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HHS OIG Issues New Guidance on Patient Assistance Programs

On May 21, 2014, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued a special advisory bulletin addressing independent charity patient assistance programs (PAPs) for federal health care program beneficiaries. The bulletin builds on prior OIG guidance on the topic and reaffirms OIG's position that properly structured PAPs help beneficiaries and cautions that PAPs with certain problematic characteristics may experience increased regulatory scrutiny. The bulletin and the following discussion focus on risks arising in three areas: disease funds, eligible recipients and the conduct of donors. The special advisory bulletin calls on PAPs and manufacturers to follow additional substantive safeguards not present in prior guidance or advisory opinions. The OIG and other enforcement agencies are expected to apply the new guidance prospectively following a reasonable transition period and avoid an unfair retroactive application of these new standards.

About PAPs

PAPs provide important assistance to patients of limited means, including through offering cash subsidies, free or reduced price drugs, or both. Some PAPs replenish drugs furnished by pharmacies to eligible patients, while others offer assistance directly to patients. PAPs may be affiliated with a particular pharmaceutical manufacturer or may be operated by independent charitable organizations. Recognizing the important role PAPs provide to beneficiaries, OIG issued a special advisory bulletin in 2005 that identified potentially abusive PAP structures, as well as methods of providing assistance that reduce the potential for fraud and abuse.[1] Since issuing its original guidance, the OIG has issued nearly a dozen advisory opinions on the subject that further clarified the characteristics and safeguards it believed were necessary to ensure compliant PAP arrangements.[2] While OIG asserts that the new guidance is a mere "clarification," it more accurately expands on the agency's prior guidance and describes new substantive safeguards the agency will consider in assessing PAP-manufacturer relationships.

Disease Funds

OIG's new bulletin states that a charity with narrowly defined funds may be subject to scrutiny if the disease-specific funds result in funding exclusively and primarily the products of donors. Charities also may be subject to scrutiny if the circumstances suggest that the disease fund is operated to induce the purchase of a donor's products. This is true regardless of whether the charity has obtained a favorable advisory opinion. The OIG raised concerns regarding PAPs that limit assistance to a subset of available FDA-approved products for treatment of the disease. Disease funds should not be defined for the purpose of limiting the drugs for which the PAP provides assistance. The OIG advises PAPs to define disease funds in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of products.

1 70 Fed. Reg. 70623.

2 *See, e.g.*, OIG Advisory Opinions 6-14, 6-21, 7-04, 7-18, 10-06 and 13-19 (available at https://oig.hhs.gov/reports-and-publications/archives/advisory-opinions/index.asp).

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Eligible Recipients

The OIG guidance also addresses PAPs that restrict the pool of eligible recipients of assistance only to federal health care program beneficiaries. The OIG states that, standing alone, this practice does not increase risk to federal health care programs. However, regardless of whether the fund is restricted to federal beneficiaries or available broadly, the PAP must determine eligibility according to a "reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner." And while the OIG does not endorse any particular method of determining financial need, it states that the cost of the drug itself is not an appropriate standalone factor but one of many obligations that affect a patient's financial circumstances. The OIG advises PAPs to adopt the safeguards on this topic it identified in the 2005 PAP guidance — that is, that the PAP awards assistance in a truly independent manner that severs any link between a donor's funding and the recipient.

Donor Conduct

Lastly, the OIG shifts its focus from PAPs to donors. OIG warns that donors face increased scrutiny where donations to a PAP are correlated with the PAP's support for the donor's products. The OIG states that favorable advisory opinions on the topic address the relationship between the requesting entity — the charity — and its donors. The OIG emphasizes that it approved these relationships in part because of the charity's certification that it will take measures to ensure the independence of its PAP from the PAP's donors. One limitation of this certification however, and therefore a limitation of the favorable advisory opinions, is that it does not address relationships between donors and third parties outside the arrangement. OIG warns that arrangements between donors and third parties that enable donors to correlate their support to PAPs may be indicative of a donor's intent to channel financial support to copayments of its own products. For example, a contract between a donor and a third-party market research company for services, including the aggregation of data points on a PAP's support for the donor's products, would expose the donor to increased risk under the federal Anti-Kickback Statute.

Looking Ahead

In light of OIG's recent guidance, PAPs may want to reexamine the criteria they employ in defining disease funds or when determining patient eligibility. Recipients of previous favorable advisory opinions will be notified by the OIG of required changes and any necessary modification of prior opinions to reflect the OIG's new "current practice." Manufacturers also should examine their relationships with PAPs and, importantly, third parties whose services may give rise to an inference of improper intentions. A key point here is that *bona fide* third-party services may taint otherwise compliant donations to PAPs where those services enable manufacturers to track PAP support of their product.

PAPs and the manufacturers that support them serve an important role in the health and treatment of patients who lack the resources necessary to pay for critical medicines, but the May 21 special advisory bulletin should serve as a reminder that the OIG believes there is potential for fraud and abuse within these relationships and will continue to scrutinize arrangements under evolving regulatory enforcement theories.