



HEALTHWELL FOUNDATION PROGRAM AUDIT

- I. Executive Summary**
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I. Executive Summary

Commencing in June, 2023 the law firm of Dilworth Paxson, LLP conducted an independent review of HealthWell's compliance with certain Compliance and Program Requirements. The review covered activities, processes, systems and controls extant during calendar year 2022. The scope of the review was formulated to assess and measure the Foundation's corporate compliance and material compliance with the established protocols, processes, systems and controls in place related to the administration of the Program. The review examined the extent to which the Program and the HealthWell Foundation comply with the compliance and program specifications contained in Management's Assertions Over Compliance, attached hereto as Attachment A. To wit, in addition to compliance with standard donor agreements, compliance with the following was assessed:

- (a) HealthWell is a charitable organization described in Code Section 501(c)(3). This includes compliance with the public support percentage within the meaning of Code Section 509(a).
- (b) HealthWell is a public charity described in Code Section 509(a). This includes compliance with the public support percentage within the meaning of Code Section 509(a).
- (c) HealthWell is independent of any donor to the Program (collectively, the "Program Donors"), or any other entity with which HealthWell has a transaction or arrangement.
- (d) HealthWell receives referrals from multiple sources, including physicians, suppliers, patient advocacy groups, other relevant third-party organizations including Program Donors.
- (e) HealthWell's determination of whether to provide assistance does not consider the source that referred the patient to the Program.
- (f) HealthWell bases all 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.
- (g) HealthWell 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.
- (h) Assistance is available to beneficiaries with demonstrable financial need and who meet HealthWell's income and/or asset criteria, for a period of up to one (1) year, after which each beneficiary's eligibility is reevaluated.

- (i) Patient requests for assistance under the Program are reviewed on a first-come, first-served basis to the extent funding is available.
- (j) HealthWell 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).
- (k) HealthWell does not refer patients to, or recommend, a particular provider, supplier or product.
- (l) HealthWell does not inform patients, providers, other donors, or any other third parties of the identity of Program Donors.
- (m) 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.
- (n) Donors may earmark their contributions for the support of patients covered by one of 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.
- (o) To the extent feasible, HealthWell 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, HealthWell obtains proof from the patient that the assistance is to satisfy qualifying expenses.
- (p) HealthWell has a process to solicit donations for the Program from a multitude of sources.
- (q) HealthWell uses commercially reasonable efforts to publicize the availability of the Program to patient advocacy organizations, other relevant third parties and patients.
- (r) HealthWell defines its funds using widely recognized disease states. Specifically, HealthWell does not define its funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of artificially or inappropriately narrowing the definitions.
- (s) 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.

(t) HealthWell provides financial assistance under the Program for products from more than one manufacturer, including any available generic drugs. If HealthWell establishes a fund for a disease for which the FDA has approved only one drug, or only the drugs made or marketed by one manufacturer or its affiliates, HealthWell will provide support for other medical needs of patients with the disease, in addition to copayment support for the FDA-approved treatment of the disease.

The specifications above are derived from the favorable Department of Health Human Services Office of Inspector General Advisory Opinion 07-06, as modified by Letters of September 23, 2011, and December 21, 2015, the Internal Revenue Service's classification of HealthWell both as a 501(c) (3) entity and 509(a) public charity, and the standard donor agreements existing between HealthWell and its donors.

This firm is independent of HealthWell, and our responsibility under this engagement is to plan and conduct an examination adequate to reasonably assure that management's Assertions Over Compliance are fairly stated in all material respects. To achieve this goal, we designed information requests, a process that in some cases required secondary requests, and analyzed and documented our assessment of the information received. We were not blocked by management in any aspect of our review.

The information and evidence we obtained and reviewed is sufficient and appropriate to provide a reasonable basis for our conclusion that HealthWell Foundation is in compliance with Compliance and Program Requirements as asserted, that it has an internal control process, including policies and procedures purpose-built to verify the qualification of patients for assistance, and that the funds and grants are properly established and administered. Thus, managements' assertions are fairly stated in all material respects.

Prepared by: Christina W. Strong, Esq., Partner
Kiliaen Strong, Esq., Of Counsel
Dilworth Paxson, LLP

Signature: 

Date: November 13, 2023

Signature: 

Date: November 13, 2023

II. Attachment A

MANAGEMENT ASSERTIONS OVER COMPLIANCE

Christina Woodward Strong

Dilworth Paxson, LLP

2 Research Way,

Princeton, New Jersey 08502

November 10, 2023

RE: Management's Assertions over Compliance, 2022

Dear Ms. Strong:

We are providing you with this letter in connection with Dilworth Paxson's independent examination of whether HealthWell Foundation's management assertion that, for the year ended December 31, 2022, HealthWell Foundation's compliance with the Compliance and Program Requirements set forth below is fairly stated in all material respects.

This letter is to serve as the assertion of the Management of HealthWell that it is in compliance with the following Compliance and Program Requirements:

Compliance Requirements-

1. HealthWell is a charitable organization described in Code Section 501(c)(3) and is a public charity described in Code Section 509(a). This includes compliance with the public; support percentage within the meaning of Code Section 509(a);
2. The terms and conditions set forth in its Advisory Opinion, including the specific requirements ((a)-(t)) outlined in the Program Requirements below; and
3. HealthWell's standard donor agreements.

Program Requirements-

- (a) HealthWell is a charitable organization described in Code Section 501(c)(3) and is a public charity described in Code Section 509(a). This includes compliance with the public support percentage within the meaning of Code Section 509(a).
- (b) HealthWell is a public charity described in Code Section 509(a).
- (c) HealthWell is independent of any donor to the Program (collectively, the “Program Donors”), or any other entity with which HealthWell has a transaction or arrangement. For purposes of determining independence, the majority of members of HealthWell's governing body may not have any direct or indirect impermissible "financial relationship" as defined below. For these purposes, “financial relationship” shall mean one of the following relationships, whether through business investment or family: (i) an ownership or investment interest in any entity with which HealthWell has a transaction or arrangement; (ii) a compensation arrangement with HealthWell or with any entity or individual with which HealthWell has a transaction or arrangement; or (iii) a potential ownership or investment interest in, or compensation arrangement with, any entity or individual with which HealthWell is negotiating a transaction or arrangement. For these purposes, compensation includes direct and indirect remuneration as well as substantial gifts, contributions or favors.
- (d) The Program receives 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).
- (e) HealthWell's determination of whether to provide assistance does not consider the source that referred the patient to the Program.
- (f) HealthWell bases all 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.
- (g) HealthWell 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.
- (h) Assistance is available to beneficiaries with demonstrable financial need and who meet HealthWell's income and/or asset criteria, for a period of up to one (1) year, after which each beneficiary's eligibility is reevaluated.
- (i) Patient requests for assistance under the Program are reviewed on a first-come, first-served basis to the extent funding is available.

(j) HealthWell 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).

(k) HealthWell does not refer patients to, or recommend, a particular provider, supplier or product.

(l) HealthWell does not inform patients, providers, other donors, or any other third parties of the identity of Program Donors.

(m) 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.

(n) Donors may earmark their contributions for the support of patients covered by one of Health Well'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.

(o) To the extent feasible, HealthWell 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, HealthWell obtains proof from the patient that the assistance is to satisfy qualifying expenses.

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(q) HealthWell uses commercially reasonable efforts to publicize the availability of the Program to patient advocacy organizations, other relevant third parties and patients.

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(s) 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.

(t) HealthWell provides financial assistance under the Program for products from more than one manufacturer, including any available generic drugs. If HealthWell establishes a fund for a disease for which the FDA has approved only one drug, or only the drugs made or marketed by one manufacturer or its affiliates, HealthWell will provide support for other


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medical needs of patients with the disease, in addition to copayment support for the FDA-approved treatment of the disease.

Signature:  Title: President and Chief Executive Officer

Signature:  Title: Chief Development Officer