

EXECUTIVE SUMMARY HealthWell Foundation Program Audit

July 2020

Conduent Patient Access Solutions, LLC, an independent review organization performed a review of the program for qualification and disbursement activity occurring throughout the 2019 calendar year. This assessment included interviews with HealthWell Corporate and HWF Direct, LLC personnel, extensive policy and procedure review, training documentation and data analysis to verify that the HealthWell Foundation is in compliance with the OIG Advisory Opinion 07-06, and subsequent modifications issued in September 2011 and December 2015. The auditor evaluated the foundation's compliance standards/procedures, internal controls and monitoring to mitigate risk, patient qualification for assistance and grant payment disbursements.

The review examined the extent to which the program and HealthWell meet the requirements of:

1. Department of Health and Human Services Office of Inspector General favorable advisory opinion 07-06, as modified;
2. Department of the Treasury Internal Revenue Service classification as a 501(c)(3); and
3. HealthWell standard donor agreements.

and comply with the specifications below:

General

- A. HealthWell is a bona fide, non-profit organization.
- B. HealthWell, its Board, and its staff are independent of any donor or prospective donor to the program.
- C. HealthWell uses commercially reasonable efforts to publicize the availability of the program to patient advocacy organizations, other relevant third parties, and patients.
- D. HealthWell receives referrals from several sources, including physicians, pharmacies, other patient groups, advocacy groups and donors (typically through their patient assistance programs).

Funds

- A. HealthWell defines its funds using widely recognized disease states. Specifically, HealthWell does NOT define its funds:
 - a. by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a disease, type of drug treatment, or any other way of artificially or inappropriately narrowing the definitions.
- B. HealthWell has accepted the OIG-defined single drug fund as a fund where i) only one FDA-approved product has been approved for the disease state or ii) more than one product is FDA-approved for the disease state but all such products are manufactured

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by the same company, including its affiliates. *IF* HealthWell establishes a “single drug” fund, it is set up in a manner compliant with its OIG advisory opinion and modifications and provides support for other medical needs of the patient related to managing the disease.

- C. Assistance is not limited only to high cost or specialty drugs. HealthWell covers all products, both branded and generic used to treat (based on FDA-approval and compendia-listing) its defined disease states regardless of price.

Donors

- A. Donors may earmark their contributions for the support of patients covered by one of the HealthWell’s disease funds. Donations are restricted for their intended purpose, i.e., support patients enrolled under the earmarked disease fund, HOWEVER, donations are unrestricted within the disease fund, i.e., may be used for any product covered under the disease fund.
- B. Patients are not informed of the identity of specific donors. Neither patients nor donors, corporate or individual, are informed of the donations made to HealthWell by others.
- C. Donors receive reports containing only aggregate data related to activity in the fund(s) they support. No individual patient’s information is conveyed to donors. Donor reports do not contain any information that would enable any donor to correlate the amount or frequency of its donations with the number or medical condition of patients that use its products or services, or the volume of those products or services.
- D. HealthWell solicits donations for the program from a multitude of sources.

Applications

- A. Patient requests for assistance under the program are reviewed on a first-come, first-served basis to the extent funding is available.
- B. HealthWell does not take into account the identity of a provider, supplier, or treatment that the patient may use or the amount of contributions made by a donor (or lack of contributions from prospective donors) whose services or products are used by the applicant at any time during the application process, throughout the patient’s enrollment year, or in consideration of re-enrollment.
- C. HealthWell does not consider the source of the patient referral to the program when evaluating whether to provide assistance.
- D. HealthWell does not refer patients to or recommend a provider, supplier, or product.
- E. HealthWell makes all eligibility determinations using established and published eligibility criteria applied in a consistent fashion:
 - a. Patient’s disease is covered by the program;
 - b. Patient has some form of health insurance;
 - c. Patient’s medication is listed as an eligible treatment under the disease fund;

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- d. Patient's income falls within HealthWell guidelines (household size and total household income at or below a set percent of the Federal Poverty Limit of the program); and
 - e. Patient is receiving treatment in the United States.
- F. HealthWell verifies each patient's income eligibility through information provided by a third-party service. If the patient's income cannot be verified based on the information provided during application OR the verified income is above the income threshold for the fund, HealthWell requests full income documentation from the patient for review.

Grant Use

- A. Patients are informed during the application process by HealthWell that they are free to change providers, suppliers or treatments at any time and will continue to receive assistance (unless they become ineligible for other reasons).
- B. To the extent feasible, HealthWell furnishes assistance under the program to the physician, supplier, or insurer on behalf of the patient. Efforts to reduce direct-to-patient assistance are supported by access through the HealthWell pharmacy card and direct bill relationships with providers, hospitals/clinics, pharmacies, and insurers.

Results of the assessment performed by the program auditor indicate that the HealthWell Foundation is in compliance with Program requirements and has established an effective control process and standard operating procedures (SOPs) to verify that patients receiving assistance are qualified and grants are properly processed according to HealthWell Foundation criteria.

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SIGNATURE PAGE FOR EXECUTIVE SUMMARY

PROGRAM: HealthWell Foundation
TYPE OF AUDIT: Annual Program Analysis
PRINCIPLE INVESTIGATOR: Melissa Plant
COMPANY: Conduent Patient Access Solutions, LLC

I believe the audit evidence I have obtained is sufficient and appropriate to provide an objective assessment of the Foundation's compliance to policies and procedures, OIG requirements and program operations.

Melissa Plant

7/29/2020

Signature

Date

Melissa Plant, Director, Auditing Services, Conduent Patient Access Solutions, LLC