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HEALTH LAW NEWS

FEBRUARY 19, 2016

OIG APPROVES FINANCIAL ASSISTANCE PROGRAMS IN TWO FAVORABLE ADVISORY OPINIONS

The Department of Health and Human Services Office of Inspector General ("OIG") recently issued Advisory Opinions 15-16 and 15-17 approving two financial assistance programs offered by nonprofit, tax-exempt, charitable organizations. Based on the structure of each program, OIG concluded that the arrangements would not constitute grounds for the imposition of civil monetary penalties or result in the imposition of administrative sanctions under the federal Anti-Kickback Statute.

SUMMARY OF ADVISORY OPINION 15-16

A 501(c)(3) charitable foundation ("Requestor") proposed to establish a program to provide financial assistance for out-of-pocket expenses related to outpatient prescription drugs used to treat two specific diseases to certain patients that demonstrate financial need. Under the proposed arrangement, Requestor would maintain two separate disease funds, one would provide assistance to patients with certain types of cancer and the other would provide assistance to patients with chronic kidney disease. Assistance would be provided to qualifying individuals on a first-come, first-served basis. In order to qualify for assistance, patients must have an existing health care provider and treatment regimen in place. Financial eligibility would be determined based on the federal poverty guidelines and according to a reasonable, verifiable and uniform methodology applied consistently. Patients would be permitted to change providers, drugs or insurance plans at any time while receiving assistance.

Donations would be solicited from individuals, foundations and corporations (including drug manufacturers). Requestor's discretion to use the donations would be independent and autonomous. No donor, immediate family member, director, officer, employee or person affiliated with a donor would be eligible to serve on Requestor's Board of Directors. While donors may specify that their donations go to a specific disease fund, they could not earmark contributions for treatment of a specific disease covered by either fund. Additionally, donors would not receive individual patient information, and patients would not receive any information regarding donors.

SUMMARY OF ADVISORY OPINION 15-17

A nonprofit, tax-exempt, charitable organization ("Requestor") proposed a program to help financially needy patients with their copayment obligations, health insurance premiums and deductibles for outpatient prescription drugs used to treat a specified disease. Patients in stages 3 or 4 of the disease, and those who meet financial eligibility based on federal poverty guidelines, would be eligible to apply for assistance. Similar to the proposed arrangement in Advisory Opinion 15-16, financial assistance would be provided on a first-come, first-served basis, and patients must have an existing health care provider and treatment regimen in place. Patients would be permitted to change providers, drugs or insurance plans at any time while receiving assistance.

Donations would be in large part provided by drug manufacturers. Donors would not be permitted to earmark their donations to support any particular drug or type of cost-sharing obligation. Additionally, no donor, immediate family member, director, officer, employee or person affiliated with a donor would be eligible to serve on Requestor's Board of Directors. Requestor's discretion to use the donations would be independent and autonomous. Donors would not receive individual patient information, and patients would not receive any information regarding donors.

OIG ANALYSIS

In both cases, OIG analyzed two aspects of each arrangement: (1) donor contributions; and (2) Requestor's assistance to patients (specifically, to federal and state health care program beneficiaries).

1. In issuing each favorable opinion, OIG noted the following factors that minimized the risk of direct or indirect referrals by Requestors as a result of donor contributions:
    - Donors would not have any control or influence over the Requestor's structure or program operations.
    - Patients would have already selected their health care providers and treatment plan prior to applying for assistance and would remain free to change health care providers, drugs or insurance plans while receiving assistance.

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- Donors would not receive any data that would allow them to correlate their donations to the use of their drugs or services subsidized under the proposed arrangement, individual patient information would not be conveyed to any donor and patients would not receive any information regarding donors.
- The diseases covered by each proposed arrangement would be defined in accordance with widely recognized clinical standards and would not be defined by specific symptoms or severity of symptoms, except in the case of Advisory Opinion 15-17 where access to the patient assistance program is based on the stage of the disease. Moreover, each proposed arrangement would provide financial assistance for all drugs approved by the Food and Drug Administration, including generic and bioequivalent drugs. While donors under Advisory Opinion 15-16 would be able to earmark to which disease fund their contributions went, in neither proposed arrangement would a donor be able to designate their funds for the use of a specific treatment or drug.

1. OIG concluded each proposed arrangement presented a low risk for fraud and abuse to federal and state health care program beneficiaries based on the following factors:
   - Qualification would be based solely on financial need without considering the identity of a patient's health care provider, drugs or insurance plan, and financial eligibility would be determined based on a reasonable, verifiable and uniform methodology applied consistently.
   - Assistance would be provided on a first-come, first-served basis if the patient met the financial eligibility criteria, which would not be based on whether the patient's provider, practitioner or supplier made contributions to the proposed arrangement. Furthermore, before receiving assistance, patients would have already selected a health care provider and treatment plan, and patients would be free to change providers, drugs or insurance plans while receiving assistance. Lastly, patients would not be informed of the identity of the donors.

PRACTICAL TAKEAWAY

In issuing each favorable opinion, OIG reiterated its position that industry stakeholders can contribute effectively to the health care safety net for financially needy patients, including federal and state health care program beneficiaries, by donating to independent, bona fide, charitable assistance programs.

If you have any questions or would like additional information about this topic, please contact:

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