

OIG ISSUES FAVORABLE OPINION ON FINANCIAL ASSISTANCE PROGRAM

OVERVIEW

Recently, the Department of Health & Human Services Office of the Inspector General ("OIG") issued Advisory Opinion 15-06 addressing a 501(c)(3) charitable organization's proposed arrangement to provide financial assistance to individuals with certain chronic diseases. Using donated funds, the organization would assist qualifying individuals with health insurance costs, drug/device therapy costs and other incidental health care expenses. OIG concluded that such an arrangement would not constitute grounds for civil monetary penalties or result in the imposition of administrative sanctions under the Anti-Kickback Statute. OIG's favorable opinion was based on the unique structure of the proposed arrangement, which significantly limits donor influence, determines eligibility for assistance based on a uniform and unbiased methodology and preserves a qualifying individual's right to select his/her health care provider.

PROGRAM STRUCTURE

Pursuant to the proposed arrangement, the organization would establish multiple disease funds based on broadly defined disease states using widely recognized clinical standards. The organization would then seek donations for these disease funds from key industry stakeholders such as pharmaceutical and device companies, specialty pharmacies, distributors, individuals and corporations. Further, given the independent nature of the organization's board and its operations, donors would not be able to exert influence over the assistance program and would only have access to limited information regarding the organization's operations. Donors may, however, subject to certain restrictions discussed below, earmark their contributions to a specific disease fund.

The organization would provide financial assistance to qualifying individuals on a first-come, first-served basis. In order to qualify for assistance, an individual must have an existing provider and treatment regimen in place and satisfy the financial assistance requirements established by the organization, which are based on the Federal Poverty Guidelines. Qualifying individuals would need to apply on an annual basis and notify the organization if their financial situation changes throughout the course of the assistance period. Further, the organization intends to contract with a third party to determine eligibility for individuals applying for financial assistance. Also, the qualifying individuals are free to change providers, drugs/device therapies or insurance plans at any point in time during the assistance period. Finally, the organization would not refer qualifying individuals to any providers, drugs/device therapies or insurance plans.

OIG ANALYSIS

In reviewing the proposed arrangement, OIG reiterated its position 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 organizations. In issuing its favorable opinion, OIG noted that: (i) the proposed arrangement effectively separates donors from the organization as well as from the qualifying individuals who receive financial assistance; (ii) donors would not have influence over the organization's structure or program operations; (iii) donors would not acquire any data that would allow them to correlate their donations to use of their products/services; (iv) donors would not receive any information about other donors to the organization; and (v) donors would not have access to information about qualifying individuals. Similarly, qualifying individuals will not have access to information about donors aside from the organization's annual report and public list of donations.

OIG also noted that while donors may earmark donations to a specific disease fund, no greater specificity beyond a particular disease fund is permitted, and as such, a donor would not have the ability to direct funds to their own products. Moreover, aside from limited exceptions, the organization would not sponsor a disease fund with limited treatment options (e.g., where only one drug/device treatment option is available or where there is only one manufacturer of the drug/device).

Finally, OIG concluded that the proposed arrangement would not likely influence a qualifying individual's selection of a particular provider, practitioner, supplier, product or service, and that the overall risk presented by the proposed arrangement was limited due to the following protections to be implemented by the organization: (i) the organization would provide assistance on a first-come, first-served basis to the extent that funding is available; (ii) the conditions for financial assistance are based solely on financial need according to a reasonable, verifiable and uniform measure; (iii) qualifying individuals must have an existing provider and treatment regimen in place in order to receive assistance; (iv) qualifying individuals may freely change their providers, drug/device therapies or insurance plans at any time during the

assistance period; and (v) the organization will not provide referrals to any industry stakeholders.

PRACTICAL TAKEAWAY

Given the structure of the proposed arrangement discussed above, OIG determined that the organization's receipt of donated funds from industry stakeholders to provide, among other things, health insurance support entails minimal fraud and abuse risk. This advisory opinion continues to support the notion that independent, bona fide charitable organizations can receive funds donated from industry stakeholders and use such funds to provide financial support to qualifying individuals in need of assistance, including federal health care program beneficiaries.

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