

A GUIDE TO PATIENT ASSISTANCE PROGRAMS:



*What you need to know to Promote patient advocacy
and Maximize charitable contributions.*



Chronic Disease Fund, Inc.TM

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Summary

Foreword — Why this Guide is so Important!

Every pharmaceutical manufacturer in the United States should contemplate the value of patient assistance programs (PAPs). If you haven't, then you have missed one of the most significant opportunities to assist patients, promote patient advocacy, and potentially increase revenues for your organization.

Manufacturers have significantly improved the health of individuals around the world and increased life expectancy. The industry remains at the forefront of advancing healthcare through innovative pharmaceutical development and drug delivery technology. However, manufacturers can do everything right from developing break-through drug therapies, to providing access through managed care, to creating comprehensive marketing programs, but still not reach over 35% of patients who cannot afford the copay associated with their prescription drug plans. The number of patients who cannot afford copays increased in 2006 with the introduction of the Medicare Part D prescription drug plan.

For years, pharmaceutical manufacturers have looked at PAPs the same way. They either view these programs as lost dollars to the organization or the best means possible to promote corporate image. As long as manufacturers continue to view philanthropy as a line item expense fewer dollars will be available to assist patients in need. Since the need increases year after year, we must design a compelling solution to increase contributions or continue losing an increasingly significant portion of the patient population to underinsured patients who cannot afford their copay.

This Guide will provide an overview of PAPs, the legal issues that impact them, and insight into value-added program design. More importantly, the Guide will describe why traditional PAPs are inefficient and provide the tools necessary to analyze and compare programs within the industry.

Section 1 — An Introduction to Patient Assistance Programs

Patient assistance programs (PAPs) have been around for years. These programs fall into 2 distinct categories: 1. Free Drug Programs, and 2. Patient Financial Assistance Programs. They are administered by three types of organizations; Manufacturer Foundations, Third Party Organizations, and Charitable Organizations.

Free Drug Programs

There are traditionally two types of free drug programs, those maintained in-house (manufacturer foundations) and those outsourced to a third party organization. Free drug programs are designed for uninsured patients who typically meet a multiple of the poverty level. Underinsured patients who cannot afford the copay associated with the prescription drug coverage may also be included in free drug programs. Prior to receiving free drug exhaustive efforts are made to find alternative prescription drug coverage for patients so that they can either afford their copay or be referred to a Copay Assistance Program.

Patient Financial Assistance Programs

Patient financial assistance programs are often referred to as “Copay assistance programs” or “Underinsured Programs.” In these programs, insurance verification is conducted to determine the patient’s out-of-pocket costs and copay. Patients typically pay their copay and submit their bills for reimbursement. Patient financial assistance programs tend to be managed by Charitable Organizations.

Patient Premium Assistance Programs

Patient premium assistance programs are for uninsured patients that may qualify for both commercial and government prescription insurance programs, but who cannot afford the premium costs associated with the plans. Premium Assistance programs also tend to be run by Charitable Organizations.

Manufacturer Foundations

Manufacturer foundations are fully staffed and housed within the organization. They maintain patient outreach programs in order to get these drugs to patients who need them. Distribution of these drugs to patients is often unremarkable, but can become complicated and expensive especially when determining insurance benefits and alternative sources of funding. The manufacturer foundation is an inefficient model and can cost far more to implement and manage than the drugs that are given away.

Third Party Organizations (TPO)

Third party organizations are typically for-profit organizations that provide a range of services to manufacturers including the administering of free drug programs as well as providing patient financial assistance. The larger of these organizations are full service models that address clinical trials, marketing, research, data analysis, and a host of other services. They clearly maintain significant corporate overhead and infrastructure that is calculated in the cost of program administration.

Charitable Organizations (CO)

Charitable organizations are tax-exempt 501(c)(3) organizations that are established to provide a host of services to patients. The most sophisticated tend to raise money to promote research such as the American Heart Association, the American Cancer Society, and the National Multiple Sclerosis Society. Service organizations specialize in providing specific services such as insurance overruns and alternative funding while others focus on providing financial assistance. For the purpose of discussion, we are only focusing on charitable organizations that specialize in providing financial assistance to patients as they tend to be the largest of these organizations. Charitable Organizations achieve economies of scale by providing financial assistance for multiple disease states funded by multiple manufacturers.

Section 2 — Legal Issues

This Section will provide you with a simple, straight-forward analysis of the specific issues surrounding PAPs.

This is not intended to be a legal opinion.

Determining which laws impact the provider of PAPs depends upon the type of organization. If the organization is a TPO then the OIG Guidelines are the most relevant. If the organization is a charity then IRS and OIG Guidelines are equally relevant.

IRS Guidelines

Tax exempt organizations are required to follow very specific rules and regulations. Before a charity receives its tax-exempt status, it must give the IRS a detailed description of the services it intends to provide. In describing the purpose, the charity outlines the specific services as well as the distribution and delivery of such services. Most importantly a PAP must not exhibit the characteristics of a marketing program. The charity must take all patients on a first-come, first-served basis and not prejudice patients based upon product, provider, etc. To comply with these requirements, the charity must set up written guidelines for patient acceptance that are specific and equally applied to each patient seeking assistance regardless of product or provider.

OIG Guidelines

The OIG guidelines are the most complex. The two most relevant statutes surrounding PAPs are the Anti-kickback and Stark Laws.

Anti-kickback

The federal law is a criminal statute that prohibits providers from accepting “remuneration” directly or indirectly for referrals of Medicare or Medicaid patients. The law was enacted due to providers referring patients to facilities in which the provider has a financial interest. The anti-kickback provisions apply most appropriately to physicians, pharmacies, and manufacturers. Since Charitable Organizations literally own themselves (no shareholders), there is no financial interest incentive for any provider. Further, since no payments are made for referrals there is no incentive. More importantly, in a properly designed PAP, the patient has selected a doctor and comes to the CO with a prescription in hand seeking assistance. Therefore, no inducement can exist.

Stark Laws

The Stark Law, Amendments I and II, is a civil statute similar to the anti-kickback law that prohibits physicians from referring Medicare and Medicaid patients for certain laboratory services and other types of services known as “designated health services” for which the physician has a financial interest. The financial interest includes an ownership interest or a compensation arrangement, regardless of whether the physician is giving or receiving compensation. Again, since Charitable organizations own themselves and there are no payments made to providers, there is no financial interest incentive.

Medicare Part D

Perhaps the most commonly asked question is whether a CO can provide financial assistance to Medicare Part D recipients. The OIG has issued guidance concerning Part D under a Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees (November 2005). Since the OIG published the Industry Guidance several Advisory Opinions have been approved for both Manufacturer Free Drug programs and Charitable copay and premium assistance programs.

Simply put, independent Charitable Organizations are permitted to provide financial assistance to Medicare Part D recipients. Specifically, under Part II of the Bulletin the OIG distinguishes between A. Pharmaceutical Manufacturer PAPs and B. Independent Charity PAPs. Whereas pharmaceutical manufacturer controlled PAPs are cautioned that assistance provided to Part D recipients would implicate the Anti-kickback Statute, assistance provided through independent charities would not. The emphasis is placed on whether or not a CO is truly independent. The Bulletin provides 5 criteria that define independence:

- 1** The manufacturer or any affiliate can not exert any direct or indirect control over the CO or the subsidy program;
- 2** The CO must award assistance in a truly independent manner and not link the manufacturer’s assistance to the beneficiary;
- 3** The CO must award assistance without regard to the manufacturer’s interest or the beneficiary’s choice of product, provider, practitioner, supplier, or Part D drug program;
- 4** The CO must award assistance based upon reasonable, verifiable, and uniform measure of financial need that is applied consistently; and
- 5** The manufacturer does not solicit or receive data from the charity that would correlate the amount or frequency of its donations to the number of subsidized prescriptions for its products.

The industry guidance was further clarified by the issuance of OIG Opinions 06-13, 06-10, and 06-04 for charitable organizations and 06-14 and 06-03 for manufacturer free drug programs.

In short, independent Charitable Organizations provide the safest means in providing financial assistance to underinsured patients.

Section 3 — Program Design

Proper program design ensures compliance with IRS and OIG Guidelines. It also enables the PAP to create the most effective and efficient model for delivering assistance to patients. There are several essential criteria associated with proper design. We will discuss the most relevant here.

Household Income

The PAP's financial guidelines should be proprietary. It is essential that donors do not participate in the design or determination of patient financial acceptance criteria to avoid scrutiny. Moreover, in order to ensure non-discriminatory and compliant criteria, the PAP should base their household income thresholds based upon public data such as Poverty Level or Median Income. Further, the criteria and the appropriate calculations should be clearly written into a formal document so that they can withstand IRS and OIG inspection.

Patient Applications & Patient Approval

The application and the application process must be simple, fast, and readily available to any patient seeking assistance. The longer it takes for applications to be received and the more complex the application, the more confusing the process becomes. Understand that patients may have spoken to several different organizations prior to finding a PAP that may be able to provide assistance. In short, simpler applications and faster turnaround times yield better programs.

Patient Support

Patient support is critical to any PAP. Patients must be able to immediately access customer service. Since patients diagnosed with chronic disease have many questions and concerns a clear and concise process must exist to handle inquiries. Patients should be provided with contact information and supporting material so that they can get information quickly and easily. Using a value-added approach to PAPs ensures the greatest patient satisfaction. The two most important value-added benefits to increasing patient satisfaction are therapy management and specialty pharmacy.

Therapy Management

Patients diagnosed with chronic or life-altering disease need assistance in managing their disease. They need to be able to track their symptoms, measure their health over time, and become pro-active with their treatment. A compliance and persistence program offering the ability to track and measure patient health and disease progression is essential in proper PAP design.

Specialty Pharmacy

All specialty therapeutics should be exclusively dispensed through specialty pharmacy. Due to the complex nature of specialty therapeutics, patients need the support offered by the specialty pharmacy through their patient education and clinical support programs. PAPs using a value-added approach will find specialty pharmacy essential in increasing patient compliance and increasing patient satisfaction. The preference of specialty pharmacy among PAPs will continue to be a key component of a properly designed PAP.

Organizational Focus

Often overlooked, the focus of the organization directly determines how efficient the organization will be in providing assistance. Most organizations whether they are TPOs or COs can be divided into transactional models or high-touch models. High-touch models require significant human resources to counsel patients, find insurance and fund premiums, and provide emotional support. Transactional models specialize in providing copay assistance. It is essential that manufacturers understand the focus of organizations to ensure that patients receive the greatest benefit from donations.

Properly designing a PAP increases its success. There are varying approaches to proper design based upon the specialty or focus of the organization providing the program. It is essential that manufacturers who utilize PAPs select both the type of organization and the PAP model for each product they intend on supporting.

Section 4 — Why Traditional Patient Assistance Models Don't Work

The primary reason for lack of PAP effectiveness is that program performance was never intended to be measured or provide a return. In every area of business we consider financial margin. However, until now, no one has considered measuring the performance of philanthropic behavior. This tends to go against the very nature of charitable giving. Why? Donors have been conditioned to believe that charitable giving is its own reward. Not so. The true reward is funding organizations that maximize benefits to patients.

The reality today is that there are not enough charitable donations to PAPs to cover every patient in need. This is completely reasonable given the current understanding and practices of TPOs and COs. We must refocus our efforts in designing the most cost effective and efficient models for delivering patient assistance. Year over year, the financial needs of patients grow and yet the delivery of patient assistance programs remains inefficient.

In order to effect change, we must examine the cost to administrate PAPs. TPOs are in the business of making profit; although the purpose is charitable their interests are financial. As such, they can invest in infrastructure and human resources and pass the cost plus their profit margin on to the donor.

Charitable organizations on the other hand are in the business of providing assistance. Since they tend to be under-utilized they tend to be under-funded. Therefore most charities do not have enough assets from charitable contributions to invest in improving operational efficiency and effectiveness in the delivery of PAPs. Most Charitable Organizations that are well funded are poorly designed to effectively provide patient financial assistance.

The key to developing an efficient program is to only pay for the services that are essential and avoid paying for services that are duplicative or can be done more efficiently elsewhere. The best example of this is insurance verification. Whether you employ a TPO or CO, neither can legally dispense drugs. As such, when the patient attempts to fill their prescription the pharmacy must re-verify the insurance to determine their ability to dispense under the plan and calculate the patient's copay. The cost of insurance verification is built into the pharmacy dispensing model yet some donors pay a TPO for this service

Section 5 — Measuring Performance

Measuring performance is essential in determining the efficiency and effectiveness of any program. PAPs are no different. We must stop believing that charity is its own reward. The true reward is providing patients who cannot afford medications the assistance they so desperately need. In order to achieve this end, we must be able to convince contributors that we are effective and efficient in using charitable grants. To evidence this we must be able to calculate and measure performance.

Measuring performance is most easily explained in analyzing chronic diseases that are being treated with expensive, specialty therapeutics. As such, we will measure performance using some of the same criteria used in effective marketing programs:

- 1 Compliance** — The amount of product taken as it relates to the recommended drug protocol.
- 2 Persistence** — The length of time a patient stays on therapy prior to discontinuing treatment.
- 3 Direct-to-Patient-Assistance (DTPA)** — The amount of dollars that go directly to patients compared to the administrative costs of the program.
- 4 Charitable Margin** — Measures the effectiveness of charitable contribution as a return on donations.
- 5 Revenue Multiple** — Measures the efficiency of charitable contributions by calculating revenues generated for all products in a program.
- 6 Tax-Advantaged Transaction** — Tax benefit of charitable contributions.

Compliance

Compliance varies with the cost of treatment, the method of drug administration, and the frequency of treatment. In analyzing the effect of compliance on revenue, let's examine a monthly treatment with a Wholesale Acquisition Cost (WAC) of \$1,000. If a patient were fully compliant, revenue from the product would be \$12,000. At 70% compliance, assuming no partial fills, the patient would have dispensed 8 times yielding total revenue of \$8,000. If you were able to drive compliance to 92% for this patient, you would increase revenue by 37.5%.

Persistence

Persistency significantly differs by therapy; therefore let us assume that a patient who is fully persistent will take a chronic therapy for life. Since companies are most concerned with market share, we will define persistency as the length of time a patient stays on a specific therapy. As such, if an average patient persistency is 20 months prior to dropping or switching therapy then a patient who stays on a specific therapy for 26 months will be defined as being 130% persistent.

Given compliance and persistence are directly correlated patients who exhibit higher compliance rates maintain higher persistency rates. Simply put, patients who take their prescriptions in accordance with the prescribed drug protocol realize the maximum benefit. The better the patient responds to therapy, the longer they tend to stay on therapy.

Direct-to-Patient-Assistance (DTPA)

Determining DTPA is not easy for a reason. Most TPOs or COs do not measure their financial performance using this criterion. When dealing with a TPO administering a free drug program DTPA is measured by the total cost it takes to provide the product to the patient. As such, your measure of effectiveness is simple to calculate by taking the total dollars paid for administration, plus the dispensing fees, mail costs, etc. as it compares to the next best quote.

Financial assistance programs make calculating DTPA quite simple. Just take the total dollars paid to patients for financial assistance and divide it by the total donations received.

Example:

Total Donations: \$10,000,000

Patient Assistance: \$8,000,000

DTPA Formula = $\$8,000,000 / \$10,000,000$

DTPA = 80%

In no event should DTPA fall below 80%. If it does, the model is inefficient!

Many organizations, be it TPOs or COs, will attempt to break out direct marketing dollars, insurance verification costs, dedicated human resources, etc. from administrative costs. This is absolutely unacceptable. Administration and marketing is an all-in cost. To calculate the cost of Administrative Overhead is simple:

Example:

Total Donations: \$10,000,000

Patient Assistance: (\$8,000,000)

Administrative Costs = \$2,000,000

Admin. Formula = $\$2,000,000 / \$10,000,000$

Admin. Overhead % = 20%

These financial calculations put all organizations on equal footing. Larger organizations should exhibit better DTPAs due to more efficient infrastructure costs spread across larger amounts of revenues and donations.

Charitable Margin

Charitable margin is merely a measure of the effective performance of assets dedicated to a charitable program. In order to better understand this we will use the chronic disease example illustrated above in the definition of Compliance and Persistence.

Assume that your organization donates \$10,000,000 to an underinsured patient financial assistance program to support the treatment of a specific disease state. Assume that the disease state contains four monthly therapies of which all maintain a WAC of \$1,000 and an equal market share of 25%. Therefore, if patients receive funding of \$125 copay per script in accordance with the current market share of the products and an average compliance of 70% we would calculate Charitable Margin as follows:

- 1 DTPA = 80%. $\$10,000,000 \times .8 = \$8,000,000$
- 2 Compliance = $70\% \times 12 \text{ dispenses/yr.} = 8.4 \text{ or } 8 \text{ dispenses/yr. (no partials)}$
- 3 Cost Per Patient = $\$125 \text{ copay} \times 8 = \$1,000$
- 4 Target New Patients = $\$8,000,000 / \$1,000 = 8,000 \text{ patients}$
- 5 Patients on Your Product = $8,000 \times 25\% \text{ market share} = 2,000 \text{ patients}$
- 6 Revenue Per Patient = $\$1,000 \text{ WAC} \times 8 \text{ dispenses/yr} = \$8,000/\text{patient}$
- 7 Total New Revenue = $2,000 \times \$8,000 = \$16,000,000 \text{ New Revenue}$
- 8 Charitable Margin = $(\$16,000,000 - \$10,000,000) / \$10,000,000 = 60\%$

In performing this analysis we clearly see the value of our charitable contributions. A 60% return on any investment is significant. However, because charitable contributions are tax-advantaged the returns are more significant.

Tax-Advantaged Transaction

Charitable contributions are a line item expense to reduce your income before taxes. Therefore, a \$10,000,000 contribution reduces your corporate tax exposure by your corporate tax rate. Using a 35% corporate tax rate, your \$10,000,000 charitable contribution provides you with \$3,500,000 of tax savings. Applying the 35% return to the Charitable Margin in the example above would increase the performance as follows: $1.35 \times 60\% = 81\%$ Return. In other words, to achieve the same return as your charitable patient financial assistance program you would need to run a pre-tax for-profit program with a Return of 81%.

Revenue Multiple

The Revenue Multiple measures the efficiency of contributed grant dollars. It provides an analysis of the leverage associated with each dollar contributed. Taking the example above we measure our leverage as follows:

- 1 Total Contributions: \$10,000,000
- 2 Total New Patients: 8,000
- 3 Revenue Per Patient: \$8,000
- 4 Total New Revenue: \$64,000,000 (8,000 New Patients x \$8,000/Patient)
- 5 Calculation: $\$64,000,000 / \$10,000,000$
- 6 Revenue Multiple = 6.4

The Revenue Multiple measures the efficiency of the grant by showing how much new revenue is generated by contributing \$1 in a patient financial assistance program.

Measure and Compare

The most important aspect of any program your organization supports is the ability to measure performance. You will find that patient financial assistance programs that are designed and implemented effectively will provide the most cost-effective means of delivering the maximum amount of financial assistance to patients while minimizing administrative costs.

“Charitable contributions are a line item expense to reduce your income before taxes.”

Section 6—Increasing the Impact of Charitable Contributions

Now that we are able to measure performance, we need to determine a strategy to increase the impact of charitable contributions through the PAP. Most corporate strategies involve increasing market share or increasing the number of units sold. In PAPs the measure of performance is the ability to get patients started on therapy and increasing compliance among patients to maximize health benefits.

Increasing Compliance

We all understand the impact of increasing compliance within our for-profit programs. The same strategy is effective in increasing Charitable Margin in a PAP. Let's examine the impact to Charitable Margin by increasing compliance from an average of 70% to 92% using the previous model. The impact of increasing compliance reduces the number of patients on therapy and therefore reduces administrative costs. As such, let's assume a DTPA of 85%.

- 1 DTPA = 85%. $\$10,000,000 \times .85 = \$8,500,000$
- 2 Compliance = 92% x 12 dispenses/yr. = 11.04 or 11 dispenses/yr. (no partials)
- 3 Cost Per Patient = \$125 copay/mo. x 11 = \$1,375 copay/yr.
- 4 Target New Patients = $\$8,500,000 / \$1,375 = 6,182$ new patients
- 5 Patients on Your Product = $6,182 \times 25\% \text{ market share} = 1,546$ Patients
- 6 Revenue Per Patient = \$1,000 WAC x 11 = \$11,000 Revenue/Patient
- 7 Total New Revenue = $1,546 \times \$11,000 = \$17,006,000$
- 8 Charitable Margin = $(\$17,006,000 - \$10,000,000) / \$10,000,000 = 70\%$

Through compliance we were able to increase the impact of our charitable donation from 60% to 70%. This is a significant increase by any measure.

“The most important aspect of any program your organization supports is the ability to measure performance.”

Increasing Market Share

Product market share presents a significant impact on Charitable Margin. Since COs must accept patients on a first come, first served basis the quality of the manufacturer's products and marketing will directly impact the model. Let us take the previous example and assume that the manufacturer's market share increases by 10% ($1.10\% \times 25\% = 27.5\%$).

- 1 DTPA = 85%. $\$10,000,000 \text{ Contribution} \times .85 = \$8,500,000$
- 2 Compliance = $92\% \times 12 \text{ dispenses/yr.} = 11.04 \text{ or } 11 \text{ dispenses/ yr. (no partials)}$
- 3 Cost Per Patient = $\$125 \text{ copay/mo.} \times 11 = \$1,375 \text{ copay/yr.}$
- 4 Target New Patients = $\$8,500,000 / \$1,375 \text{ copay/yr.} = 6,182 \text{ New Patients}$
- 5 Patients on Your Product = $6,182 \times 27.5\% \text{ market share} = 1,700 \text{ New Patients}$
- 6 Revenue Per Patient = $\$1,000 \text{ WAC} \times 11 = \$11,000 \text{ Revenue/Patient}$
- 7 Total New Revenue = $1,700 \times \$11,000 = \$18,700,000$
- 8 Charitable Margin = $(\$18,700,000 - \$10,000,000) / \$10,000,000 = 87\%$

Product market share within the grant can vary significantly from overall market share. OIG guidelines prohibit PAPs from providing manufacturers with product specific data. However, donors should know that it is not uncommon for manufacturers who do not contribute to a program to direct their patient assistance calls to PAPs that support their disease state. As such, it is important that participating manufacturers similarly ensure that they are referring patients to the program as well. A charitable organization can neither share product or provider data with manufacturers, nor provide market share or drug utilization data.

Maximizing Returns

One of the most costly components of PAPs is associated with accepting new patients. The impact of increased compliance and persistence to a PAP is a significant decrease in administrative costs. The longer patients stay on therapy the less administrative work it takes to keep them on therapy. The longer the patient stays on therapy, the healthier the patient becomes. Therefore patient drug therapy compliance is directly related to reducing the administrative costs of the program.

Increasing the impact of charitable contributions directly correlates to the number of patients a CO can assist. Since the competition for charitable dollars is significant a CO must focus on creating an effective and efficient model. In doing so, the CO can measure and report performance and successfully compete for charitable donations.

Summary:

Most organizations believe that because they cannot direct their charitable contributions to be used solely for their own products that PAPs do not make sense. As we have learned, this is simply not true. By contributing to PAPs, donors can promote advocacy and assist patients in need. As long as PAPs can efficiently and effectively address the needs of patients, donors will continue to support these worthwhile programs. Although contributions should not be made for purely financial reasons, as long as patient populations can be funded efficiently and effectively we can expect years of financial support to Charitable Organizations.

For more information on Patient Assistance Programs or to set up a meeting to discuss these programs, please contact:

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