

# Compliance Today – November 2018

## Effective compliance for an independent charity patient assistance program

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by Thomas E. Herrmann, JD

**Thomas E. Herrmann** ([therrmann@strategicm.com](mailto:therrmann@strategicm.com)) is a Managing Senior Consultant at Strategic Management Services, LLC in Alexandria, VA, and serves as the Chief Compliance Officer for the Patient Access Network (PAN) Foundation in Washington DC.

Independent charity patient assistance programs (PAPs) provide financial assistance to eligible underinsured patients, covering out-of-pocket costs associated with prescription medications, including co-payments, deductibles, coinsurance, and in some instances, premium and travel support. These charitable programs differ significantly from pharmaceutical company patient assistance programs that typically provide support to patients for company branded products.

Independent charity PAPs operate pursuant to Advisory Opinions issued by the Office of Inspector General (OIG) in the U.S. Department of Health and Human Services (HHS). These opinions identify significant risk areas and provide direction on how an organization can operate in a legally compliant manner. In recent years there has been increased scrutiny of the relationships between pharmaceutical manufacturers and independent charity PAPs. Never has it been more important for an independent charity PAP to address key risk areas to ensure that the organization fulfills its mission in a fully compliant manner. This article describes the potential legal risks faced by independent charity PAPs, and outlines the components of an effective compliance program for such organizations.

### Government guidance

With the enactment of the Medicare Part D benefit, effective January 1, 2006, the OIG issued a Special Advisory Bulletin. The HHS OIG recognized that:

Patient assistance programs (PAPs) have long provided 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. Some PAPs are affiliated with particular pharmaceutical manufacturers; others are operated by independent charitable organizations... without regard to specific donor or industry interests.<sup>[1]</sup>

The Special Advisory Bulletin highlighted lawful avenues “...for pharmaceutical manufacturers and others to help ensure that all Part D beneficiaries can afford medically necessary drugs.” The OIG noted support for the “efforts of charitable organizations and others to assist financially needy beneficiaries, as long as the assistance is provided in a manner that does not run afoul of the Federal anti-kickback statute or other laws.” The OIG issued its guidance “to identify potentially abusive PAP structures, as well as methods of providing assistance that mitigate or vitiate the potential for fraud and abuse.” It also re-affirmed the circumstances whereby “cost-sharing subsidies provided by bona fide, independent charities unaffiliated with pharmaceutical manufacturers [would] not raise anti-kickback concerns, even if the charities receive manufacturer contributions.” It further

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noted that “pharmaceutical manufacturers can donate to bona fide independent charity PAPs provided appropriate safeguards exist.”<sup>[2]</sup>

In its bulletin, the OIG stated that a properly structured and administered independent charity PAP would not be subject to legal exposure under the federal Anti-Kickback Statute (AKS) if the following principles were followed:

- No pharmaceutical manufacturer or agent thereof exerts any direct or indirect control over the charity or the subsidies it makes to patients;
- The charity provides assistance in an independent manner with no linkage between a pharmaceutical manufacturer or another donor and patients;
- The charity provides assistance without regard to a donor’s interests or a patient’s choice of product, provider, practitioner, or supplier;
- The charity provides assistance based on a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner; and
- A pharmaceutical manufacturer does not receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.

The OIG emphasized that an “independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries’ drug choices.”<sup>[3]</sup>

In 2014, the OIG reaffirmed that properly structured PAPs can help federal healthcare program beneficiaries. It issued a Supplemental Special Advisory Bulletin for Independent Charity Patient Assistance Programs to provide additional guidance on addressing specific risks, including legal exposure under the federal AKS, the Beneficiary Inducements Prohibition, and the False Claims Act (FCA).<sup>[4]</sup>

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