



2022 Examination

Patient Access Network Foundation

Year Ended December 31, 2022

PATIENT ACCESS NETWORK FOUNDATION

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INDEPENDENT ACCOUNTANT’S REPORT

To the Board of Directors of
Patient Access Network Foundation:

We have examined the Patient Access Network Foundation’s (the Foundation) compliance with certain terms and specifications set forth in Advisory Opinion No. 07-18 (as modified) (the Advisory Opinion) issued by the Office of Inspector General (OIG) in the U.S. Department of Health and Human Services and *Exhibit A Program Audit Parameters* (Exhibit A) included in the donor agreement for the year ended December 31, 2022. Management of the Foundation is responsible for the Foundation’s compliance with the specified requirements set forth in the Advisory Opinion and Exhibit A. Our responsibility is to express an opinion on the Foundation’s compliance with the specified requirements set forth in the Advisory Opinion and Exhibit A based on our examination.

Our examination was conducted in accordance with attestation standards established by the American Institute of Certified Public Accountants. Our examination was also conducted in accordance with the objectivity and independence standards set forth by the *Government Auditing Standards* issued by the Comptroller General of the United States. These standards require that we plan and perform the examination to obtain reasonable assurance about whether the Foundation complied, in all material respects, with the specified requirements set forth in the Advisory Opinion and Exhibit A. An examination involves performing procedures to obtain evidence about whether the Foundation complied with the specified requirements set forth in the Advisory Opinion and Exhibit A. Our firm has expertise in tax-exempt, non-profit organizations and in conducting reviews in accordance with OIG specifications. The nature, timing, and extent of the procedures selected depend on our judgment, including an assessment of the Foundation’s systems, processes, policies and practices and an assessment of the risks of material noncompliance with the specified requirements set forth in the Advisory Opinion and Exhibit A, whether due to fraud or error. We believe that the evidence we obtained is sufficient and appropriate to provide a reasonable basis for our opinion.

Our examination does not provide a legal determination on the Foundation’s compliance with the specified requirements set forth in the Advisory Opinion and Exhibit A. Additionally, we did not perform procedures specifically related to and are not providing an opinion on the Foundation’s compliance with the OIG Integrity Agreement executed October 24, 2019.

In our opinion, the Patient Access Network Foundation complied, in all material respects, with the specified requirements set forth in the Advisory Opinion and Exhibit A for the year ended December 31, 2022.

This report is intended solely for the information and use of management and the Board of Directors of the Foundation, the applicable donors and the OIG and is not intended to be and should not be used by anyone other than these specified parties.

PYA, P.C.

Knoxville, Tennessee
May 23, 2023

PATIENT ACCESS NETWORK FOUNDATION

Examination Criteria

Year Ended December 31, 2022

This *Examination Criteria* is being provided as supplemental information and is not intended to be all-inclusive of the procedures we performed in order to express our opinion on the Foundation's compliance with the specified requirements set forth in the Advisory Opinion No. 07-18 (as modified) (Advisory Opinion) and *Exhibit A Program Audit Parameters* (Exhibit A). This supplemental information will not include or disclose: (1) individually identifiable health information about any patient of the Foundation; or (2) other information protected from disclosure pursuant to applicable law or a confidentiality or similar agreement executed between the Foundation and a donor to a Foundation program. As part of our examination, we performed the following:

TAX EXEMPT STATUS

Requirement: The Foundation is a bona fide, non-profit organization that serves the interests of patients with particular diseases or conditions. The Foundation is a public charity described in Code Section 501(c)(3) and 509(a).

Methodology:

- We examined and evaluated the most recent Form 990 filed with the Internal Revenue Service for classification as 501(c)(3) tax status.
- We determined the Foundation qualifies for public charity status as an organization that normally receives a substantial part of its support from a government unit or from the general public as described in section 170(b)(1)(A)(vi) of the Internal Revenue Code.
- We obtained supplemental disclosure that the Foundation meets the "facts-and-circumstances" test based on the most recent Form 990 filed.
- We obtained and verified the Foundation's public support percentage.

Finding: None.

Recommendation: None.

GOVERNANCE INDEPENDENCE

Requirement: The Foundation is independent of any donor to its programs. For purposes of determining independence, the majority of members of the Foundation's governing body may not have direct or indirect impermissible financial or employment relationships with a program donor.

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Examination Criteria - Continued

Year Ended December 31, 2022

Methodology:

- We examined and reviewed resumes for each Board Member active during the year under examination.
- We obtained and reviewed conflict of interest statements for each active Board Member during the year under examination.
- We obtained and examined policies and standard operating procedures related to governance independence and donor communications and guidelines.
- We obtained and reviewed meeting minutes to ensure Board Members with known potential conflicts abstained from discussions or decisions regarding organizations with identified conflicts.

Finding: The Foundation's Board Members are required to disclose any conflicts that could potentially be perceived as an impairment of their independence through completion of the Foundation's conflict of interest statement on at least an annual basis. We noted one instance where an active Board member did not have a conflict of interest statement that had been completed during the year under examination.

Recommendation: We recommend the Foundation adhere to policy and ensure all active Board Members complete a conflict of interest statement on at least an annual basis.

PERSONNEL COMPENSATION

Requirement: The Foundation must compensate its employees, officers, and Board Members in a manner consistent with fair market value in an arm's length transaction. Their compensation may not take into account the volume or value of business generated for any donors or any of its affiliates.

Methodology:

- We obtained and examined policies and standard operating procedures related to Foundation personnel compensation.
- We obtained and reviewed the most recently available compensation study to determine management's adherence to fair market arm's length transactions.

Finding: None.

Recommendation: None.

PATIENT ACCESS NETWORK FOUNDATION

Examination Criteria - Continued

Year Ended December 31, 2022

PROGRAM ESTABLISHMENT

Requirement: The Foundation must define its disease funds so that supported diseases represent “widely recognized disease states.” Disease funds may not be defined according to specific symptoms, the severity of symptoms, the method of drug/product administration, the stages of a disease, the type of drug treatment, or any other method of narrowing the definition of a widely recognized disease state. However, the Foundation may establish disease funds limited to patients with metastatic cancers. In these funds, the Foundation must cover all U.S. Food and Drug Administration (FDA)-approved drugs for that type of cancer (not just drugs for the metastatic stage of cancer).

The Foundation may not maintain any fund that provides assistance for only one drug or only drugs made by one manufacturer. If there is only one relevant product or only one manufacturer that makes all relevant products, the fund must also provide support for the other medical needs of patients with the disease, including drugs to treat symptoms of the disease (e.g., pain medication) and drugs to treat the side effects of treatment (e.g., anti-nausea medications).

The Foundation must make assistance available for all prescription medications that are FDA-approved or indicated in compendia, evidence-based guidelines, or clinical guidelines for a diagnosis that qualifies the patient for assistance from the fund.

Methodology:

- We obtained and examined policies and standard operating procedures related to program establishment and approval, formulary creation and maintenance and medical director involvement.
- During detailed testing, we noted the source of the donation and verified that no language provided indicated a specific course of treatment or product be utilized from funds provided.
- During detailed testing, we noted the type of support options available for medical needs other than pharmacy claims.
- We obtained documentation detailing a “walkthrough” of the disease fund determination process for seven funds. The walkthroughs included documentation of the fund approval process which incorporates the preparation of a dossier describing why the fund should be considered.

Finding: None.

Recommendation: None.

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Examination Criteria - Continued

Year Ended December 31, 2022

ASSISTANCE AVAILABILITY

Requirement: 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 beneficiaries' eligibility is reevaluated. The Foundation routinely monitors and evaluates the processes and formulae under which financial assistance is allocated to patients in the program as a reserve based on a patient's expected and actual financial assistance needs.

In addition, the Foundation provides assistance exclusively to patients suffering from the disease state for which the fund donation is allocated.

Methodology:

- We obtained and examined policies and standard operating procedures related to assistance determination and enrollment.
- We selected a sample of patient applications and examined for adherence to applicable policies and procedures related to the specific fund criteria for financial eligibility.
- We selected a sample of patient applications and examined for adherence to applicable policies and procedures related to eligibility reevaluation.
- We selected a sample of patient applications. Formulae details by respective fund were provided by the Foundation. We reperformed calculation of the fund formulae under which financial assistance is allocated.

Finding: None.

Recommendation: None.

FINANCIAL ELIGIBILITY

Requirement: 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 nor the identity of a program donor whose services or products are used by the applicant. Financial needs are assessed based upon a "reasonable, verifiable, and uniform measure" applied in a consistent manner (e.g., based on the federal poverty guidelines).

Methodology:

- We obtained and examined policies and standard operating procedures related to the criteria for financial eligibility and noted that the identity of a provider, supplier, or

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Examination Criteria - Continued

Year Ended December 31, 2022

treatment used by the patient, or donor whose services or products are used by the patient is not taken into account.

- We obtained and reviewed minutes in order to evaluate that the Board's Patient Assistance Committee established fund criteria and eligibility requirements based upon a reasonable, verifiable, and uniform measure applied consistently.
- We selected a sample of patient applications and examined for adherence to applicable policies and procedures related to the specific fund criteria for financial eligibility which is based on the federal poverty guidelines.

Finding: None.

Recommendation: None.

PARTICIPANT NOTIFICATION

Requirement: 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). The Foundation does not refer patients to, or recommend, a particular provider, supplier, or product. The Foundation does not inform patients nor other third parties of the identities of program donors.

Methodology:

- We obtained and examined policies and standard operating procedures related to the participant notifications and third-party communications.
- We obtained and reviewed standard letters:
 - For a sample of participants, we ensured the standard language advising of ability to change providers, suppliers or treatment was utilized;
 - For a sample of participants, we ensured communications did not refer patients to particular providers, suppliers or products; and
 - For a sample of participants, we ensured communications did not indicate funds were provided by a specific donor.

Finding: None.

Recommendation: None.

PATIENT ACCESS NETWORK FOUNDATION

Examination Criteria - Continued

Year Ended December 31, 2022

APPLICATION TIMING AND DETERMINATION

Requirement: Patient requests for assistance under the program are reviewed on a first-come, first-served basis to the extent funding is available. Thus, when making assistance determinations, the Foundation does not consider: (i) the interests of any donor; (ii) the applicant's choice of product, provider, practitioner, supplier, or insurance company; (iii) the identity of the referring person/organization, including whether the referrer is a donor; or (iv) the amount of contributions made by any pharmaceutical company or donor whose services/products may be used by the recipient.

Methodology:

- We obtained and examined policies and standard operating procedures related to the criteria for application timing and assistance determinations.
- We selected a sample of patient applications and examined for adherence to applicable policies and procedures related to the timing of awards being made on a first-come, first-serve basis.

Finding: None.

Recommendation: None.

PARTICIPANT PAYMENTS

Requirement: To the extent feasible, the Foundation furnishes assistance under the programs 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.

Methodology:

- We obtained and examined policies and standard operating procedures related to the participant payments.
- For a sample of participants, we examined payment/distribution support to determine assistance was allocated to qualifying expenses.

Finding: None.

PATIENT ACCESS NETWORK FOUNDATION

Examination Criteria - Continued

Year Ended December 31, 2022

Recommendation: None.

PROGRAM REFERRALS

Requirement: The Foundation's programs receive referrals from multiple sources, including physicians, suppliers, patient advocacy groups, other relevant third-party organizations and program donors (e.g., through program donors' patient assistance programs).

Methodology:

- We obtained and examined policies and standard operating procedures related to program referrals.

Finding: None.

Recommendation: None.

REFERRAL SOURCES

Requirement: The Foundation's determination of whether to provide assistance does not consider the source that referred the patient to the programs.

Methodology:

- We obtained and examined policies and standard operating procedures related to patient enrollment and referral sources.
- During detailed testing for a sample of participants, we verified the source of referral was not one of the eligible criteria for determining assistance provided.

Finding: None.

Recommendation: None.

PROGRAM PROMOTION

Requirement: The Foundation uses commercially reasonable efforts to publicize the availability of the programs to patient advocacy organizations, other relevant third parties and patients, consistent with Foundation established criteria.

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Examination Criteria - Continued

Year Ended December 31, 2022

Methodology:

- We obtained and examined policies and standard operating procedures related to publicizing programs.
- We obtained and examined the Foundation's promotional and communications materials and noted they appear to be relevant commercially reasonable means of publicizing availability of the Foundation's programs.
- We obtained and examined the Foundation's promotion and communication materials used to publicize the organization, its disease funds available to patients, patient advocacy groups, and other third parties.

Finding: None.

Recommendation: None.

DONATION SOLICITATION

Requirement: The Foundation has a process to solicit donations for the programs from a multitude of sources.

Methodology:

- We obtained and examined policies and standard operating procedures related to soliciting donations.
- We evaluated policies and procedures for processes that allowed fundraising activities to be performed by Foundation employees who had no ties with associated administrative services contractors or affiliates consistent with the Advisory Opinion's guidance.
- We evaluated the means used by the Foundation to attract and inform potential donors about the Foundation and its programs. We also evaluated the Foundation's tax return noting the various types of donors contributing to the Foundation.

Finding: None.

Recommendation: None.

DONOR COMMUNICATION

Requirement: The Foundation may provide periodic reports to donors regarding the aggregate number of applicants in a particular fund and the aggregate number of applicants qualifying for

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Examination Criteria - Continued

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assistance in a particular fund. The Foundation may not provide reports to donors containing information that would enable a donor to correlate the amount or frequency of its donations with (i) the number or medical condition of patients that use its products/services or (ii) the amount or frequency of the use of those products/services. The Foundation may not inform donors of the donations made by others. The Foundation may not share patient information with a donor.

Methodology:

- We obtained and examined policies and standard operating procedures related to Foundation donor reporting.
- We obtained and reviewed reporting provided to donors and verified information provided omitted non-aggregated data and any data that would allow correlation of support. In addition, there was no information provided regarding donations made by others.

Finding: None.

Recommendation: None.