

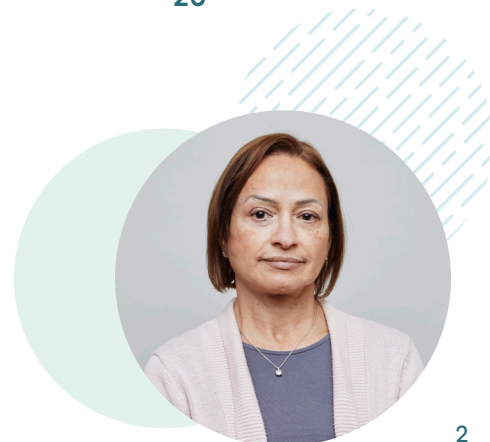


COMPLIANCE PROGRAM SUMMARY

Rigorous compliance. Ethical behavior.

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MESSAGE FROM PAN Foundation leadership

As an independent public charity with 20 years of experience delivering financial assistance to and advocating for patients, the PAN Foundation is committed to meeting the highest standards of compliance, integrity, and operational excellence to carry out our critical, life-saving mission.

The PAN Foundation was the one of first independent charitable patient assistance foundations to proactively establish a seven-element Compliance Program as recommended by the U.S. Department of Health and Human Services Office of Inspector General. Since then, the PAN Foundation has built a rigorous Compliance Program and an extensive set of internal safeguards and controls to ensure our compliance obligations are woven into our daily operations.

Our investment into best-in-class operational safeguards and processes have allowed us to quickly and compliantly deliver financial assistance to more than one million seriously ill patients since 2004 across all 50 states and U.S. territories so they can start and stay on their lifesaving and life-extending medications.

Our commitment to compliance is reinforced and upheld by the Board of Directors, who provide oversight of PAN's compliance initiatives and operations with the objective of ensuring that we meet and exceed all legal and regulatory requirements.

Rigorous compliance and ethical behavior are foundational to who we are and how we operate as an organization.

Through the implementation of the Compliance Program, PAN is committed to:

- Demonstrating ethical, honest, and responsible conduct and compliance with our Office of Inspector General Advisory Opinion and all other federal laws, regulations, and guidance.
- Preventing, identifying, and correcting unethical or unlawful behavior at an early stage.
- Encouraging Board members, employees, and contractors to report potential problems to allow for appropriate internal inquiry and corrective action.
- Minimizing any financial loss through early detection and reporting.¹

We pledge to keep patients at the center of our mission by keeping compliance at the forefront of all that we do and woven into every aspect of our work.



A handwritten signature in black ink that reads "Kevin L. Hagan".

Kevin L. Hagan
President and CEO



A handwritten signature in black ink that reads "James Dunlop".

James Dunlop, JD, MD
Board Chair

Our guiding inspiration

The needs of our patients guide everything we do:



Our mission:

Advance equitable health outcomes by providing financial assistance and advocating for healthcare access and affordability



Our vision:

A nation where no patient goes without treatment due to cost



Our values:

The principles that guide our organization and our conduct

Who we are

The PAN Foundation is an independent, national 501(c)(3) organization dedicated to helping federally and commercially insured people living with life-threatening, chronic, and rare diseases with the out of-pocket costs for their prescribed medications.

Since 2004, we have provided more than one million underinsured patients with \$4 billion in financial assistance. Partnering with generous donors, healthcare providers and pharmacies, we provide the underinsured population access to the healthcare treatments they need to best manage their conditions and focus on improving their quality of life and advocating for healthcare access and affordability.

Our values

Integrity

Excellence

Dignity

Intention

Purpose of the Compliance Program

“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.”²

–U.S. Department of Human Services Office of Inspector General 79 FR 31120 –Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, May 30, 2014

Independent charitable patient assistance foundations—such as the PAN Foundation—have long been recognized by the U.S. government for their role in providing a critical safety net for patients on Medicare and commercial insurance who are living with life-threatening, chronic, and rare diseases.

To provide financial assistance to patients in a compliant and ethical way, charitable foundations must adhere to local, state, and federal laws, regulations, and government guidance—including but not limited to the U.S. Department of Health and Human Services Office of Inspector General (OIG) Advisory Opinions and the federal Anti-Kickback Statute.

The PAN Foundation is committed to complying with all laws and regulations, including the Federal Anti-Kickback Statute³ the Federal Health Care Program Beneficiary Inducement Prohibition,⁴ and the Internal Revenue Service Code.⁵ Moreover, to ensure compliance with all applicable legal standards, PAN operates 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.⁶

To meet its legal and regulatory requirements, PAN has developed and implemented a rigorous Compliance Program in accordance with principles established by the U.S. Sentencing Commission and the OIG with monitoring and oversight from its Board of Directors and a comprehensive audit and risk management function. This document outlines the PAN Foundation’s Compliance Program and its obligations.

Federal laws, regulations, and guidance

U.S. Department of Health and Human Services Office of Inspector General: Special Advisory Bulletins and Advisory Opinions

The Office of Inspector General publicly issued two special advisory bulletins in 2005 and 2014⁷ regarding the operation of all independent charitable patient assistance foundations. The special advisory bulletins give guidance on how pharmaceutical companies can donate to independent charitable patient assistance foundations—which can in turn provide support to patients—without violating the Anti-Kickback Statute.

In addition, the OIG has issued advisory opinions to certain independent charitable assistance foundations that set out rules for the foundation to follow. A foundation that follows its advisory opinion is protected from enforcement under the Anti-Kickback Statute. In large measure, the advisory opinions issued to independent charity assistance foundations restate the guidance contained in the two special advisory bulletins. In some respects, these advisory opinions provide more specific rules to follow.

OIG Advisory Opinion 07-18 (as modified)

The PAN Foundation's Compliance Program has been designed to meet the requirements based on OIG Advisory Opinion 07-18, which was issued to the organization on December 19, 2007⁸ and modified on October 11, 2011 and again on October 26, 2015. The Advisory Opinions and modifications are available on panfoundation.org and publicly available through the OIG.

The PAN Foundation designs all of its policies, procedures, and operations to comply with its OIG Advisory opinion and has implemented extensive safeguards throughout its operations. Related OIG guidance, such as OIG's Supplemental Special Advisory Bulletin for Independent Charity Patient Assistance Programs, helps PAN interpret adherence to its Advisory Opinion.⁹

The PAN Foundation adheres to a comprehensive set of practices and principles as part of its compliance with its OIG 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.

DISEASE FUNDS

The PAN Foundation independently determines the diseases that it supports, and the terms and conditions of its disease funds, based on an independent assessment of whether a new fund will best serve patient needs.

Donors to the PAN Foundation 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.

In accordance with OIG guidance, the PAN Foundation maintains an independent and standardized process for identifying, establishing, and modifying disease funds without influence from donors. If the PAN Foundation receives input from a pharmaceutical company donor regarding the design of new or existing disease funds, we will not accept or pursue their proposals and advise donors of this rule.

Disease funds must be defined in accordance with widely recognized clinical standards.

The PAN Foundation defines its disease funds in accordance with widely recognized clinical standards, specifically using ICD-10 codes to specify the clinical scope and supplement the definition of a widely recognized disease state. Diagnostic coding translates descriptions of diseases, illnesses, and injuries into codes that are widely used in the medical community.

The OIG has specified that disease funds cannot be defined or narrowed based on specific symptoms, severity of symptoms, method of drug administration, type of drug treatment, stages of a particular disease, or any other narrowing criteria. However, the OIG clarified in PAN's Advisory Opinion that cancer disease funds may be limited to metastatic forms.

FORMULARIES

The PAN Foundation makes financial assistance available for all prescription medications, including generic or bioequivalent drugs approved by the FDA, listed in official compendia, or published in evidence-based clinical guides for treatment of the disease state(s) covered by the disease fund.

Per PAN's Advisory Opinion, PAN creates and maintains standardized formularies for each disease fund that contain all prescription medications, including generic or bioequivalent drugs that are FDA-approved, listed in official compendia, or published in evidence-based or clinical guidelines for a diagnosis that qualifies a patient for the assistance program. PAN also reviews and updates its formularies regularly and lists all covered medications and treatments for each disease fund directly on panfoundation.org.

The PAN Foundation does not and will not operate single drug or single manufacturer disease funds.

The OIG prohibits the establishment or operation of single drug or single manufacturer funds that serve Medicare or other federal healthcare program beneficiaries. There are

some cases where the FDA may have only approved one or several drugs that are made or marketed by a single manufacturer or its affiliates for the disease supported by the fund.

In these cases, the PAN Foundation may operate the fund and still comply with its OIG Advisory Opinion by including on its formulary other medical needs of patients with the disease, including all prescription products that manage the disease, such as ones that treat symptoms such as pain medications, and drugs that treat side effects of the treatment such as anti-nausea medications. The PAN Foundation has policies and procedures in place to ensure the list of covered products for each disease fund meets the requirements of their OIG Advisory Opinion and regularly consults with clinical experts and licensed pharmacists to create and manage compliant formularies.

ENROLLMENT

The PAN Foundation serves patients on a first-come, first-served basis.

The PAN Foundation processes applications and enrolls patients into its disease funds on a first-come, first-served basis, based on a reasonable, verifiable, and uniform measure of financial need that is consistently applied.

Processing applications on a first-come, first-served basis ensures that eligible patients have an equal opportunity for assistance and prevents PAN from providing preferential treatment to any individual or groups of individuals utilizing a specific drug or product. A standardized process also ensures that PAN provides equal opportunity for assistance on a first-come, first-served basis and prevents referral sources or donor interests from influencing eligibility or enrollment.

Although not required by the OIG's special advisory bulletins or advisory opinions, in recent years the OIG has stated that it views wait lists favorably. The PAN Foundation has maintained a wait list of patients waiting for assistance for closed disease funds since 2020.

REPORTING

The PAN Foundation will not provide any donors, directly or indirectly, with any data that would enable donors to correlate the amount or frequency of its donations with the amount or frequency of the use of its products or services, including individual patient data.

Under the OIG guidance, the PAN Foundation may report certain aggregate data to donors but are prohibited from providing any information—directly or indirectly—that would allow a donor to make a correlation between the amount or frequency of its donations with the number of patients that use its products or the volume of those products.

The PAN Foundation has safeguards in place to ensure this type of information is not intentionally or unintentionally shared with any donors, including comprehensive policies, donor communication guidelines, and list of information that can be shared in donor agreements.

Federal Anti-Kickback Statute

The federal Anti-Kickback Statute prohibits knowingly and willfully offering, soliciting, paying, or receiving—directly or indirectly, overtly or covertly—anything of value to induce or in exchange for the purchase or ordering of items or services, or the referral of patients for items or services, which may be paid for by any federal healthcare program, including Medicaid and Medicare.

For many years, the federal government has interpreted the Anti-Kickback Statute as prohibiting pharmaceutical companies from providing financial assistance directly to Medicare beneficiaries to help them to afford the co-payments for their drugs. The government views such assistance as being made in part to induce patients to purchase the pharmaceutical company's products. The Anti-Kickback Statute is a criminal statute. It can also be enforced civilly under the federal False Claims Act.

Behavior prohibited by the Federal Anti-Kickback Statute:

- Receiving a donation, gift, or benefit of any kind from a donor in exchange for influencing prescribers' or patients' choice of medications or treatment.
- Offering or providing a gift or payment to a physician or other prescriber to influence the prescribing or recommending of particular prescription products.
- Offering or providing goods or services at a below market value for the purpose of inducing a prescribers' referrals.



Federal Beneficiary Inducement Provision

The Beneficiary Inducement provision of the federal Civil Money Penalties Law prohibits an individual or entity from offering or providing any type of remuneration to Medicare or Medicaid beneficiaries if doing so is likely to influence the patient's decision to use a particular healthcare provider or facility.

Behavior prohibited by the Federal Beneficiary Inducement provision:

- Influencing patients in any way to use a particular healthcare provider or facility.

Internal Revenue Code Tax Exemption Requirements

A charitable organization is eligible for tax-exempt status under section 501(c)(3) of the Internal Revenue Code if it is organized and operated exclusively for charitable purposes, and none of its earnings inure to any private party. In addition, a charitable organization may not attempt to influence legislation as a substantial part of its activities or participate in any campaign activity for or against political candidates.

Behavior prohibited by the Internal Revenue Code Tax Exemption Requirements:

- Operating for non-charitable purposes.
- Influencing legislation as a substantial part of its activities or campaigning for or against political candidates.



Compliance Program



While the seven elements necessary for an effective compliance program have been recommended by the OIG for entities that receive funds directly or indirectly through federal healthcare programs such as Medicare and Medicaid, PAN believes that these compliance steps are also key to ensuring the integrity and transparency of independent patient assistance programs.

The PAN Foundation recognizes the risks identified by the OIG in its Advisory Bulletin for Independent Charitable Patient Assistance Programs and is committed to maintaining a rigorous compliance program based on a foundation of ethical behavior to address and mitigate these risk areas, implementing and embedding the seven core elements throughout the organization.

1. Compliance program organizational structure and oversight

The PAN Foundation Compliance Program is overseen by the Board of Directors and implemented by the Chief Compliance and Privacy Officer through the Compliance Office.

Board of Directors: Oversight responsibility of the Compliance Program

The Audit, Risk Oversight, and Compliance Committee (AROC Committee) of the Board of Directors oversees and monitors the PAN Foundation Compliance Program. The AROC Committee 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 Foundation Compliance Office and establishes the priorities and direction of the Compliance Program. The AROC Committee 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 AROC Committee reports to the full Board of Directors at each of its meetings to provide updated information regarding the Compliance Program, internal audits, and how identified risk areas are being addressed. Based on these reports, the full Board of Directors provides oversight and strategic direction for the Compliance Program.

Chief Compliance and Privacy Officer: Manages the Compliance Office

The Chief Compliance and Privacy Officer serves as the PAN Foundation's top compliance leader and is responsible for the implementation and management of the Compliance Program and ensuring adherence to applicable laws, regulations, and policies and procedures. The Chief Compliance and Privacy Officer is an independent, objective professional who reports to the Board of Directors AROC Committee and the President and CEO. As part of their duties to the Board, the Chief Compliance and Privacy Officer prepares a monthly report that details the organization's compliance activities.

The Chief Compliance and Privacy Officer manages the Compliance Office, which has additional full-time compliance staff.

Executive Compliance Committee

The Executive Compliance Committee is comprised of PAN senior executives across a wide range of the organization's operational areas of focus. The Executive Compliance Committee meets on a regular basis to review and discuss risk areas and provide guidance to the Compliance Office based on operational areas of expertise and assist with the implementation of compliance within day-to-day operations.

2. Written compliance guidance

Written policies and procedures are a key element of an effective compliance program. The PAN Foundation Compliance Program is guided by a thorough set of policies that have been approved by the Board of Directors and are easily accessible for all through a shared file system.

These policies and procedures include, but are not limited to:

- Code of Business Conduct and Ethics Policy
- Conflict of Interest Policy
- Whistleblower Policy

The PAN Foundation's leadership has also established compliance policies and procedures for other areas, including:

- Anti-Kickback Statute Compliance
- Auditing and Monitoring
- Compliance Responsibilities: 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 and is publicly available on PAN's website for all interested parties to review. The Code of Conduct and Ethics helps guide the PAN Foundation's work in accordance with its organizational values.

3. Compliance education and training

The PAN Foundation believes that education and training is integral to the ongoing implementation and management of an effective Compliance Program, and that every Board member, employee, and covered contractor plays a part. PAN's Compliance Office has developed a robust education and training program for all covered persons around the Compliance Program and compliance-related policies and procedures.

General and specialized compliance training programs are provided to the PAN Foundation 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 Foundation Code of Conduct and Ethics, as well as receipt of appropriate compliance training. The Compliance Office maintains written documentation of training completion for all Board members, staff, and relevant contractors.

Compliance training is mandatory for all PAN Foundation Board members, staff, and identified contractors. Failure to comply may lead to disciplinary action or revocation of a contract with PAN.

Compliance orientation and annual training for Board of Directors

All new Board members complete robust compliance training relevant to their corporate governance responsibilities and Compliance Program oversight. The in-depth training covers the PAN Foundation's Compliance Program and all applicable federal healthcare program requirements. All Board members receive annual training.

Compliance orientation and annual training for employees and contractors

All newly hired employees and relevant contractors must complete robust compliance training as part of their orientation program. Through this intensive program, staff understand PAN's obligations as an independent charitable patient assistance organization and requirements for compliance with its OIG Advisory Opinion, as well as relevant laws, regulations, and associated internal policies and procedures. All staff are required to participate in several hours of training regarding the PAN Foundation's Compliance Program and federal healthcare program requirements. The Compliance Office assesses PAN contractors, and subcontractors as applicable, to identify those that should be required to participate in PAN's compliance training.

Specialty training

Representatives performing certain job functions may be required to receive specialized training on an annual basis to address high-risk areas associated with their work responsibilities. The Compliance Office works with members of PAN's Executive Compliance Committee to identify these individuals and provide appropriate training.



4. Open lines of communication

As part of the PAN Foundation's duty to report policy, all individuals acting as or representing PAN have an affirmative duty to report any concerns or issues relating to potential non-compliance with applicable laws, regulations, policies, or procedures. PAN recognizes the importance of bringing potential risks or problems forward and believes that open lines of communication facilitate good-faith efforts to identify and remedy issues.

The PAN Foundation does not tolerate retaliation of any kind and adheres to a non-retaliation policy to protect individuals who report concerns or compliance issues. PAN's Compliance Office, leadership, and team supervisors encourage both awareness and adherence to the Compliance Responsibility, Duty to Report and Non-Retaliation Policy.

How to report concerns

All individuals acting as or representing the PAN Foundation must follow all laws, regulations, government guidelines, policies, and procedures. Anyone who is aware of a potential or actual violation should report this information. In addition, if individuals have a question or concern about potentially wrongful, unethical, or illegal activity, the following options are available:

- Discuss the issue or concern with a supervisor. A direct supervisor is most familiar with an individual's responsibilities and applicable laws, regulations, policies, and procedures.
- If the individual is not comfortable contacting a direct supervisor or does not receive an adequate response, they are encouraged to contact a member of PAN's leadership team, including the President and CEO or the Chief Compliance and Privacy Officer.

Anonymous, confidential reporting

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. The hotline is available 365 days a year, seven days a week, and 24 hours per day. There are five ways to report concerns through the compliance hotline, which can be found in the "Report a Concern" section of this document.

Sharing information about the Compliance Program and related policies

Information about the Code of Conduct and Ethics, the Compliance Program, and how to report concerns are provided on the PAN Foundation website.

In addition, detailed information about PAN's policies are internally available to all Board of Directors and staff members. Documents providing details on PAN's compliance policies and procedures, are readily available to PAN employees through a shared file system.

Other means of sharing compliance program information with stakeholders are routinely explored and developed to ensure awareness and adherence.

5. Disciplinary and enforcement standards

The PAN Foundation has developed and adopted a Disciplinary Action and Enforcement Policy, which provides guidance regarding the equitable and uniform application of disciplinary action and enforcement where misconduct is determined to have occurred.

As part of this policy, the Compliance Office and Human Resources Department have established a protocol 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.

When violations happen

Reports received by the Compliance Office are reviewed and responded to appropriately and in a timely fashion. All allegations of wrongdoing are carefully investigated before any action is taken. The rights of all individuals, including any who are subject to a compliance hotline report, will be respected and protected.



6. Auditing and monitoring

Independent audits conducted by third-party organizations are critical components of verifying PAN's compliance with its OIG Advisory Opinion, mitigating emerging risk areas, and strengthening its operations. The PAN Foundation has built a rigorous audit function to ensure that the organization meets and exceeds its compliance obligations and continues to monitor and strengthen organizational effectiveness. Audits and risk assessment are overseen and monitored by the Board of Directors AROC Committee.

Audit management

A third-party contractor serves as the PAN Foundation's 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 Board of Directors AROC Committee.

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 the Board of Directors AROC Committee, Executive Compliance Committee, and PAN leadership.

The Compliance Office maintains an audit tracking system to monitor the conduct of audits, findings and recommendations, management responses, and follow-up remedial actions if applicable. Monitoring of contractor activities is conducted on a regular basis by dedicated PAN operations staff.

The PAN Foundation's annual audit program

The PAN Foundation engages in a variety of annual audits, including:

Internal audits: A third-party contractor serves as PAN's internal auditor and based on the annual risk assessment, prepares and implements an annual audit work plan. The Board of Directors AROC Committee oversees risk identification and the related audit workplan.

Program audits: An Independent Review Organization (IRO) conducts an annual independent, objective audit of PAN's programs to confirm that PAN complies with the specifications set forth in its OIG Advisory Opinion, in addition to other specified review criteria and reviews. PAN makes the attestation of its program audits publicly available on its website for all stakeholders. The IRO conducts its examination in accordance with American Institute of CPAs (AICPA) and Generally Accepted Government Auditing Standards (GAGAS).

As part of the annual program audit, the IRO conducts an examination in accordance with both AICPA and GAGAS standards and issues a compliance attestation to confirm PAN has complied with its Advisory Opinion, donor agreements, and additional parameters.

Financial audits: An independent accounting firm conducts an annual objective audit of PAN's financial statements to ensure they are presented fairly and in accordance with U.S. generally accepted auditing standards. PAN makes its financial audits publicly available on its website for all stakeholders.

Donor audits: PAN regularly works with prospective and current donor companies to conduct a third-party, independent audit of its programs to verify fulfillment of donor agreements.

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

The PAN Foundation has developed and adopted a Compliance Investigation and Resolution Policy, that guides the organization in its responsibility to investigate complaints or concerns and respond to detected offenses.

The Compliance Office is responsible for investigating and reviewing all complaints, issues, concerns that are raised relating to compliance with applicable laws, regulations, governmental guidance, as well as internal policies and procedures.

A tracking system, maintained by the Compliance Office, is used to document all investigations and reviews from initiation through resolution and subsequent remedial action, if warranted.

The Compliance Office reports to the Board AROC Committee and the Executive Compliance Committee on a regular basis regarding investigations and reviews to ensure strategic direction and guidance is provided for implementing an effective Compliance Program.



Contact the Compliance Office

Mia Harmon, JD

Chief Compliance & Privacy Officer
mharmon@panfoundation.org



Report a concern

The compliance hotline is a confidential and anonymous way to report concerns. There are five ways to report concerns through the compliance hotline:

- **Phone:** Call 877-210-0006 to speak with a live operator. The hotline is available 24 hours a day. You can choose to remain anonymous while reporting the nature of your concern.
- **Third-party website:** Use the [Lighthouse Services website](#) to submit a concern.
- **Email:** Email a concern to reports@lighthouse-services.com. Please include the PAN Foundation as the company name with your report.
- **Smartphone application:** Download The Anonymous Reporting app, available in the [Apple Store](#) and [Google Play Store](#), to report a concern. On the app, use the keyword **panfoundation** to save and submit your report. If you need help navigating the app, [reference these instructions](#) to submit or follow up on a report.
- **Fax:** Fax your report to 215-689-3885 (please include the PAN Foundation as the company name with your report).

References

- ¹ U.S. Department of Health and Human Services Office of Inspector General – General Compliance Program Guidance (November 2023). <https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf>
- ² U.S. Department of Health and Human Services Office of Inspector General – 79 Fed. Reg. 31120 – Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs (May 30, 2014). <https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf>
- ³ 42 U.S.C. 1320a-7b(b)
- ⁴ 42 U.S.C. 1320a-7a(a)(5).
- ⁵ See, e.g., section 501(c)(3) of the IRS Code.
- ⁶ OIG Advisory Opinion 07-18 (as modified).
- ⁷ OIG Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. at 31123.
- ⁸ OIG Advisory Opinion 07-18 (as modified).
- ⁹ 70 Fed. Reg. 70623 (November 22, 2005); 79 Fed. Reg. 31120 (May 30, 2014).

About the PAN Foundation

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To learn more, visit panfoundation.org.