

## Gov't Paying Close Attention To Patient Assistance Programs

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Many pharmaceutical companies operate their own or contribute to patient assistance programs to ensure that patients in need have access to medically necessary products. PAPs may provide services such as copayment assistance, benefit review, education and referral to patient advocacy groups, one-on-one counseling, and free product as needed.

While companies are often well intentioned in their support of PAPs, it is important that they watch government enforcement trends. Companies are increasingly focused on the commercialization of drugs that treat very serious but less prevalent diseases. Such treatments are often extremely expensive and not covered by insurance because of cost and a lack of awareness of the disease states given that they affect relatively small populations. The Office of the Inspector General has taken an intensified interest in companies' policies and procedures relating to PAPs, and earlier this year issued new guidance specifically related to PAPs operated by independent charities.



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### Past OIG Guidance On PAPs Informs the Future

In November 2005, the OIG issued a special advisory bulletin providing guidance on the application of fraud and abuse laws to PAPs. In this guidance, the OIG recognized that PAPs provide “important safety net assistance to patients of limited means who do not have insurance coverage for drugs, typically serving patients with chronic illnesses and high drug costs” and that PAPs may be structured in a variety of ways, including operated by pharmaceutical manufacturers. However, the OIG was concerned that “cost-sharing subsidies provided by pharmaceutical manufacturer PAPs pose a heightened risk of fraud and abuse under the Federal anti-kickback statute.”

Specifically, the OIG noted that if a manufacturer offered subsidies “tied to the use of the manufacturer’s products (often expensive drugs used by patients with chronic illnesses),” those subsidies would present traditional fraud and abuse risks associated with kickbacks. According to the OIG, this scenario could result in manufacturer PAPs steering beneficiaries to particular drugs, increasing health care costs, providing financial advantages over competitor products, and reducing patients’ incentives to identify and use less expensive drugs.

The OIG's 2005 bulletin offered "non-abusive alternatives" as long as certain safeguards are in place. Generally, the suggested safeguards work to ensure that the PAP does not operate as a "conduit" for payments by manufacturers to patients and does not influence the patient's treatment choices.

The OIG identified the following specific safeguards: (1) neither the donor nor any affiliate should exert any direct or indirect influence or control over the PAP; (2) the PAP should award assistance in a truly independent manner that severs any link between the donor's funding and the beneficiary; (3) the PAP should award assistance "without regard to the pharmaceutical manufacturer's interests and without regard to the beneficiary's choice of product, practitioner, supplier, or Part D drug plan;" (4) the PAP should provide assistance "based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner;" and (5) the manufacturer should not solicit or receive data from the PAP that would allow it to link its donations, in frequency or amount, to the number of subsidized prescriptions for its products.

The OIG also recognized that some charities focus their efforts on patients with particular diseases, and that donors may earmark funds for patients with specific diseases. While donations by manufacturers that are earmarked for certain broad disease categories should not increase the risk of abuse, charities "may artificially define their disease categories so narrowly that the earmarking effectively results in the subsidization of one (or a very few) of donor's particular products." Donations in these scenarios, according to the OIG, presented an "elevated risk" of fraud and abuse. As a result, the OIG recommended that companies limit their earmarked donations to PAPs that "define categories in accordance with recognized clinical standards and in a manner that covers a broad spectrum of available products."

#### **Charities Get a Closer Look in 2014**

The OIG weighed in on PAPs again in May 2014, and its position remained consistent. The 2014 bulletin was intended to provide "additional guidance regarding PAPs operated by independent charities" and reiterated the OIG's concerns that donor contributions to PAPs might implicate the Anti-Kickback Statute if made to induce a PAP to recommend the donor's products or otherwise influence patients to purchase specific products.

The OIG warned again that charities 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." The OIG noted that it had seen certain charitable PAPs seeking to cover copayments solely for "expensive or specialty drugs," and this raised concerns about steering patients away from cheaper and better options, increasing costs for federal healthcare programs. The OIG restated its opinion that a disease fund including only one drug, or drugs made by only one manufacturer, would not on its own be determinative, but added that "a disease fund that covers only a single product, or the products made or marketed by only a single manufacturer that is a major donor to the fund, will be subject to scrutiny." In such an instance, the OIG suggested that it would look to whether the fund appeared "narrowly defined in a manner that favors any of the fund's donors." The OIG was concerned that charitable PAPs that narrowly defined disease funds or provided assistance only for specific products would steer patients toward those products, which would in turn incentivize manufacturers to contribute to those PAPs and use them as a conduit to influence use of their own products. Funds specific to less prevalent diseases could have a disease category that is "narrowly" defined by OIG's standards, so companies should pay careful attention to their support of PAPs in this space.

The OIG further elaborated that donors not be provided with information sufficient to match their donations with the number of recipients using their products, stating that efforts by donors to do that “may be indicative of a donor’s intent to channel its financial support to copayments of its own products, which would implicate the anti-kickback statute.”

### **Advisory Opinions Regarding PAPs**

Many of the OIG’s advisory opinions evaluating the compliance of PAPs have focused on whether the PAP was able to make independent decisions regarding patient assistance or whether the donor had influence over the beneficiaries, including whether the donor received any information about patients’ use of its products. If the company did not exert control over the PAP’s decision-making process and was not given information linking its donation to the volume of its product that was used, the OIG found no kickback concerns.

For example, in a 2010 opinion, the OIG found that a charitable organization assisting patients with copayment obligations did not run afoul of federal law because it established objective criteria for selecting grant recipients which did not include the interests of any donor or affiliate or the applicant’s choice of product, provider, or practitioner. Similarly, in 2007, the OIG opined that industry contributions to a PAP would not warrant an administrative penalty in part because the design of the PAP “insulat[ed] beneficiary decision-making from information attributing the funding of their benefit to any donor.”

In November 2013, the OIG addressed this issue again when it posted an opinion in response to a request from a supporting organization of an independent charitable foundation. The requestor operated two PAPs funded primarily by the foundation for individuals suffering from a rare genetic disorder. The PAPs helped patients pay their insurance premiums and covered certain costs not covered by insurance. All of the funds coming through the foundation to the requestor were from pharmaceutical manufacturers that produced drugs to treat the disease in question and were earmarked for one of the two PAPs. No donor or affiliate exerted any direct or indirect influence over the foundation, the requestor or the PAPs. The OIG cautioned that, “earmarking donations for a rare disease with a relatively limited number of treatments increases the risk that the charity would serve as an improper conduit for donors to provide funds to patients who use their specific products.”

The OIG found in this case, however, that there were aspects of the PAP’s structure that decreased the risk of impropriety, including: (1) multiple products from more than one manufacturer were available to treat it; (2) the PAP provided grants to patients instead of direct assistance for insurance copayments, deductibles and coinsurance; (3) patients did not need to receive or seek any particular treatment (or any treatment at all) to receive funds; and (4) because the PAP’s programs provided grants to pay insurance premiums and products outside of insurance coverage, its ability to influence how patients ultimately chose services or products payable by federal healthcare programs was minimized.

The OIG also identified features of the foundation’s organization that reduced the risk of improper inducement, including that: the PAP acted independent of any “direct or indirect control” by its donors when making assistance decisions; assistance was based solely needs-based; and the PAP did not provide any information to the donor allowing it to link its donation with the amount or frequency of use of its product.

## Implications for Pharmaceutical Manufacturer PAPs and Contributions

Pharmaceutical manufacturers operating or contributing to independent charitable PAPs should be cognizant of OIG guidance. While PAPs facilitate treatments for patients in need and the OIG recognizes their importance in providing access to care, PAPs do present compliance risks. The OIG has remained committed to ensuring that PAPs not serve as conduits for pharmaceutical manufacturer donors to induce patients to use the company's products.

Companies should ensure that the PAPs they support have proper safeguards in place to “firewall” their donations. It is critical to protect against any actual or perceived control or influence of PAPs by industry. For example, industry should separate their interactions with PAPs from sales and marketing activities and personnel. Specific protocols are necessary to identify how companies will contribute to PAPs and refer patients for assistance. Particular vigilance may be warranted in instances where charitable PAPs are focused on specific and less prevalent diseases, or where treatment options are limited, as kickback risks may be elevated.

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