



Alerts

OIG Provides Guidance on Health Care Assistance to Needy

December 17, 2015

Health Law Alert

The Office of Inspector General (“OIG”) has posted two publications over the last six weeks relating to providing financial and other assistance to the financially needy. Taken together, these publications give guidance as to what charitable organizations may do to promote access to health care services to the financially needy.

The most recent publication posted on December 7, 2015, modifies previous Advisory Opinion 07-11 issued in 2007. In 2007, the OIG issued a favorable opinion regarding a particular charity’s operation of a Patient Assistant Program (“PAP”) to help financially-needy cancer patients pay for their drugs to treat certain types of cancer, as well as certain conditions incident to cancer therapy. In a letter to that particular charitable organization in 2014, the OIG highlighted certain areas of concern that would have to be modified for the charity to retain a favorable advisory opinion for the PAP. The OIG indicated that the charity must address the concerns through certain certifications.

- First, the charity could not define its disease funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of particular of disease, types of drug treatment or any other way of narrowing the definition of widely-recognized disease status. The charity would have to develop and maintain disease funds that would be limited to patients with certain metastatic cancers, and the charity will cover, at a minimum, all drugs that are approved by the Food & Drug Administration (“FDA”) for that type of cancer.
- Secondly, the charity may not make any disease funds available that provide copayment assistance for only one drug or only the drugs made or marketed by one manufacturer or its affiliates. At a minimum, the charity must provide copayment support for all prescription medication used by a patient for FDA-approved indications relating to managing the disease.
- Third, the charity may not limit assistance to high-cost or specialty drugs. Instead, the charity must make assistance available, at a minimum, for all products, including generic or the bioequivalent drugs approved by the FDA for treatment of the specific disease state.
- Finally, the charity was asked to certify, and it did certify, that it determined eligibility according to a reasonable, verifiable and uniform measure of financial need applied in a consistent manner.

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The second OIG posting, OIG Advisory Opinion No. 15-14, was dated November 20, 2015. In this Advisory Opinion, the OIG reviewed a nonprofit tax-exempt charitable organization program to help financial needy patients, including Medicare and Medicaid beneficiaries, to obtain magnetic resonance imaging (“MRI”) for the diagnosis or ongoing evaluation of a certain disease. The 501(c)(3) charitable organization was dedicated to providing resources, services and supplies for patients with a specific disease.

To be eligible for assistance under the arrangement, the patient must have a physician’s order for an MRI and meet certain financial need criteria based on the Federal Poverty Guidelines. The criteria was verifiable and applied in a consistent manner, with assistance awarded on a first-come, first-served basis for any financially-qualified patient who has not received subsidized MRI services within the previous 24 months, to the extent that such funding is available.

The requestor certified 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 of any donor; or refer patients to, recommend, or arrange for the use of any product or services of a donor or affiliate; and does not recommend the use of any product or services of a donor or affiliate.

The charity is organized such that the requestor solicits donations from its regular donor sources, which include corporations such as pharmaceutical manufacturers, as well as individuals and foundations. All donations are in the form of cash or cash equivalents. The requestor is also governed by an independent Board of Directors. No donor or affiliate donor exerts direct or indirect influence over the requestor’s board.

The OIG concluded that industry stakeholders can contribute effectively to the health care safety net for financially needy patients by contributing to independent, bona fide charitable assistance programs. The OIG concluded that for several reasons, it felt that the arrangement involved only minimal risk of donors’ contributions influencing direct or indirect referrals by requestors.

- First, no donor or affiliate of any donor exerted any indirect or direct control over the requestor or its program. The requestor was an independent nonprofit tax exempt charitable organization with no donor or immediate family members of a donor serving as a director, officer or employee.
- Secondly, all patients remain free to change their health care providers, practitioners, suppliers, drug or insurance plans. The requestor does not refer patients to, recommend or arrange for the use of any practitioner, provider or supplier.

Similar to the modification of the Advisory Opinion 07-11, the OIG felt that this arrangement would not constitute grounds for the imposition of civil monetary penalties, and while it could potentially generate prohibited remuneration in the Medicare or Medicaid statute if the requisite intent to induce or reward referrals was present, the OIG would not impose administrative sanctions in connection with the arrangement.

The assessment made by the OIG involved the following key criteria: (i) independent boards; (ii) that made their financial assistance available in uniform and consistent manner; (iii) to those in need without regard to who the provider was; (iv) for any recognized FDA-approved drug or service for a particular disease category.

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