

June 5, 2022

# Program Review Report

Prepared for: Patient Access Network Foundation

Prepared by:

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## **INTRODUCTION**

Ankura Consulting Group, LLC (“Ankura”) has been retained by the Patient Access Network Foundation (“PAN” or the “Foundation”) to serve as its Independent Review Organization (IRO) and to perform Program Review audits.

As the IRO, Ankura performed the Program Review audit for calendar year 2021 to assess PAN’s compliance with its OIG Advisory Opinion 07-18 (as modified), and with the program audit parameters as specified in Exhibit A of various PAN donation agreements. Ankura performed all work in accordance with the independence and objectivity specifications set forth in the Government Auditing Standards issued by the Comptroller General of the United States. See

<https://us.aicpa.org/interestareas/governmentauditquality/resources/auditpracticetoolsaids/yellowbookaudittoolsandaids>.

Our findings with respect to the Program Review audits performed for calendar year 2021 reflect and affirm PAN’s compliance with OIG Advisory Opinion 07-18 (as modified), and with the program audit parameters as specified in Exhibit A of various PAN donation agreements for the 2021 calendar year.

Our review procedures were limited to those described in this Report. We relied on documentation supplied to us by PAN without any independent verification. Had we performed additional procedures, other matters might have come to our attention that may have impacted our findings and recommendations. The procedures we performed do not constitute an “examination” or “review,” as those terms are defined by the American Institute of Certified Public Accountants. We performed no procedures to evaluate the reliability or completeness of the information provided.

## **CREDENTIALS OF THOSE WHO PERFORMED THE PROGRAM REVIEW**

The Program Review was conducted by Sarah Couture and Christopher Tonellato.

Sarah Couture, RN, CHC, CHRC, is a Managing Director at Ankura with more than 20 years of healthcare experience, including ten years of experience helping organizations successfully manage complex healthcare compliance concerns. She has expertise assisting organizations with developing, implementing, maintaining, and assessing compliance programs. She is based in Chicago. Prior to her career in healthcare compliance, Sarah worked as a Registered Nurse in both patient care and management roles.

Chris Tonellato, JD, CHC, is a Director at Ankura where he has several years of experience assisting healthcare organizations with a variety of compliance and regulatory matters. He is



based in Chicago. Prior to joining Ankura, Chris worked for a large law firm's healthcare practice group and two different Chicago area hospitals, supporting their legal teams with various regulatory, transactional, and compliance projects. Chris graduated from Loyola University Chicago School of Law with certificates in both compliance and health law.

## **PROGRAM REVIEW ANALYSIS:**

As described in Exhibit A of the Donation Agreement, Ankura conducted the Program Review to assess and evaluate PAN's systems, processes, policies and practices related to their Disease Fund Programs. To supplement this review, Ankura also reviewed documentation and stored data PAN maintains related to a sample of 210 patient applications, hereinafter referred to as "Sample Applications." These Sample Applications were reviewed to evaluate and verify PAN's adherence to its policies and procedures. The assessment and evaluation included an examination of the following parameters.

PAN no longer utilizes an Administrator as defined in the OIG Advisory Opinion 07-18 (as modified). Therefore, requirements related to the Administrator are not applicable for this year's review.

### ***I. The Foundation is a bona fide, non-profit organization that serves the interests of patients with particular diseases or conditions.***

#### **Review Methodology:**

Ankura reviewed PAN's original IRS 501(c)(3) Application Form, 501(c)(3) Determination Letter, and PAN's 2020 IRS Form 990 when evaluating this parameter. This included a review of the public charity test in the IRS Form 990 and the proportion of donations provided by the general public. We also reviewed PAN's current tax-exempt status as listed by the Internal Revenue Service ("IRS").

#### **Evaluation:**

PAN is a bona fide, non-profit, tax-exempt organization and classified by the IRS as a 501(c)(3) public charity. As of 2020 (the most recently available Form 990), PAN receives funding from a variety of sources including more than 50 corporate donors and over 1,000 individual donors. PAN qualifies for public charity status using the 10% facts and circumstances test as described by 170(b)(1)(A)(vi) of the Internal Revenue Code. In 2020, PAN received 29.11% of its support from the public. PAN is listed as a public charity in the IRS' website (<https://apps.irs.gov/app/eos/>).



PAN's mission is: "To help underinsured people with life-threatening, chronic and rare diseases get the medications and treatments they need by assisting with their out-of-pocket costs and advocating for improved access and affordability."

***II. The Foundation is independent of any donor to the Program, including Donor (collectively, the "Program Donors"). For purposes of determining independence, inter alia, no members of the Foundation's governing body will be employed by a Program Donor.***

Review Methodology:

Ankura reviewed PAN's Conflict of Interest ("COI") Policy and Conflict of Interest Standard Operating Procedure to ensure adherence to the standards set by the Office of Inspector General ("OIG") of the Department of Health and Human Services Advisory Opinion 07-18 (as modified) ("AO" or "Advisory Opinion") and the Integrity Agreement entered into by and between the OIG and PAN (the "IA"). The review also included all COI disclosure forms submitted by PAN's Board Members as well as any follow-up questions or correspondence required to clarify disclosed potential COIs.

Ankura also reviewed PAN's Policies and Standard Operating Procedures ("SOP") related to PAN's independence from donors including the Donor Communication Guidelines, Donor Communication Policy, Establishing New Disease Funds SOP, Identifying New Disease Funds SOP, and Disease Fund Definition SOP.

Evaluation:

In 2021, PAN received and reviewed all COI Disclosure Forms as were required by its COI Policy and SOP. All directors, committee members and employees are required to follow the COI Policy and annually report any COIs that they may have.

PAN's COI Policy requires that its Board members, officers and employees are all independent. Consistent with OIG conflict-of-interest provisions, any PAN Board member who receives compensation from or who owns a material amount of stock in a pharmaceutical company that is or may be a donor to PAN must disclose that relationship and must recuse themselves from any Board conversations or decisions that could affect that pharmaceutical company or any disease fund for which the pharmaceutical company has a product in the disease fund's formulary. At no time may a majority of the Board or any Board Committee be composed of members who either receive compensation from, or who have a material amount of stock ownership in, any pharmaceutical company donor.



No members of PAN's Board of Directors reported being employed by a Program Donor. One Board member reported that they may receive compensation from a potential donor as a result of the potential donor being a client of that Board member, however, this was not a violation of the Advisory Opinion independency requirements nor a breach of PAN's COI policies and procedures. As required by policy, PAN requested additional details from the Board member. No evidence existed that an actual COI existed. If there was a COI, the Board member would have been required to recuse himself from any Board meeting and take no part in discussions and decisions related to any transaction or arrangement in which he may be perceived to have a COI.

PAN's Policies and SOPs ensure it remains independent of any Program Donor and maintains compliance with the independency requirements described in its Advisory Opinion, IA, and other relevant guidance from the OIG. Per our review of the 2021 annual Board COI Disclosure Forms, these independency requirements were followed. Donor and potential donors are prohibited from making recommendations or suggestions regarding the design or creation of a new or existing disease fund.

### ***III. The Program receives referrals from a number of sources, including physicians, suppliers, patient advocacy groups, and other relevant sources.***

#### Review Methodology:

During discussions between Ankura and PAN, PAN confirmed that it does not track referral sources. Ankura reviewed PAN's Patient Assistance Policy and the Disease Fund New Enrollment SOP to evaluate whether referrals may be tracked or recorded. In addition, documentation from the Sample Applications was reviewed to evaluate how the Policy and SOP are implemented. PAN's marketing and advertising plan was reviewed to evidence that PAN makes a concerted effort to promote its programs to numerous sources.

#### Evaluation:

PAN allows applications to be submitted by patients, their caregivers, providers, and pharmacies. Applications may be submitted through PAN's call center, website, or portals. When applications are submitted, PAN does not track or record any potential referral source because it plays no role in the applicant's eligibility. As such, there is no way to know the demography of referral sources. This was verified by the review of the Sample Applications. PAN makes a significant effort to promote its programs to various sources such as physicians, suppliers, patient advocacy groups, and patients. PAN's marketing and advertising efforts include:

- Promoting assistance programs on PAN's website and the FundFinder website;



- Promoting programs and disseminating PAN's educational and advocacy resources through newsletters and email communications;
- Collaborating with other patient assistance organizations as alliance partners;
- Promoting its programs and educational materials through social media and YouTube;
- Publishing op-eds and providing media interviews when requested (in 2021, PAN was featured in 7 different media outlets);
- Publishing matte releases, brief articles that educate consumers about lowering their out-of-pocket medications costs and assistance PAN can provide; and
- Attending and speaking at 19 various in-person and virtual conferences.

#### ***IV. The Foundation's determination of whether to provide assistance does not consider the source that referred the patient to the Program.***

##### Review Methodology:

PAN has confirmed that it does not track referral sources. Ankura reviewed PAN's Patient Assistance Policy, Disease Fund New Enrollment SOP, Grant Renewal SOP, Second Grant SOP, and Disease Fund Wait List SOP to evaluate whether or not the referral source is used as a criterion of eligibility for patients applying to assistance. In addition, documentation from the Sample Applications was reviewed to evaluate how the Policy and SOPs are implemented.

##### Evaluation:

PAN does not consider the referral source when determining a patient's eligibility for assistance. An applicant's eligibility is determined using PAN's established criteria including the following for all assistance programs:

- The patient must be getting treatment for the disease named in the assistance program to which he or she is applying.
- The patient must have health insurance that covers his or her qualifying medication or product.
- The patient's medication or product must be listed on PAN's list of covered medications.
- The patient's income must fall at or below the Federal Poverty Level specified by the assistance program.
- The patient must reside in and be receiving treatment in the U.S. or its territories. (U.S. citizenship is not a requirement.)

The review of Sample Applications demonstrated that when patients apply for assistance from PAN, referral sources are not a factor when determining an applicant's eligibility.



***V. The Foundation bases all financial eligibility determinations on its own established criteria and does not take into account the identity of a provider, supplier or treatment that the patient may use or the identity of a Program Donor whose services or products are used by the applicant.***

Review Methodology:

Ankura reviewed PAN's Policies and Standard Operating Procedures ("SOP") related to PAN's independence from donors including the Patient Assistance Committee ("PAC") Charter, Donor Communication Guidelines, Donor Communication Policy, Patient Assistance Policy, Establishing New Disease Funds SOP, Identifying New Disease Funds SOP, and Disease Fund Definition SOP to evaluate that PAN's established criteria does not take into account the identity of a provider, supplier, treatment used by the patient, or donor whose services or products are used by the patient.

The Patient Rights Policy, Patient Assistance Policy, Disease Fund New Enrollment SOP, Grant Renewal SOP, Second Grant SOP, and Disease Fund Wait List SOP, and a template welcome letter were also reviewed to evaluate the requirement for patients to meet the financial eligibility criteria.

A sample of seven (7) disease funds were evaluated to ensure their creation and continued operation are conducted is independent from donor influence. The Sample Applications were reviewed in order to evaluate their compliance with PAN's Policies and SOPs.

Evaluation:

PAN bases all financial eligibility determinations on its own established criteria. The PAC, a standing committee of PAN's Board, is responsible for setting policies concerning patient eligibility requirements, the disease funds served, and program requirements of the disease funds. The eligibility criteria must be set in compliance with the Advisory Opinion, the IA, and other applicable guidance, regulations, and laws.

Applicants are required to meet PAN's financial eligibility criteria for each program which is set at either 400% or 500% of the federal poverty line ("FPL"). Patients are screened for income eligibility before they are approved for a new grant and at minimum every year following if they apply for renewal grants.

PAN's financial eligibility criteria are approved by the PAC when the disease fund is created and is reviewed and approved by the PAC if a modification is needed. Documentation from each of the sampled disease funds demonstrates the financial eligibility was set for the fund pursuant to PAN's Policies and SOPs and that the PAC reviewed and approved of the funds creation independent from any donor or potential donor influence.



A review of PAN's application process and all 210 of the Sample Applications demonstrated that applicants are screened based on the fund's approved criteria and that the various providers, suppliers, and treatments do not affect the determination of eligibility. None of Sample Applications were denied due to a particular provider, supplier, or treatment, so long as the treatment was a part of the Disease Fund's formulary. The template welcome letter provided to new patients approved for assistance includes the following language:

Assistance through the Patient Access Network (PAN) Foundation is not tied to any doctor or healthcare provider, treatment or pharmacy that you are currently using. You have the right to choose any healthcare provider, treatment or pharmacy covered by your insurance plan and associated with your disease, and you may change any of these during your eligibility period without any effect on your assistance through the PAN Foundation (as long as you continue to meet the set eligibility criteria). If there are any changes to the treatment you have been prescribed, your healthcare provider, your insurance status, your financial situation or your medical condition (as it relates to your disease), please contact the PAN Foundation so we can update your records.

***VI. Assistance is available to financially needy beneficiaries who meet the Foundation's income and/or asset criteria, for a period of up to one (1) year, after which each beneficiary's eligibility is reevaluated.***

Review Methodology:

A review of PAN's Policies and SOPs was conducted, including the Patient Assistance Policy, Disease Fund New Enrollment SOP, Grant Renewal SOP, Second Grant SOP, and Disease Fund Wait List SOP.

In addition, Ankura reviewed the Sample Applications including their application record and supporting documentation to ensure compliance with this criterion.

Evaluation:

As described above in Section V, PAN provides assistance to financially eligible individuals based on established parameters. When applying, a patient is required to self-attest to their income in order to meet this requirement. Real-time income verifications are required for one hundred percent of applicants. PAN uses an automated system check via PayNav to verify reported income. PAN's uses an automated system to verify this reported income. If an issue is flagged, applicants are conditionally approved and must submit additional documentation or verification to prove they are financially eligible. This process must be repeated at minimum once a year in order for a patient to continue to be financially eligible.



The review of the Sample Applications verified that applicants are required to meet the disease fund's financial eligibility criteria. Several of the sampled applications demonstrated the financial audit process when a patient's eligibility could not be automatically verified.

Eleven (11) of the Sample Applications reviewed required an Income Verification Audit. Each time the process worked correctly, and the patient was either approved after providing verification of their financial eligibility or denied after failing to do so in a timely manner. If the documentation showed the patient was above the FPL limit, they were removed from being conditionally approved and denied assistance. This review also demonstrated that all approved applicants had an eligibility period of one calendar year from the date they were approved. If funding was available, the patient has the option to renew their grant, but their income would be re-verified prior to approval of a renewal.

***VII. Patient requests for assistance under the Program are reviewed on a first-come, first-served basis to the extent funding is available.***

Review Methodology:

Ankura reviewed PAN's Policies and SOPs including the Patient Assistance Policy, Disease Fund New Enrollment SOP, Grant Renewal SOP, Second Grant SOP, and Disease Fund Wait List SOP.

In addition, Ankura reviewed PAN's application process and timing during the review of the Sample Applications including their application date, eligibility start date, and eligibility end date.

Evaluation:

PAN ensures patients are provided assistance on a first-come, first-served basis when funding is available. If funding for a particular fund is exhausted, an applicant has the option to join the fund's wait list. The wait list is also maintained on a first-come, first-served basis. When a fund receives additional funding and can open to waitlisted applicants the approved applicants receive funding in the order that they were added to the wait list.

***VIII. The Foundation informs patients that they are free to change providers, suppliers or treatments at any time and will not lose their assistance as a result (unless they become ineligible for other reasons).***

Review Methodology:

Ankura reviewed PAN's Patient Rights Policy, Patient Assistance Policy, and Disease Fund New Enrollment SOP to evaluate if patients are free to change providers, suppliers, or treatments. In addition, documentation from the Sample Applications was reviewed to evaluate how the Policies and SOPs are implemented.



### Evaluation:

PAN's Patient Rights Policy, Patient Assistance Policy, and Disease Fund New Enrollment SOP detail that recipients of assistance have freedom of choice regarding their products, practitioners, providers, suppliers, insurance companies, and treatment regimens. PAN does not refer to, recommend, or arrange for the use of any particular product, practitioner, provider, supplier, or insurance plan.

The review of the Sample Applications and screening process demonstrated that applicants have various providers, suppliers, and treatments and that PAN does not make its eligibility decisions on that basis. In addition, a review of the template letter sent to approved applicants and copies of actual letters sent to sampled approved applicants shows that patients all receive the following language:

Assistance through the Patient Access Network (PAN) Foundation is not tied to any doctor or healthcare provider, treatment or pharmacy that you are currently using. You have the right to choose any healthcare provider, treatment or pharmacy covered by your insurance plan and associated with your disease, and you may change any of these during your eligibility period without any effect on your assistance through the PAN Foundation (as long as you continue to meet the set eligibility criteria). If there are any changes to the treatment you have been prescribed, your healthcare provider, your insurance status, your financial situation or your medical condition (as it relates to your disease), please contact the PAN Foundation so we can update your records.

### ***IX. The Foundation does not refer patients to, or recommend, a particular provider, supplier or product.***

#### Review Methodology:

Ankura reviewed PAN's Patient Rights Policy, Patient Assistance Policy, and Disease Fund New Enrollment SOP to evaluate if PAN ever refers patients to particular providers, suppliers, or products. In addition, documentation from the Sample Applications was reviewed to evaluate how the Policies and SOPs are implemented.

#### Evaluation:

As described in more detail in Section VIII above, PAN does not refer to, recommend, or arrange for the use of any particular product, practitioner, provider, supplier, or insurance plan.

No evidence was found in the Sample Applications that PAN makes a referral to a particular provider, supplier, or product. Patients are notified they have the right to choose their own provider, supplier, or product.



***X. The Foundation does not inform patients of the identities of Program Donors.***

Review Methodology:

Ankura reviewed PAN's Donor Communication Guidelines, Donor Communication Policy, Disease Fund Enrollment SOP, and Inbound Call Management SOP to evaluate this parameter. In addition, documentation from the Sample Applications was reviewed to evaluate how the guidelines, Policy, and SOPs are implemented.

Evaluation:

PAN's policies and SOPs ensure that donor information, including the identity of Program Donors is not made available to the public. Additionally, this information is not available to applicants when applying for assistance or when they are approved for assistance.

To evidence this, a review of the communications and welcome letters from the sampled patient applications found that they did not contain any donor information. Templates PAN uses for those letters also do not contain any donor information.

***XI. To the extent feasible, the Foundation furnishes assistance under the Program to the provider, supplier or insurer on behalf of the patient, and where assistance is furnished directly to the patient, the Foundation obtains proof from the patient that the assistance is to satisfy qualifying expenses.***

Review Methodology:

Ankura reviewed PAN's Assistance Program Parameter Management SOP and Grant Allocation Model SOP to evaluate this parameter.

Evaluation:

PAN provides assistance for products directly to providers and pharmacies when applicable. Patients may be reimbursed directly if they incur the costs or in the case of some premium assistance programs. PAN verifies the patient's expenses and obtains proof from the patient for qualifying expenses or requires proof of premium payment from an insurance statement, employer paystub, COBRA statement, or Social Security statement with Medicare premium. If a patient is unable to provide documentation, the premium cost must be obtained verbally and validated with the insurance company.



## ***XII. The Foundation has a process to solicit donations for the Program from a multitude of sources.***

### Review Methodology:

Ankura reviewed PAN's Donor Communication Guidelines and PAN's public facing guidance and information available for individuals and others to use when considering donating to PAN. Details from PAN's 2020 IRS Form 990 were also reviewed to evaluate this parameter.

### Evaluation:

PAN's policies and procedures demonstrate that PAN obtains funding from multiple donors and sources to fulfil the patient need. PAN's Donor Communications Guidelines ensure donors and potential donors are aware of the restraints and requirements when communication with PAN regarding a donation or development of a disease fund. PAN does not solicit, nor will it accept recommendations or suggestions from donors regarding the creation or modification of a new or existing disease fund.

PAN's public website contains a page titled "Ways to Give" which describes the various ways individuals and other entities may donate to PAN. PAN solicits donations from a multitude of sources including more than 50 corporate donors and over 1,000 individual donors since 2015 according to PAN's 2020 IRS Form 990. In 2020, 29.11% of its support from the public, demonstrating PAN's solicitation to various sources is successful.

## ***XIII. The Foundation uses commercially reasonable efforts to publicize the availability of the Program to patient advocacy organizations, other relevant third parties and patients.***

### Review Methodology:

Ankura reviewed a summary of all of PAN's marketing and advertising materials used in CY 2021. Ankura also reviewed various communications, articles, and websites to evaluate PAN's efforts to publicize its disease funds to patients, patient advocacy groups, and other relevant third parties.

### Evaluation:

PAN puts significant effort into publicizing all of its disease funds and assistance programs to patients, patient advocacy organizations, providers, pharmacies, and other relevant third parties. PAN's quarterly newsletters to providers, pharmacies, donors, and the patient advocacy community regularly provide important updates regarding new funds that may be available and any changes to existing funds when applicable. In addition, some of PAN's other publicization efforts include the following:

- Promoting assistance programs on PAN's website and the FundFinder website;



- Promoting programs and disseminating PAN's educational and advocacy resources through newsletters and email communications;
- Collaborating with other patient assistance organizations as alliance partners;
- Promoting its programs and educational materials through social media and YouTube;
- Publishing op-eds and providing media interviews when requested (in 2021, PAN was featured in 7 different media outlets);
- Publishing matte releases, brief articles that educate consumers about lowering their out-of-pocket medications costs and assistance PAN can provide; and
- Attending and speaking at 19 various in-person and virtual conferences.

**The Foundation otherwise complies with the requirements of OIG Advisory Opinion 07-18 (as modified).**

The Advisory Opinion outlines many requirements PAN must follow when creating and maintaining its Disease Fund programs. Many of these requirements are functionally similar or identical to the parameters discussed above and have been considered as part the described assessment and evaluation. The following are the remaining assessed and evaluated requirements from the Advisory Opinion.

***XIV. PAN may establish minimum claim amounts if motivated by a desire to reduce administrative expenses but must allow patients to aggregate claims to reach the minimum threshold.***

Review Methodology:

Ankura reviewed PAN's Assistance Program Parameter Management SOP as well as the "What is a Minimum Claim Requirement?" internal document PAN uses for education. The information reviewed detailed which funds currently have claim threshold limits and which funds had a limit in CY 2019.

Evaluation:

As of January 1, 2020, PAN has no disease funds or assistance programs with a claim minimum threshold. In 2019, only two disease funds had claim minimum thresholds of \$25 and \$50, respectively, but both of those were removed as of January 1, 2020.

PAN's Assistance Program Parameter Management SOP describes this process and the requirements, if applicable. If a minimum claim threshold were to exist, it must be publicized to all patients enrolled in the assistance program.



***XV. Cost-sharing grants must be paid directly to physicians, providers, suppliers, insurance companies, or in cases where third-party payment is not accepted, to the patient, upon proof that the patient incurred the costs.***

Review Methodology:

Ankura reviewed PAN's Assistance Program Parameter Management SOP and Grant Allocation Model SOP to evaluate this parameter.

Evaluation:

PAN's Premium Assistance Support SOP describes the process of paying for or reimbursing patient's premium's amounts. PAN verifies the patients costs and requires proof of premium payment from an insurance statement, employer paystub, COBRA statement, or Social Security statement with Medicare premium. If a patient is unable to provide documentation, the premium cost must be obtained verbally and validated with the insurance company.



## **Exhibit A**

### Documents Reviewed

1. 501(c)(3) Application Form
2. 501(c)(3) Determination Letter
3. PAN's 2020 Form 990
4. Conflict of Interest Policy
5. All Board Member's completed COI Disclosure Forms
6. PAN Foundation Marketing and Advertising Program 2020
7. Patient Rights Policy
8. Disease Fund New Enrollment SOP
9. Patient Assistance Policy
10. Assistance Program Parameter Management SOP
11. Grant Renewal SOP
12. Disease Fund Wait List SOP
13. Second Grant SOP
14. Template Welcome Letter
15. Donor Communication Policy
16. Report of claims administered from Sampled Disease Funds
17. Donor Communication Guidelines
18. Ways to Give webpage
19. Assistance Program Parameter Management SOP
20. "What is a Minimum Claim Requirement? - PAN Foundation Contact Center
21. Premium Assistance Support SOP
22. Underlying documentation and data from 210 Sample Applications
23. PAC Charter
24. PAC Policy
25. PAC Approvals for seven sampled disease funds