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Compliance TODAY

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

NOVEMBER 2018

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ARTICLES

Compliance TODAY

Compliance Today (CT) (ISSN 1523-8466) is published by the Health Care Compliance Association (HCCA), 6500 Barrie Road, Suite 250, Minneapolis, MN 55435. Subscription rate is $295 a year for nonmembers. Periodicals postage-paid at Minneapolis, MN 55435. Postmaster: Send address changes to Compliance Today, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435.

VOLUME 20, ISSUE 11

by Thomas E. Herrmann, JD

Effective compliance for an independent charity patient assistance program

» Patient assistance programs (PAPs) provide financial assistance to eligible individuals who incur high drug bills.
» PAP organizations face heightened governmental review.
» The HHS OIG has identified specific risk areas associated with PAPs.
» A compliance program is needed to maintain a PAP's operational integrity.
» An independent charity PAP should develop an effective compliance program.

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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.


Herrmann

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.[1]

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 noted that "pharmaceutical manufacturers can donate to bona fide independent charity PAPs provided appropriate safeguards exist."[2]

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...impermissibly influence beneficiaries' drug choices.

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."[3]

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).[4]

Potential legal risks

The federal AKS (42 USC 1320a-7b) prohibits the knowing and willful offer, payment,

solicitation or receipt of "remuneration" to induce or reward the referral or generation of business that is paid for by a federal health-care program (e.g., Medicare and Medicaid). In its 2014 guidance, the OIG stated:

> Two remunerative aspects of PAP arrangements require scrutiny under the anti-kickback statute: donor contributions to PAPs (which can also be analyzed as indirect remuneration to patients) and a PAP's grants to patients. If a donation is made to a PAP to induce the PAP to recommend or arrange for the purchase of the donor's federal reimbursable items, the statute could be violated. If a PAP's grant of financial assistance to a patient is made to influence the patient to purchase (or to induce the patient's physician to prescribe) certain items, the statute also could be violated.[5]

The Beneficiary Inducement Prohibition (42 USC 1320a-7a(a)(5)) authorizes the OIG's imposition of civil money penalties (CMPs) on an individual or entity that offers or pays "remuneration" to a Medicare or Medicaid beneficiary that it should know is likely to influence the beneficiary to order or receive from a particular provider, practitioner, or supplier an item or services that is paid for by either Medicare or Medicaid. The OIG advised:

> A subsidy for cost-sharing obligations provided by a pharmaceutical manufacturer through a PAP may implicate the Beneficiary Inducements CMP if the subsidy is likely to influence a Medicare or State health care program beneficiary's selection of a particular provider, practitioner, or supplier, such as by making eligibility dependent on the patient's use of certain prescribing physicians or certain pharmacies to dispense the drugs.

The OIG highlighted three potential risk areas for an independent charity PAP:

- **Establishment of specific disease funds:** Disease funds should be defined in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of products.
- **Eligibility of patients to receive assistance:** The independent charity PAP must determine eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.
- **Conduct of donors:** A charity should not give a donor any information that would enable a donor to correlate the amount or frequency of its donations with the number of aid recipients who use its products or services or the volume of those products supported by the PAP.

The OIG's 2014 Supplemental Bulletin concludes:

> OIG continues to believe that properly structured, Independent Charity PAPs provide a valuable resource to financially needy patients. We also believe that Independent Charity PAPs raise serious risks of fraud, waste, and abuse if they are not sufficiently independent from donors.[6]

Recent government activity

With increased public attention on high drug prices, several years ago the U.S. Department of Justice (DOJ) launched an investigation into the relationships between pharmaceutical companies and independent charity PAPs. Although the investigation is ongoing, several governmental actions have been announced in recent months:

- The DOJ announced that it had entered into settlement agreements with several

pharmaceutical companies resolving claims involving their relationships with PAPs.[7]

- The OIG entered into parallel corporate integrity agreements (CIAs) with the pharmaceutical companies, requiring the implementation of "controls and monitoring designed to ensure true independence from any charity patient assistance programs to which [they] donate in the future."[8]
- The OIG revoked a favorable Advisory Opinion that had previously been issued to an independent charity PAP based on a determination that the organization had failed to "fully, completely, and accurately disclose all relevant and material facts."[9]

The OIG has advised of its continued belief that properly structured, independent charity PAPs provide a valuable resource to financially needy patients, but it has also noted the need for such charitable organizations to be sufficiently independent from donors.[10] Recent enforcement actions relating to the relationships between pharmaceutical manufacturers and independent charity PAPs highlight the need to have policies and procedures in place and operational for ensuring such independence.

The OIG has provided no instructions regarding the establishment of an independent charity PAP compliance program...

For an independent charity PAP to be insulated from legal exposure, it must follow and comply with the representations it has made to the OIG, as well as the specifications set forth by the OIG in the controlling Advisory Opinion. Further, to ensure the adherence of an independent charity PAP to the terms of its Advisory Opinion, mitigate the risks identified by the OIG under the AKS and Beneficiary Inducement Prohibition, and maintain its tax-exempt status, the organization should establish and implement a formal compliance program.

Purpose and elements of a compliance program

The OIG has provided no instructions regarding the establishment of an independent charity PAP compliance program, but it has issued compliance program guidance directed toward other sectors of the healthcare industry, and which address common themes. The *Compliance Program Guidance for Pharmaceutical Manufacturers* states:

> The OIG believes a comprehensive compliance program provides a mechanism that addresses the public and private sectors' mutual goals of reducing fraud and abuse; enhancing health care provider operational functions; improving the quality of health care services; and reducing the cost of health care. [It has recommended that organizations] develop and implement or refine (as necessary) compliance elements that uniquely address the areas of potential problems, common concern, or high risk that apply....[11]

Developing and implementing an effective compliance program

A compliance program needs to be responsive to the mission, structure, and culture of an organization while also addressing the seven core elements referenced by the federal government. In addition, it should address the identified risk areas and be responsive to the

needs of all stakeholders (e.g., government, donors, patients, physicians, pharmacists, contractors). As has been stated, there is "no one size that fits all organizations." However, a compliance program should address the seven core elements and "foster a culture of compliance that begins at the executive level and permeates throughout the organization."[12]

Compliance program organizational structure

The board of directors of an independent charity PAP should take formal action to establish, maintain, and conduct regular oversight of the compliance program through a resolution or charter setting forth its commitment to develop and implement an effective compliance program. Oversight should be exercised by the board (or a designated committee) through the receipt of regular reports on the operations of the compliance program.

An executive compliance committee (ECC) should be established for management oversight and support for the compliance program. The committee should be made up of senior managers, chaired by the CEO or compliance officer, and meet on a regular basis.

A compliance officer, reporting directly to the CEO, should be designated to be responsible for the development and operation of the compliance program. The individual should also have direct reporting access to the board of directors. The compliance officer should possess sufficient experience and expertise to carry out the responsibilities of the office. A position description should be established setting forth the core duties and responsibilities, along with sufficient authority to carry them out.

Written policies and procedures

The organization should develop and publicize written compliance guidance in the form of a code of conduct and implement policies and procedures approved by the board and/or CEO.

As noted by the OIG:

> The code should function in the same fashion as a constitution, i.e. as a document that details the fundamental principles, values, and framework for action within an organization. The code of conduct… should articulate the [PAP's] expectations of commitment to compliance by management, employees, and agents, and should summarize the broad ethical and legal principles under which the [organization] must operate.[13]

Policies and procedures should address key compliance concepts, including:

1. Compliance responsibilities, duty to report, and non-compliance
2. Conflicts of interest
3. Donor communications
4. Compliance education and training
5. Anti-Kickback Statute compliance
6. Investigation and resolution of complaints and issues
7. Disciplinary and enforcement actions
8. Auditing and monitoring.

Compliance education and training

General and specialized compliance education and training programs need to be developed and presented to the board of directors, management, employees, and contractors. As noted by the OIG in Advisory Opinions, certain independent charity PAPs contract with one or more separate companies to serve as the:

> "Administrator" to provide many services for running the [organization's] daily operations, including administering the funds, staffing the phone lines for patients and physicians…, processing applications for assistance, providing the financial

> assistance for documented cost-sharing needs, maintaining records, and preparing research reports for the Board…. [T] the Administrator separates its commercial-oriented functions from the work it performs for the [Independent Charity PAP] by means of an "ethical wall" that combines various elements.[14]

It is imperative that the compliance officer take steps to ensure that contractors undertaking "administrator" functions for the PAP are aware of compliance standards, receive adequate compliance training, and agree to adhere to compliance principles. Further, the compliance officer needs to receive regular reports from PAP contractors with respect to receipt of and adherence to ethical principles, practices, and compliance training. Documentation should be maintained evidencing that compliance training was received by both staff and contractors.

Lines of communication

An effective compliance program needs multiple channels of communication regarding the compliance program, including a hotline through which employees can report suspected wrongdoing confidentially or anonymously. Information about the compliance program and related materials (e.g., code of conduct, policies and procedures) needs to be easily accessible to all employees and other stakeholders (e.g. donors and patients) via the internet, intranet, and other established systems. The organization needs to promote and publicize its policy regarding "compliance responsibility, duty to report, and non-retaliation" with employees, managers, supervisors, and contractors.

Enforcement of disciplinary and other standards

Oversight agencies have made it clear that an effective compliance program must include consistent enforcement of the code and policies, regardless of the position of individuals within the organization. This requires collaboration between the Compliance and Human Resources departments. It is important to formalize their working relationship to ensure coordination of investigations and consistent application of disciplinary standards. To meet this standard, there should also be a policy and procedures guiding the disciplinary and enforcement process. Further, in light of the importance of independence from pharmaceutical companies and other healthcare entities, there needs to be an established process for collection, review, and action (where necessary) with respect to conflict of interest reports by board members, senior staff, contractors, and others.

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Auditing and monitoring

The ongoing assessment of all compliance risk areas is necessary. For each risk area, the responsible operational manager must engage in ongoing monitoring for compliance. This includes being aware of changes in regulations, providing written guidance in the form of standard operating procedures (SOPs), training, and monitoring performance to verify compliance. In addition, regular audits of operational and compliance issues are necessary.

A formal internal audit process needs to be established to ensure that the standards certified by the independent charity PAP to the OIG are maintained and followed. These

audits should review risk areas identified by the OIG, including:

- Establishment of disease funds and formularies
- Determining eligibility of patients for assistance
- Disbursing financial assistance
- Communicating with donors

The compliance officer should conduct/oversee an annual risk assessment process, establish an audit work plan, conduct/oversee audits, review the response of operational units to recommendations, and monitor recommended corrective actions. Further, to the extent that representations have been made to the OIG, the independent charity PAP should ensure that:

> safeguards are implemented and the ethical wall is maintained, [an organization] employee or contractor who is neither an employee nor an agent of the Administrator [should] be designated as Compliance Auditor… [and] assigned the task of producing detailed reports to the Board reviewing the operation of the safeguards and the ethical wall.[15]

A formal audit tracking system should be established and maintained to record information regarding audits from initiation to completion and the resolution of recommendations.

Investigation of complaints, response to detected offenses, and corrective actions

The compliance officer should be responsible for investigating/reviewing all complaints, concerns, or issues that are raised relating to compliance with applicable laws, regulations, governmental guidance, and independent charity PAP policies and procedures. To the extent necessary, detected offenses and necessary remedial steps should be reported to the CEO, legal counsel, ECC, and board of directors. Moreover, a comprehensive compliance issue tracking system should be maintained to document all investigations/reviews from initiation through resolution, including remedial actions. Further, to the extent that systemic problems are identified, they should be raised and resolved by the compliance officer in conjunction with the ECC.

...detected offenses and necessary remedial steps should be reported to the CEO, legal counsel, ECC, and board of directors.

Conclusion

Independent charity PAPs serve an important role in providing support and assistance with out-of-pocket prescription medication costs for financially needy patients who are living with serious and/or life-threatening diseases. Although these organizations do not directly receive payments from federal healthcare programs, they receive government benefits through tax-exempt status and OIG Advisory Opinions. Currently, all Independent Charity Patient Assistance Programs operate under a favorable OIG Advisory Opinion that is applicable to the specific charity. These AOs set forth general operating specifications that are consistent for all Independent Charity Patient Assistance Programs. This is a significant government benefit that allows these organizations to operate without legal exposure under the AKS or the Beneficiary Inducements Prohibition.

In these times of enhanced government scrutiny, required accountability, and necessary transparency to ensure independence and appropriate operations, an independent charity PAP should develop and implement an effective compliance program, which should be reflective of OIG guidance and should support a collaborative culture of compliance throughout the organization and its stakeholders.

1. 70 CFR 224 at 70623 (OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees) November 22, 2005. Available at https://bit.ly/2ph3NMx
2. Idem at 70624-25
3. Idem at 70626-27
4. 79 CFR 104 at 31120-21 (OIG Supplemental Special Advisory Bulletin for Independent Charity Patient Assistance Programs) May 30, 2014. Available at https://bit.ly/2OsCvNX
5. Idem
6. Idem at 31122-23
7. See, e.g., Department of Justice (DOJ) press release: "Drug Maker Aegerion Agrees to Plead Guilty; Will Pay More Than $35 Million to Resolve Criminal Charges and Civil False Claims Allegations. September 22, 2017. Available at https://bit.ly/2NSvqJM
8. See, e.g., Corporate Integrity Agreement between HHS OIG and Aegerion Pharmaceuticals, Inc. Available at https://bit.ly/2NOm8OS
9. HHS OIG: Letter referencing rescission of Advisory Opinion 06-04. November 28, 2017. Available at https://bit.ly/2MH8IzJ
10. 79 CFR 31121 (OIG Supplemental Special Advisory Bulletin for Independent Charity Patient Assistance Programs) May 30, 2014. Available at https://bit.ly/2QEdSzp
11. 68 CFR 86 at 23731-43 (OIG Compliance Program Guidance for Pharmaceutical Manufacturers) May 5, 2003. Available at https://bit.ly/2kIXcHs
12. Idem at 23742
13. Idem at 23733
14. HHS OIG: OIG Advisory Opinion 07-18 at 6 and 7. December 19, 2007. Available at https://bit.ly/2PMzclf
15. Idem, Modified October 26, 2015. See https://bit.ly/2D7tY1R