



HEALTHWELL  
FOUNDATION®

When health insurance is not enough.®

HealthWell Foundation & Our  
Commitment to OIG Compliance





## HealthWell Foundation & Our Commitment to OIG Compliance

The HealthWell Foundation (HealthWell) is an independent 501(c)(3) charitable organization that provides eligible patients with financial assistance to help cover the cost of prescription drug coinsurance, copayments and deductibles, health insurance premiums and out-of-pocket costs for supplies, supplements, surgeries and more. Since 2004, HealthWell has awarded more than 368,000 grants in over 50 therapeutic categories to more than 250,000 underinsured Americans in need of financial assistance.

HealthWell operates in compliance with all applicable laws, including specifically the requirements and guidance of the U.S. Department of Health and Human Services, Office of Inspector General (OIG), which provides oversight for charitable patient assistance programs (CPAPs). In 2007, the OIG issued HealthWell a favorable advisory opinion (OIG Advisory Opinion 07-06), which concluded that HealthWell's operations as a CPAP complied with applicable legal and OIG requirements and guidance. In 2011 the OIG approved a modification to HealthWell's advisory opinion that permits HealthWell to create and maintain funds providing assistance solely to qualified Medicare beneficiaries -- such modification was the first time the OIG formally approved "Medicare-only" funds. The OIG's most recent guidance for CPAPs was issued in a May 2014 Supplemental Special Advisory Bulletin (Supplemental Bulletin). HealthWell received written confirmation of its compliance with this guidance in December 2015.

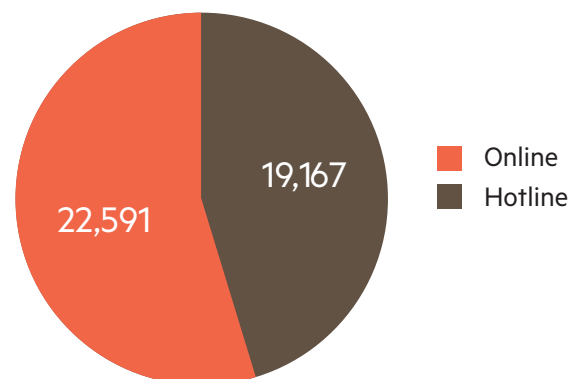
**320,000+**  
patients served

**\$840 million**  
in grants awarded

**\$3,099**  
average grant amount

**400+**  
children served through our  
Pediatric Assistance Fund

GRANT APPLICATIONS 2016



# OIG Guidance: An Inside Look

In 2003, the U.S. Congress expanded Medicare to cover prescription drugs through Medicare Part D. Under applicable law, biopharmaceutical companies are permitted to give direct financial assistance to patients covered by commercial insurers, but they may not do the same for Medicare beneficiaries. Such assistance to a Medicare beneficiary may be considered an illegal kickback because it may steer the patient to a particular company's drug instead of less expensive alternatives.

The OIG issued its first Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees in November 2005 in order to identify potentially abusive patient assistance program structures as well as methods of providing assistance that mitigate or vitiate the potential for fraud and abuse. That original Bulletin gave independent, bona fide CPAPs a lawful avenue for pharmaceutical manufacturers and others to provide financial assistance to Part D beneficiaries in obtaining medically necessary drugs without running the risk of violating the Anti-Kickback Statute.

As described above, HealthWell received its original, favorable OIG advisory opinion in 2007, which concluded that HealthWell's program to provide financial assistance to financially needy and eligible individuals with specified chronic diseases complied with applicable regulatory requirements. As also described above, in 2011 the OIG issued a modification to HealthWell's original advisory opinion allowing HealthWell to create and maintain, in connection with specified chronic diseases, new disease funds that provide assistance solely to qualified Medicare beneficiaries.

## Did You Know?

The Anti-Kickback Statute imposes criminal liability on parties on both sides of an impermissible "kickback" arrangement. Violations constitute a felony punishable by a maximum fine of \$25,000, imprisonment up to five years or both.

Recently the OIG and the Department of Justice have been more closely scrutinizing the operations of CPAPs for potential fraud and abuse. In its Supplemental Bulletin, the OIG reiterated its position on certain areas of concern for CPAPs from a fraud and abuse perspective. It also disallowed certain practices that had not been previously prohibited, including the maintenance of single-drug or single manufacturer funds in certain very limited circumstances. The Supplemental Bulletin also expressed concerns about, and provided certain guidance with respect to: practices related to disease fund definitions, limiting assistance to high-cost or specialty drugs, the consistent application of eligibility criteria and donor reporting. Many (if not most) CPAPs (including HealthWell) were required to submit certifications to the OIG confirming compliance with the new guidance set forth in the Supplemental Bulletin. The Supplemental Bulletin and the certification required the CPAPs to slightly modify certain of their practices to ensure compliance.

## Organizational Values

While HealthWell is in full compliance with all requirements of the law and of OIG guidance, **at the core of HealthWell's organizational values is the belief that CPAPs should do more than just meet the applicable legal and OIG requirements. They should make full and strict compliance the cornerstone of their operations by adopting and enforcing best compliance practices.** Donors, patients, providers and patient support communities place their trust in HealthWell because it takes its responsibilities seriously and strives to be the industry leader in practices that meet the highest ethical and compliance standards.

HealthWell has become a highly regarded and trusted CPAP, in large part, because it focuses on always putting its patients' needs first by creating an environment in which compliance and the highest ethical standards are the cornerstones of its operations.

## Fund Management

HealthWell has moved beyond traditional copayment assistance to address patient needs for premium assistance as well as assistance with out-of-pocket costs for supplies, supplements, surgeries and more. HealthWell's service to its patients is further supported by:

- ▶ An independent and diverse board. HealthWell's Board of Directors includes a broad range of respected professionals with deep experience in the fields of health care administration, clinical practice and research, direct patient care, patient advocacy and health law. HealthWell's board is chaired by one of the country's leading healthcare lawyers who, along with its legal counsel, helps to ensure compliance with all applicable legal and OIG requirements and guidance. None of HealthWell's Board members, and none of its Board members' families, are, have been or will be engaged as officers, directors, trustees or indirect owners of HealthWell's donors or any other organization that would pose any conflict of interest.
- ▶ Financial transparency. HealthWell files an IRS Form 990 (Return of Organization Exempt from Income Tax) annually and makes the Form available on its web site at [www.HealthWellFoundation.org](http://www.HealthWellFoundation.org). In that form, HealthWell certifies that it does not undertake any business arrangement that is likely to lead to a conflict of interest or result in a private party improperly receiving financial gain from HealthWell as a tax-exempt entity.
- ▶ A commitment to dedicating 100 percent of donor dollars to patient grants and services. HealthWell has a proven track record of using donations effectively and efficiently. All administrative and fundraising costs are financed by HealthWell and are not taken out of donations.

HealthWell structures and manages its operations to fully comply with its original advisory opinion, as modified (the "Advisory Opinion"), and all applicable OIG and other legal requirements and guidance while helping patients access life-saving health care. We do this by:

- ▶ Broadly defining therapeutic categories. HealthWell does not define its disease funds by reference to specific symptoms, severity of symptoms, method of drug administration, stage of a particular disease, type of drug treatment or in any other impermissible way of narrowing the definition of widely recognized therapeutic categories. HealthWell works with an independent health care consulting firm to help define its funds in a way that is compliant with applicable OIG and other legal requirements and guidance in terms of fund names, definitions and lists of medications covered. All funds are reviewed and approved by clinicians on HealthWell's Board prior to launch.
- ▶ Including all appropriate drugs, regardless of price. HealthWell makes assistance available for all products, including generic or bioequivalent drugs, indicated for the treatment of a disease state(s) covered by a fund. This includes marketed products that are listed in various compendia for treatment of the disease state(s) covered by the fund.
- ▶ Appropriately managing "single drug" funds when applicable. If HealthWell establishes a fund for a disease for which the FDA has approved only one drug, or if all the drugs to treat the disease are made or marketed by only one manufacturer or its affiliates, HealthWell will provide financial support for other medical needs associated with that disease, such as prescription medications to treat symptoms of the disease or side effects of the disease.

### FUNDS WITH ACTIVE PATIENT GRANTS



### Top Disease Areas by Volume

Multiple Sclerosis - Medicare Access  
Cystic Fibrosis  
Non-Small Cell Lung Cancer - Medicare Access  
Pulmonary Fibrosis  
Multiple Myeloma - Medicare Access

# Working with the HealthWell Foundation

HealthWell is ready to work with donors interested in contributing to existing funds or opening new funds. It takes less than two weeks for HealthWell to establish a new fund, and existing funds are already established for diseases in the following categories:

- Autoimmune disease
- Blood disorders
- Endocrine disorders
- Eye disease
- Gastrointestinal disease
- Infectious disease
- Inherited Metabolic disorder
- Kidney Disease
- Musculoskeletal conditions
- Neurological disorders
- Oncology
- Pulmonary disease
- Transplants
- Urologic disorders

To learn more about starting a new HealthWell fund or contributing to an existing fund, contact **Alan Klein, Chief Development Officer, at 240-632-5312 or [alan.klein@healthwellfoundation.org](mailto:alan.klein@healthwellfoundation.org)**.

- ▶ Applying consistent patient eligibility guidelines. HealthWell bases fund eligibility on consistently-applied, objective criteria, to include a patient's medical, financial and insurance status. All grant recipients must receive treatments in the United States for a disease covered by a HealthWell fund. To be eligible for assistance, patients must have insurance (public or private) that covers their medication. In addition, to be eligible for assistance the patient's income must fall within HealthWell's guidelines, which is up to 400 to 500 percent of the Federal Poverty Level adjusted for household size and geographic location.
- ▶ Providing grants on a first-come, first-served basis. To ensure equal access for all eligible patients, HealthWell grants assistance on a first-come, first-served basis. All grant requests must be made via HealthWell's toll-free telephone hotline or through its online portal, both of which place requests in a combined queue. Patients receiving assistance are free to change their physicians, pharmacies, or other providers, or the types of medications they are taking for a specific disease, at any time without affecting their eligibility for assistance.
- ▶ Maintaining the anonymity of our donors and operating funds independently of our donors. In compliance with HealthWell's Advisory Opinion and OIG guidance, HealthWell does not disclose the identity of its donors, thereby ensuring that HealthWell operates independently and in the best interest of its grant recipients. No donor exerts direct or indirect control over HealthWell, its operation or its decision-making process regarding grants of financial assistance.
- ▶ Providing only aggregate data to donors. In its reporting to donors, HealthWell provides aggregate approval volume and outflow totals. Reports to donors never include any details that would allow any donor to determine the correlation between the amount and frequency of its donations and the frequency with which grant recipients use HealthWell assistance to aid in the purchase of such donor's products.

## Making the Most of Your Donation

