

USING PHARMACEUTICAL COMPANY PATIENT ASSISTANCE PROGRAMS

A Volunteers in Health Care Guide



A national resource on caring for the uninsured
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The proper citation for this manual is: Richardson K and Geller S (2004). *Using Pharmaceutical Company Patient Assistance Programs: A Volunteers in Health Care Guide*, Pawtucket, RI: Volunteers in Health Care.

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Introduction

In an era of rising drug costs, does the prospect of free medications sound too good to be true? It is a reality. Drug manufacturers provide free and reduced cost medications to eligible patients through charitable programs commonly known as patient assistance programs (PAPs). Drug manufacturers have designed these programs to serve the neediest patients, those who have exhausted other options and have no health insurance to cover needed medications or money to purchase them. Manufacturers operate patient assistance programs voluntarily; there is no legal requirement that they provide free and low-cost medications to patients in need.

Although patient assistance programs provide many benefits, locating information on these programs and navigating the application process can be complex and overwhelming. This manual is intended to serve as a reference for both individual prescribers and organizations that want to implement a PAP system to help patients who cannot afford needed medications.

Patient assistance programs are not the only means of providing medications to needy patients. Both states and drug manufacturers operate programs that provide discounted medications to specific populations, including the poor, elderly, and disabled, and there are community resources in many counties, cities, and towns that may help as well. While we recommend that organizations develop a comprehensive pharmaceutical access strategy that utilizes multiple methods to secure free and low-cost medications, this manual only addresses PAPs in detail. Volunteers in Health Care and other organizations offer many other resources on other pharmaceutical access strategies (see *Appendix IX* for more information).

WHAT ARE PATIENT ASSISTANCE PROGRAMS?

Patient assistance programs are charitable programs offered by pharmaceutical manufacturers. These programs are designed to make medications available to the neediest patients, those with low incomes and no prescription drug coverage. Medications are provided for free or for very low cost.

The vast majority of **brand name** medications are available through PAPs; generic medications are not available. As of October 2003, pharmaceutical companies operated about 150 different patient assistance programs, offering access to more than 850 different medications.¹ In 2002, about 53% of the 200 most commonly prescribed medications were available through these programs.²

ELIGIBILITY

Although specific eligibility requirements vary from manufacturer to manufacturer, typically patients must meet the following requirements:

1. **United States Residency** – The patient must be a United States resident. For some programs, this simply means that the patient must reside in the United States. Other programs require that the patient be a legal resident, and some go even further and limit eligibility to patients who are U.S. citizens.
2. **No prescription coverage** – The patient must not have (or in some cases be eligible for) any public or private insurance that covers prescriptions. Such assistance includes private health insurance through an employer, Medicaid, the state's children's health insurance program (S-CHIP), Veteran's benefits, or access to a state-supported prescription assistance program. If the patient has any prescription assistance he or she is not eligible for assistance from most pharmaceutical companies, because the companies want to be the payer of last resort. Some companies may make an exception for patients that have insurance with extremely limited benefits for medications. They may provide assistance for medications excluded from the patient's insurance policy or for medications in excess of the number covered by a public or private insurance policy that limits the number of medications covered in a month or year.
3. **Low income** – Each company has its own income eligibility standards. However, most do not provide assistance to patients with monthly household incomes that are over 200% of the federal poverty level. There are a few companies that assist patients with higher income levels or that make special exceptions for patients with high medical costs, so applicants should always review each program's eligibility requirements and inquire if the program will consider the patient's special circumstances.

4. **Long-term medication needs** – The patient must be taking a long-term medication. Patient assistance programs are generally not appropriate for acute medication needs since the application process may take several weeks.

STATISTICS

Between 1996 and 2002, there was a tremendous growth in patient assistance programs. In 1996, the Pharmaceutical Research and Manufacturers of America (PhRMA), the pharmaceutical industry trade association, reported that there were 800,000 patients enrolled in patient assistance programs, and that these patients received 1.8 million medications. More recent reports from PhRMA show that in 2002 there were 5.5 million patients enrolled in patient assistance programs and that these patients received 14.1 million medications valued at \$2.3 billion.³

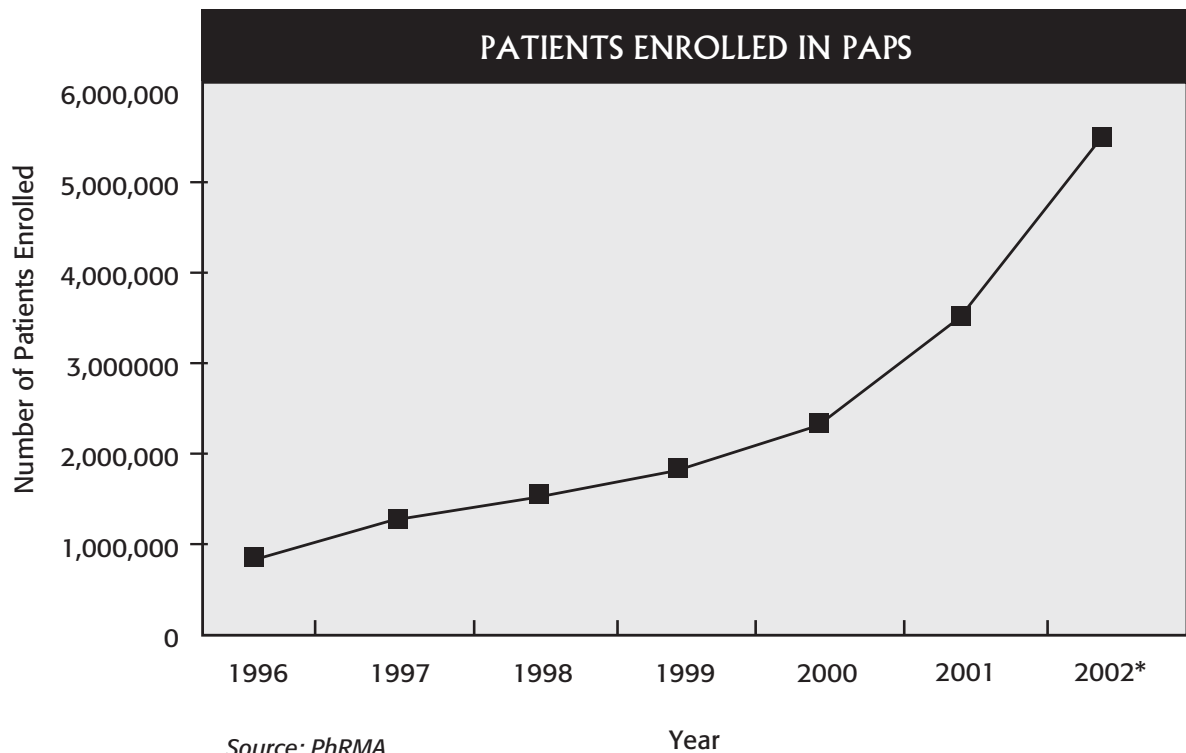
2003 FEDERAL POVERTY GUIDELINES

Size of Family Unit	48 Contiguous States & D.C.	Alaska	Hawaii
1	\$ 8,980	\$11,210	\$10,330
2	12,120	15,140	13,940
3	15,260	19,070	17,550
4	18,400	23,000	21,160
5	21,540	26,930	24,770
6	24,680	30,860	28,380
7	27,820	34,790	31,990
8	30,960	38,720	35,600
For each additional person, add	3,140	3,930	3,610

Note: Current guidelines may be found on the Internet at: <http://www.cms.hhs.gov/medicaid/eligibility>

Some of this growth is probably due to the huge number of people in the United States (nearly 44 million⁴) who have no health insurance. Other factors that are probably contributing to this growth include:

- Increasing public awareness of the large number of Medicare recipients who have no source of prescription coverage,
- The trend of both public and private insurers to curtail medication benefits,
- Heightened awareness of PAPs on the part of patients and providers,
- The increasing cost of new drugs.



BENEFITS OF PATIENT ASSISTANCE PROGRAMS

The benefits of PAPS are numerous, and include benefits to patients, health care providers, communities, and drug manufacturers.

Benefits to patients include:

- Access to needed medications
- Improved health outcomes
- Decreased out-of-pocket expenses
- Reduced emotional and financial stress

Benefits to health care providers include:

- Increased patient compliance with recommended course of treatment
- Ability to provide highest quality of care
- Decreased emergency room visits, hospitalizations, and nursing home placements
- Healthier and more satisfied patients
- Allows sample medications to be used for other purposes

Benefits to communities include:

- Support for community's safety net
- Reduction in funds currently being spent on medications
- Ability to direct resources toward other community needs

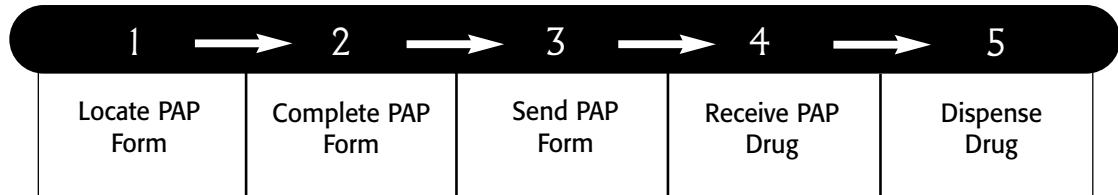
Benefits to drug manufacturers include:

- An opportunity to contribute to improved patient outcomes
- A marketing opportunity
- A potential tax deduction

How Patient Assistance Programs Work

THE APPLICATION PROCESS

The process of applying to PAPs appears relatively simple upon first glance:



CHALLENGES

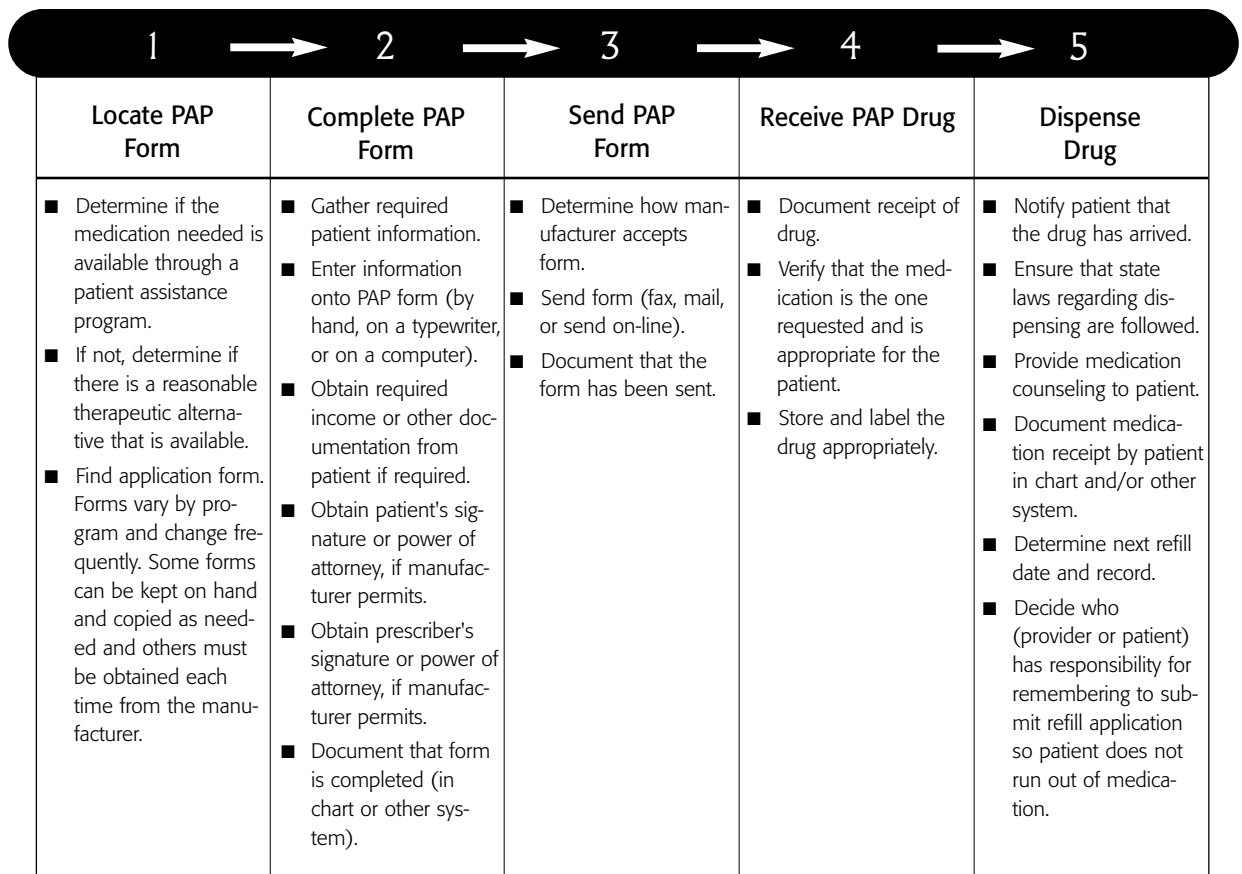
However, the actual details of the PAP process are much more complex. While patient assistance programs provide a great deal of help to needy patients and the health care providers that care for them, they also present some challenges. These challenges include:

1. **Idiosyncratic programs** - Each company's patient assistance program is operated individually and therefore application processes, eligibility criteria, mechanism of medication delivery (most programs send medications to the physician, some send them directly to the patient, and others provide a voucher for the patient to use at a retail pharmacy), and application forms are different for each program. This means there is no single form that can be used to apply to all programs, patients that are eligible for one program may not meet the eligibility standards set by another company, and prescribers and advocates assisting patients must learn each program's unique application process.
2. **Limited access to forms** - Some programs make their forms available on the company's website, through pharmaceutical company representatives, or on websites that compile information on all patient assistance programs into a one-stop resource. Others will allow health care providers to copy their forms. However, some programs distribute patient specific forms that must be requested each time a patient in need is identified. Waiting to receive a form in the mail may delay the application process.
3. **Barriers to non-citizens/residents** - Many programs require that the patient be a legal resident, and some go even further and limit eligibility to patients who are U.S. citizens. Health care providers that serve a recent immigrant population may find it difficult to help patients who are undocumented residents or who are not yet citizens.

4. **Frequent changes** - Medications covered, application processes, eligibility criteria, and application forms change quite frequently*, so patients and health care providers must keep abreast of these changes so they can complete the application process correctly. These changes may occur because pharmaceutical companies merge, federal or state regulations affecting patient assistance programs go into effect (e.g., the Health Insurance Portability and Accountability Act - HIPAA), new medications are developed, or medications go off patent.
5. **Long waiting times** - It may take as long as 4-6 weeks to receive a medication ordered through a patient assistance program and as a result health care providers often struggle to provide for a patient's short-term medication needs. For this reason, when a patient needs a medication for an acute condition, patient assistance programs are probably not the best answer. However, when the medication is for an ongoing condition (e.g., hypertension or diabetes), a patient assistance program will help but other resources will have to be pursued to meet a patient's immediate needs.
6. **Frequent reapplication required** - Many patient assistance programs provide only a 90-day supply of medication and then require that the patient reapply in order to obtain additional 90-day supplies. This means that in many cases the patient and his/her provider or advocate must negotiate the application process again every 90 days.
7. **Complicated forms** – The application forms differ by program. While some are quite short and simple to fill out, others are several pages long and require detailed information on a patient's income sources and assets.
8. **Requirements for detailed documentation** - Some programs require that the patient provide supporting documentation, including pay stubs, the patient's most recent tax return, or a Medicaid denial letter.

* *While updating the RxAssist website, Volunteers in Health Care has found that about 10 forms change each month.*

In truth, the simple process outlined above actually looks more like this.



While it is possible for patients to initiate and coordinate the PAP process, the intricacies of the process are overwhelming for many patients. Even staff working in physicians' offices, health centers, and hospitals are constantly challenged by the process and sometimes feel "as if they are lost in a maze." Implementing a system to manage the PAP process will save time, energy, money, and frustration for staff, patients, and providers. What is needed is a strategy to navigate the PAP maze.

Although patients are the ultimate beneficiaries of PAP medications, health care providers and patient advocates often facilitate the application process. There are two basic models for how organizations can assist patients in accessing PAP medications:

MODEL 1: HEALTH CENTER OR PROVIDER BASED



MODEL 1: HEALTH CENTER OR PROVIDER BASED A health care provider assists patients in applying.

In this model, a private physician's office, free clinic, health center, hospital or other site delivering health care to patients assists its patients in accessing the patient assistance programs. This process would normally be initiated when a physician or other prescriber determines that a patient needs a medication that he or she cannot afford. Once this determination is made, the organization would research whether the medication is available through a PAP, assist the patient in applying for the program and eventually dispense the medication obtained.

Organizations wishing to develop a *health center or provider based* system for PAP management can use the following chart to plan for implementation:

STEP	DATE	RESPONSIBLE PARTY
<p>1. Establish need. Establish that providers, administrators and patients have a need for a PAP system and that they are willing to participate.</p>		
<p>2. Determine target population. Determine how many providers, patients, and prescriptions this program will support and who will be eligible for assistance.</p> <ul style="list-style-type: none"> ■ Low-income uninsured ■ Medicare recipients ■ Only those with a certain number of medications ■ Only those with certain chronic conditions ■ Geographic area served 		
<p>3. Evaluate staff needed. Determine the number and type of staff/volunteers needed to run program.</p> <ul style="list-style-type: none"> ■ Who will screen patients? ■ Who will fill out application forms? ■ Who will obtain supporting documentation needed? ■ Who will get patient and prescriber signatures? ■ Who will be responsible for storing medications? ■ Who will log in medications when they arrive? ■ Who will label medications? ■ Who will dispense medications? ■ Who will be responsible for record keeping? 		
<p>4. Identify the resources available for the program.</p> <ul style="list-style-type: none"> ■ Financial ■ Staff or volunteers ■ Space (for staff to work in and to store medications) ■ Equipment (computer, Internet access, printer, fax machine, phone, desk, file cabinet, copier). ■ Supplies (envelopes, paper, labels, postage, pharmacy reference guide) 		
<p>5. Determine the days and hours of service.</p>		
<p>6. Develop funding strategy. Estimate the cost of the program, and determine how funds will be secured for the program in the long run.</p>		
<p>7. Hire any additional staff needed.</p> <ul style="list-style-type: none"> ■ Write job descriptions. ■ Advertise for positions needed. ■ Hire staff. 		
<p>8. Determine fees. Decide if the patient will be asked to pay an administrative fee to cover the costs of the program and determine this fee.*</p>		
<p>9. Determine how patients will be referred</p> <ul style="list-style-type: none"> ■ By prescribers ■ By billing clerks ■ By pharmacists 		

*See Frequently Asked Questions and *Appendix V* for more information on setting appropriate administrative fees.

STEP	DATE	RESPONSIBLE PARTY
<p>10. Develop a PAP formulary. Determine a starting point for a formulary of drugs based on safety, efficacy, and the easiest PAP medications to obtain. Remember to obtain the buy-in of the prescribers.</p>		
<p>11. Develop reference tools for prescribers. If possible, develop a pocket tool or brief list to post in prescribers' offices to remind them of the drugs available and the referral process.</p>		
<p>12. Research PAP software products and other tools. Decide on a system or tool to "navigate the PAP maze" based on the size of the program and the available resources. (see <i>Appendix VIII</i>)</p>		
<p>13. Develop intake form or system for collecting patient information.</p>		
<p>14. Develop strategy for short-term medication needs. Determine how patients will receive medications while waiting for the PAP medication to arrive (sample, voucher, etc.).</p>		
<p>15. Develop Policy and Procedure Manual. Write down the steps in the PAP system, starting at the point of the patient requesting help obtaining a medication he/she cannot afford and ending with the patient receiving the PAP medication. Designate this as the PAP Policy and Procedure Manual. (see <i>Appendix VI</i>).</p>		
<p>16. Get final go-ahead. Write an overview that includes the main points of the Policy and Procedure Manual and the benefits and costs of the program and present to prescribers and administrators involved in the program to obtain their final buy-in/approval and suggestions.</p>		
<p>17. Allocate and set up space.</p>		
<p>18. Train staff/volunteers how to use the PAP system.</p>		
<p>19. Implement PAP process/system.</p>		
<p>20. Establish process to evaluate and improve system. Evaluate process after two weeks and incorporate necessary process changes; evaluate monthly or quarterly thereafter.</p>		

A health center or provider-based system might look like one of the following programs:

(1) A Physician Practice with a Completely Manual PAP System

A suburban practice including 13 practitioners – family physicians, internists, pediatricians, and a nurse practitioner – has been helping patients access medications through patient assistance programs for about five years. There are no staff members formally dedicated to this effort. Instead, nurses and administrative staff assigned to each physician or nurse practitioner build these responsibilities into their existing workload.

The patient's insurance status is labeled on his/her chart, so health care providers are aware of their patient's status and can offer assistance to patients who are uninsured or who have Medicare and no prescription coverage. Providers at this practice preferentially prescribe generic medications or the least costly brand name available, and they always ask patients if they can afford to fill a medication. If the patient cannot afford a needed medication, the practice tries to help by applying to a patient assistance program. Providers usually see at least one patient a day who needs this kind of assistance. Providers refer patients with medication needs to their nurses or receptionists for help in filling out the patient assistance program applications. All providers have to do is provide the prescription and sign the form. Their nurses and receptionists keep forms on hand, fill out the forms with the patient, collect all necessary documentation, and send the forms in. When the medication arrives, it is labeled and bagged and stored in a locked cabinet or drawer until the patient can come in and pick it up. The practice is able to help patients with short-term medication needs by handing out samples or referring patients to a nearby free clinic. Patients are asked to take responsibility for contacting the practice 4-6 weeks before their 90-day supply is gone to initiate the process of applying for a refill.

The practice does not track the value of medications obtained or the time that staff members spend administering this program.

KEYS TO SUCCESS

- Well-documented information on patient's insurance status, availability of information on medication costs, and well-established procedures for asking patients about their ability to afford the medication prescribed.
- An on-site dispensary carrying commonly prescribed generics that patients can purchase at prices well below those available at local, retail pharmacies.

CHALLENGES

- Each prescriber and his/her staff of nurses and receptionists handle the PAP process their own way. There are no centralized files with forms and information on PAPs that all staff members can access.
- Nurses and receptionists do not have access to the Internet so they are unable to use websites with information on PAPs to access up-to-date forms and other information.

(2) A Health Center with a Completely Manual PAP System

A health center serving approximately 25,000 patients with 18 medical providers and six delivery sites assists patients in obtaining PAP medications through a program run out of its in-house pharmacies. Patients are either referred by their prescriber or identified at the pharmacy when they come to fill a prescription. They are enrolled at the pharmacies. There are no staff members devoted solely to PAP management; however, the pharmacy technicians spend a total of about 12 hours a day administering the program.

The health center's record-keeping system consists of three-ringed binders that list the patients alphabetically and have instructions for each participating company's process. Each PAP request is made "anew," (i.e., for each refill or new request a new form is completed by hand). The patient picks up the medication from the pharmacy, or in some cases the manufacturer mails the medication to the patient or the patient receives a voucher/coupon for the medication. The patient is responsible for requesting refills, and the average waiting time for patients (from application to receipt of medications) is between 4-6 weeks. If the patient needs a short-term supply of medication, the prescriber gives the patient samples or the patient purchases a small amount from the pharmacy.

The pharmacy staff periodically checks the RxAssist website to make sure that they have the most up-to-date forms and application criteria for the most commonly used programs. Unfortunately, the staff does not always have time to check the RxAssist website, so sometimes they only learn of a program change when a PAP form is rejected by the drug manufacturer. When this happens, technicians contact the manufacturer and obtain updated program information so they will have up-to-date information for future applications.

The approximate cost to run this program is about \$150,000/year, including salaries and supplies, and the patients pay a \$7.00 administrative fee for each medication which offsets the costs of the program by about 50%. The annual value of the PAP medications received is estimated to be about \$1.7 million, and an estimated 13,800 prescriptions are filled annually.

KEYS TO SUCCESS

- Organizing the system as much as possible.
- Employing experienced pharmacy technicians who understand and are familiar with the system.

CHALLENGES

- Keeping track of the current forms and application criteria. The pharmacy staff tries to update the forms by periodically checking the RxAssist website, but they do not always have the time, so they often only learn of changes in PAP forms and criteria when applications are rejected.
- Educating prescribers about the availability of PAPs (explaining that not all medications are available through PAPs and that there may be other cost-effective options for patients when drugs are not available through PAPs).

(3) A Rural Health Center with a Computerized PAP System

A rural health center with approximately 70,000 patient visits per year uses the RxAssist Plus software to manage its PAP service. Although the clinic has an in-house pharmacy, a 0.5 FTE (20 hours per week) staff person was hired to work exclusively on the PAP program.

Patients are referred to the PAP administrator by their prescriber or by the pharmacist. After referral, the PAP staff person gathers the patient information, enters it into the RxAssist Plus software, prints out the appropriate form or letter, and submits the request to the manufacturer. The waiting time for receipt of the medication is approximately 30-45 days but varies greatly by manufacturer. If the patient needs a short-term supply of medication to cover his/her needs until the PAP medication arrives, the prescriber provides samples or the patient purchases a small amount of the needed medication from the pharmacy. The medication is delivered to the clinic, and stored in the pharmacy. The pharmacy staff then dispenses the medication to the patient for a \$5.00/prescription fee. The refills for patients are automatically tracked by the software, and reports are generated from the software to notify the administrator of upcoming refills.

The cost to administer the program is less than \$50,000/year, and consists mostly of the dedicated PAP staff (0.5 FTE) and program supplies. The clinic does not currently track the value of the medications obtained through this program. The program currently serves about 35 patients a week (seven for every 1/2 day, or about one every 30 minutes) and has generated 157 PAP prescriptions in the last four months.

KEYS TO SUCCESS

- Following through with PAP requests (often companies lose forms) and taking the initiative to call companies and stay on top of PAP requests.
- Good PAP system monitoring, record-keeping/tracking (computerized system) that saves the health center time especially when contacting companies for follow-up on missing prescriptions.

CHALLENGES

- Challenges have been minimal due to a good initial program set-up of infrastructure.

(4) A Public Hospital with Satellite Clinics Accessing Medications through Bulk Programs

An urban county funds indigent care through county taxes. Low-income, uninsured patients are cared for at the county hospital or at one of several health centers located in the surrounding neighborhoods. The hospital uses several strategies to obtain low-cost medications so they can help their low-income, uninsured patients while keeping the hospital's pharmacy costs as low as possible. The hospital purchases medications through the 340B program*, applies to individual patient assistance programs and receives bulk donations from seven pharmaceutical companies. The hospital currently has a five-person Pharmacy Patient Assistance Department that facilitates the process of accessing medications through individual and bulk PAPs.

Physicians and other staff at the hospital and associated health centers know that patients enrolled in the county's indigent program are eligible for most patient assistance programs. They write out prescriptions and refer patients to the Pharmacy Patient Assistance Department. The patient picks up his/her medication at the hospital pharmacy or at one of the pharmacies located at a satellite health center, usually that same day. The hospital then applies to an individual PAP on the patient's behalf or records that the patient has obtained a medication through a bulk program. (Note: The Pharmacy Patient Assistance Department Coordinator requests a limited power of attorney to sign forms for both the patient and physician to facilitate this process.+) If the patient's application is accepted, the hospital's stock is replaced. Patients pay a \$5 dispensing fee for all medications and receive a voucher to recoup the \$5 dispensing fee if their individual PAP application is approved.

The hospital submits 600-1,000 applications to individual and bulk PAPs each week, and some of the satellite centers submit applications on their own as well. The hospital estimates that they recover about \$6 million in medications from individual and bulk PAPs each year. They continue to build on their program by approaching new companies about providing bulk donations so they anticipate that this savings will be even higher in the future.

KEYS TO SUCCESS

- A centralized system of applying to patient assistance programs coordinated by the hospital and implemented at satellite health centers.
- Extensive use of bulk programs♦.
- Use of limited power of attorney forms for both patients and prescribers.

* *The 340B Program is a federal program that limits the price that certain "covered entities" (e.g., community health centers and certain disproportionate share hospitals) can be charged for pharmaceuticals. See Appendix IX for more information.*

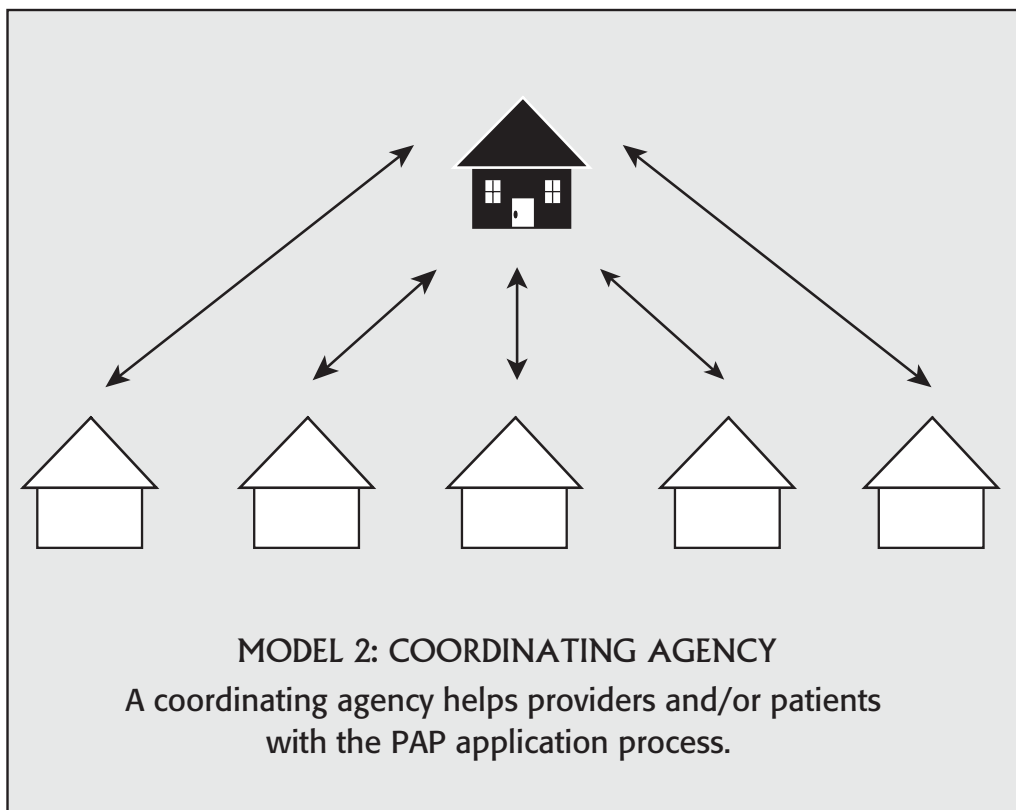
+ *See Managing the Application Process and Frequently Asked Questions for more information.*

♦ *See Bulk Replenishment Systems for more information.*

CHALLENGES

- Physicians at some of the satellite health centers continue to apply to individual PAPs on their own as a means of circumventing the hospital's formulary which prevents them from obtaining some medications through the hospital system.
- Some health centers and individual staff are unaware of the service that the Pharmacy Patient Assistance Department provides.

MODEL 2: COORDINATING AGENCY



In this model, an organization, such as an Area Agency on Aging, health department, church or other community-based agency would be contacted by a patient or provider requesting help accessing a medication. The organization would then research whether the medication is available through a PAP, assist the patient in applying for the program, and communicate with the prescriber who would eventually dispense the medication obtained. Because this model does not require that the coordinating agency dispense the medication, this model is most appropriate for organizations that are not housed in health care facilities and do not have physicians and/or pharmacists on site.

Organizations wishing to develop a coordinating agency system for PAP management can use the following chart to plan for implementation:

STEP	DATE	RESPONSIBLE PARTY
<p>1. Establish need. Establish that providers, administrators and patients have a need for this service and that they are willing to participate.</p>		
<p>2. Determine target population. Determine how many providers, patients, and prescriptions this program will support and who will be eligible for assistance.</p> <ul style="list-style-type: none"> ■ Low-income uninsured ■ Medicare recipients ■ Only those with a certain number of medications ■ Only those with certain chronic conditions ■ Geographic area served 		
<p>3. Determine how patients will be referred. Determine the number and type of staff/volunteers needed to run program.</p> <ul style="list-style-type: none"> ■ Will patients refer themselves? ■ Will patients be referred by individual prescribers? ■ Will you obtain referrals from specific health care organizations (e.g., free clinics, health centers, hospitals)? ■ Will you obtain referrals from social services agencies? 		
<p>4. Evaluate staff needed. Determine the number and type of staff/volunteers needed to implement this program. Many organizations use volunteers (e.g., senior citizens, college students, medical or pharmacy students, VISTA or AmeriCorps volunteers) to supplement and support paid staff.</p> <ul style="list-style-type: none"> ■ Who will screen patients? ■ Who will fill out application forms? ■ Who will obtain supporting documentation needed? ■ Who will get patient and prescriber signatures? ■ Who will be responsible for record keeping? 		
<p>5. Identify the resources available for the program.</p> <ul style="list-style-type: none"> ■ Financial ■ Staff or volunteers ■ Space (Consider sharing space with an organization with a like mission. Select a site that is in a safe neighborhood, near public transportation, well-lit, and handicapped accessible.) ■ Equipment (computer, Internet access, printer, fax machine, phone, desk, file cabinet, copier). ■ Supplies (envelopes, paper, labels, postage, pharmacy reference guide) 		

STEP	DATE	RESPONSIBLE PARTY
6. Determine the days and hours of operation.		
7. Develop funding strategy. Estimate the cost of the program, and determine how funds will be secured for the program in the long run.		
8. Hire staff. <ul style="list-style-type: none"> ■ Write job descriptions. ■ Advertise for positions needed. ■ Hire staff. 		
9. Determine fees. Decide if the patient will be asked to pay an administrative fee to cover the costs of the program and determine this fee.*		
10. Develop a PAP formulary. Determine a starting point for a formulary of drugs based on safety, efficacy, and the easiest PAP medications to obtain. Remember to obtain the buy-in of the prescribers.		
11. Develop reference tools for prescribers. If possible, develop a pocket tool or brief list to post at health care organizations or in prescribers' offices to remind them of the drugs available and the referral process.		
12. Research PAP software products and other tools. Decide on a system or tool to "navigate the PAP maze" based on the size of the program and the available resources. (see <i>Appendix VIII</i>)		
13. Develop intake form or system for collecting patient information.		
14. Develop strategy for short-term medication needs. Determine how patients will receive medications while waiting for the PAP medication to arrive (e.g., sample, voucher, etc.).		
15. Develop Policy and Procedure Manual. Write down the steps in the PAP system, starting at the point of the patient requesting help obtaining a medication he/she cannot afford and ending with the patient receiving the PAP medication. Designate this as the PAP Policy and Procedure Manual. (see <i>Appendix VI</i>)		
16. Get final go-ahead. Write an overview that includes the main points of the Policy and Procedure Manual and the benefits and costs of the program and present to prescribers and administrators involved in the program to obtain their final buy-in/approval and suggestions.		
17. Allocate and set up space.		
18. Train staff/volunteers how to use the PAP system.		
19. Obtain prescriber information. <ul style="list-style-type: none"> ■ Names ■ Specialties ■ Street address medications should be mailed to ■ Mailing address for paperwork ■ DEA number ■ State license number ■ Office contact name and telephone/fax numbers 		
20. Implement PAP process/system.		
21. Establish process to evaluate and improve system. Evaluate process after two weeks and incorporate necessary process changes; evaluate monthly or quarterly thereafter.		

* See *Frequently Asked Questions* and *Appendix V* for more information on setting appropriate administrative fees.

A coordinating agency might look like one of the following programs:

(1) An Independent Non-Profit Organization with a Completely Manual System

This non-profit agency helps private physicians, clinics, and hospitals in their community access medications through the pharmaceutical company patient assistance programs. The agency has two full-time and two part-time staff, including a director, two case managers, and an office manager. Their paid staff is supplemented by a large corps of volunteers so there are at least two volunteers on site at all times when the agency is open. These volunteers include retirees, Welfare to Work assignees, students, and others.

The agency receives referrals from physicians, hospitals, clinics, senior citizens' organizations, churches, and other social service and health care agencies. The referring agency either faxes or mails a referral form to the coordinating agency. The agency reviews the referral form to see if the patient appears to be eligible for patient assistance programs based on his/her household income, insurance status, and the medication needed. If the patient appears to be eligible, staff or volunteers from the coordinating agency mail the patient a letter describing the program, the appropriate application form, and a request for documentation needed (e.g., most recent tax return). The patient fills out the form, attaches the appropriate documents, and mails these materials back to the coordinating agency. The coordinating agency reviews the application form for completeness, highlights the areas of the form that the physician must fill out, and then sends the entire packet to the physician's office. Generally all the physician has to do is fill in the patient's diagnosis, attach a prescription, and sign the form. The coordinating agency does not receive the medication since they are not a health care provider and do not have a dispensary or pharmacy. The patient's doctor usually receives the medication and dispenses it, though sometimes medications are sent directly to the patient.

The coordinating agency receives about 100 referrals each month. Since they have been in operation, they have helped over 5,000 clients obtain the medications they need.

KEYS TO SUCCESS

- Their extensive use of volunteers allows a small staff to do a great deal.
- They have instituted a service that allows local physicians to help their patients obtain needed medications without overburdening physicians or office staff.

CHALLENGES

- It is difficult to track which clients obtain the medications requested since the coordinating agency does not receive the medications.
- The process of sending forms to patients and then to physicians takes a long time.
- Staff and volunteers must constantly verify that the application forms and materials are up-to-date and replace old materials with newly updated ones.

(2) A Statewide Prescription Assistance Center with a Computerized System

A state-funded program helps senior citizens across the state apply to the pharmaceutical companies' patient assistance programs. This program is a partnership between the state's Department of Senior Services and local Area Agencies on Aging (AAA). State funds are used to pay staff and purchase computers. The state provides training to AAA staff and also collects data from each local AAA so they can report back to the state legislature. Area Agencies on Aging provide additional resources, including funds to purchase software to track the application process. Pharmaceutical companies also support this program by providing funds to purchase fax machines, printers, and other necessary equipment and supplies.

The program has a website and a toll-free number. State residents ages 60 and over who have chronic medical conditions, no prescription coverage, and limited financial means (i.e., a household income no higher than 200% of the federal poverty) are eligible for assistance. Clients work directly with their local Area Agency on Aging. They mail their local AAA an intake form, income verification (e.g., W2 forms, tax returns, and bank statements) and list of their medications and prescribing physicians. The AAA then uses this information to fill out the appropriate application forms and sends the forms to the prescribing physician to sign and send to the appropriate company.

Last year, the program received \$1.5 million in funding from the state. With this investment, they were able to obtain over \$20 million in medications for their clients.

KEYS TO SUCCESS

- They have a computerized system that they have implemented at all local sites.
- They are able to document the value of the medications they help seniors obtain and demonstrate that the state's investment is paying off.
- They have a consistent source of funding.

CHALLENGES

- They have found it difficult to convince some physicians to participate; some physicians have started charging patients a fee to sign application forms.

Regardless of the system chosen to manage PAPs, there are some helpful hints that may make it easier to navigate the PAP maze:

DEVELOPING A PAP FORMULARY

1. Identify which medications are most in demand.
2. Decide when accessing medications through PAPs is the best option vs. purchasing low-cost generics, providing samples, and other strategies. For example, what is the cost of the administrative time spent obtaining a PAP medication compared to purchasing a generic version of a medication that costs \$10.00? Is the patient charged an administrative PAP fee, and if so, is the fee the same or more than a generic equivalent or a generic alternative? Does the clinic, health center, or hospital have access to 340B Pricing, a federally mandated discount that applies to patients of eligible facilities? (This program can save facilities 25-50% or more off of the price of medications.) Would it be simpler to pursue 340B Pricing for some or all patients? (See *Appendix IX* for more information on 340B Pricing.)
3. Decide which programs are easy to use and which are not, and use this information in conjunction with safety and efficacy information to guide drug selection/formulary creation.
4. Start small with a few easy to use programs and the most commonly prescribed medications. It will be easier to add medications to the system than to remove medications that patients are accustomed to receiving.
5. If you already have a formulary for non-PAP medications, it may be useful to simply designate which medications are available through PAPs by placing an asterisk next to the names of these medications. Another option would be to create a list of all medications commonly prescribed and include a column designating whether the medication is available through PAPs.
6. If you do not already have a formulary, you may want to create a pocket-sized, laminated card or short booklet that fits into prescribers' lab coat pockets or post a laminated list of medications available through PAPs in nursing stations or exam areas. It is also a good idea to include basic instructions about how your PAP system works.

MANAGING THE APPLICATION PROCESS

1. To prevent potential problems, you should call the program or check a reliable resource (See *Tools for Navigating the PAP Maze*) before applying to verify that the medication needed is still available.
2. If the manufacturer doesn't have a formal program, many will accept a letter describing the patient's need. (See *Appendix II* for an example of a letter certifying the patient's need for assistance.)
3. Even when the program has its own form, it is often a good idea to include a cover letter with information on a patient's special circumstances along with the PAP application. You can use such a letter to explain a patient's special circumstances (e.g., unusually high medical expenses or limited insurance coverage).
4. If your patient does not meet published eligibility guidelines but has unique problems/needs, it may be worthwhile to write a letter to the drug manufacturer explaining the situation. Some health care facilities have reported that manufacturers make some exceptions to published eligibility guidelines on a case-by-case basis. Writing a letter explaining the patient's situation may also prove beneficial if a patient's initial application is rejected.
5. If a patient needs multiple medications, try to arrange the patient's initial fill schedule so that the patient applies for all medications at the same time and refill dates are also coordinated.
6. Develop strategies for meeting patients' needs until their PAP medication arrives. Such short-term needs may be met through samples, vouchers or contracts with local pharmacies, or help from local charities that have emergency medication funds.
7. Make sure that you have filled in all required information on applications, so that the company doesn't return or reject your application due to an oversight.
8. The following supporting documents are required by some programs. It may be useful to keep these documents on hand for patients:
 - Medicaid rejection letter
 - Pay stubs
 - Previous year's tax return (showing income)
 - IRS Form 4506 (available from pharmaceutical companies that request that this form be completed or from the IRS at www.irs.gov/pub/irs-pdf/f4506.pdf. This form is used as proof of non-filing status for patients who do not file taxes or receive Social Security benefits. Certain companies – e.g., Pfizer – have recently started requiring this form.)

9. Most PAPs send medications out within 30-45 days. If more time has elapsed since you submitted an application, it may be a good idea to contact the drug company to follow up.
10. Write a policy and procedure manual that describes each step of the PAP process and include everything from who is responsible for filling out the application to what happens when the patient picks up the PAP refills. At a minimum describe orienting prescribers, pharmacists and other staff to PAPs, informing patients about the PAP process and the clinic's role in the application procedure, necessary record-keeping, proper storage and dispensing of medication, how to handle medications that are not picked up, and how to track medications that are sent to the patient directly or dispensed through a pharmacy via a voucher or card. (*Appendix VI* provides further guidance regarding writing a Policy and Procedure Manual.)
11. Consider having patients sign a signature consent letter (basically stating that they give permission for the PAP administrator to sign the PAP form on their behalf). This will save time obtaining signatures. It may be possible to prepare a formal power of attorney for this specific instance (check with legal counsel). If a power of attorney or signature consent letter is not possible, consider having the patients sign more than one application at a time to facilitate refills.

DEVELOP SYSTEM FOR RECORD KEEPING

1. Develop a general questionnaire that you can use to collect the data most commonly requested by PAPs. (See *Appendix III* for a list of information needed.) Some computer programs will automatically collect this information (see *Appendix VIII*).
2. Find out if the program will accept copies of its form. If so, make multiple copies of the form and have the patient sign them all at once to prevent duplicate work for the next refill. If the manufacturer does not accept copies of forms, request multiple forms (many manufacturers will allow up to 10 forms to be sent at once) and create a file or notebook of commonly used forms. Keep in mind that some manufacturers require a patient specific form (e.g., a form with a tracking number). In this case, you will have to obtain a patient specific form each time you apply.
3. At a minimum, track the date the application is sent out, the date the medication is dispensed, and the date the refill will be needed. Develop a tickler file (either hard copy with index cards) or electronically (see *Appendix VIII*), that will help the PAP staff remember to request refills. It is advisable to apply for refills at least 30 days in advance to avoid delays on the receiving end.

4. It is also advisable to track the value of the PAP medication dispensed so you can demonstrate the economic value and success of your PAP program. Some computer programs (see *Appendix VIII*) will automatically provide this information. Otherwise, ask a local pharmacy to provide estimates of the average wholesale prices for PAP medications commonly used and use a simple spreadsheet to keep track of medication costs and sum costs at the end of the month, year, etc. Remember that average wholesale prices change frequently, and it is advisable to update estimates of price at least twice a year.
5. Be sure that policies are in place for proper storage and labeling of medications received.

FOLLOW RULES FOR DISPENSING

1. Dispensing regulations vary by state (such as who is permitted to dispense and how the product should be labeled.) In most states, the board of pharmacy governs pharmacist and other practitioner dispensing, although sometimes the board of medicine governs practitioner dispensing (such as physician dispensing). PAPs tend to fall into a gray area somewhere between samples and traditional prescriptions, and many states have no specific regulations regarding how PAPs should be dispensed. What this means is that it may be difficult to ascertain exactly what rules to follow. A good place to start would be to call both the state boards of medicine and pharmacy to inquire about state regulations of PAPs. (See *Appendix IX* to find out how to contact your state board.) If there is no specific guidance, the safest approach would be to follow the state dispensing regulations as closely as possible (i.e., drug must be labeled, lot numbers and expiration dates recorded, drug must be stored appropriately, patient must receive counseling, etc.).
2. It is a good idea to have the patient sign a log when the medication is dispensed for accountability of the medication.
3. Develop a policy regarding narcotics. Many narcotics are not covered by manufacturers' PAPs, and some organizations elect not to help patients obtain narcotics through patient assistance programs due to concerns about drug seeking.
4. Prescribers should take responsibility for checking for drug interactions. Most PAP medications are mailed to physicians' offices, thus circumventing the involvement of a pharmacist. Pharmacists rely on their drug knowledge, in combination with printed references and computer programs, to check for drug interactions. They also typically have the luxury of a drug profile (a list of all of the drugs the patient takes and has taken). However, the prescriber may only be aware of the medications that have been prescribed at the prescriber's clinic. For this reason, it is extremely important for the prescriber to take an updated drug history at each visit. In addition, the prescriber may wish to use a drug-interaction tool to check for drug interactions.*

* Two commonly used drug interaction tools include ePocrates Rx® (Copyright ©2003 ePocrates, Inc., visit <https://www.epocrates.com/catalog.do>), and Drug Facts and Comparisons,® (©2003 Wolters Kluwer Health, Inc, visit <http://www.factsandcomparisons.com/index.asp>).

DISPOSE OF UNUSED MEDICATION PROPERLY

Many PAP system administrators report that they often have medications that are not picked up or are only partially used by the patients for whom they were requested. Is it permissible to reuse the medication for another patient? The answer is dependent on two issues:

1. Does the state have specific regulations concerning reusing medication? Once a medication leaves a clinic with a patient, most states will not permit the repackaging of returned medication even if the patient brings back the unopened medication. One reason for such regulations is that it can not be assured that the patient stored the drug properly and the drug could have lost potency. Most states have very specific regulations about disposal of such medications, especially controlled substances, so this policy is definitely worth investigation with the board of pharmacy. If the medication has not been opened and has not left the clinic, it may be possible to reuse the medication. See the next question for more detail.
2. Does the drug manufacturer permit giving the medication to another patient? Each drug manufacturer will have a different policy about this, and inquiries will have to be made with each individual manufacturer.

KNOW RULES ABOUT MAILING MEDICATIONS TO PATIENTS

1. The legality of this policy is determined state by state, usually by the board of pharmacy. States typically have mail order requirements. They may require that an organization have a special mail order permit or that the mailing include a phone number the patient can call to receive medication information. Be sure to inquire about mailing drugs to patients that live outside the state, as there may be different requirements to conduct this activity.
2. If mailing is permitted in your state, be aware that the mailing costs may become expensive. If possible, try to eliminate postage whenever possible. Have patients come to the site to sign applications instead of mailing them to the patient, and have patients pick up medications whenever possible.

DEVELOP EFFECTIVE STRATEGIES FOR WORKING WITH SPECIAL POPULATIONS

Develop strategies if it is anticipated that special populations (e.g., non-English speakers, non-citizens/non-residents, mental health patients, homeless patients, low literacy, etc.) will be served.

Consider issues such as:

1. Are translation services available for medication counseling?
2. Are mental health patients being routinely monitored for compliance?
3. Are homeless patients storing their medication safely?

FOLLOW PROPER MEDICATION SAFETY PROTOCOL

1. Store PAP medications in a secure (preferably locked) location, away from heat and light.
2. Label all medication with patient name, address, phone number, drug name, strength, quantity, directions for use, expiration date, and lot number. For state-specific requirements for labeling, storage, and record-keeping, contact your state boards of medicine and pharmacy. (See *Appendix IX*.)
3. Ensure that the health professionals involved in the PAP process have dispensing licenses, if required by state law. Contact the state boards of medicine and pharmacy to learn if this is a requirement in your state.

See the safety checklist in *Appendix VII* for a helpful guide to promoting medication safety when using PAPs.

Tools for Navigating the PAP Maze

There are several different tools that may be employed to simplify the PAP process, but there is no single tool that stands out as the “best” or “perfect” tool for all organizations. The needs, philosophy, staff, budget, and scope of the PAP system desired should help each organization determine the tool that will provide the greatest benefit for their organization. These tools are grouped into categories based on the level of technology required for implementation and presented from the simplest to the most complex technology.

To assist organizations in understanding their needs, a nationwide survey was conducted of organizations using different categories of tools for PAP management. The article, “Use of Drug Manufacturers’ Patient Assistance Programs by Safety Net Providers,” summarizes the costs and benefits reported by the different organizations and may provide a benchmark for organizations to use in evaluating the different PAP options.⁵ A summary of the results appears in *Appendix V*. Medicine for People in Need (MedPin) also conducted a survey of how safety net providers handle patient assistance programs and the tools they use to manage PAP information. For more information on Medpin and to obtain the results of this survey, go to www.medpin.org. See *Appendix IX* for more information on Medpin’s resources.

PATIENT INITIATED PROGRAM RESOURCES

These resources rely on the patient to coordinate the PAP process by accessing an organization that maintains PAP forms and program knowledge. The patient typically contacts an independent, off-site organization and pays an enrollment fee and sometimes a per prescription fee. The patient initiated program resource then determines if the medication needed is available through a patient assistance program and provides the patient with the program information and application form. Some also gather patient information and help the patient fill out the form. While some of these resources are helpful to patients and health care providers with little knowledge of how PAPs work, in many cases the same information is available through free websites (see Basic Information and Form Resources below).

Examples of patient initiated program resources include:

- The Medicine Program
- The We Care Medical Mall
- The Patient Assistance Network

ON-SITE STAFFING BY A THIRD PARTY

Recently, a few companies have begun offering to place their staff on site at a clinic, health center, or hospital to process PAPs. The site pays a fee to the company to have these staff present. Sites pay either a flat management fee or a percentage of the value of the PAP medications recovered.

Examples of companies that provide on-site staffing include:

- Cardinal Health
- McKesson
- Indicare (staff provided Pharmacy Health Care Solutions)

While the patient initiated programs and the on-site staff programs are the simplest of PAP systems because they remove the provider from direct management of PAPs, they also have limitations. Such limitations may include the inability of patients or providers to pay the fees, the lack of patient motivation to initiate the system, and if the staff is not on-site, the complications involved in collecting information accurately and in a timely fashion.

BASIC INFORMATION AND PROGRAM RESOURCES

The simplest way to remove the patient from the responsibility of initiating the PAP process is to use a free or low-cost resource that provides PAP information and forms. These resources are available at no cost on the Internet, or in some instances may be paid for and ordered as a hard copy manual. Many of these resources offer PAP application forms for some programs, and where no forms are available, provide information about how to obtain the form directly from the drug company operating the PAP. The PAP forms can be printed or copied from these resources and completed by hand; however, this can be a time consuming. The health care provider or patient advocate can then develop a paper tracking system or an individually created computer database (e.g., in Microsoft Excel or Access) to keep track of the patients, refills, and medications, and generate reports manually.

Examples of basic information and form resources include:

- www.rxassist.org (developed by Volunteers in Health Care)
- www.needymeds.com (hard copy directory also available for \$100)
- www.benefitscheckup.org
- www.phrma.org or call 1-800-762-4636 for a hard copy directory updated annually
- www.helpingpatients.org
- www.medicare.gov
- www.rxhope.com

Note: You also may be able to find information on a specific pharmaceutical company's program by searching that company's own website.

DATABASE MANAGEMENT RESOURCES

Over the last few years, many computer programs have emerged that allow health care providers and patient advocates to collect basic information on the patients they are assisting, find information about PAP programs, merge this information directly onto forms electronically, and keep track of the patients, refills, and medications with automatic report generation. These programs are typically easy to use and simplify the process greatly for health care providers and patient advocates. However some organizations may find it difficult to afford the up-front cost and monthly fees that most vendors charge.

Examples of database management resources include:

- RxAssist Plus (developed by Volunteers in Health Care)
- CIMS, The Practical Solution
- DataNetSolutions
- Indicare
- M & D Cares
- MEDagement
- MedDataServices
- Patient Prescription Services
- RxBridge

Appendix VIII includes a detailed chart describing the features of each.

BULK REPLENISHMENT SYSTEMS

Several health care providers have established bulk donation or replacement agreements with pharmaceutical manufacturers. These agreements allow large health care facilities (e.g., large community health centers, hospitals, and free clinics) to obtain bulk quantities of commonly used medications either as bulk donations or as bulk replenishment of existing stock. These programs are often called institutional patient assistance programs because they allow health care facilities to obtain bulk quantities of medications for low-income, uninsured patients seen at their institutions rather than applying for each patient individually.

The advantages of this approach are obvious. Bulk arrangements save both drug companies and health care providers time and money because it is no longer necessary to submit or review individual applications. In addition, having bulk stock ensures that medication will be available when patients need it. Finally, brokering such an arrangement establishes a collaborative agreement between the organization and a pharmaceutical company that may lead to other mutually beneficial partnerships.

Health care providers that have negotiated such agreements usually develop their systems gradually, adding one drug company at a time. Organizations that have successfully implemented such systems have used the following strategies to encourage manufacturers to provide bulk donations:

1. They have demonstrated to the manufacturer that they submit a large volume of patient assistance program applications and that a bulk replenishment system will save the manufacturer both time and paperwork processing PAP applications.
2. They have convinced the manufacturer that the institution is diligently screening patients and that all patients who receive bulk medications are eligible for the company's patient assistance program (e.g., are uninsured and have income levels below the company's eligibility cutoff).
3. They have demonstrated an ability to generate reports showing the medications dispensed and the patients assisted. Manufacturers generally request that such forms be submitted at regular intervals so the manufacturer can ensure that no diversion is taking place.

Frequently Asked Questions

Q: *How can I find out which medications are available through patient assistance programs?*

A: The large majority of brand name medications are available through patient assistance programs. You can find out if a particular drug is available by contacting the manufacturer directly or by looking the medication up on one of the websites that compile information on patient assistance programs. (See Basic Information and Form Resources).

Q: *Why isn't there a single application form to use for all programs?*

A: Many health care providers are frustrated by the fact that each program has its own application procedure, eligibility criteria, and application form and have asked why there can't be a single, universal form. While a single form would certainly be easier for the applicants, the manufacturers have been unable to accommodate this request. Many manufacturers have stated that they want to retain control over their own program since access to commonly abused and/or expensive drugs must be tightly controlled. Other manufacturers have said that they cannot create a common form because this type of collaboration among manufacturers would violate anti-trust regulations.

Q: *How often should we collect patient information to establish eligibility for the programs?*

A: Most programs have patients fill out a detailed intake form the first time they request assistance with medications. They also ask the patient if any information has changed each time a medication is requested. In addition, it would be advisable to have all patients fill out a complete intake form on an annual basis and provide updated documents (e.g., most recent tax return) at that time.

Q: *What percentage of applications are accepted/rejected?*

A: The answer to this question depends on how closely you screen patients' eligibility before submitting an application. However, the large majority of applications submitted are accepted, assuming that the forms are filled out properly and the patients appropriately screened.

Q: *Are patient assistance programs open to undocumented residents?*

A: Each pharmaceutical company establishes its own eligibility criteria, therefore, some programs are open to undocumented residents and others are not. Some websites (e.g., RxAssist) provide information on eligibility and may state whether the program is open to such patients or not. In other cases, the eligibility criteria are spelled out on the application form itself. Whether the program specifically states that undocumented residents are eligible or not, it is worth contacting the company to explain a patient's situation and to inquire what their formal eligibility criteria are and if it is possible to make an exception. While most companies require a social security number, some do so in order to collect a unique patient ID number rather than to verify a patient's legal status.

Q: *How can I address the short-term medication needs of patients who are waiting to receive medications requested from a patient assistance program since the application process may take four weeks or longer?*

A: Many health care providers use samples for this purpose. Others may suggest that the patient pay for the first 30-day supply out-of-pocket, pay for this medication out of the organization's own funds, or turn to charitable organizations, such as civic groups, churches, etc. that provide funding for short-term emergency needs.

Q: *How can I help patients who need medications for acute conditions?*

A: Patient assistance programs are not an appropriate solution for acute care needs (e.g., immediate needs for antibiotics) since it may take four weeks or longer to receive medications from patient assistance programs. In such cases, using samples, purchasing low-cost medications, or seeking assistance from charitable organizations is a more appropriate response.

Q: *Some of the physicians in my community are unwilling to help patients apply to patient assistance programs. How do I convince them to help?*

A: It is always a good idea to get physician buy-in from the very beginning. Explain to physicians how your program works and assure them that you will do all you can to complete the paperwork for them. This way all they will be responsible for is writing the prescription, signing the form, and dispensing the medication. It may also be helpful to have a physician leader speak to others about the program so he or she can reassure them about the worth of your program and that participating will help patients without putting an unnecessary burden on providers.

Q: *How can I make it easier to get prescribers' signatures on application forms?*

A: Some organizations have obtained a limited durable power of attorney that allows the patient assistance program coordinator to sign applications on behalf of physicians.

Q: *How can I make it easier to get patients' signatures on application forms?*

A: Some organizations have obtained a signature consent letter or a formal power of attorney that allows the patient assistance program coordinator to sign applications on behalf of patients. Getting permission to sign forms for patients may make it easier to process initial applications and requests for refills for patients who are difficult to locate when forms need to be signed (e.g., homeless or migrant farm workers).

Q: *Can we charge for medications obtained from patient assistance programs?*

A: Because health care providers obtain these medications from manufacturers at no cost, it is both unethical and illegal to charge patients for the medication itself. However, it is permissible to charge a reasonable administrative or dispensing fee to cover the costs of handling the paperwork and labeling and dispensing the medication. Those organizations that charge an administrative fee generally charge fees that range from \$1-10 for a 90-day supply.

Q: *Is there a simple way to track when it is time to apply for a refill?*

A: It's a good idea to keep track of the amount of time it takes for each program to process an application. If, for instance, a program takes six weeks, you will need to begin the process of submitting a refill application six weeks before the patient's 90-day supply is up (i.e., about six weeks after you submit the initial application). Some organizations use calendars or paper file systems to remind them when it is time to submit a refill application. Others use software programs that include reports that generate lists of patients that need refills or that flag patients with refills due (see *Appendix VIII*).

Q: *How can a coordinating agency keep track of when medications are received and dispensed since the medications are sent to the doctor rather than to the agency?*

A: It is definitely more complicated to track this information as a coordinating agency. Many organizations provide postcards or fax forms that physicians send back to alert the agency when the medication is received. Other agencies provide postcards or return reply envelopes to patients and ask them to contact the agency when they receive their medication.

Q: *What do you with unused patient assistance program medications?*

A: If a patient assistance program medication is unused because a patient doesn't pick up a patient assistance program medication, because their prescription is changed, etc., it is appropriate to contact the patient assistance program to ask what they would like you to do with the medication. In most instances, the company would prefer that you use this medication for another patient in need rather than return it or dispose of it.

Q: *How do the Health Insurance Portability and Accountability Act (HIPAA) regulations affect PAPs?*

A: The HIPAA regulations require that certain organizations which the regulations call "covered entities" take measures to protect patients' privacy, to ensure the security of confidential patient information, and to share information with other health care organizations in a consistent manner using standard codes and formats. If your organization is a covered entity, you must comply with the HIPAA regulations when helping patients access medications through patient assistance programs. For example, you should obtain written authorization from patients before disclosing protected health information to pharmaceutical company patient assistance programs. You should also assure that both staff members and volunteers understand the importance of ensuring patients' privacy. Privacy concerns should be addressed through training sessions and in the Policy and Procedures manual and staff members and volunteers should be asked to sign contracts agreeing to keep patient information private. See Volunteers in Health Care's manual, *Understanding the Health Insurance Portability & Accountability Act* for more information.

Q: *How can we track the value of medications we obtain for patients so we can report this information to our board and/or funders?*

A: Tracking the value of the medications you obtain for patients will help you justify the time and expense associated with your program. You may wish to use the Average Wholesale Price (AWP), Medicaid Price, or retail price as a measure of the value of the medications you are obtaining. You can find the AWP in publications such as The Red Book, the Medicaid price from your state Medicaid agency, and the retail price from local pharmacies.

Pharmacy prices are based on the "AWP;" this is the gold standard or starting point in pharmacy pricing. AWP is universally available via computers from pharmacies and wholesalers — AWP is the "currency" of pharmacy drug pricing. In contrast, the "retail price" is not a universal term and may mean different things to different people (e.g., the retail price might mean the cost that the patient pays for the medication (including or not including dispensing fees), OR it might mean the price a retail pharmacy pays its wholesaler. Calculations based on AWP will be more meaningful to a wide variety of users than using the loose term "retail price." In addition, if you are interested in benchmarking numbers, using AWP pricing makes it possible to compare what you are doing to most published statistics. In theory, an organization could use retail pricing for calculations, but they should do this with the understanding that it may be difficult to obtain the "retail price," since there is no standard "retail price" (which makes calculations over time difficult), and their data will be most useful for use and analysis within their organization alone. Using the retail price would make it harder to provide meaningful numbers to outsiders who understand pharmacy pricing.

References

1. Volunteers in Health Care. *Statistics obtained from RxAssist database*. Pawtucket, RI: Volunteers in Health Care; October 3, 2002.
2. Chisholm, MA., DiPiro JT. Pharmaceutical manufacturer assistance programs. *Archives of Internal Medicine*. 2002;162(7):780-784.
3. Website. www.rxforohio.org/questions.htm. Accessed November 7, 2003. Sponsored by Rx for Ohio.
4. Mills RJ, Bhandari S. *Health insurance coverage in the United States: 2002*. Washington DC: U.S. Census Bureau; September 2003.
5. Richardson, K., Basskin LE. Use of drug manufacturers' patient assistance programs by safety net providers. *American Journal of Health-Systems Pharmacy*. 2002;59:1105-1109.

SAMPLE PAP APPLICATION FORMS



CONNECTION TO CARE Application

P.O. Box 66585 • St. Louis, MO 63166-6585 • (800) 707-8990

Please Read: Be sure the healthcare provider and patient sections are completed. Mail this form, along with your original signed prescription, a copy of your last year's tax return, and all supporting income documentation to avoid a delay.

1 Healthcare Provider *(This section must be completed and signed by the provider.)*

Name/Professional Designation: _____ DEA#: _____ Expiration Date: _____

Office Contact Person (Name and Title): _____ If you do not have a DEA#, include your state license# & Exp. Date: _____

Mailing Address (No P.O. Box) _____ Shipping Address (No P.O. Box) _____
 Hospital or Clinic name (if applicable): _____ Hospital or Clinic name (if applicable): _____

Suite: _____ Suite: _____

City: _____ City: _____

State/Zip: _____ State/Zip: _____

Phone: (____) _____ Fax: (____) _____

Healthcare Provider Certification: My signature attests that medications received from Pfizer for patient assistance are only for the use of the patient named on this form. These medications will not be offered for sale, trade, or barter. Additionally, they will not be submitted for Medicare, Medicaid, or any third-party reimbursement, nor returned for credit. By signing, I also agree that Pfizer has the right to contact the patient directly to confirm receipt of medications, and to revise, change, or terminate this program at any time. Additionally, to the best of my knowledge, my patient meets Pfizer's criteria for patient assistance.

Original signature of licensed practitioner: _____ Date: _____

2 Patient *(This section must be completed and signed by the patient.)*

1. Enclose an original signed prescription from your physician.
2. Attach a copy of the most recent year Federal Tax Return (Form 1040, 1040EZ, etc.)
3. Attach a copy of all other supporting financial documentation. Examples of income supporting documents may include Wages and Tax Statement (W-2), Social Security and Disability Benefit Verification Statement (SSA-1099), Dividend and Distributions (1099-DIV), and Interest income (1099-INT), if applicable.
4. If you did not file a tax return, please attach an IRS Form 4506 to verify that you did not file. If you need assistance with this form, please call (800) 707-8990.

***You need to apply for your medications every three months. Tax return and supporting documentation are only required once a year.**

Name: _____

Address (no P.O. Box): _____

City: _____

State/Zip: _____

Phone: (____) _____

Social Security Number: _____

Date of Birth: _____

Applicant is: Male Female

Number of dependents in your household: _____
(including yourself)

Please fill in your marital status: _____

Check only one:

Single household income is \$16,000 or less.

Family household income is \$25,000 or less.

Do you belong to a state or public program that pays for your medicines? *Examples of ways to pay for your medicines:*

- Medicaid
- A state prescription drug program
- Employers'/retiree drug coverage
- Any other program with prescription drug coverage (public or state program, military)

Please check the box that applies to you:

Yes, I am in a program which pays for my medicines.

No, I am not in a program which pays for my medicines.

Please read the following, then sign: I know that all the information I provide in applying will be used to decide if I can be part of Connection to Care. By signing below I verify that the information on this application, including the signed copy of my prior year's tax return and the supporting income documentation, is complete and accurate. I also verify that I have no other coverage for prescription medications, including Medicaid, Medicare or any public or private assistance programs. I also agree that Pfizer has the right to verify my eligibility, including the audit of reported financial and insurance information and medical records. I understand that Pfizer has the right to contact me directly to confirm receipt of medications, and to revise, change, or terminate this program at any time. All personal information I provide will be kept confidential. Non-personal information (like your gender, location, or age) may be used to help Pfizer assess this program, or create new programs.

Patient Signature: _____ Date: _____

Refill Information

To apply for refills, submit a new application and original prescription well before you finish the medication(s) you are taking.

Proof of income is only required once a year.

SAMPLE

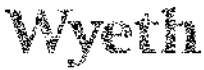
Pfizer medications available through *Connection to Care*

Accupril® (quinapril HCl)	Lipitor® (atorvastatin calcium)
Accuretic™ (quinapril HCl/hydrochlorothiazide)	Minipress® (prazosin HCl)
Antivert® (meclizine HCl)	Minizide® (prazosin polythiazide)
Arthrotec® (diclofenac Na/misoprostol)	Navane® (thiothixene)
Bextra® (valdecoxib)	Neurontin® (gabapentin)
Cardura® (doxazosin mesylate)	Norvasc® (amlodipine besylate)
Celebrex® (celecoxib)	Procardia® (nifedipine)
Covera HS® (verapamil HCl)	Procardia XL® (nifedipine extended release)
Cytotec® (misoprostol)	Relpax® (eletriptan HBr)
Detrol® (tolterodine tartrate)	Sinequan® (doxepin HCl)
Detrol LA® (tolterodine tartrate)	Viagra® (sildenafil citrate)
Diabinese® (chlorpropamide)	Vibramycin® (doxycycline hyclate)
Dilantin® (phenytoin)	Vistaryl® (hydroxyzine pamoate)
Dostinex® (cabergoline)	Xalatan® (latanoprost)
Feldene® (piroxicam)	Zarontin® (ethosuximide)
Glucotrol® (glipizide)	Zoloft® (sertraline HCl)
Glucotrol XL® (glipizide extended release)	Zyrtec®* (cetirizine HCl)
Glyset™ (miglitol)	

**If you need help with your application, or would like more information,
please call (800) 707-8990.**

All trademarked/registered names listed above in this application are owned by Pfizer Inc and its affiliates.

*ZYRTEC® is a registered trademark of UCB Pharma, Inc.



Patient assistance application form

Wyeth Pharmaceutical Assistance Foundation will provide a 3-month supply of medication for approved requests. Additional requests may be made by submission of a new form. Blank forms may be copied. In approximately 4-6 weeks, medication will be shipped directly to the requesting licensed practitioner who has appropriate prescribing privileges. Please submit requests accordingly. For a faxed copy of complete information including income guidelines and products provided by the Wyeth Pharmaceutical Assistance Foundation, call (800) 568-9938. This Program is not meant to induce a licensed practitioner to use or prescribe a Wyeth Pharmaceutical product.

Please print or type. Do not fax.

Section 1 Licensed practitioner's information

Medication will be shipped directly to the licensed practitioner in approximately 4-6 weeks. If this is a change of address, please check here and advise what has changed Entire Address Street Suite # Zip Code Other

Licensed practitioner full name (first, middle, last)	
Street address (UPS will not ship medication to P.O. boxes)	
City, state, zip	Address is: <input type="checkbox"/> Hospital <input type="checkbox"/> Clinic <input type="checkbox"/> Office
Telephone	Fax
Specialty: <input type="checkbox"/> FP <input type="checkbox"/> PSYCH <input type="checkbox"/> IM <input type="checkbox"/> CD <input type="checkbox"/> OBGYN <input type="checkbox"/> Other	

SAMPLE

I, (Licensed Practitioner) _____ request that the medication listed below be provided to me for the following patient who certified that he/she is a U.S. resident earning less than 200% of the current HHS Poverty Guidelines and is not eligible for any third-party payment (Medicaid, Insurance, Government Agencies) for the medication requested. I agree that if this application is approved, the medication will be provided to the patient identified below free of charge, i.e., neither the patient nor any third party will be billed for the medication.

Licensed practitioner original signature No copies or stamps will be accepted.	<input checked="" type="checkbox"/>	Date
State license number required	<input checked="" type="checkbox"/>	

Section 2 Patient information

Patient's full name (first, middle, last)					
Street address					
City, state, zip					
Last Four Digits of Social Security #	Male <input type="checkbox"/>	Female <input type="checkbox"/>	Date of Birth	Annual Household Income	# of People in Household

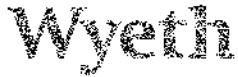
I authorize Wyeth Pharmaceuticals and the Wyeth Pharmaceutical Assistance Foundation to use this information to assess my eligibility for participation in the Patient Assistance Program, including the audit of my medical records and/or by contacting me directly to confirm my eligibility or receipt of drug and matters related to such program. I understand that this assistance is temporary and that this program may be discontinued or changed at any time. I understand that Wyeth Pharmaceuticals and the Wyeth Pharmaceutical Assistance Foundation will use my personal information in connection with the operation of the patient assistance program and issues related to such program. I certify I do not have the ability to pay for my medication, earn less than 200% of the current HHS Poverty Guidelines, am a U.S. resident, and that I have no government or private insurance to pay for my medication. I also certify that I do not have other sufficient financial resources or assets to pay for the medication requested or that paying for the medication from my own resources or assets would cause me a severe financial hardship. I attest that the information I have provided is correct and complete.

Patient (or guardian) original signature No copies or stamps will be accepted.	<input checked="" type="checkbox"/>	Date
---	-------------------------------------	------

Section 3 Product information

The following medications are *not* covered: Controlled products (class III-IV), oral contraceptives, OTC, injectables

Product name	Strength	Sig (three-month supply)
Product name	Strength	Sig (three-month supply)



Patient Assistance Program Authorization

This Patient Assistance Program Authorization Form authorizes your health care provider to disclose your health and medical information to Wyeth and to the Wyeth Pharmaceutical Assistance Foundation and their respective employees, representatives and agents (collectively, "Wyeth") in connection with your application to the Wyeth Patient Assistance Program (the "Wyeth PAP") as required by the Health Insurance Portability and Accountability Act of 1996 and related federal regulations and rules ("HIPAA").

Authorization.

I, _____ [First, Middle and Last Name], hereby authorize _____ [Name of Physician or Medical Group] ("Health Care Provider") to disclose my individually identifiable health and medical information described below to Wyeth solely for the authorized purposes described in this authorization form.

Description of Health and Medical Information That May Be Disclosed.

My Health Care Provider may disclose individually identifiable health and other information that supports my application to the Wyeth PAP and that may include my name, address, date of birth, social security number, financial information, medical records and the specialty of my health care provider.

Authorized Purposes.

The authorized purposes are: (1) to permit Wyeth to evaluate my eligibility for participation in the Wyeth PAP; and (2) if Wyeth, in its sole discretion, approves my request to participate, for Wyeth's administration of my participation in the Wyeth PAP.

Expiration of Authorization.

My authorization shall expire (1) when Wyeth does not approve my application for participation in Wyeth's PAP, or (2) at the conclusion of my participation in the Wyeth PAP, whichever is earlier.

Acknowledgments.

(1) I understand that Wyeth is not an entity covered by HIPAA and related federal privacy regulations and that my medical and health information may be subject to redisclosure by Wyeth and no longer protected by such federal privacy regulations. I further understand and agree that Wyeth may retain my medical and health information as disclosed to Wyeth by my Health Care Provider under this authorization after this authorization expires for purposes related to the administration of the Wyeth PAP.

(2) I understand that I may refuse to sign this authorization form and that, unless allowed by law, my refusal to sign will not affect my ability to obtain treatment from my Health Care Provider, or to seek payment or my eligibility for benefits. However, I understand that I may not participate in the Wyeth PAP if I refuse to sign this authorization form.

(3) I understand that I may revoke my authorization at any time by providing a written notice of same to my Health Care Provider that refers to (or with a copy of) this authorization form, or as set forth in my Health Care Provider's Notice of Privacy Practices (if any). However, I understand that if I revoke this authorization, it will not affect prior disclosures made by my Health Care Provider to Wyeth in reliance on this authorization.

Signature of Patient or Patient's Personal Representative

Date

Patient's Name

Name of Personal Representative (if applicable)

Relationship to Patient

HEALTH CARE PROVIDER MUST GIVE PATIENT AND/OR PATIENT'S REPRESENTATIVE A SIGNED COPY

Health Care Provider has verified Patient Representative's authority to act on Patient's behalf (check)

SAMPLE

**Wyeth Patient Assistance Program
General Information**

Patients must attest that they are a U.S. resident, do not have the ability to pay for their medication, have no government or private insurance to pay for the medication requested, and must have an annual income less than or equal to the amounts listed below.

Size of Family Unit	48 Contiguous States and D.C.	Alaska	Hawaii
1	\$17,960	\$22,420	\$20,660
2	\$24,240	\$30,280	\$27,880
3	\$30,520	\$38,140	\$35,100
4	\$36,800	\$46,000	\$42,320
5	\$43,080	\$53,860	\$49,540
6	\$49,360	\$61,720	\$56,760
7	\$55,640	\$69,580	\$63,980
8	\$61,920	\$77,440	\$71,200
For each additional person, add	\$6,280	\$7,860	\$7,220

(The chart is based on 200% of the 2003 HHS Poverty Guidelines and will be updated annually.)

- All medication is shipped directly to the health care provider’s street address. Allow 4 – 6 weeks from the receipt of a completed application for processing.
- The following medications are not covered: Over-the-Counter products, Diagnostics, Class II – IV Drugs, Oral Contraceptives, and Injectables.
- The attached blank application form may be copied and used for additional requests or renewal applications. Patients, through their health care provider, may reapply for additional medication every three months as long as they continue to meet all current qualification guidelines. This program and its guidelines are subject to change at any time.
- All inquiries about the program should be made by the health care provider’s office or patient advocate.
- All applications must be mailed to the Wyeth Pharmaceutical Assistance Foundation at the address indicated on the application form.
- Incomplete or illegible applications may be returned for clarification possibly resulting in a delayed shipment of medication to the patient. To ensure that your application will be processed as quickly as possible:
 - Type or print clearly
 - Complete all sections of the application
 - Indicate the full product name and strength
 - Mail the application to the address indicated on the application form
 - Verify that the health care provider and patient (or guardian) have signed the application (copies of signatures will not be accepted)
 - Verify that the product requested is provided by the Wyeth Pharmaceutical Assistance Foundation by checking the attached product list.
 - Complete the Wyeth Patient Assistance Program Authorization Form (HIPAA)

SAMPLE

Products Provided by the Wyeth Pharmaceutical Assistance Foundation:**

Last Updated on 10/8/2003

Cordarone® (amiodarone HCl) Tablets 200mg
Effxor® (venlafaxine HCl) Tablets 25mg, 37.5mg, 50mg, 75mg, & 100mg
Effxor® XR (venlafaxine HCl) Extended-Release Capsules 37.5mg, 75mg, & 150mg
Inderal® (propranolol HCl) Tablets 10mg, 20mg, 40mg, 60mg, & 80mg
Inderal® LA (propranolol HCl) Long-Acting Capsules 60mg, 80mg, 120mg, & 160mg
Inderide® (propranolol HCl and hydrochlorothiazide) Tablets 40/25mg & 80/25mg
Lodine® (etodolac) Capsules 200mg & 300mg
Lodine® (etodolac) Tablets 400mg & 500mg
Lodine® XL (etodolac) Tablets 400mg, 500mg, & 600mg
Materna® (Prenatal vitamin and mineral tablets, USP)
Minocin® (minocycline HCl) Capsules 50mg & 100mg
Oruvail® (ketoprofen) Capsules ER 100mg, 150mg & 200mg
Phenergan® (promethazine HCl) Suppositories 12.5mg, 25mg, & 50mg
Phenergan® (promethazine HCl) Tablets 12.5mg, 25mg, & 50mg
Phospholine Iodide (echothiophate iodide) 6.25mg per 5mL
Premarin® (conjugated estrogens tablets, USP) 0.3mg, 0.45mg, 0.625mg, 0.9mg, & 1.25mg
Premarin® (conjugated estrogens) Vaginal Cream 0.625mg
Premphase® (conjugated estrogens/medroxyprogesterone acetate tablets) 0.625/5mg
Prempro™ (conjugated estrogens/medroxyprogesterone acetate tablets) 0.45/1.5mg, 0.625/2.5mg & 0.625/5mg
Protonix® (pantoprazole sodium) Tablets 40mg
Trecator®-SC (ethionamide) Tablets 250mg

**This product list is subject to change at any time.

To obtain future updates to this list via our fax-back system, call (800) 568-9938.

Refer to the information below for assistance with other Wyeth Pharmaceutical products.

BeneFIX® Coagulation Factor IX (Recombinant) –
The BeneFIX® Reimbursement Patient Assistance Program (888) 999-2349
Enbrel® (etanercept) – ENCourage (800) 393-4675
Mylotarg™ (gemtuzumab ozogamicin for injection) – Wyeth Oncology Reimbursement Program (888) 638-6342
Neumega® (Oprelvekin) – Wyeth Oncology Reimbursement Program (888) 638-6342
Rapamune® (sirolimus) RapAssist Patient Assistance Program (877) 472-7268
ReFacto® Antihemophilic Factor (Recombinant) – Hemophilia Reimbursement Hotline (888) 999-2349
Synvise® (hylan G-F 20) – Synvise® Reimbursement Hotline (800) 982-8292

Appendix II

SAMPLE LETTER CERTIFYING PATIENT'S NEED

Date

Pharmaceutical Company

Patient Assistance Program

Street Address

City, State Zip Code

Patient Name

Street Address

City, State Zip Code

To Whom It May Concern:

The above-named patient is being treated for clinical diagnosis.

Enclosed is a prescription for medication name and dosage.

In accordance with your eligibility criteria, this patient is currently unable to afford to pay for this medication due to financial hardship. The patient also has no insurance coverage to help pay for the cost of this medication, and is ineligible for any public assistance.

Please forward an application/medication to this office at:

Physician Name

Organization Name

Street Address

City, State Zip Code

If you have any questions, please call me at telephone number. We greatly appreciate the assistance that your company makes available to the patients we serve.

Sincerely,

Original Signature

Physician Name

DEA #: _____

Attachments: List them here.

FIELDS TO INCLUDE IN PATIENT INTAKE FORM

- Patient name (first name, middle initial, last name):
- Address (Street and Mailing, include apartment number):
- City:
- State:
- Zip Code:
- County:
- Home telephone number:
- Work telephone number:
- Social security number:
- Date of birth:
- Sex:
- Referral source:
- U.S. citizen?
- U.S. resident?
- Veteran or spouse of Veteran?
- Race/ethnicity:
- Marital status:
- Rent or own home:
- Number living in household:
- Employment status:
- Occupation:
- Employer:
- Primary health insurance with Policy #:
- Secondary health insurance with Policy #:
- Do you have prescription coverage?
- Known drug allergies:
- Emergency contact information (name, relationship, address, phone number):
- Monthly household income by source (wages, disability, unemployment, social security, pension, alimony, child support, workmen's comp, other):
- Assets (savings account, checking account, other investments):
- Prescriber's name:
- Prescriber's telephone number:

INFORMATION NEEDED FROM PRESCRIBER

- Prescriber name (first name, middle initial, last name):
- Designation (e.g., MD, DO, NP, PA):
- Specialty:
- DEA #:
- DEA expiration date:
- State license #:
- State license expiration date:
- Practice or facility name:
- Address (street and mailing):
- City:
- State:
- Zip code:
- Office contact:
- Telephone number:
- Fax number:
- Email address:

Appendix V

BENCHMARK STATISTICS FOR PAP OPERATIONS

This information is a summary of survey results from 1200 safety net providers (clinics and hospitals).⁵ While it is the only survey that has been published that presents multiple site PAP cost and benefit information, it has limitations and should be interpreted with the following in mind:

- Survey was conducted in 2000; sites reported 1999 figures in US dollars.
- Survey sample was for providers participating in the 340B program ("benefit" from PAPs was calculated using the 340B price).
- Response rate was 10%.
- Results were presented as aggregate numbers, and there was considerable variability between sites in responses (thus the figures are reported as annual median values with 25-75% interquartile ranges).
- "Manual" group was defined as completing PAP forms by hand, "Computer" group used a computer (either a purchased program or a created program).

CATEGORY (ANNUAL)	CLINIC RESULTS		HOSPITAL RESULTS	
	MANUAL	COMPUTER	MANUAL	COMPUTER
# STAFF HOURS	520 (195-1,371)	3,952 (3,224-4004)	3,328 (416-4,576)	4,160 (208-6,240)
% PAP RECOVERY (recovered/requested)	94%	90%	95%	96%
PAP MEDS RECEIVED	490 (163-1,200)	5,118 (1,900-7,176)	1,680 (1,138-3,910)	9,000 (600-50,000)
COST (staff+supplies)	\$4,740 (2,320-13,526)	\$36,159 (12,742-49,552)	\$51,323 (2,132-72,632)	\$70,940 (4,592-105,980)
GROSS BENEFIT (value of meds)	\$48,500 (10,000-183,304)	\$345,735 (146,470-590,603)	\$200,000 (64,750-627,000)	\$1,000,000 (266,400-1,000,000)
FEE RANGE TO PATIENT/RX	\$1.00-10.00	\$0.17-5.00	\$1.00	\$3.00-5.00
AVG. STAFF TIME TO PROCESS 1 PAP	60 minutes	46 minutes	120 minutes	28 minutes

DEVELOPING A POLICY AND PROCEDURES MANUAL

In general:

- The Manual should be dated and signed by the organization's Chief Executive Officer (CEO), Chief Medical Officer (CMO) or Medical Director, and PAP coordinator.
- Each page of the manual should be devoted to a particular subject, and each page should have a title, list the responsible staff member for the subject, and the date last updated.

Topics to Include:

1. Goals and objectives of PAP system
2. The hours of operation of the PAP system
3. Responsible person(s) for PAP coordination, additional staff, and contact information
4. PAP coordinator's supervisor, including to whom the supervisor reports
5. Process for PAP application-this should be spelled out step by step, and should include descriptions of the policies and procedures involving:
 - Patient referral
 - Prescribers/other staff education regarding PAPs
 - Marketing plan for PAP system to patients
 - Prescribers with authority to prescribe for PAP medications
 - Record-keeping (medication profiles, medication history, etc.)
 - Medication storage (who has keys to the medication storage area, who may dispense medications, etc.)
 - Medication dispensing and labeling
 - Patient education
 - Documentation of medication pick-up and patient education/ charting
 - Handling medications not picked up or returned
 - Mailing
 - Fees charged to patients
 - Formulary (description of the role of a Pharmacy and Therapeutics Committee, if applicable)
6. Purchasing PAP supplies
7. Licensing (state licenses for dispensing practitioners or pharmacy permits, if applicable)
8. Computer operation and back-up, if applicable
9. Method of evaluating PAP system's success (patient satisfaction, prescriber satisfaction, economic savings for clinic or patients, etc.)
10. Medication safety policy/procedures

PAP SAFETY CHECKLIST

1. Prior to ordering PAP medication, check:

- The complete patient medication record to ensure there are no drug interactions, unintended duplication of medications, or allergies. If possible, ask the patient for a current list of medications BEFORE ordering the medicine. Update any changes in the medical record and any other medication tracking system.
- The medication record to see if there are any other PAP medications that the patient receives. Would it be possible to align the medications so that the PAP requests may be made at the same time?
- Will the patient receive a short-term supply of this medication through another source (sample, voucher, etc.) before it arrives from the drug manufacturer? Record this information in the patient record and/or PAP record system.

2. Upon arrival of PAP medication, check:

- The PAP medication requested is the same as the PAP medication received.
- The patient name, drug strength, quantity, and directions for use are appropriate.
- There are no drug interactions, therapeutic duplications, food interactions or possible compliance problems between the PAP medication(s) and the other medications the patient takes.
- The PAP medication is labeled, stored, and recorded according to state guidelines.

3. Upon patient pick-up of PAP medication, check:

- Ask the patient for a list of ALL medications that the patient takes (include over the counter medications and vitamins). Make sure this list is reflected in the patient record/medication record. This question should be asked every time the patient presents to ensure new medications or medication changes are included.
- Ask the patient if he is having any problems or possible side effects with any medications. Suggestions include: barriers to taking medications (difficulty remembering to take the medication, the medication might be too expensive to buy), physical complaints possibly associated with medications, etc.

- ❑ Have a qualified healthcare professional (physician or pharmacist) review the complete list of current medications as well as the problem/barrier list to ensure that there are no drug interactions or other problems between the PAP medication and other medications.
- ❑ Remind the patient of the PAP drug name, strength, quantity, directions for use, common side effects, and when and where to seek medical attention for a drug-related problem. Have the patient verbalize these elements to demonstrate understanding.
- ❑ Remind the patient to tell the pharmacist(s) that fill other prescriptions for the patient that he/she takes this PAP medication as well.
- ❑ Remind the patient to request a refill of this PAP medication within ___ of running out (i.e. 6 weeks before he runs out) if the medication is needed for a long-term treatment of a chronic condition and a refill will be needed. As a reminder, give the patient a card with the refill request date and the appropriate phone number to call to request a refill.

Appendix XIII

**PATIENT ASSISTANCE PROGRAM COMPUTER MANAGEMENT
OPTIONS**

CIMS THE PRACTICAL SOLUTION		DATANETSOLUTIONS		MEDAGEMENT		MEDDATASERVICES	
Contact Information	www.cims-technologies.com 801-966-3794 HienHoang@cims-technologies.com Hein Hoang 6596 South Slalom Way West Jordan, UT 84084	www.datanetsolutions.org 423-479-6729 keith@datanetsolutions.org Keith Weigand 200 Bell Crest Drive Cleveland, TN 37312	www.medagement.com 806-672-7053 sales@medagement.com Mike Fisher PO Box 51351 Amarillo, TX 79159	www.meddataservices.com 888-246-1085 Donald Kaker 1926 Camelot Drive Grapevine, TX 76051			
# Companies Included	N/A (varies)	40	Varies	N/A		N/A	
# Programs Included	N/A (varies)	N/A	Varies	Varies		180	
# Forms Included	N/A (varies)	Varies	Varies	Varies		N/A	
# Medications included	N/A (varies)	Varies	Varies	Varies (can be added by facility)		1200	
Frequency of Form updates	A couple of times/year; ongoing-- immediately if requested by client	Ongoing	Ongoing	Reactive based on users; ongoing.		Monthly	
Demo Program available?	Yes, online	Yes, Power Point presentation online, demo can be mailed	Yes, online	Yes, online		Yes	
# Organizations Currently Using Program	N/A	50	50	About 10		200	
Types of Users	CHCs, free clinics, and govt. agencies	CHCs, free clinics, govt. agencies, hospitals, and medication assistance programs	CHCs, free clinics, govt. agencies, hospitals, and medication assistance programs	CHCs, free clinics, govt. agencies, hospitals, and medication assistance programs		CHCs, free clinics, govt. agencies, and hospitals	
Any Restrictions on Users?	Usually only non-profits, but exceptions are made	No	No	Call or email for details		No	
Internet Access necessary?	Internet recommended, but it is possible to run locally on a network	No	No	No		Yes, required	
Product Available on ...	Internet	CD-ROM	CD-ROM	CD-ROM or high-speed dial-up via Virtual Private Network (VPN)		Internet + password	
HIPAA Compliant?	Yes	Not required	Not required	Responsibility of facility		Yes	
Network Capability	Yes	Yes	Yes	Yes		Yes	

Link to Other Databases in Organization? (Data Conversion)	Yes	Yes	Possibly, with setup assistance	No
Customization Capability?	Yes	Yes	Yes	Yes, possibly
User's Manual?	Yes	Yes	Yes	Yes
Technical Assistance	Yes, contracts are case by case; available by email, phone, in person-- usually phone + in person, 24 hours a day, 7 days a week	Yes, free, phone + email, M-F 9-5 EST	Yes, included in contract and available by phone and email 24 hours a day, 7 days a week	Yes, free, phone, M-F 9-5 CST
Cost	Varies; 6-month promo. for free clinics/non-profits (12/02-6/03); waive cost of software w/all modules (valued at \$30K+)	Varies by module selected	Varies by setup	Contact MedData
Program Available Since	2000	1999	2002	1999
Recommended Minimum Hardware and Software Requirements	Internet Explorer 5.0, Windows	Any Windows operating system except Windows ME	Windows 98 or higher, 400 Mhz processor or higher, 128 MB RAM	Windows 95 or higher, 300 Mhz processor or higher, 128 MB RAM, SVGA monitor (800 X 600 resolution), Microsoft Internet Explorer 5.0 or higher, Macromedia Flash 4.0, Adobe Acrobat Reader 4.0, Internet connection
Names of Available PAP Meds	•	•	•	•
Contact Info for PAPs	•	•		•
Application Instructions/ Eligibility Info	•	•		•
Automatic Patient Eligibility Determination		•	Yes, if program is set up with link to pharmacy system (or computer system that supplies financial information)	

N/A = not available

CIMS THE PRACTICAL SOLUTION				DATA/NET/SOLUTIONS	MED/AGEMENT	MED/DATA/SERVICES
Automatic Form Completion		•		•	•	•
Automatic Form Submission						
Cover Letter with Application	•	•		•	•	•
Mailing Labels	•	•				
Medication Labels	•	•				
Tracking Process from Start to Finish	•	•		•	•	•
Refill Information	•	•		•	•	•
\$ Value of PAP Meds	•	•		Users enter value themselves		•
Acceptance/Denial Rate by Company	•	•				•
Tracking Meds by Patient	•	•		•	•	•
Summary Stats	•	•		•	•	•
Other Capabilities	Real time query system available to produce dynamic queries & reports; several additional CIMS modules available (i.e., encounters, labs, demographic info.)	Generates graphs to accompany reports. Includes a real-time query builder.	Allows users to generate a spreadsheet for use in reporting to manufacturers providing bulk replacement medications, a wide range of summary reports can be generated by patient, doctor, facility, company, program, or drug.	Uses AWP pricing, creates prescriptions if needed, report generator available for programs using bulk PAP recovery (compiles desired patient data), rates difficulty of PAPs from 1-5		

**PATIENT PRESCRIPTION SERVICES
(PAPRX)**

RXASSIST PLUS

RXBRIDGE

Contact Information	www.paprx.com 512-306-1916 Risinger@PAPrx.com Ed Risinger 3207 Bee Caves Road Austin, TX 78746	www.rxassist.org and www.volunteersinhealthcare.org 877-844-8442 Email via websites Volunteers in Health Care 111 Brewster Street Pawtucket, RI 02860	www.medbankmd.org 410-821-9262 x102 Rnmcewan@medbankmd.org Bob McEwan 7400 York Road, Ste. 400 Towson, MD 21204
# Companies Included	177	87	235
# Programs Included	142	151	139
# Forms Included	N/A	80	99
# Medications included	1166	850+	846
Frequency of Form updates	Reactive based on users; ongoing	Each company is contacted every 4 months for an update, also receive information in between updates from both companies and users.	3-4 weeks
Demo Program available?	No, tutorial built-in + 30-day \$ back guarantee	Free, 90-day trial	Yes
# Organizations Currently Using Program	180+	450	12
Types of Users	CHCs, free clinics, hospitals, and medication assistance programs	CHCs, free clinics, govt. agencies, hospitals, medication assistance programs, and other nonprofits, and physician's offices	CHCs, free clinics, govt. agencies, hospitals, medication assistance programs, and other
Any Restrictions on Users?	No	Currently available to non-profit organizations, government agencies, and practicing clinicians caring for the uninsured	No
Internet Access necessary?	Yes, for updates only; system runs locally	Yes, required.	Yes, required
Product Available on...	CD-ROM or Internet + password	CD-ROM with password for Internet portion	Internet + password
HIPAA Compliant?	Yes	Yes, Version 3.0 and higher	Yes

N/A = not available

PATIENT PRESCRIPTION SERVICES
(PAPRX)

RXASSIST PLUS

RXBRIDGE

Network Capability	Yes	Yes, recommend no more than 10-15 simultaneous users	Yes
Link to other Databases in organization? (data conversion)	No, but a free one-time data conversion is included	Yes, with setup assistance	Yes, requires an interface
Customization Capability?	Yes	Yes, some customization possible	Yes, depends on the nature of the request
User's Manual?	Yes, CD	Yes, CD	Yes, plus training CD in development
Technical Assistance	Yes, free, phone, M-F 9-5 CST	Yes, free, by phone and email, M-F 8:30-3:30 EST	Yes, built into the subscription cost, phone, email or in person, M-F 8:30-5:00 EST
Cost	Volume dependent price (\$1/Rx)	\$200	Subscription basis; contact Medbank of Maryland for more information
Program Available Since	2001	2001	2002
Recommended minimum hardware and software requirements	Windows 95, Internet connection necessary for updates	Microsoft Windows 95 or higher, 100 MB Hard Disk Space, 32 MB RAM, 250 Mhz Pentium Processor or higher, CD-Rom Drive, Office 97 or higher with graphics filters installed, Internet access	Pentium 233 MHz, 64MB RAM, Windows 98, 128K Internet Access speed, Adobe Acrobat Reader 4.0, Microsoft Internet Explorer 5.5
Names of Available PAP Meds	•	•	•
Contact Info for PAPs	•	•	•
Application Instructions/Eligibility Info	•	•	•
Automatic Patient Eligibility Determination	•		

N/A = not available

PATIENT PRESCRIPTION SERVICES (PAPRX)			RXASSIST PLUS	RXBRIDGE
Automatic Form Completion	•		•	•
Automatic Form Submission				
Cover Letter with Application	•		•	•
Mailing Labels	•		•	
Medication Labels	•			
Tracking Process from Start to Finish	•		•	•
Refill Information	•		•	•
\$ Value of PAP Meds	•		Users can enter \$ value of medications and reports calculate overall \$ value for defined date ranges, company, and other criteria	•
Acceptance/Denial Rate by Company			•	•
Tracking Meds by Patient	•		•	•
Summary Stats	•		•	•
Other Capabilities	System tracks samples, low cost mail order Rx info available for bridge meds/ PAP alternative, form 4506 included/printable		Also tracks patient demographics, patient visits, and volunteer provider info.	Allows reporting on patient demographics by user, site, and geographic area; harnesses all data captured within it.

N/A = not available

OTHER PRODUCTS

Indicare declined to participate in this survey.

- For more information on Indicare, visit <http://www.indicare.com>.

M & D Cares did not respond to this survey in time for inclusion.

- For more information on M & D Cares, visit <http://www.morrisdickson.com>.

The Pharmacy Connection is distributed by the Virginia Health Care Foundation and only available to Virginia programs.

- For more information on The Pharmacy Connection, visit <http://www.vhcf.org/pharm/htmtpc@vhcf.org>.

USEFUL WEBSITES AND OTHER RESOURCES FROM VOLUNTEERS IN HEALTH CARE & OTHER ORGANIZATIONS

WEBSITES

VOLUNTEERS IN HEALTH CARE

<http://www.volunteersinhealthcare.org>

Resources include:

- RxAssist website (<http://www.rxassist.org>)
 - Searchable database of patient assistance programs
 - Information on statewide prescription assistance programs
 - Information on discount cards
 - A patient information packet
- RxAssist Plus software
- *Starting a Pharmaceutical Access Program: A VIH Guide*
- *Managing Medication Samples: A VIH Guide*
- Case studies on pharmaceutical access programs
- Resource tips on pharmaceutical access programs
- Presentations on pharmaceutical access issues

AMERICAN ACADEMY OF FAMILY PHYSICIANS

<http://www.aafp.org>

Resources include:

- Article in November/December 2002 issue of Family Practice Management, *How to Help Your Low-Income Patients Get Prescription Drugs*.
- Tool in November/December 2002 issue of Family Practice Management, *Resources for Affordable Prescription Medication*.

AMERICAN MEDICAL ASSOCIATION

<http://www.ama.org>

Resources include:

- A state by state listing of medical boards at <http://www.ama-assn.org/ama/pub/category/2645.html>

ASSOCIATION OF CLINICIANS FOR THE UNDERSERVED

<http://www.clinicians.org>

Resources include:

- *Pharmaceutical Assistance Programs in Basic Language* by Katherlyne Richardson.
- Information on statewide programs
- Useful links

ASSOCIATION FOR UTAH COMMUNITY HEALTH

http://www.auch.org/pharmacy_services/index.html

Resources include:

- *Guide to Using Prescription Drug Assistance Programs: Free Medicine Resource Manual*, a document describing this program.
- Useful links

BUREAU OF PRIMARY HEALTH CARE, PHARMACY AFFAIRS BRANCH

<http://www.bphc.hrsa.gov/opa>

Resources include:

- Information on the 340B program
- Eligibility for 340B
- Instructions on how to apply for the 340B program
- Technical assistance available to 340B entities

COMMUN-I-CARE

<http://www.commun-i-care.org>

Resources include:

- Information on their statewide model selected as one of the "Models that Work for 2000"
- A PAP formulary

MEDBANK OF MARYLAND

<http://www.medbankmd.org>

Resources include:

- Information on their statewide model
- Sample physician referral form
- A PAP formulary
- RxBridge

MEDICINE FOR PEOPLE IN NEED (MEDPIN)

<http://www.medpin.org>

Resources include:

- *PAP Information Management Resources for Clinics to Help Uninsured Patients*, a summary of information on how safety net providers use information management resources to manage PAP information.
- *Pharmaceutical Assistance Programs: Their Design, Use and Impact*, a study of how California clinics use PAPs.
- Useful links

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

<http://www.nabp.org>

Resources include:

- A state by state listing of boards of pharmacy.

NEW HAMPSHIRE MEDICATION BRIDGE PROGRAM

<http://www.healthynh.com>

Resources include:

- New Hampshire Medication Bridge Program, a document describing this program created by the Foundation for Health Communities/New Hampshire Hospital Association.

PAUL H. HUNTER, MD, FAMILY PHYSICIAN

<http://home.wi.rr.com/phunter1/PAPprimer.html>

Resources include:

- *Patient Assistance Programs (PAPs): A Primer for Family Physicians*
- A list of medications commonly prescribed by family physicians that are available through PAPs

ARTICLES AND MONOGRAPHS ON PATIENT ASSISTANCE PROGRAMS (EXCLUDES THOSE PREVIOUSLY CITED IN REFERENCES)

1. Baptist Memorial Hospital, Memphis, TN. Indigent Care Drug Procurement Program: Large Return on Investment Justifies Salary Outlay. *Formulary*. 2000;35-918-21. Commentary.
2. Chisholm MA, Vollenweider LJ, Mulloy LL, Wynn JJ, Wade WE, DiPiro JT. Cost-benefit analysis of a clinical pharmacist-managed medication assistance program in a renal transplant clinic. *Clin Transplant*. 2000;14(4):304-307.
3. Chisholm MA, Reinhardt BO, Vollenweider LJ, Kendrick BD, DiPiro JT. Medication assistance reports medication assistance programs for uninsured and indigent persons. *Am J Health-Syst Pharm*. 2000;57(12):1131-1136.
4. Decane BE, Chapman J. Program for procurement of drugs for indigent patients. *Am J Hosp Pharm*. 1994;51:669-671.
5. Dent LA, Stratton TP, Cochran GA. Establishing an on-site pharmacy in a community health center to help indigent patients access medications and to improve care. *J Am Pharm Assoc*. 2002;42(3):497-507
6. *GAO Report. Prescription Drugs: Drug Company Programs Help Some People Who Lack Coverage*. November 2000.
7. Hotchkiss BD, Pearson C, Lisitano R. Pharmacy coordination of an indigent care program in a psychiatric facility. *American Journal of Health-Systems Pharmacy*. 1998;55(12):1293-1296.
8. Nykamp D, Ruggles D. Impact of an indigent care program on use of resources: experiences on one hospital. *Pharmacotherapy*. 2000;20(2):217-220.
9. Weiner S, Dischler J, Horvitz C. Beyond pharmaceutical manufacturer assistance: broadening the scope of an indigent drug program. *American Journal of Health-Systems Pharmacy*. 2001;58(2):146-50.



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