

**Prescription  
Assistance  
Programs**

**Resource  
Manual**

# *Prescription Assistance Programs Resource Manual*

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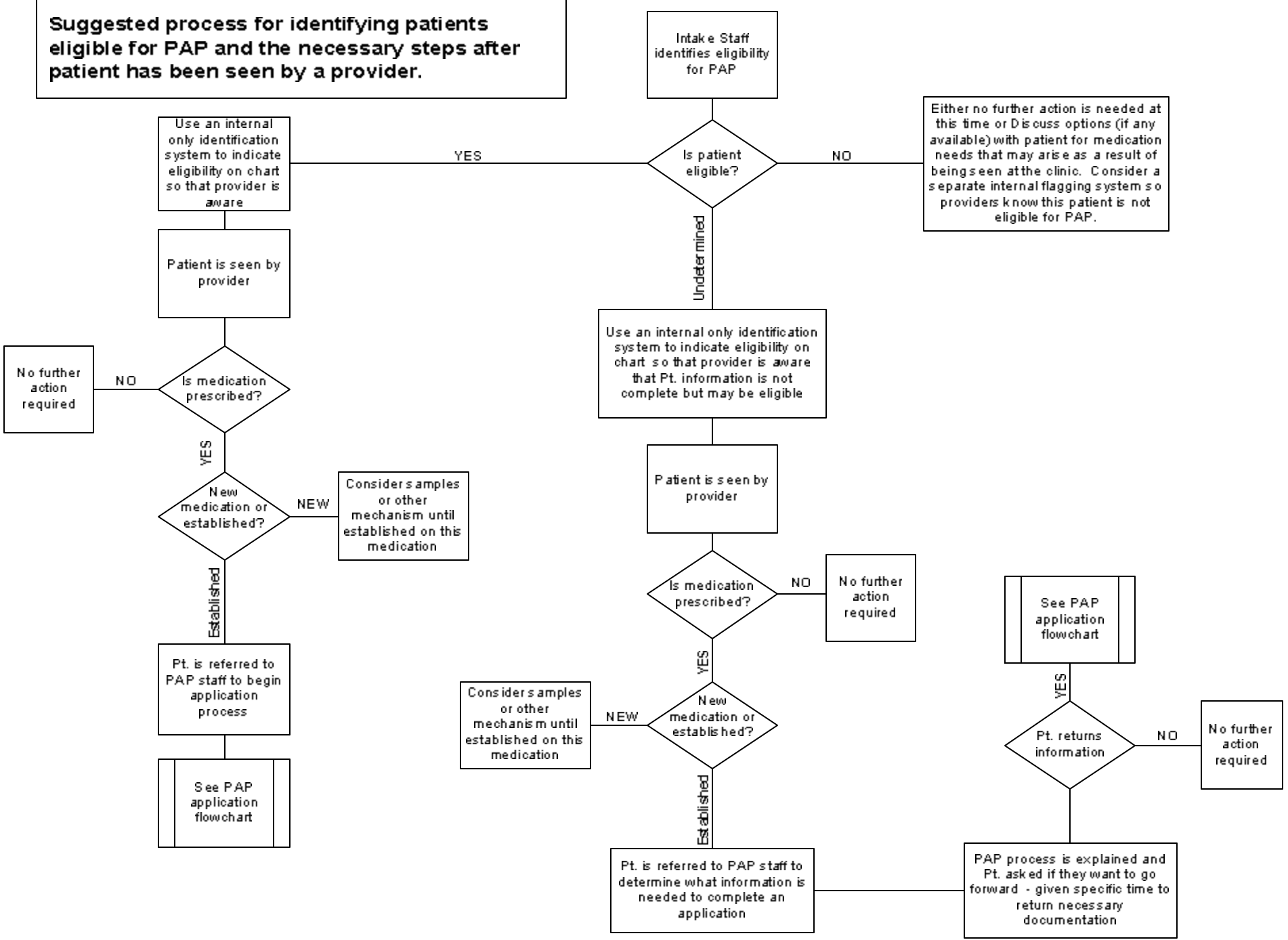
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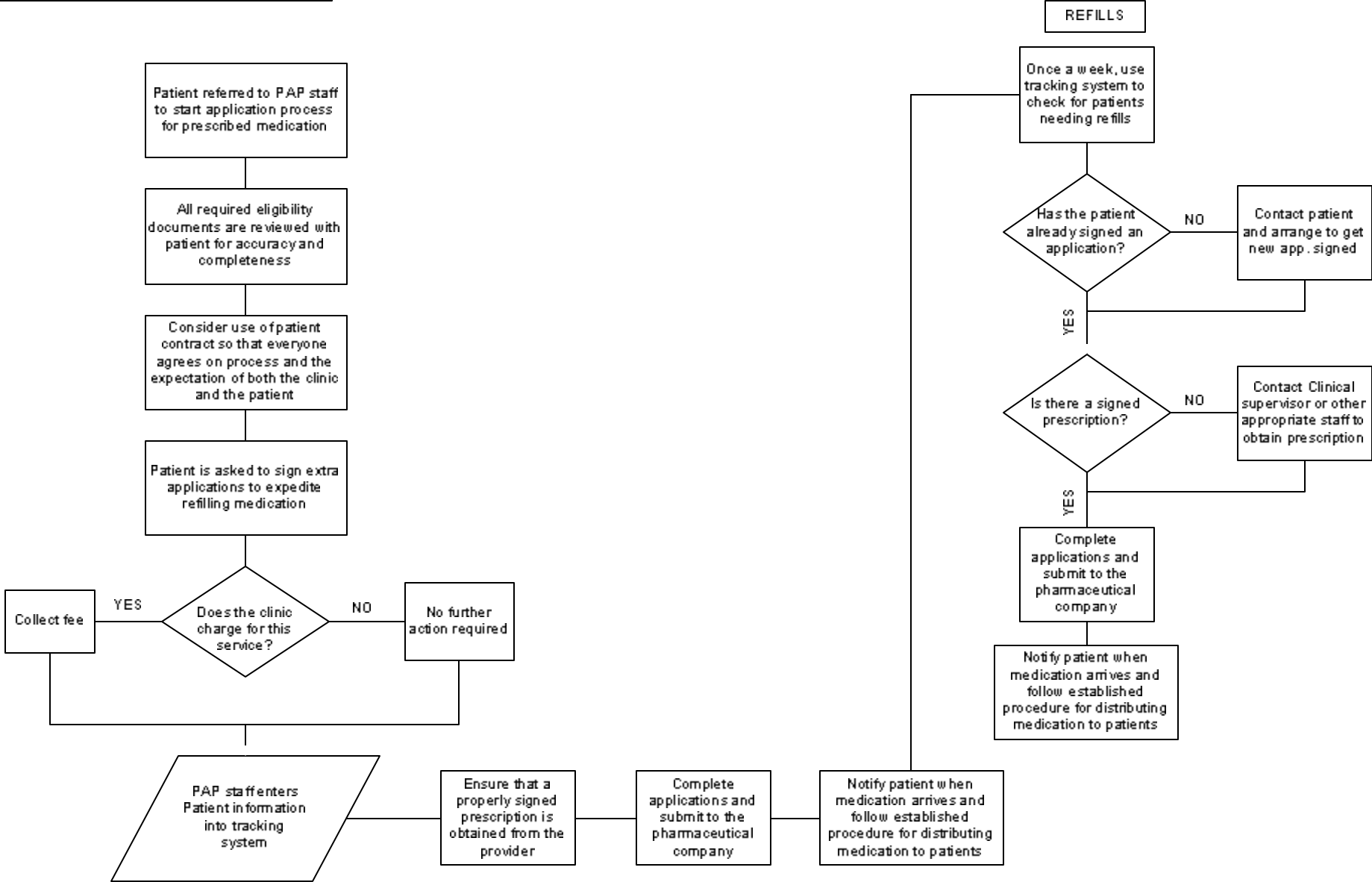
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**Suggested process for identifying patients eligible for PAP and the necessary steps after patient has been seen by a provider.**



# Suggested PAP Application Process



# Elements of a PAP program

(Adapted from <http://www.volunteersinhealthcare.org/home.htm>)

## 1. Staffing

Determine the number and type of staff/volunteers needed to run program. (based on number of patients who need the service; average number of prescriptions per patient; and length of time it takes for each application/patient)

- 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?

## 2. Resources available for the program.

- 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)

## 3. Days and hours of service.

## 4. Staff roles:

- Write job descriptions.

## 5. 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. A suggested administrative fee is \$5 per application. This helps cover the cost of submitting the application. Each application can take approximately 1 hour to complete and submit.

## 6. Determine how patients will be referred

- By prescribers
- By clerical staff
- By Nurse

## 7. Consider a PAP formulary.

Determine a starting point for a formulary of drugs based on safety, efficacy, and the easiest PAP medications to obtain. This has to be done in conjunction with clinic providers.

## 8. Consider developing 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.

## 9. 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.

10. Develop intake form or system for collecting patient information. Or if the clinic already has an intake form, work with other staff to refine it so that all necessary information is captured in one form so the patient is not filling out multiple forms.

## 11. 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.

## 12. Establish process to evaluate and improve system.

Periodically evaluate the process and incorporate necessary process changes; evaluate monthly or quarterly to improve operations and efficiency.

13. Be sure to get administrative/clinical approval for any and all changes you make to the PAP process. Write an overview of changes you want to make in the program and present it to your immediate supervisors for consideration and possible implementation.

# 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 pickup 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

## Sample Patient Contract

(this can be modified to meet you particular clinic's requirements)

Dear Patient,

We will try our best to secure free or discounted medications on your behalf; however, each pharmaceutical company has its own policy and financial guidelines that we must follow. Below are a few of the things that we expect from you:

- Provide proof of income. This can be a copy of last year's tax return, a copy of your statement of benefit from Social Security; copies of the last four check stubs, or other documentation that the pharmaceutical company stipulates. Your financial information does not go into your medical chart and will be used only to apply for the programs.
- If you are accepted into an assistance program, you will be notified. The medication will come to your doctor's office, and you will have to sign for it. Medications usually come with a 90-day supply or less. When you pick up the medication, we will ask you to sign a new application form, which we will keep on file until you need to order a refill.
- Notify the office when you are down to a 30-day supply of medication. This will ensure that you receive your refill in a timely manner, since it can take the pharmaceutical company as long as three to four weeks to issue a refill. If you do not notify our office within this time frame, you may run out of your medication. We will not be able to provide you with samples if this situation occurs. We will give you a prescription for your medication, but you will be responsible for the cost of the medicine. If through no fault of your own the medication does not arrive in time, we will issue you free samples (if we have them) until your medication arrives. It will be your responsibility to pick up your medication as soon as possible.
- Notify our office if your financial or insurance situation changes.
- Keep in mind that once a medication has a generic substitute, many pharmaceutical companies will no longer provide assistance for that drug. We will do our best to keep you informed when this happens. Your cost for a generic drug is much cheaper than the brand name form. Assistance programs do not offer over-the-counter medications available at pharmacies.
- If you are habitually late in contacting the office for refills, completing forms or picking up your medications, or if you abuse your assistance medication, fail to provide the office with required financial information or fail to schedule and keep appointments with your physician, we will no longer assist you with these programs.

Given the increasing size of our Patient Assistance Program, it has become necessary for us to put these rules into place to ensure that all of our patients receive the same benefits. We ask that you read this document carefully and sign it if you understand and agree to comply with these requirements. If you have any questions about them, please do not hesitate to ask.

Thanks for your understanding.

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Patient Signature

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Date

## **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.

# 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/she 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.

## **Specified set of office procedures designed to be used as quality of care practices in patient assistance programs.**

### **Diabetes:**

- At visit, when client arrives to pick up medication, before seeing physician:
  1. Monitor and record blood pressure
  2. Measure and record weight (Make sure there is height recorded to calculate BMI)
  3. If urinalysis is negative for protein, and a urinary microalbumen has not been obtained in the past year, place a requisition on the chart for the test;
  4. Request for patient to remove socks and shoes in the exam room
  5. Examine feet and record findings and record on the chart any abnormalities
  6. Make sure the patient has had an annual influenza and pneumovax vaccine.
  7. Discuss with client about self-management goals to manage the disease

Before next visit:

- 1) If no HgA1c was ordered in the past 6 months, order one on or before next visit based on your clinic protocol
- 2) If no lipid profile was obtained in the past year, schedule the patient for a fasting lipid profile on or before next visit
- 3) If the patient has not had a dilated eye exam in the past 12 months, make a referral to optometry/ophthalmology

### **Depression:**

At visit, when client arrives to pick up medication, before seeing physician:

1. Screen for depression using (Patient Health Questionnaire) PHQ-9
2. Evaluate patient's condition before giving medication  
<http://www.pfizer.com/pfizer/download/do/phq-9.pdf>.

### **Cardiovascular:**

At visit, when client arrives to pick up medication, before seeing physician:

1. Monitor and record blood pressure
2. If no lipid profile was obtained in the past year, schedule the patient for a fasting lipid profile on or before next visit
3. Calculate patient risk for heart disease using ATP III Assessment Tool  
<http://hin.nhlbi.nih.gov/atpiii/calculator.asp>
4. Measure and record weight (Make sure there is height recorded to calculate BMI)
5. Calculate BMI using PECS (Patient Electronic Care System), CDEMS (Chronic Disease Electronic Management System) or an online BMI calculator to determine overall body mass.  
<http://www.nhlbisupport.com/bmi/bmicalc.htm>.

From the MedPin website: <http://www.medpin.org/>

## **Links to Patient Assistance Program Information**

### **Sites that offer no-cost information**

#### **RxAssist.org/RxAssist Plus**

<http://www.rxassist.org/>

(877) 844-8442

Contains a free and searchable database of patient assistance programs, with up-to-date information on how to access assistance from nearly 100 companies and more than 700 medications. Searches can be performed on any of a multitude of variables: company name, brand drug name, generic name, and drug therapy class. Funded by Robert Wood Johnson Foundation, it includes .pdf versions of more than 40 patient assistance program applications that can be printed out and used. Volunteers in Health Care, the nonprofit organization that operates RxAssist, also makes available patient and medication tracking software called RxAssist Plus to help address the administrative needs of free clinics and other community-based health care programs serving the uninsured.

#### **Partnership for Prescription Assistance**

<http://pparx.helpingpatients.org>

Working closely with the Pharmaceutical Research and Manufacturers of America (PhRMA), the Partnership for Prescription Assistance offers a single point of access to information on more than 275 public and private patient assistance programs, including more than 150 programs offered by pharmaceutical companies. Similar information is offered on PhRMA's <http://www.helpingpatients.org>

#### **RxHope.com**

<http://www.rxhope.com/>

(908) 850-8004

Another website providing free prescription drugs information, it is financially supported by PhRMA and participating pharmaceutical companies. It has a Drug Information Center, which contains the PDR® Family Guide to Prescription Drugs and an Alphabetic Drug Index. There is also a Patient Assistance Information section that allows for retrieval of Indigent Patient Program information for a particular product or company.

#### **NeedyMeds.com**

<http://www.needymeds.com/>

(215) 625-9609

This web site includes an alphabetical list of approximately 1,000 drugs. There are many ways to access the information: by manufacturer, by drug name, or by drug category. An updated book on available programs is offered to physicians and administrators to help fund the web site.

#### **National Organization for Rare Diseases (NORD)**

<http://www.rarediseases.org/>

(203) 744-0100

NORD administers 14 prescription drug assistance programs for people who are uninsured or underinsured. NORD works in conjunction with nine drug manufacturers to offer free medication assistance to patients suffering from uncommon disorders. NORD also administers early access programs for investigational new drugs (IND) under the Food and Drug Administration's (FDA's) approved "Treatment IND" programs.

#### **Medicare.gov**

<http://www.medicare.gov/Prescription/Home.asp>

Sponsored by the Medicare program, this is a clearinghouse of information, including a downloadable database. It provides information on programs that offer discounts or free medication to individuals in need. It helps

people find information on prescription drug assistance programs, Medicare managed care plans, and Medigap plans that offer prescription drug coverage in their area.

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### **Sites that charge for their assistance**

#### **The Medicine Program**

<http://www.themedicineprogram.com/>

(573) 996-7300

Offers to help patients apply for assistance from the many indigent drug programs available. There is a \$5 processing fee for each medication.

#### **We Care Medical Mall**

<http://www.wecaremedicalmall.org/383.htm>

(888) 380-6337 ext 205

This site helps patients obtain free medications. The service includes writing a letter on the patient's behalf, providing the physician with relevant information about the free programs and requests his/her cooperation. Patients have the responsibility to read, sign, and then forward the letter to their physician for further action. This site charges \$7 per medication application.

#### **The Institute**

<http://www.institute-dc.org/prescrip.htm>

This site sells a revised 4th edition booklet for \$5 dollars that claims to provide information on how and where to get free and low-cost prescription drugs from pharmaceutical companies. Over 75 pharmaceutical programs and 1,100 drugs are listed in this 32-page booklet.

#### **Indicare**

<http://www.indicare.com>

(866) 909-2888

This site is an Internet-based software application that streamlines the process of obtaining free pharmaceuticals via patient assistance programs. IndiCare is an independent organization, however does have a distribution partnership with AmerisourceBergen-the 340B Prime Vendor. They have approximately 1,500 prescription drugs listed on their database. Cost varies depending on the subscriber's needed services.

#### **MedData Services**

<http://www.MedDataServices.com>

(888) 246-1085 TX

(818) 363-5162 CA

MedDataServices contains more than one hundred major pharmaceutical manufacturers prescription assistance programs. This site provides an overview of each program and their requirements. For more information and the cost for this service, fill out and E-Mail the application available on the website.

#### **Indigent Patient Services Inc.**

<http://www.ipsc.cc>

(727) 821-7333

Indigent Patient Services assists in accessing Patient Assistance Programs. Their services can include administrative, research, and reporting functions. For more information and cost, an e-mail address is provided on their home page.

#### **PAPrx**

<http://www.paprx.com>

(512) 306-1780

PAPrx provides software that includes over 130 pharmaceutical companies Patient Assistant Programs, as well as more than 580 medication forms. The system is sold on a per prescription basis at \$1.00 per PAPrx prescription.

### **RxBridge**

<http://www.medbankmd.org>

(410) 821-9262

A product by MEDBANK of Maryland, Inc., RxBridge is a web enabled relational database application to assist non-profit organizations in obtaining medications from over 130 pharmaceutical company patient assistance programs. RxBridge is priced at \$1/active patient/ month with a negotiable cap per year depending on the number of patients a clinic serves and a training and set-up fee.

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Medpin provides the above list of program resources for general information, not for the purpose of endorsing or recommending any of the above resources. Medpin encourages clinics and individuals interested in using PAPs to spend some time researching more than one available resource, then checking with other clinics or individuals who have experience using a specific company or information resource.

### **Food and Drug Administration Regulations on Samples**

You can access the FDA Drug Sample regulations at  
[http://www.access.gpo.gov/nara/cfr/waisidx\\_01/21cfr203\\_01.html](http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr203_01.html)

**203.30** Sample distribution by mail or common carrier.

**203.31** Sample distribution by means other than mail or common carrier (direct delivery by a representative or detailer).

**203.32** Drug sample storage and handling requirements.

**203.33** Drug sample forms.

**203.34** Policies and procedures; administrative systems.

**203.35** Standing requests.

**203.36** Fulfillment houses, shipping and mailing services, comarketing agreements, and third-party recordkeeping.

**203.37** Investigation and notification requirements.

**203.38** Sample lot or control numbers; labeling of sample units.

**203.39** Donation of drug samples to charitable institutions.