



**OIG Advisory Opinion No. 15-14**  
**By [Richard Kusserow](#) | November 2015**

The OIG issued an [advisory opinion](#) regarding a non-profit, tax-exempt, charitable organization's ("Requestor's") program (the "Arrangement") to help financially needy patients obtain magnetic resonance imaging (MRI) for diagnosing or evaluating diseases. The OIG concluded that the Arrangement does not constitute grounds for imposing civil monetary penalties. Further, although the Arrangement could generate remuneration under the Anti-Kickback Statute (AKS) if the requisite intent to induce or reward referrals was present, the OIG decided not to impose sanctions.

Requestor is a 501(c)(3) organization providing resources, services, and support for patients with a particular disease. Requestor helps patients, including Medicare and Medicaid beneficiaries, by fully subsidizing the costs they would otherwise incur for MRIs. Patients learn about the Arrangement through Requestor, health care professionals (e.g., primary care doctors, neurologists, and nurse practitioners), social workers, healthcare charities, and others. To be eligible for assistance under the Arrangement, a patient must have either (1) a physician's order for an MRI for diagnosis of the disease if already diagnosed; or (2) a physician's order for an MRI for ongoing evaluation of the disease.

Requestor assesses a patient's financial eligibility for assistance based on the Federal poverty guidelines and determines eligibility based on a specified measure. The measure is applied consistently. Applicants are screened for compliance with the designated financial eligibility criteria prior to enrollment. Financial assistance is awarded on a first-come first-serve basis to qualified patients who have not received a Requestor-subsidized MRI within the last 24 months, provided that funding is available. Requestor does not determine eligibility based in whole or in part on: (1) the interest of persons or entities contributing to Requestor's grant program funds ("Donor") or their affiliate(s), including contributions made by Donors who provide drugs or services to patients; (2) the patient's choice of provider, practitioner, supplier, drug, or insurance plan; or (3) the identity of the referring person or entity (including whether the person or entity is a Donor). Patients must re-apply each time they seek an MRI through the Arrangement.

Requestor uses preset criteria to determine the most cost-effective means to assist patients in obtaining an MRI. Patients are categorized as either "Co-Pay" or "Full-Pay" based on their insurance status, deductible balance, and cost-sharing obligations. Co-Pay patients are insured patients (including those insured through Federal health care programs) whose combined deductible balance and cost-sharing obligations are less than the average MRI charge. A Co-Pay patient chooses an MRI provider in his or her insurer's network. Requestor then remits payment directly to the provider to cover the patient's applicable deductible and/or cost-sharing obligation. Co-Pay patients choose MRI providers subject only to their insurance plan's requirements. Full-Pay patients are either (i) uninsured or (ii) insured with a combined deductible balance and cost-sharing obligation that exceeds the average charge for an MRI. Requestor



matches Full-Pay patients with a local contracted MRI provider based on pre-determined criteria such as cost, service, and proximity to the patient. Requestors may accommodate patients requesting different MRI providers due to particular needs, such as access to an open MRI machine or service in a specific geographic location. Donor “affiliates” include, without limitation, a Donor’s employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager).

Requestor certified that it contracts with any willing MRI provider that meets Requestor’s quality and cost criteria. Requestor further certified that the disease is defined in accordance with widely recognized clinical standards without reference to specific symptoms, severity of symptoms, method of drug administration, stages, type of drug treatment, or by other means of narrowing the definition. According to Requestor, no Donor or affiliate directly or indirectly influences the identification or delineation of Requestor’s fund. Requestor attested that it does not refer patients to, recommend, or arrange for the use of any particular practitioner, provider, supplier, or insurance plan that is a Donor or affiliate. It also does not refer patients to, recommend, or arrange for the use of any product or service of a Donor or affiliate. Patients have complete freedom of choice in such matters. Patients receive financial assistance regardless of their choice of provider, practitioner, supplier, drug, or insurance plan. While receiving Requestor’s financial assistance, patients are free to change providers, practitioners, suppliers, drugs, or insurance plans. Requestor solicits donations from its regular donor sources, including corporations (primarily pharmaceutical manufacturers), individuals, and foundations. All donations are in the form of cash or cash equivalents. Donors may change or discontinue contributions at any time. Donors may also either provide unrestricted donations to Requestor or earmark contributions for the Arrangement.

Requestor certified that multiple pharmaceutical manufacturers marketing a variety of drugs are available to treat the disease. While some manufacturers are also Donors, the Arrangement is limited to financial assistance to support patients in obtaining MRIs. Requestor does not maintain any disease funds providing assistance for drugs. Outside of the Arrangement, Requestor engages in certain educational activities, which may include providing information on treatments to patients diagnosed with the Disease State. Requestor attested to having internal policies requiring these activities to be free from bias.

Requestor’s discretion to use the donations is absolute, independent, and autonomous. An independent Board of Directors (the “Board”) governs Requestor. No Donor or affiliate exerts direct or indirect influence over Requestor or the Arrangement. No Donor or immediate family member, director, officer, employee, or person otherwise affiliated with a Donor currently serves on Requestor’s Board. Requestor further certified that no former director, officer, or employee who maintains an ongoing relationship with the Donor (via consulting or otherwise), or immediate family member of such former director, officer, or employee of a Donor, currently serves on the Board. Requestor also certified that it maintains a conflict of interest policy to ensure independence in the Board’s decision-making. As a courtesy, Requestor may give Donors aggregated data, such as the number of MRIs provided through the Arrangement. It may also

provide other aggregated data obtained through patient surveys, including data regarding patients' use of FDA-approved treatments for the disease (but not specific to any particular treatment). Requestor certified that it does not provide Donors with any individual patient information or information that would enable a Donor to correlate donations with use of its drugs or services. While Requestor's website and the Arrangement application for assistance disclose multiple pharmaceutical manufacturer Donors' identities, the Arrangement does not provide financial assistance for a Donor's drugs, products, or services.

While Requestor's policies do not prohibit a Donor from serving on the Board, Requestor only permits such Board service if a majority of disinterested Board members determined that the individual's contribution was critical to achieving Requestor's overall mission. Moreover, Requestor certified that it requires Board members to recuse themselves from considering matters involving an entity that a Board member has an interest in through ownership, employment, or otherwise. Board members must also disclose potential conflicts of interest according to an established process.

Entities paying remuneration purposefully to induce or reward referrals of items or services payable by a Federal health care program violate the AKS. The AKS ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. "Remuneration" includes transferring anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The AKS covers any arrangement where one purpose of the remuneration is to obtain money for the referral of services or to induce further referrals. The OIG scrutinized two aspects of the Arrangement: (1) Donors' contributions to Requestor; and (2) Requestor's assistance to patients. OIG guidance indicates that industry stakeholders can contribute effectively to the health care safety net for financially needy patients, including Federal health care program beneficiaries, by donating to independent, *bona fide* charitable assistance programs. The OIG stated that the Arrangement entails minimal risk of Donors' contributions influencing direct or indirect referrals.

1. No Donor or affiliate exerts direct or indirect control over Requestor or its program. Requestor is an independent, non-profit, tax-exempt charitable organization that operates with absolute, independent, and autonomous discretion as to the use of Donors' contributions. No Donor, or immediate family member, director, officer, employee, or person otherwise affiliated with a Donor currently serves on Requestor's Board. Although such individuals are not prohibited from serving on Requestor's Board, safeguards are in place to appropriately identify and screen potential conflicts of interest.
2. While Requestor matches Full-Pay patients with contracted MRI providers for MRIs covered under the Arrangement, all patients otherwise remain free to change their providers, practitioners, suppliers, drugs, and insurance plans. Requestor does not refer patients to, recommend, or arrange for the use of any practitioner, provider, supplier, or insurance plan that is a Donor or affiliate. Further, it does not refer patients to, recommend, or arrange for the use of any product of a Donor or affiliate.

3. Requestor does not provide Donors with any data that permit them to correlate donations with the use of Donor's drugs or services. No individual patient information is conveyed to any Donor. Requestors may, however, provide Donors with aggregated data as a courtesy. While identifying Donors may be problematic in other circumstances, it is not problematic in this case because the Arrangement does not support Donors' products.
4. Finally, Donors' ability to earmark donations to the Arrangement does not significantly raise the risk of abuse. Requestor certified that no Donor or affiliate directly or indirectly influenced the identification or delineation of Requestor's fund. Requestor further certified that: (i) it defines the disease based on widely recognized clinical standards; and (ii) it does not use specific symptoms, severity of symptoms, the method of administration of drugs, stages of the disease, type of drug treatment, or a narrowed definition to define the disease. Moreover, the Arrangement is limited to providing financial assistance to offset patient costs associated with MRIs. Donors can earmark contributions for the Arrangement, but not with great specificity (e.g., not for patients requiring certain treatments). For these reasons, such earmarking is unlikely to result in the Arrangement serving as a disguised conduit for Donors providing financial assistance to induce patients to use their drugs.

Requestor is a 501(c)(3) charitable entity that must use donated funds to maximize its charitable mission. The OIG determined that the design and administration of the Arrangement provide sufficient insulation so that Donors should not influence Requestor's assistance to patients. Therefore, the OIG concluded that the contributions Donors make to Requestor cannot reasonably be construed as payments to Requestor to arrange for referrals. Requestor's providing financial assistance with deductible and cost-sharing obligations for certain eligible, financially needy patients, including Federal health care program beneficiaries, presented a low risk of fraud and abuse. The Arrangement was not likely to influence any beneficiary's selection of a particular provider, practitioner, or supplier for items or services for which payment may be made in whole or in part by Medicare or a State health care program. The OIG reached this conclusion based on the following factors:

- While Requestor matches Full-Pay patients with contracted MRI providers, Requestor reimburses the contracted provider in full for the MRI in such circumstances. Because Requestor is paying the full fee, those MRI costs are not services reimbursable by the Medicare or Medicaid programs. For Co-Pay patients, Requestor has certified that aside from directing a patient to obtain an MRI within the patient's insurance network, Requestor does not otherwise refer Co-Pay patients to, recommend, or arrange for the use of any particular practitioner, provider, supplier, drug, or insurance plan.
- Second, Requestor's determination of a patient's qualification for assistance is based solely on his or her financial need. Requestor does not consider the identity of health care providers, practitioners, suppliers, drugs, insurance plans, referring parties, or Donors that may have contributed to the Arrangement or the amount of the donation. Requestor



determines eligibility according to a uniformly applied, reasonable, verifiable, and uniform measure of financial need. Requestor verifies applicants' financial need either before providing assistance or within a reasonable period of time after assistance is initiated.

- Third, Requestor assists all eligible, financially needy patients on a first-come first-serve basis to the extent funding is available. Patients are not eligible for assistance unless they meet Requestor's eligibility criteria. All patients already select a provider, practitioner or supplier, and have a treatment regimen in place that includes a physician's order for an MRI for diagnosis or ongoing evaluation of their disease. Requestor does not make eligibility determinations based on whether a provider, practitioner, or supplier has contributed to the program. Requestor does not refer patients to, recommend, or arrange for the use of any practitioner, provider, supplier, or insurance plan that is a Donor or affiliate. Further, Requestor does not refer patients to, recommend, or arrange for the use of any product or service of a Donor or affiliate of a Donor. While certain Donors' identities are disclosed on Requestor's website and the Arrangement application for assistance, the Arrangement does not provide financial assistance for drugs or any other product or service of any Donor. Therefore, while the identification of Donors as problematic in other circumstances, the OIG determined that it is not problematic here because the Arrangement does not support the Donors' products.