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May 23, 2014

On May 21, 2014, the United States Department of Health & Human Services Office of Inspector General ("HHS OIG") issued a fifteen page *Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs* ("Supplemental Bulletin") to expand on guidance provided in the 2005 *Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees*[1] ("2005 Bulletin") regarding industry support provided to patient assistance programs ("PAPs").

The Supplemental Bulletin provides a number of significant clarifications related to independent charity PAPs that provide cost-sharing assistance for prescription drugs. Incorporating information learned from Advisory Opinion[1] requests submitted to the OIG by PAPs and pharmaceutical manufacturers that provide financial support to PAPs, the Supplemental Bulletin expands on the guidance provided in the 2005 Bulletin by focusing on three specific areas: (1) disease funds; (2) eligible recipients; and (3) the conduct of donors.

1. Disease funds

The OIG stated in the Supplemental Bulletin that an "Independent Charity PAP must not function as a conduit for payments or other benefits from the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices." Key considerations outlined in the Supplemental Bulletin include the following:

- Does the PAP define the disease fund so narrowly that the earmarking effectively results in a donor's subsidization of its own products?
- Does a pharmaceutical manufacturer or its affiliate exert any direct or indirect influence or control over the charity or its assistance program?
- Does a donor influence the identification of disease funds?
- Is a disease fund defined by reference to specific symptoms, severity of symptoms, method of administration of drugs, reference to the stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of a widely recognized disease state?
- Does the disease fund limit assistance to a subset of available products, such as only expensive or specialty drugs?

The OIG also stated in the Supplemental Bulletin that a charity with narrowly defined disease funds may be subject to scrutiny if the disease funds result in funding exclusively or primarily the products of donors or if other facts and circumstances suggest that the disease fund is operated to induce the purchase of donors' products, even if the charity previously obtained a favorable OIG Advisory Opinion.

2. Eligible recipients

The OIG emphasized in the Supplemental Bulletin that the cost of a particular drug for which the patient is applying for assistance is not an appropriate stand-alone factor in determining individual financial need, but may be one of many obligations that affects the patient's financial circumstances. A key consideration is whether the independent charity PAP determines eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.

3. Conduct of donors

The OIG stated that actions by donors to correlate funding provided to a PAP and support for the donor's own products may be "indicative of a donor's intent to channel its financial support to copayments of its own products" in violation of the federal Anti-Kickback Statute.

PAPs that previously used the OIG Advisory Opinion process should carefully review the Supplemental Bulletin.

The OIG stated in its press release that the "OIG will work with charities that previously received favorable advisory opinions to ensure that their operations are consistent with current guidance. OIG intends that there be no disruption of patient care during this process."[2]

For questions about the implications of the Supplemental Bulletin for your organization or for assistance with submitting an OIG Advisory Opinion request, contact one of the attorneys listed here.

NOTES

1. The OIG issues Advisory Opinions regarding the application of the OIG's fraud and abuse authorities to requesting parties related to existing or proposed business arrangements, including the application of the federal Anti-Kickback Statute and Civil Monetary Penalties Law.
2. OIG, *New Special Advisory Bulletin Provides Additional Guidance on Independent Charity Patient Assistance Programs for Federal Health Care Program Beneficiaries* (May 21, 2014).

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