



**PAN** Foundation

## Compliance Program Summary

March 2019

# Introduction

**T**he Patient Access Network (PAN) Foundation is an independent, charitable patient assistance organization. Established in 2004, PAN's mission is to help underinsured people with life-threatening, chronic and rare diseases get the medications and treatments they need by helping them pay for their out-of-pocket costs and by advocating for improved access and affordability.

In furtherance of its mission, PAN is committed to complying with all laws and regulations, including the Federal Anti-Kickback Statute,<sup>1</sup> the Federal Health Care Program Beneficiary Inducement Prohibition<sup>2</sup> and the Internal Revenue Service (IRS) Code.<sup>3</sup> Moreover, to ensure compliance with all applicable legal standards, PAN strives to operate in full accordance with an Advisory Opinion issued by the Office of Inspector General (OIG) in the U.S. Department of Health and Human Services.<sup>4</sup> Related OIG guidance, for example, OIG's Supplemental Special Advisory Bulletin for Independent Charity Patient Assistance Programs, helps PAN interpret adherence to its Advisory Opinion.<sup>5</sup>

The OIG has stated:

*Patients who cannot afford their cost-sharing obligations for prescription drugs may be able to obtain financial assistance through a patient assistance program (PAP). PAPs have long provided important safety net assistance to such patients, many of whom have chronic illnesses and high drug costs. . . .*

*OIG continues to believe that properly structured, Independent Charity PAPs provide a valuable resource to financially needy patients.<sup>6</sup>*

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1 42 U.S.C. 1320a-7b(b).

2 42 U.S.C. 1320a-7a(a)(5).

3 See, e.g., section 501(c)(3) of the IRS Code.

4 OIG Advisory Opinion 07-18 (as modified).

5 70 Fed. Reg. 70623 (November 22, 2005); 79 Fed. Reg. 31120 (May 30, 2014).

6 79 Fed. Reg. at 31120.

# OIG Advisory Opinion 07-18 (as modified)

Compliance with its OIG Advisory Opinion requires PAN's adherence to the following principles:<sup>7</sup>

- » PAN will define its disease funds in accordance with widely recognized clinical standards. PAN will not define disease funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, types of drug treatment or any other way of narrowing the definition of widely recognized disease states, except that PAN may maintain disease funds limited to patients with certain metastatic cancers, but will cover, at a minimum, all drugs approved by the U.S. Food and Drug Administration (FDA) for the type of cancer, regardless of stage.
- » PAN will make assistance available for all prescription medications, including generics and bioequivalents, that are FDA-approved or indicated in compendia, evidence-based guidelines or clinical guidelines for a diagnosis that qualifies the patient for assistance from a given disease fund.
- » PAN will not maintain any disease fund that provides assistance for only one drug, or only the drugs made or marketed by one manufacturer or its affiliates. If PAN establishes a fund for a disease for which the FDA has approved only drugs made by a single manufacturer (including its affiliates), PAN will provide support for other medical needs of patients with the disease, which, at a minimum, means all prescription drugs for an FDA-approved indication related to managing the disease, including but not limited to drugs to treat symptoms of the disease (e.g. pain medications) and drugs to treat side effects of treatments (e.g. anti-nausea medications).
- » PAN, in its sole discretion, will determine the diseases that it will support and the terms and conditions of its disease funds based on an independent assessment on whether a new fund will best serve patient needs. Donors to PAN may not directly or indirectly influence the identification or delineation of any disease fund, or otherwise exert any influence or control over PAN or its disease funds.

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<sup>7</sup> These principles are only some of the requirements set forth in PAN's Advisory Opinion, which may be found at <https://panfoundation.org/index.php/en/compliance/office-of-inspector-general-advisory-opinion>. By identifying the ones here, PAN does not intend to diminish in any way the need to adhere to the other requirements set forth in PAN's Advisory Opinion.

- » PAN will consider all applications for support on a first-come, first-served basis to the extent of available funding, based on a reasonable, verifiable and uniform measure of financial need that is applied in a consistent manner.

## Compliance Program

To ensure that it is in full compliance with legal and regulatory requirements, PAN has developed and implemented a comprehensive Compliance Program (CP) in accordance with principles established by the U.S. Sentencing Commission and the OIG.

*The OIG believes a comprehensive compliance program provides a mechanism that addresses the public and private sections' 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.<sup>8</sup>*

Further, as referenced by the OIG, through the implementation of its CP, PAN desires to:

- » Demonstrate its commitment to honest and responsible conduct;
- » Increase the likelihood of preventing, identifying and correcting unlawful and/or unethical behavior at an early stage;
- » Encourage employees and contractors to report potential problems to allow for appropriate internal inquiry and corrective action; and
- » Through early detection and reporting, minimize any financial loss.<sup>9</sup>

Consistent with the OIG's Compliance Program Guidance, the core elements of the PAN CP are:

- » CP Organizational Structure/Oversight
- » Written Compliance Guidance
- » Compliance Education and Training

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8 OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23732 (May 5, 2011).

9 OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4859 (January 31, 2005).

- » Lines of Communication
- » Disciplinary and Enforcement Standards
- » Auditing and Monitoring
- » Investigation of Complaints, Response to Detected Offenses and Corrective Actions

While the seven elements necessary for an effective compliance program have been recommended by the OIG for entities that receive (directly or indirectly) funds through Federal healthcare programs (e.g. Medicare and Medicaid), the PAN Foundation believes that these compliance steps are also key to ensuring the integrity and transparency of Patient Assistance Programs. The PAN Foundation recognizes the risks identified by the OIG in its Advisory Bulletin for Independent Charitable Patient Assistance Programs (referenced above) and is committed to establishing a comprehensive CP to address and mitigate these risk areas, implementing the seven core elements as follows:

## 1. COMPLIANCE PROGRAM ORGANIZATIONAL STRUCTURE/OVERSIGHT

- » The Audit, Risk Oversight and Compliance Committee (AROCC) of the Board of Directors oversees and monitors the PAN CP. The AROCC is focused on ensuring that PAN takes appropriate steps to mitigate risks that can negatively impact its mission, reputation and operations. It receives regular reports from the PAN Compliance Team and establishes the priorities and direction of the CP. The AROCC also oversees PAN internal audits, in accordance with an annual risk assessment and audit work plan prepared with staff input, which is reviewed and approved by the Committee.
- » The AROCC reports to the full Board at each of its meetings to provide updated information regarding the CP, internal audits and how identified risk areas are being addressed. Based on these reports, the Board provides oversight and strategic direction for the CP.
- » The Executive Compliance Committee (ECC), comprised of PAN senior executives and directors, meets on a regular basis to review and discuss risk areas and provide guidance to the Compliance Team on how the CP should be implemented.
- » The PAN CP is managed by the Compliance Team, comprised of the Chief Compliance Officer and Manager of Compliance. They administer the day-to-day operations of the CP and respond to issues and risks that may arise.

## 2. WRITTEN COMPLIANCE GUIDANCE

- » The PAN CP is guided by core policies that have been approved by the Board of Directors, including:
  - » Code of Business Conduct and Ethics Policy
  - » Conflict of Interest Policy
  - » Whistleblower Policy
- » Compliance policies and procedures have also been established by Executive Management for other areas, including:
  - » Anti-Kickback Statute Compliance
  - » Compliance Responsibility, Duty to Report and Non-Retaliation
  - » Compliance Education and Training
- » Based on the Code of Business Conduct and Ethics Policy approved by the Board of Directors, a Code of Conduct and Ethics has been developed and disseminated to employees, contractors and other stakeholders.

## 3. COMPLIANCE AND EDUCATION TRAINING

- » General and specialized compliance training programs are provided to the PAN Board of Directors, employees and contractors. Special attention is given to contractor staff to ensure adherence to applicable laws, regulations and policies and procedures, including the PAN Code of Conduct and Ethics, as well as receipt of appropriate compliance training.

## 4. LINES OF COMMUNICATION

- » A Compliance Hotline is maintained by an independent, third-party vendor, through which complaints can be made and issues raised on a confidential (and if desired, anonymous) basis. It can be reached toll-free at: **1-866-580-6442**.
- » Awareness and adherence to the PAN “Compliance Responsibility, Duty to Report and Non-Retaliation” policy is encouraged through managers, supervisors, the Compliance Team and the Compliance Hotline.
- » Information about the CP is provided through a link on the PAN website (<https://panfoundation.org/index.php/en/compliance/compliance-program>).

- » Documents, including compliance policies and procedures, are readily available to PAN employees through a shared file system.
- » Other means of sharing CP information with stakeholders are routinely explored and developed to ensure awareness and adherence.

## 5. DISCIPLINARY AND ENFORCEMENT STANDARDS

- » A Disciplinary Action and Enforcement Policy has been developed and adopted by PAN. This policy is intended to provide guidance regarding the equitable and uniform application of disciplinary action and enforcement where misconduct is determined to have occurred.
- » A protocol between the Compliance Office and the Human Resources Department has been established for coordinating the receipt, investigation and resolution of misconduct by employees.
- » A complaint and resolution tracking system has been established and is maintained to document the handling and resolution of substantiated non-compliance in an equitable, reasonable and appropriate manner.

## 6. AUDITING AND MONITORING

- » An Independent Review Organization (IRO) conducts an annual independent, objective audit of PAN's programs to confirm that PAN is in compliance with the specifications set forth in its OIG Advisory Opinion, in addition to other specified review criteria.
- » A third party contractor serves as the PAN Internal Auditor. The Internal Auditor coordinates the implementation of an annual risk assessment and prepares an annual audit work plan (which is approved by the AROCC).
- » Based on results of the annual risk assessment, the Internal Auditor conducts audits and issues audit reports with findings, observations and recommendations for review by management, the ECC and the AROCC.
- » As specified in the OIG Advisory Opinion, the Internal Auditor conducts an annual OIG Compliance Audit to assess whether PAN is operating in accordance with the delineated criteria.
- » The Compliance Team maintains an audit tracking system to monitor the conduct of audits, findings and recommendations, management responses and follow-up remedial actions.

» Monitoring of contractor activities is conducted on a regular basis by dedicated PAN operations staff.

## 7. INVESTIGATION OF COMPLAINTS, RESPONSE TO DETECTED OFFENSES AND CORRECTIVE ACTIONS

- » A Compliance Investigation and Resolution Policy has been developed and adopted by PAN.
- » The Compliance Team investigates/reviews all complaints, concerns or issues that are raised relating to compliance with applicable laws, regulations and Governmental guidance, as well as internal policies and procedures.
- » A tracking system, maintained by the Compliance Team, is used to document all investigations/reviews from initiation through resolution and subsequent remedial action, if warranted.
- » The PAN Compliance Team reports to the ECC and AROCC on a regular basis on investigations and reviews to ensure strategic direction and guidance is provided for an effective CP.

## Conclusion

PAN's comprehensive CP is intended to ensure compliance with all applicable laws, regulations and Government guidelines, as well as adherence to the requirements set forth in OIG Advisory Opinion 07-18 (as modified). It is designed to

*Foster a culture of compliance [at PAN] that begins at the executive level and permeates throughout the organization.<sup>10</sup>*

PAN recognizes the Governmental benefits it receives through its 501(c)(3) tax-exempt status and OIG Advisory Opinion and is committed to ensuring that it fulfills its charitable mission in a legal, ethical and compliant manner. The PAN CP is applicable to all stakeholders—donors, patients, providers, pharmacies, Board members, employees and contractors. As stated by the OIG, PAN strives to be “a valuable resource to financially needy patients.”<sup>11</sup> To achieve this objective, it desires to develop and maintain an effective CP.

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10 OIG Compliance Program Guidance for Pharmaceutical Manufacturers 68 Fed. Reg. at 23742.

11 OIG Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. at 31123.

If further information about the program is desired, or if there is a concern/issue to be raised, please contact:

- » Tom Herrmann, Chief Compliance Officer at [therrmann@panfoundation.org](mailto:therrmann@panfoundation.org) (703-915-1908)
- » Melissa Kuhta, Manager of Compliance at [mkuhta@panfoundation.org](mailto:mkuhta@panfoundation.org) (202-836-8832)
- » PAN Compliance Hotline: 1-866-580-6442 (toll free).



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