serve on the requestor's Board and the requestor implemented safeguards to screen potential conflicts of interest for Board members.

2. Besides the contracted MRI providers for Full-Pay patients, patients have freedom of choice for practitioners, providers, suppliers, and insurers. Financial assistance is not predicated upon use of particular providers, practitioners, suppliers, and insurers. The requestor certified that contracted MRI providers are not donors or affiliates of donors.
3. Although the requestor may provide donors with aggregated data related to the program and patients' use of Disease State treatments, the requestor does not convey individual patient information to donors, nor does it provide data that could be used to correlate donations with use of a donor's drugs or services. The financial assistance is limited to MRIs and cannot be used to support purchases of a donor's products or services.
4. The requestor defined the Disease State fund using recognized clinical standards. Though donors may earmark contributions for the arrangement, the OIG thought it unlikely that pharmaceutical manufacturer donors could use the arrangement as a conduit to induce patients to use their drugs.

Next, the OIG analyzed the requestor's assistance to patients, including federal health care program beneficiaries, under the civil monetary penalty prohibition against inducements to beneficiaries. The OIG concluded that the requestor's assistance presents a low risk of fraud and abuse and is not likely to influence a beneficiary's selection of a particular provide, practitioner, or supplier. The OIG cited three factors in support of its conclusion:

5. While Full-Pay patients are matched with contracted MRI providers, the requestor pays the full, discounted rate for the MRI. Therefore, those MRIs are not services reimbursable by the Medicare or Medicaid programs. Co-Pay patients' choice of MRI provider is determined by their insurance network. The requestor does not otherwise refer, recommend, or arrangement for patients to use particular providers, practitioners, suppliers, drugs, or insurance plans.
6. Eligibility determinations are based solely on financial need using a consistently applied uniform measure, regardless of providers, practitioners, suppliers, drugs, or insurance plan used by the patients.
7. Assistance is provided on a first-come, first-served basis to patients who meet the eligibility criteria. Whether a patient's provider, practitioner, or supplier has contributed is not a factor in determining a patient's eligibility. The requestor does not refer patients to donors, nor does the arrangement provide financial assistance for donors' drugs, products, or services.

Ober|Kaler's Comments

Advisory Opinion 15-14 is important because it reveals that the OIG's guidance on patient assistance programs is applicable outside of just the pharmaceutical context. The instant program does not support pharmaceuticals, but rather MRIs. Regardless, the OIG recognizes that industry stakeholders can help health care safety net programs "by contributing to independent, *bona fide* charitable assistance programs."