

Summary of OIG Guidance and the HealthWell Foundation

The HealthWell Foundation is a nationally recognized, independent 501(c)(3) non-profit organization that provides financial assistance to qualifying adults and children facing medical hardship resulting from gaps in their insurance that cause out-of-pocket medical expenses to escalate rapidly. HealthWell operates under a favorable advisory opinion (Advisory Opinion No. 07-06, as amended (Advisory Opinion)) issued to it by the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG).

HealthWell is entirely independent and is not controlled or influenced by any of its donors. The assistance that HealthWell provides to patients is based on objective criteria that it applies consistently and in accordance with applicable law and its Advisory Opinion. As an independent patient assistance foundation, HealthWell operates within a complex regulatory framework. The regulations governing the health care industry, as well as the favorable Advisory Opinion issued to HealthWell, set standards that HealthWell must meet to be compliant with applicable law.

HealthWell's leadership believes that clear OIG guidance makes for a strong charitable patient assistance program. HealthWell has always sought to meet or exceed the requirements set forth in its Advisory Opinion, and to comply with all applicable law.

In December, 2015, the OIG issued a [modification](#) to HealthWell's Advisory Opinion. That modification was in response to the OIG's May 2014 Supplemental Advisory Bulletin (Bulletin) that applied to all independent charitable patient assistance programs that have favorable OIG advisory opinions. The Bulletin was the basis for the OIG's request that such programs make certain modifications to their advisory opinions. Insofar as HealthWell's most recent Advisory Opinion modification is concerned, among other things HealthWell certified to the OIG (and its modified Advisory Opinion so reflects) that:

- HealthWell will not define its disease 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 narrowing the definition of widely recognized disease states. However, that disease funds may be limited to patients with certain metastatic cancers in which case HealthWell will cover, at a minimum, all drugs that are approved by the FDA for the type of cancer (not limited to drugs expressly approved for the metastatic stage of the cancer).
- HealthWell will not maintain any disease fund that provides copayment assistance for only one drug, or only the drugs made or marketed by one manufacturer or its affiliates. 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.

- HealthWell will not limit its assistance to high-cost or specialty drugs, but will make assistance available for all prescription medications, including generic or bioequivalent drugs, approved by the FDA for treatment of the disease state(s) covered by the fund.
- HealthWell will employ a process for screening all applicants for compliance with a fund's designated financial eligibility criteria prior to enrolling applicants in a fund or within a reasonable time thereafter; and such screening process will be applied uniformly across funds, and will involve: verifying each applicant's financial resources through information provided by a third party service, collecting documentation of financial need from the applicant, or some combination thereof.
- The third-party administrator (Administrator) identified in HealthWell's Advisory Opinion no longer provides services for running many aspects of HealthWell's daily operations, and the only services the Administrator still performs are staffing HealthWell's telephone contact lines and entering information obtained via telephone, surface mail, and fax communications into HealthWell's database.

Also noteworthy is that in 2011 the OIG issued a modification to HealthWell's Advisory Opinion to permit the creation of "Medicare access funds" from which grants can be made solely to qualified Medicare beneficiaries with specific diseases covered by those funds; and the creation of such funds is still permissible under HealthWell's Advisory Opinion.

Finally, as has been the case under HealthWell's Advisory Opinion since its issuance in 2007:

- HealthWell assists all eligible, financially needy applicants on a first-come, first-served basis, to the extent funding is available.
- HealthWell's determination of an applicant's financial qualification for assistance is based solely on his or her financial need, without considering the identity of any of his or her health care providers, practitioners, suppliers, products, or plans; the identity of any referring party; or the identity of any donor that may have contributed for the support of the applicant's condition.
- No donor or affiliate of any donor exerts any direct or indirect control over HealthWell or its programs.
- HealthWell awards assistance in a truly independent manner that severs any link between donors and beneficiaries.
- HealthWell awards assistance without regard to any donor's interests and without regard to the applicant's choice of product, provider, practitioner, supplier, or insurance plan.
- HealthWell provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.
- HealthWell does not provide donors with any data that would allow a donor to correlate the amount or frequency of its donations with the amount or frequency of the use of its products or services. Patients do not receive any information regarding donors, and donors do not receive any information regarding other donors.
- An independent review organization engaged by HealthWell conducts an annual independent audit of its compliance with the Advisory Opinion.