



HEALTHWELL
FOUNDATION®

When health insurance is not enough.®

When Health Insurance Is Not Enough: How Charitable Copayment Assistance Organizations Enhance Patient Access to Care

Guidance for Pharmaceutical &
Biotechnology Companies Looking to
Improve Treatment Compliance and
Effect Positive Health Outcomes



An estimated 29 million Americans¹—almost 10 percent of our nation’s population—are unable to afford the health insurance copayments, coinsurances and deductibles required to cover out-of-pocket costs for necessary treatments of certain chronic and life-altering medical conditions. The impact of these costs is devastating: medical expenses play a significant role in approximately 60 percent of personal bankruptcies filed in the United States.²

Cancer. Crohn’s Disease. Asthma. Arthritis. These are among the many diseases that you, as part of today’s modern life sciences community, have committed to treat with the drugs, biologicals and medical devices you have brought to market and continue to develop. **But even the most novel, breakthrough therapies can’t result in positive health outcomes if the patients who so desperately need those therapies can’t afford them.**

Fortunately, there is a way you can make a difference. By donating to a charitable copayment assistance organization, you can help hundreds to thousands of patients start and stay on their therapies. You can be part of the solution by directly increasing access to medications that patients need to live, to move, to work, to manage pain, and to breathe. Your support is vital. And the need has never been more acute.

Health Insurance in America: Today’s Realities

You can’t escape the headlines: rising expenses and high unemployment. And even for the employed, a sharp reduction in health benefits, coupled with a steep increase in out-of-pocket costs, including deductibles, copayments and coinsurance, is making access to life-saving and life-sustaining therapies out of reach for many Americans. For some individuals and families, these out-of-pocket expenses can total thousands of dollars each month—much more than many people earn.

Each year, more and more Americans are being forced to choose between paying for life-saving treatments and paying for basic necessities like food, housing and utilities—decisions no one should have to make. When people in these circumstances need help, many of them turn to the HealthWell Foundation. Founded in 2003, the HealthWell Foundation is an independent 501(c)(3) non-profit charitable organization. Its mission is to address the financial dilemma facing individuals with health insurance who need important medical treatments but cannot afford their out-of-pocket costs and premiums. HealthWell’s vision is to ensure that no patient—adult or child—goes without health care because he or she cannot afford it.

HealthWell expects the demand for copayment assistance to rise over the next decade, as more uninsured people get health insurance as a result of the Patient Protection and Affordability Care Act (ACA). While increasing the number of insured Americans (moving millions from uninsured to insured status), **the ACA does not address the issue of the tens of millions of people who will still lack adequate insurance and the means to cover the copayments required by their new health insurance coverage.** These are America’s “underinsured.”

Did you know?

Three out of five Americans have skipped or delayed seeking health care due to cost.³

Three out of ten Americans do not fill a prescription due to cost.³

Three out of five Americans cut their pills in half or skip doses due to cost.³

Excess health care costs due to medication non-adherence in the U.S. are estimated to be **\$300 billion annually.**⁴

To minimize the risk of newly insured individuals lacking the financial resources to fully cover their medication costs, plans would ideally have to ensure access to high-cost treatments and provide financial protection from the costs of those treatments and overall proper patient care. Until that happens effectively, all indications point to an increasing and expanding need for copayment assistance. **There is no credible evidence supporting a decline in the nationwide need for copayment assistance.**

40%
increase in
consumer out-of-
pocket health care
expenses from
1999 to 2009.

The Struggle for Affordable Care

Individuals are considered to be lacking in adequate insurance if they spend more than 10 percent of their income on out-of-pocket medical expenses (5 percent if they are low-income) or more than 5 percent on deductibles.⁵

Consumers' out-of-pocket costs for health care expenses increased 40 percent from 1999-2009.⁶

From 1999 to 2009, health insurance premiums more than doubled—rising by more than \$7,500 for the average family with employer-sponsored insurance.⁷

For Amber, of Riverbank, California, the panic and tears started when her employer changed her health insurance to a high-deductible plan with no prescription coverage. A liver transplant at the age of 10 meant Amber desperately needed her prescription to survive.

The panic continued when Amber searched far and wide for help. Unfortunately, other copay assistance organizations turned her down because she already had insurance and made “too much money.”

“I’m employed, but my medication costs thousands of dollars,” she says. “There was no way I could pay my mortgage and bills and buy food with that kind of extra expense.”

Finding HealthWell and picking up her first prescription with copayment assistance brought new tears to Amber’s eyes...but this time they were “tears of happiness.”

The Changing Face of Health Care: Uncertainties and New Realities

Every day brings new challenges and new opportunities to the health care industry. Will traditional pharmaceutical-company-sponsored patient assistance programs be able to assist patients acquiring coverage through state exchanges? What will happen to manufacturer-sponsored coupons and copay cards? What will be the results of pressures from payors to drive down the overall costs of health care? And how will the outcome of upcoming federal elections affect the entire health care landscape?

The ACA focuses on bringing more Americans into the ranks of the insured, though it does not address the affordability of care in terms of premiums and out-of-pocket costs. **Under the ACA, there continues to be a risk that individuals will remain or become “underinsured”—especially if they have chronic diseases.** Sadly, the need for copayment assistance is expected to significantly increase as reform progresses, even though more Americans will be insured.

Public health researchers have long held that higher copayments diminish patients’ willingness to take their prescribed medications regularly and at the therapeutic dosage. Indeed, some employers have eliminated or greatly reduced their copayment requirements, resulting in lower overall costs, higher adherence/compliance and improved health status for employees suffering from chronic disease.

In 2009, RAND Corporation released a study of retirees who received health coverage from their former employers from 1997 to 2002 and who were covered by 31 different health plans. The study focused on 17,183 people who were newly diagnosed with chronic diseases such as diabetes, high blood pressure and high cholesterol. RAND researchers examined patient records to determine when they began to fill prescriptions for the medications prescribed for them. The researchers found that newly diagnosed patients are significantly more likely to delay initiating recommended drug treatment if they faced higher copayments for the medication. The delay was significant across all conditions, but the impact was largest among patients who had not previously used prescription drugs.⁸

As we move into an era of “bending the cost curve,” we can expect increased cost containment efforts to result in higher copayments. As has been repeatedly demonstrated, proper medication compliance and adherence (consistently the right medication, at the right dosage, for the right patient), essential to mitigating chronic disease, is inversely correlated with the level of individual copayment responsibility.

David L. Knowlton, President & CEO
NJ Health Care Quality Institute
HealthWell Foundation Board Member

It can be tough to find affordable health care insurance when you’re self-employed. So to find a plan with a premium she could meet, Linda of Powell, TN, chose one with a \$5,500 deductible and no drug coverage. As a cancer survivor, Linda was faced with high out-of-pocket costs for ongoing mammography, colonoscopy, endoscopy, and lab work.

“When I found out the cost of my medication, I was scared,” Linda says. “But without it, my oncologist said the cancer could come back.”

Linda’s search for help took her to one charitable copayment assistance organization, which turned her down, because her salary was a mere \$50 over their cap. Another turned her

down because she had a deductible. Only HealthWell was able to help.

“I am so thankful every time I have my prescription filled,” she adds. “I can see why Forbes Magazine recognized HealthWell, and I wish I could personally thank each and every donor.”

What is Copayment Assistance?

Copayment assistance provides direct financial support to eligible individuals—typically those with household incomes up to 400 or 500 percent of the federal poverty level (FPL)—to pay for coinsurance, copayments, health care premiums and deductibles for patients requiring FDA approved therapies for specific conditions for which assistance funds are established. It helps underinsured patients better afford the costs associated with certain prescribed medications. **This assistance would not be possible without the generous support of pharmaceutical and biotechnology industry donors.** Copayment assistance organizations are conduits in the circuit of patient access to medication. The real power that drives the entire circuit comes primarily from manufacturer donations.

Evaluating the Copay Assistance Landscape

Copayment assistance may be available from a variety of sources. Eligibility criteria, covered expenses and grant amounts vary by the organization and program. Some organizations allow patients to be served only by their programs, while others allow patients to be served concurrently by multiple assistance programs. It can be difficult to decide which organization(s) to support. Later, you'll find a checklist of questions to ask and features to consider when evaluating various programs and organizations. Meanwhile, here is an overview of several options.

Perhaps your company is among the many pharmaceutical manufacturers that offer **Patient Assistance Programs (PAPs)** providing free or discounted medicines for low-to-moderate-income uninsured and underinsured people who meet certain guidelines. Or perhaps you offer copay cards, but also want to offer assistance to patients with Medicare Part B, Part D, or Medicaid.

Many states also offer limited programs that help those in need obtain their medications. State assistance programs are typically funded via tax dollars or other state-sanctioned means, and programs vary state to state.

Patient advocacy groups such as CancerCare, the Leukemia & Lymphoma Society, and others, may provide counseling, support groups, education, and financial assistance, including copayment assistance, to patients suffering from specific diseases. Other patient advocacy groups, such as Caring Voice Coalition and the National Organization for Rare Disorders, provide such services for a range of supported diseases, including orphan diseases. Assistance with paying insurance premiums may or may not be available, depending upon the organization's policies and mission.

Disease-based assistance programs help with costs associated with care for specific diseases or types of diseases. They may cover many types of expenses, including drugs, insurance copayments, office visits, transportation, nutritional supplements, medical supplies, and child or respite care. Some assist patients with one specific disease, such as Hodgkin's Lymphoma or kidney disease, while others assist patients within broader therapeutic areas, such as a Breast Cancer Fund covering all forms of breast cancer, or an Autoimmune Disease Fund that could cover Rheumatoid Arthritis, Psoriasis and Psoriatic Arthritis under the same umbrella. Typically funded by either private or government organizations, some of these programs are national in scope, while others are limited to people in specific states.

*It's not enough
to just get by—
people deserve
a chance to
get better.*

Charitable copayment assistance organizations, including the HealthWell Foundation, The Assistance Fund, and others, focus solely on copayment assistance for a variety of disease treatments. These organizations (sometimes called Charitable Patient Assistance Programs, or Charitable PAPs) have the necessary infrastructure and expertise to fully manage assistance programs and to carefully comply with applicable federal laws. By working with a charitable copayment assistance organization, you will have a true partner to assist you in your efforts to improve access to treatments for a wide variety of individuals. The advantages of partnering with a charitable copayment assistance organization like HealthWell are described on the following page.

Jennifer C. reacted quickly when she came home to find her husband Dan with a huge gash in the back of his head after falling in the bathroom. After rushing Dan to the hospital, the couple found out that Dan had anaplastic astrocytoma—an aggressive form of brain cancer.

After a right craniotomy to remove a large frontal tumor, three weeks of hospitalization, seizures and a stroke, Dan was left legally blind as he started a 30-session radiation/chemotherapy regimen.

“I had been laid off from my job the month before and was on unemployment,” said Jennifer, noting that taking care of Dan and their two young children quickly became a full-time job.

Dan’s short-term disability and FMLA coverage ended three months after his

hospitalization, so the family turned to an expensive COBRA policy, and long-term disability insurance, which paid about 60 percent of Dan’s former salary. Soon, the family’s living and medical expenses began to skyrocket.

It was at this time that HealthWell, as it has done for others facing a devastating chronic illness, stepped in to help through its Health Access Fund.

The Health Access Fund provided a financial safety net for the family to pay its \$13,000 insurance premiums over an 8-month period, until Dan succumbed to his disease slightly less than a year after diagnosis.

Thanks to the generous support of HealthWell, Jennifer and Dan were able to focus less on their financial difficulties and more on each other, their families and other loved ones during Dan’s final year.

Working with a Copayment Foundation: Advantages for Donors

Pharmaceutical manufacturers can realize multiple benefits from contributing to a tax-exempt charitable copayment assistance organization (Charitable PAP) that operates a patient assistance program. **Indeed, the Charitable PAP model offers significant advantages over other models, including direct-to-patient manufacturer discounts or rebates.**

Contributions to Charitable PAPs are generally tax deductible, and charitable contributions to those organizations tend to generate positive publicity for donors. Charitable PAPs also consolidate administrative functions that might otherwise be duplicated across several manufacturers. Moreover, the interposition of a properly structured and operated Charitable PAP between the donor (manufacturer) and recipient (patient) allows a manufacturer to provide aid to federal health care program beneficiaries (including Medicare program beneficiaries in the Part D “donut hole”), while avoiding allegations of improper beneficiary inducement or kickback schemes.

Charitable PAPs must be carefully structured and operated in compliance with applicable legal requirements of the Social Security Act (the Act). For example, Section 1128A(a)(5) of the Act establishes civil monetary penalties for inappropriate inducement of beneficiaries of a federal health care program (Federal Program Beneficiary). If a grant of financial assistance is awarded by a Charitable PAP to a Federal Program Beneficiary, and the donor knows or should know that the grant is likely to influence such beneficiary’s selection of a particular manufacturer’s product, then the government could conclude that prohibited beneficiary inducement has occurred. In addition, Section 1128B(b) of the Act (the Anti-kickback Statute) attaches criminal penalties to the knowing and willful offer, payment, solicitation, or receipt of any remuneration if the intent is to induce or reward referrals of items that are reimbursable by a federal health care program.

In various advisory opinion letters, the Department of Health and Human Services, Office of the Inspector General (OIG) has provided a roadmap for the structure and operation of an independent charitable copayment assistance organization that, if followed, assuages concerns regarding Federal Program Beneficiary inducement and the Anti-kickback Statute. **In short, the interposition of an independent, bona fide charitable copayment assistance organization between the donor and the Federal Program Beneficiary is an important starting point in order to avoid violations of the relevant prohibitions.**

The relationship between a Charitable PAP and its donors must be such that no donor exerts direct or indirect control over the organization’s decision-making process regarding grants of financial assistance. The Charitable PAP’s grants of financial assistance must be made in an independent manner that severs the link between the donor and the Federal Program Beneficiary.

In that regard, Charitable PAPs should make such grants based on reasonable, verifiable and uniform criteria. In practice, this means that a Charitable PAP’s grants of financial assistance are typically based solely on financial need, and awarded on a first-come, first-served basis. Patients usually have first consulted with a physician and have decided on a course of treatment prior to applying to the Charitable PAP for assistance, which helps to further insulate donors from violation of prohibitions against Federal Program Beneficiary inducement.

Additionally, the data provided to donors must not include detail that would allow them to determine the correlation between the amount and frequency of donations and the frequency with which Federal Program Beneficiaries utilize assistance from the Charitable PAP to aid in the purchase of donors' products.

The OIG has permitted arrangements under which Charitable PAPs may maintain individual charitable disease funds (so-called Medicare access funds) to which manufacturers may earmark donations and from which grants can be made solely to qualified Medicare beneficiaries with specific diseases covered by those funds. The OIG has indicated that those Medicare access funds should be defined in accordance with widely recognized clinical standards, and in a manner that covers within each such fund a broad spectrum of available products.

The OIG has made clear that Medicare access funds should extend financial assistance only in connection with disease states for which at least two different products from two different manufacturers are supported by the fund, and views any deviation from that as potentially implicating the Anti-kickback Statute. Thus, single-product or single manufacturer disease state Medicare access funds would likely be viewed by the OIG as problematic under the Anti-kickback Statute and should be avoided because they could steer Medicare beneficiaries to particular products based on the availability of a subsidy.

Prior to providing support, donors should do their due diligence and closely scrutinize a Charitable PAP's operations and finances to be assured that the organization's resources are focused on its charitable mission, and not unnecessarily concentrated in support of administrative or other purposes. In that regard, much can be learned from the organization's IRS Form 990 (Return of Organization Exempt from Income Tax), which is required to be filed by each tax-exempt organization and be made available to the public. Form 990 contains a number of questions designed to identify business arrangements that are likely to lead to conflicts of interest or to a private party improperly receiving financial gain from a tax-exempt entity. For example, one question asks whether the organization was "party to any business transaction with an entity of which a current or former officer, director, trustee or key employee (or family member thereof) was an officer, director, trustee or indirect owner." Responses to questions such as this can reveal whether the organization is party to potentially inappropriate arrangements that could result in revenues being diverted for inappropriate and/or non-exempt purposes. Also, Form 990 requires that the organization disclose the following information, the review of which can be helpful in the due diligence process: (i) its ratio of revenue to expenses; (ii) its program service revenue; (iii) the benefits it pays to or for members; (iv) its selection criteria for awarding assistance; and (v) the compensation it pays to officers, directors, trustees, key employees, highest compensated employees and independent contractors.

Finally, such due diligence should necessarily include a determination of whether the Charitable PAP operates under the auspices of an OIG advisory opinion, and whether it is in compliance with that letter. An organization's receipt of such an opinion offers additional security to donors in the form of clearly established guidelines that serve as a virtual safe harbor.

Robert D. Clark, Esq.
OberKaler Attorneys at Law

The HealthWell Foundation Difference

Who Receives Assistance?

HealthWell Foundation grants are designed to support proper disease management and to improve patient outcomes by helping patients afford the treatments prescribed by their physician. HealthWell manages funds across a broad spectrum of disease areas and requires the same general eligibility requirements for all of these funds.

The HealthWell Foundation disburses grants to patients on a first-come, first-served basis. HealthWell considers an individual's financial, medical, and insurance status when determining who is eligible for assistance. Financial criteria are based upon household income, adjusted for family size and geographic factors affecting cost of living. Families with incomes up to 400 percent of the federal poverty level may qualify. HealthWell also considers the cost of living in a particular city or state. Patients must have some form of health insurance (major medical or prescription drug through private insurance, Medicare or Medicaid) that covers part of their treatment.

HealthWell is able to help patients receive treatment, in the U.S. only, for a wide variety of indications and only with FDA-approved or compendia-listed medications that have been prescribed to treat the diagnosis or condition for which an assistance fund is established. Patients are free to change physicians, pharmacies or medications at any time without risk of jeopardizing their eligibility for assistance from HealthWell. Patients are never directed to specific pharmacies or therapies. HealthWell also assists people with their health insurance premiums in certain situations, so they can keep their insurance.

HealthWell manages a diverse portfolio of funds and whenever possible adds new disease funds throughout the year. For a list of current disease funds, visit: www.HealthWellFoundation.org. **When HealthWell can't help patients directly, it will refer them to other programs, including pharmaceutical manufacturer patient assistance programs and other foundations and resources.**

The HealthWell Foundation Impact:

150,000+ patients helped to date
\$144+ million in grants awarded in 2011

\$700+ million in copayment assistance
awarded since inception in 2003.

Medicare Access Funds

For donors seeking to provide assistance to Medicare patients only, the **HealthWell Foundation is currently the only patient assistance organization to receive an OIG modification specifically allowing for Medicare Access Funds, which extend financial assistance to patients with funded disease silos that offer at least two different products from two different manufacturers.** This safeguard ensures that HealthWell's Medicare Access Funds are not established for single-product or single-manufacturer disease states, even in rare instances, and thus significantly reduces the likelihood that earmarked donations would effectively steer Medicare beneficiaries to particular products based upon the availability of a subsidy—keeping HealthWell, and its donors, in compliance with the Anti-kickback Statute. Historically, approximately 65 percent of HealthWell grants have been issued to Medicare patients.

HealthWell donors have the option of directing their donation to support treatment for a particular disease state through Traditional Funds (Medicare/Commercial combined), the Medicare Access Funds (Medicare only), or both.

Pediatric Assistance Fund

HealthWell established its Pediatric Assistance Fund to help families of underinsured children gain access to critical medications. The HealthWell Pediatric Assistance Fund® allows the Foundation to help children receive life-saving medications **regardless of diagnosis or condition.** By removing the constraints of funding specific diseases or conditions, HealthWell can now provide greater access to therapy for patients under the age of 18 whose families are struggling to afford medications for a chronic or life-altering illness. To be eligible, patients' families will still need to meet HealthWell's income and insurance eligibility criteria.

Health Access Fund

HealthWell has also established a Health Access Fund in response to the growing number of requests it receives from patients fighting chronic or life-altering medical conditions and who simply can't afford their treatments and have nowhere else to turn. This is an unrestricted fund that allows HealthWell to assist patients in special circumstances who desperately need help with the cost of health care, regardless of their particular disease or condition. **Contributions to this fund will allow HealthWell to provide a safety net for patients that it would previously have been forced to turn away.** These patients have almost always exhausted all other avenues and often do not qualify for other patient assistance programs or manufacturer programs. All special exception cases are funded through the Health Access Fund.

Did you know?

24 percent of children aged 17 and under are living in a family that has had trouble paying their medical bills in the past year.⁹

A Provider's Perspective

Over the last five years, we have seen an ever-increasing role for copayment assistance in our clinical practice. **Up to 90 percent of our patients are challenged to cover their copayments, and that includes patients who are employed in stable jobs.**

In California, the few private insurers remaining have shifted their standard benefit plans to coinsurance for specialty pharmaceuticals and biologicals such that a larger portion of drug costs are borne directly by patients. For two recent patients in my practice, that translated into an \$800-a-month copayment—or almost \$10,000 a year for one drug; a drug that was actually covered by their insurance plan. As a result, some patients are asking to return to therapies that do not work as well but are more acceptable to them financially.

Compounding the problem for patients even further, insurance premiums and employee contributions to health insurance premiums have continued to increase.³

Knowledge of charitable copayment assistance organizations can be important for patients as they make decisions with their physician about a treatment plan they can live with medically and financially. Unfortunately, awareness of assistance options among patients is low. That's why it's so important for providers to initiate the conversation and act as advocates for their patients.

Consider the following real-life scenarios from our practice:

One of our patients suffered from long-standing erosive, nodular Rheumatoid Arthritis. This disabled airline flight attendant's disease was controlled on TNF blockers, but her copay for the drug increased to a level that she was not able to afford. She faced the options of either stopping or stretching out a therapy that was working, which would cause a "flare" of her painful inflammatory arthritis. She was able to secure a grant from the HealthWell Foundation that allowed her to continue an effective therapy.

Another patient has Systemic Lupus Erythematosus (SLE) and is on Medicare. The patient's secondary insurance changed to no longer cover medications, and she had missed the time to enroll in Medicare Drug coverage. She was dependent on steroids, and was a candidate for the newly FDA-approved medication for SLE typically covered under major medical. However, the medication was expensive. She was able to apply online and receive approval for a grant from HealthWell. This allowed her to schedule her first infusion.

Nancy L. Carteron, MD, FACR

Rheumatology and Autoimmune Disease Specialist

Associate Clinical Professor

University of California, San Francisco

HealthWell Foundation Board Member

Donating to a HealthWell Fund

Donating to HealthWell to help patients in need has never been easier, or more rewarding. Often, this process is initiated through a Request for Information (RFI) from a pharmaceutical manufacturer or through less formal networking between prospective donors and HealthWell. Starting from the time HealthWell receives an initial RFI, it will develop a customized approach to quickly meet the needs of the unique process you use to make patient assistance fund donations. HealthWell's legal counsel will work directly with yours to craft a mutually acceptable agreement.

Donations directed to disease state funds are allocated to those disease-specific funds to cover patient grants and services. When HealthWell launches a new fund, it works closely with physician members of its Board of Directors, an independent consultant and donors to establish an appropriate initial grant amount and to determine a limit to grants issued for the fund. The HealthWell Foundation is solely responsible for the final determination as to which funds are established; but it does solicit guidance from manufacturers, donors and independent sources to make the most informed and reasonable determinations. Information reviewed during the determination process includes a breakdown of payor mix for the proposed fund, estimated out-of-pocket cost per patient, and route of administration of the products for which the fund will provide grants.

When HealthWell establishes a new fund to cover a particular disease or condition, it identifies key national patient advocacy organizations and medical specialty societies that are able to reach out to patients and specialists to expand the reach of the fund. HealthWell invites these organizations to educate patients and physicians about the fund by posting a link to the HealthWell Foundation's website or including information about HealthWell's services in their written and online materials. HealthWell also issues a news release to the media to alert the broader health care and patient community.

New funds are simultaneously announced on the HealthWell Foundation website, which has become a respected reference for the community of medical specialists and social service professionals advocating for patients in need of financial assistance for treatments. Additionally, funds are announced in the HealthWell Foundation e-newsletter, with an audience of 30,000, driving more patients and providers to the newly opened fund.

Upon launch, HealthWell begins collecting data regarding actual utilization of grants by patients. After a full year of fund activity has passed, HealthWell revisits the initial grant amount and cap amount, adjusting these to optimize the use of resources entrusted to HealthWell. Typically, 75-85 percent of patients are fully served with their initial grant amount, but reserves exist to cover reimbursement requests over the initial grant amount.

Patients are encouraged to use their grant at least once every 60 days to avoid having the grant closed. Should a patient fail to use his or her grant, it is closed on or around day 90, and the monies are returned to that particular grant's fund so that they can be awarded to other qualified applicants.

HealthWell has relationships with more than 17,000 providers and pharmacies that directly bill HealthWell for treatments dispensed to patients. Through HealthWell, grant recipients and providers may benefit from this network as patients may not have to pay out-of-pocket expenses themselves and then seek reimbursement from HealthWell. Rather, HealthWell can often pay the provider or pharmacy directly to avoid confusion in claims and reimbursement processing, and to limit the risk of payments not reaching the medical provider or pharmacy. This direct bill process also, and most importantly, speeds patient access to medications.

Donor Reports

The HealthWell Foundation provides transparency in its operations for its donors. It keeps all of its donors fully informed of the status of their funds through monthly fund and program reports, quarterly newsletters, annual financial audit results and annual program audit results. While the law precludes donors from receiving information about the actual utilization by recipients of their own products, individual donors will receive information about:

- Funding levels (including notification of when funding begins to run out)
- Critical threshold warnings
- Application approvals by state
- Monthly call volume
- Referral sources
- Number of applications received
- Source of applications received
- Reasons for applications pending
- Number of approved patients per month, including total grant amount allocated
- Number and reasons for denials each month
- Number and average of payments made
- Total granted
- Total paid overall for the fund
- Funds that remain available for allocation

Community Outreach

Increasing positive health outcomes requires collaboration with others. HealthWell has relationships with numerous patient advocacy groups, health care organizations and medical specialty societies to promote national health observances, disseminate and exchange information and cross-refer patients.

HealthWell proactively reaches out to physician, nurse and social work organizations to educate their patients/members about copayment assistance and to help them through the application process. HealthWell also regularly disseminates patient resource materials to provider offices and pharmacies to encourage a dialogue between patients and their providers and pharmacists about copayment assistance and resources available from HealthWell.

Additionally, HealthWell supports research dedicated to helping policy makers and clinicians better understand the needs of the millions of Americans who are underinsured. The HealthWell Foundation sponsors two-year career development awards in health care policy research. It supports research addressing key issues involved in facilitating access to care for the underinsured, including cost of care, financial need and financial impact of illness, health consequences of access or lack of access, and adherence. Funding for research is established through HealthWell's administrative budget and not from donations received to support patient grants. Consistent with its mission, this funding allows HealthWell to expand its ability to make a difference for patients now and in the future, without impacting the support directly provided to patients in need.

Using Technology to Help Others

One of the reasons the HealthWell Foundation is able to assist so many people is its efficient use of technology that helps to streamline patient applications and processing. Patients may apply for assistance online, and patients and providers alike have 24/7 access to secure, online portals and a toll-free automated telephone system to manage all aspects of their grants and payments. HealthWell's Customer Service phone lines are fully staffed and open from 9:00 a.m. to 5:00 p.m., Monday through Friday, Eastern Time.

HealthWell's dual monitor system for customer service specialists allows them to have two programs running and viewable simultaneously. They can alternate between programs with a simple mouse click, thus adding flexibility, increasing efficiency, and helping HealthWell to be a "paperless" environment by eliminating the need to print documents. **HealthWell has also invested in a robust fraud detection system to bolster our responsible stewardship of donated dollars.**

Transparency and Compliance

As a charitable copayment assistance organization, HealthWell operates within a complex regulatory framework. The Office of Inspector General (OIG) has issued to HealthWell its own, direct, favorable Advisory Opinion to operate a copayment assistance program. That Advisory Opinion (#07-06) was modified in September 2011 to allow HealthWell to establish Medicare Access Funds to provide assistance only to qualified Medicare beneficiaries with specified disease states.

HealthWell's annual reports, OIG Advisory Opinion, and IRS 990 tax forms are available for public review at www.HealthWellFoundation.org

HealthWell makes its determinations of patient eligibility and pre-approval the same day it receives an application.

Under applicable law and regulations governing the structure and operations of copayment assistance organizations and programs as interpreted from the OIG, HealthWell may not disclose the identity of its donors. Moreover, the HealthWell Foundation does not refer or recommend to patients a particular provider, supplier or product. These policies ensure that HealthWell is able to operate independently and in the best interest of its patients while also complying with applicable law.

Reducing the Patient Burden

To the extent feasible, HealthWell furnishes assistance to the physician, supplier or insurer on behalf of the patient. Allowing providers and patient advocates to apply on behalf of patients (with their permission), and automatically forwarding patient documentation to providers, takes much of the “paperwork” burden off of an already burdened patient. If assistance is furnished directly to the patient, HealthWell requires proof from the patient that such assistance was used to satisfy qualifying expenses.

Governance

The HealthWell Foundation is governed by an independent Board of Directors that includes respected professionals with deep experience in the fields of health care administration, clinical practice and research, direct patient care, patient advocacy and health law. No member of its governing body is employed by a program donor, and HealthWell is regularly audited to ensure that it remains in compliance with applicable laws, regulations and standards as well as its own policies and procedures.

Accolades and Recognition

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**, which means that 100% of donor dollars go directly to patient grants and services.

In 2011, HealthWell was recognized by *Forbes* as one of America’s 20 most efficient charities and one of only 18 charities nationwide—plus the only charitable copayment assistance organization—to receive a 100 percent fundraising efficiency rating.¹⁰ The rankings are part of *Forbes’* annual list of America’s 200 Largest Charities, which includes HealthWell for the fourth year in a row. The Foundation also ranks in the top 250 on *The Chronicle of Philanthropy’s* annual “Philanthropy 400” list of 400 charities that raise the most money from private sources. HealthWell is listed in the Better Business Bureau National Wise Giving Guide and is a GuideStar Exchange Valued Partner.

“We consistently see the difference provider involvement can make in starting the pre-approval process and completing the process to full grant approval: more patients get approved without delay and begin using their grants immediately when the provider is directly involved in the process from the beginning.”

Krista Zodet
Vice President
HealthWell Foundation

100%
of donor dollars
go directly to
patient grants
and services.

Why HealthWell Needs You

A strong, reliable and diverse donor base is required to enable HealthWell to influence positive health outcomes in the United States. The HealthWell Foundation is fortunate to receive donations from more than 15,000 individual donors—many of whom are the very patients and families it helps. But those donations are not enough. **Demand for HealthWell’s services is continually increasing and shows no signs of slowing.**

Your generous support is crucial and very much appreciated by HealthWell, and, more importantly, by those it serves: America’s underinsured.

Not sure how and where to start? Contact the HealthWell Foundation. In addition to advising you on how funds are established at HealthWell, the Foundation can help point you in the direction of other charitable copayment assistance organizations that may be a good match for you.

Are you about to bring a new therapy to market? This is a great time to explore the inclusion of copayment assistance through a charitable organization, like HealthWell, into your business plan.

Are you looking to improve patient access to an existing therapy on the market? It may be possible to start a new fund with HealthWell. HealthWell may be able to help you reach this goal through copayment assistance.

This year, consider donating to more than one HealthWell fund. Support the Pediatric Assistance Fund or the safety net Health Access Fund. Or help HealthWell launch a new disease fund. Institute a workplace/employee giving program. Making these commitments means you are not only improving health outcomes, but you are allowing more people to have access to the latest and most advanced therapies that they are not otherwise able to afford.

Your research investments are bringing rapidly evolving, targeted therapeutics to market and are offering real solutions to those suffering from painful and debilitating illnesses. With your support, we can see that a much broader segment of insured Americans can access proven, gold-standard therapies, as well as recently approved and emerging therapies.

It’s never been easier to get started. Visit the HealthWell Foundation at www.HealthWellFoundation.org or call 240-632-5300.

Join us—and make a difference in so many lives.

We will receive another 20,000 requests for assistance this month alone.

Evaluating Copayment Assistance Organizations: Checklist

You've made the decision to support a charitable copayment assistance organization or you are examining the possibility of providing support. To help you choose the best organization for your philanthropy, be sure to address the following as part of your due diligence:

- How long has the organization been in existence? Is the organization financially stable?
- Request a copy of the organization's OIG opinion. This is the roadmap the organization should be following and can give you the assurance that the organization is complying with the law. Does the organization have its own OIG opinion, or is it relying upon another's?
- Request copies of the organization's IRS Forms 990 for the past 3-5 years. Is the organization being operated as a bona-fide 501(c)(3)? The 990 provides a quick glance at how much the organization receives in revenue and how much it, in turn, spends on administrative and fund-raising fees and how much it spends on patient grants. It also provides a record of whether the organization is operating under the management and operating restrictions imposed on non-profit organizations.
- Does the organization undergo regular, independent audits? How are issues raised in such audits addressed by the organization? Request copies of compliance audits to make sure the organization is adhering to applicable requirements and restrictions.
- Look at how much the organization spends on technology compared with the size of its funds.
- Check the percentage of donor dollars spent on staff and executive compensation as well as administrative and fundraising fees. How does the organization define these fees in relation to operational fees and patient grants?
- Does the organization engage in for-profit activities? Do the organization's executives or board members, or the for-profit organizations with which they are involved, maintain separate consulting or other business relationships with the organization or its donor companies? If such is the case, those relationships should be closely scrutinized.
- Does the organization have disease funds that only provide assistance for one product? This may be problematic under applicable OIG interpretation of the Anti-kickback Statute, particularly if the fund is limited to Medicare patients.
- What is the process the organization uses to define its funds?
- Does the organization offer premium assistance to help patients keep their insurance? Not all do.
- How long does it take the organization to start a fund program?
- Is there a minimum donation?
- What type of reporting does the organization provide to its donors? Are these reports fully transparent and do they account for all costs?
- What type of products do the organization's programs cover?
- What are the eligibility criteria for patients? Are they consistent across all funds?

Appendix A

Charitable Copayment Assistance Organizations

- CancerCare (www.cancercarecopay.org)
- Caring Voice Coalition (www.caringvoice.org)
- Chronic Disease Fund (www.cdfund.org)
- HealthWell Foundation (www.HealthWellFoundation.org)
- Leukemia & Lymphoma Society (www.lls.org)
- National Organization for Rare Disorders (www.rarediseases.org)
- Patient Services, Inc. (www.patientservicesinc.org)
- Patient Advocate Foundation (www.patientadvocate.org)
- Patient Access Network Foundation (www.panfoundation.org)
- The Assistance Fund (<http://theassistancefund.org>)

Appendix B

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