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CLIENT ADVISORY

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OIG Approves Another Patient Assistance Program

The Department of Health and Human Services, Office of Inspector General ("OIG") issued Advisory Opinion No. 15-06 (the "Advisory Opinion") regarding a 501(c)(3) charitable entity's proposal to establish a program to provide financial assistance to individuals with cost-sharing obligations for prescription drugs or devices, health insurance premiums, and certain incidental expenses associated with treating various chronic diseases ("Proposed Arrangement"). The OIG concluded that the Proposed Arrangement would not constitute grounds for imposing civil monetary penalties, and, although it could potentially generate prohibited remuneration under the Anti-Kickback Statute, the OIG would not impose administrative sanctions.

Proposed Arrangement

The charitable entity requesting the Advisory Opinion (the "Requestor") proposed to establish multiple disease funds with eligibility for financial assistance based on federal poverty guidelines. Each fund's eligibility criteria would be applied uniformly to all applicants on a first-come, first-served basis. Eligibility determinations would be made independently of any donor interests; the patient's choice of provider, supplier, drug, device, or plan; or the identity of the referring person or entity. Requestor would not refer patients or recommend the use of a particular provider, supplier, or plan, and patients would have complete freedom of choice of a provider.

The disease funds would be established for broadly defined disease states based on widely recognized clinical standards. Requestor may later develop funds that would be limited to the metastatic stage of certain cancers. For each fund, Requestor would provide copayment assistance for all drugs (including generics and bioequivalents) and devices covered by Medicare or the patient's primary insurer for treatment of the disease that is the subject of the fund. Requestor would not maintain a fund that provides assistance for only one drug or device, or only the drugs or devices affiliated with a single manufacturer. Where the Food and Drug Administration ("FDA") has approved only one drug for a specific disease, Requestor would provide additional support for other medical needs of patients with the disease, in addition to the FDA-approved treatment.

Donors would include pharmaceutical and device companies, specialty pharmacies, distributors, individuals, and corporations. They would direct their contributions to specific disease funds, but donations would otherwise be unrestricted and Requestor would maintain absolute discretion in their use. Donors would receive only limited, aggregate information regarding applicants for each disease fund to which they contributed.

Requestor would be governed by an independent board of directors. All directors would be subject to a conflict of interest policy and screening to ensure that no director or immediate family member maintains an ongoing financial relationship with a donor.

Legal Analysis

In concluding that the Proposed Arrangement would not constitute grounds for civil monetary penalties or result in sanctions under the Anti-Kickback Statute, the OIG undertook a two-part analysis, considering the donor contributions to Requestor and Requestor's assistance to patients. The OIG emphasized that longstanding guidance makes clear that industry stakeholders can contribute to independent, *bona fide* charitable assistance programs. The Proposed Arrangement was found to entail minimal risk of influencing patient referrals for the following reasons:

- Requestor maintained absolute discretion over the use of contributions, and no donor, immediate family member, or current or former donor affiliate could serve on Requestor's board or otherwise exert control over the program.

- Before applying for assistance, each patient would have already selected a health care provider or supplier with a treatment regimen in place. Patients would also remain free to change providers, suppliers, treatments, or plans while still receiving Requestor's assistance. Requestor would not refer patients to or recommend the use of a particular provider, supplier, drug, device, or plan.
- Requestor would not provide donors with data that would allow donor to correlate its donations with the use of its drugs, devices, or services. Patients would not receive information regarding donors.
- Although donors may earmark donations to specific disease funds, the risk of abuse is limited because disease funds are defined according to broadly defined disease states and are designed to cover all drugs and devices reimbursed by Medicare or the patient's primary insurer.

The OIG concluded that Requestor's assistance to patients presents a low risk of fraud and abuse and is not likely to influence a patient's choice of provider, supplier, or service for the following reasons:

- A patient's qualification for assistance is based solely on financial need and is consistently and uniformly applied without consideration of the patient's health care providers, suppliers, drugs or devices, the referring party, or the donor that may have contributed to the disease fund.
- All eligible patients would be assisted on a first-come, first-served basis if they meet financial need requirements. Patients would have already selected a provider or supplier and have a treatment regimen in place and would remain free to change at any time.
- Eligibility decisions would be made independently of whether a patient's provider or supplier has contributed to the patient assistance program, and Requestor would not refer or recommend the use of any particular provider, supplier, drug or device, or plan.

The OIG's conclusion is consistent with its review of previously proposed patient assistance arrangements in Advisory Opinions 06-13 and 07-18 and the modifications to those opinions. Like the Proposed Arrangement here, those programs included many of the same safeguards to insulate beneficiaries from information associated with a donor's financial assistance that would influence the selection of a particular provider, supplier, product, or service or would improperly influence referrals by the charitable organization.

For more information about patient assistance programs, the civil monetary penalties provision, or the federal Anti-Kickback Statute, please contact Mary Malone, Colin McCarthy, or Corbin Santo at (866) 967-9604 or by email at mmalone@hdjn.com, cmcarthy@hdjn.com, or csanto@hdjn.com. Additional information about Hancock, Daniel, Johnson & Nagle, P.C. is available on the firm's website at www.hdjn.com.