



Patient Assistance Programs and Their Pharma Donors can Take No Comfort from OIG's Past Advisory Opinions

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On May 21, 2014, the Department of Health and Human Services' Office of the Inspector General (OIG) released a Supplemental Special Advisory Bulletin (SAB) on patient assistance programs (PAPs) run by independent charities.¹ The SAB supplements the OIG's 2005 Bulletin, which was issued in anticipation of the Medicare Part D benefit rollout and which identified a serious risk of fraud and abuse in arrangements that are not properly structured.²

The more recent SAB addresses specific risks the OIG has identified with respect to the anti-kickback statute and the prohibition on inducements to Medicare and Medicaid beneficiaries.

The new SAB acknowledges that some Independent Charity PAPs that previously received favorable advisory opinions may need to modify their procedures in light of this new guidance. The OIG is contacting those PAPs and will modify some of its prior advisory opinions. In the interim, existing advisory opinions will protect the requestors' arrangements until any modifications are completed.

As described in the new SAB, there are two aspects of PAP arrangements that warrant scrutiny and could potentially violate the statute:

1. Donations made by a company to a PAP to induce the PAP to recommend or arrange for the purchase of its reimbursable products; and
2. The PAP's grant of financial assistance to the patient, if made to influence the patient to purchase (or the physician to prescribe) a specific product.

The OIG stresses that each determination is fact-specific, and the nature, structure, sponsorship, and funding of the PAP are all relevant factors.

In a press release accompanying the May 2014 SAB, OIG acknowledges that pharmaceutical companies may donate to independent charities that provide financial assistance with medications to needy beneficiaries. However, the agency will "closely scrutinize PAPs that do not appear sufficiently independent from their donors."

The SAB expands on the factors outlined in the 2005 SAB as fundamental to a properly structured "Independent Charity PAP," with a focus on disease funds, eligible recipients, and the conduct of donors.

Disease Funds

The OIG voices its concern that some Independent Charity PAPs have so narrowly defined their target disease funds that only a limited number of drugs are covered. The agency stresses that the 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."

¹ Department of Health and Human Services, Office of Inspector General, Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs (79 Fed. Reg. 31120, May 30, 2014).

² Department of Health and Human Services, Office of Inspector General, Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (70 Fed. Reg. 70623, Nov. 22, 2005).

The OIG reiterated its position from the 2005 Bulletin that “pharmaceutical manufacturers and their affiliates should not exert any direct or indirect influence or control over the charity or its assistance program.” Other arrangements noted in the 2005 guidance that may trigger scrutiny include:

- Donors should not influence the identification of disease funds; and
- Disease funds should not be defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs.

The recent SAB expands the list of examples of suspect arrangements and stresses that the list is not all-inclusive. Additional examples include:

- Disease funds defined by reference to the stages of a particular disease, the type of drug treatment, and any other ways of narrowing the definition of widely recognized disease states;
- Disease funds that result in funding exclusively or primarily the products of donors;
- Any other fact pattern that suggests the disease fund is operated to induce the purchase of the donors’ products; or
- PAPs that limit assistance to a few drugs, such as by covering copayments for only expensive or specialty drugs, instead of all FDA-approved products.

Eligible Recipients

The 2014 SAB outlines several factors an Independent Charity PAP may consider in determining a patient’s financial need, but it stresses the fact that the cost of a particular drug should not be used as the only factor. Eligibility should be determined based on “a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.” Poverty guidelines, local cost of living, and the scope and extent of a patient’s total medical bills are all appropriate considerations.

Conduct of Donors

The OIG acknowledges that in issuing advisory opinions to Independent Charity PAPs, the charity requesting the opinion is not in a position to certify as to the behavior of the donor. However, charities often certify that they will provide donors only with aggregate reports of the number of applicants, number of qualifying patients, and amount disbursed. The OIG stresses that these certifications are important to ensure that donors are not able to tailor the amount of their donations to subsidize only the amount used to supply their products.

As noted above, the OIG intends to modify some of its prior advisory opinions to conform to this latest SAB. Industry donors and PAPs who have been guided by existing advisory opinions should reconsider their models in light of this guidance.

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