

Playbook for a Community Charitable pharmacy

Where to start & how to grow

By those who work in them & with them across the country

In 2018, the Center for Disease Control (CDC) estimated that approximately 30.1 million people living in the United States under the age of 65 did not have <u>health insurance</u>. This does not include people over the age of 65. Some are ineligible, some cannot afford, some are in cities, some are in rural communities, some are our neighbors and friends.

This playbook is designed to help guide communities, health systems, clinics, and pharmacists in their mission to provide medication access and pharmacy services to a vulnerable population: the uninsured and underinsured. The playbook is compiled by members of CharityPharmacy.org, an organization dedicated to connecting and supporting charitable pharmacies throughout the country, with a vision to create a network of charitable pharmacies that reaches every underserved patient in the United States.

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This playbook is dedicated to

the almost 30 million people residing in the United States who do not have insurance

and

those who serve them

May those who sow in tears
reap with shouts of joy.
Those who go out weeping,
bearing the seed for sowing,
shall come home with shouts of joy,
carrying armloads of blessings.
Psalm 126: 5-6

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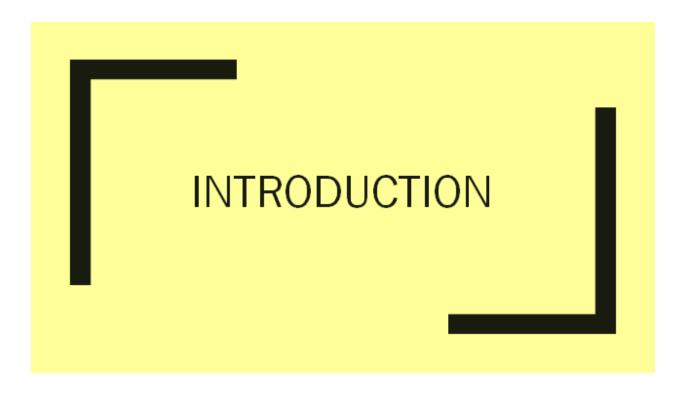
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Introduction

So you want to build a charitable pharmacy? Great news! That is a noble effort, and certainly worth your time. A charitable pharmacy is a world changing enterprise for your community's uninjured, low income population. Unlike other safety net services located in towns and cities, a charitable pharmacy is the single best way to ensure stable access to consistent supplies of medications for those unable to afford purchasing. Among other benefits, a community charitable pharmacy will provide a massive new resource serving medication access, will benefit the financial position of your local healthcare industry, and provides a substantial impact on the health and well-being of the community. While a great deal of work and funding will need to go into building a community charitable pharmacy, there is a powerful return. Further, completing this effort adds you among the ranks of many other leaders in the United States who have also built a charitable pharmacy. Among that community you will find fellowship, shared vision, and a community that is excited to learn with and from you. We applaud your vision and welcome you to this effort.

A champion is the coach, visionary, manager, and lead encourager to the work of building a safety net enterprise. Building a charitable pharmacy can take anywhere from a few months to several years of work, depending on the readiness of your community and the engagement of the much-needed resources. You and your leadership collaborative will establish operational aspects that are as varied as hiring the right staff, finding a suitable facility, creating a nonprofit corporation, raising

adequate charitable dollars, and managing supply chain. This playbook attempts to take the learnings of dozens of established community charitable pharmacy programs and the expertise of a large number of veteran leaders, and roll all of that learning into a usable document and tool set. Our hope is to make your work easier, less risky, and happen faster. So, in the spirit of collaboration, we wish you the very best, and hope to help you along the way with the following material.

What is a community charitable pharmacy?

So what does this playbook hope to empower building? A community charitable pharmacy is a pharmacy which serves with the expressed purpose of improving health outcomes among the vulnerable by reducing health disparities and increasing medication access. Typically, a community charitable pharmacy includes standard business features, such as:

- Structured as a nonprofit 501(c)3 or equivalent (university nonprofit, government nonprofit, etc.). Community charitable pharmacies can be owned by a nonprofit (like a hospital) or can be a stand-alone nonprofit corporation. This playbook, while useful in any charitable pharmacy design, will be focused on the most complex design that being a stand-alone 501(c)3 including legal, fund development, and board development activities unique to the design of such a model.
- In receipt of a valid, current pharmacy and/or pharmacist license, or similar dispensing authority. Each state manages charitable pharmacy licensing in different ways. The principle is that every charitable pharmacy is properly licensed, existing under the authority of all applicable oversight organizations pertinent to their locality.
- Adherence to all local and federal regulation pertaining to the management of a licensed community charitable pharmacy and/or clinic. Again, each state has different regulation governing a charitable pharmacy. This regulatory imperative impacts licensing, staffing, operational design, and other features of a community charitable pharmacy.
- Dispensing a therapeutically broad formulary of medications for free or at a significantly reduced cost to the patient. That means that a charitable pharmacy is primarily focused on increasing access to medications and reducing disparities.
- Bridging patients to external programs (such as Patient Assistance Programs, mail-order discount programs, vouchers, etc.) that are free or which assure a significantly reduced cost to the patient. At times, the role of the community charitable pharmacy is to dispense medication, and in other instances, it is to ensure that the most financially and operationally effective medication access solution is used. While not always the case, community charitable pharmacies generally seek to do this with and through access-expanding programs such as Patient Assistance Programs, donated medication programs, and other such services. Ideally however, community charitable pharmacy programs are organized around programs that have a broad primary care formulary, with

- medications already stationed in a local inventory (so as not to delay access to the patient) and are dispensed immediately and with as little process and delay as may be possible.
- Eligibility processes which determines qualification for income status (not precluding other eligibility status features specific to the goals of each site, such as: health insurance status, assets, etc.). Typically, community charitable pharmacies are focused on serving those with limited access to healthcare coverage, and limited financial means. This means that enrollment into a qualifying set of patient status guidelines is a part of the community charitable pharmacy's effort.
- Processes, culture, and systems which assure the dignity and respect for each patient served.
- Business hours and dispensing practices which allow for patients' continual access to their medications, should the patient seek such access.
- Integration into the community healthcare safety net to support inbound referrals from prescribers for qualifying patients as a standard business practice (private practices, hospitals, free clinics).
- Integration into the community healthcare safety net to support outbound integration with community services necessary for improving health outcomes (medical home enrollment, care management, public health coverage model enrollment, ancillary medical services, etc.)

The above features of Community Charitable pharmacies form a three-part strategy, which has been studied and proven (research described below) to result in a positive impact on health outcomes:

- 1. Carry essential medication via a smart, therapeutically-effective formulary targeted to manage primary care health conditions,
- 2. Dispense the volume of medication needed to serve all patients, and
- 3. Provide that medication in a consistent supply, day after day, year after year, for the patients who maintain health through medication therapies.

What to expect in championing a community charitable pharmacy

Every complex effort needs a champion... the person who stands for the completion of the complex effort and who manages resources and the passion of others to achieve that goal. Perhaps you have championed a large-scale effort before? If so, one of the things you will have experienced is that the attitude and beliefs of the project champion is more critical to the success of the program than any external resource that you will align, including funding or a facility. The outcome of your community effort will be impacted greatly by the attitude and mindset of the leader(s) involved in creating and managing the effort. The good news is that attitude is a choice. The following are a few attitudes that other community charitable pharmacy leaders have noticed that impacted their effort to build a community charitable pharmacy. Take a moment to consider those listed below and if they are currently a strength of you and your

coalition, or if further work can be completed to sharpen your attitude in the following areas of attitude competency.

- Administrative Cheerleading Leadership is difficult work. The primary role for the champion is to keep others engaged and moving forward. Certainly, efforts which at minimum require a collaborative leadership team's work over a series of months require a cheerleader who can be responsible for themselves, and assist others in managing their work. That calls for a deep emotional well, a willingness to not allow delays in progress and excuses to eliminate your passion, and administrative prowess. The happy news engagement and administrative skill can be learned! If you do not feel like you have every gift needed in engagement management and passion, step out and start the work. The reality is that you will have time to practice, and to strengthen your skill set as you and your collaborative team complete the work.
- Determination Have you ever helped to open a nonprofit charity before? You will be working in a great deal of ambiguity completing tasks with a consortium of others, with a definitive-though-vague sense of the destination, and an, at times, foggy vision of the priority of the next steps. This type of leadership is most comfortable for the risk taker, the entrepreneur, and the visionary. But you do not need to have gotten an MBA in business formation to step out and try. Again... determination is a skill that is learned, as you complete the work.

Often times those in the pharmacy industry, particularly pharmacists, like clear answers and guidelines to follow along with. There is not a "quick" answer to when your community charitable pharmacy should be operational, and there is a great deal of ambiguity as to which tasks should be tackled first. This playbook will offer you some idea of a rough timeline and activities involved in the work before you, however, there isn't really a firm timeline to the work you are leading. Hang in there. Stay determined. Stay positive and keep your collaborative group moving forward. And the more you and your collaborative team face ambiguity, the more your practice and add to your entrepreneurial skill set.

Here is an example. Let's say that your project needs a facility, that facility needs to be donated space, and the perfect donated space is already empty and located in a hospital physician's office. The location is vacant, on the bus line, located near the highest heat map zip codes of the uninsured. However, the CEO of the hospital owning that space is known to be difficult to engage for new work among people he does not already know. So, after a great deal of effort and networking, you present your idea to the CEO, and hear a "no". Anyone looking to start a charitable enterprise will hear "no" many times. Here is the discipline to practice – when you hear "no", train yourself to think that they are not yet ready to commit to your community charitable pharmacy, and that new ways are needed to get to your "yes". You have the opportunity to not be a victim, but instead, to make choices, strategize, and keep working to get to your yes. By not being a victim, you enable yourself to listen and determine what deals can be made. Allow the word "no" to free you to design new solutions

and create what you need to happen. Entrepreneurs are not always the smartest people in the class... but they know how to stay determined and engaged, even when they hear "no".

- Lack of Ego/Emotional Maturity People like to give, but they want to give into places where they will have ownership and be celebrated. To launch your community charitable pharmacy, you will need the help of a long list of others. Those that your project will need might not be as emotionally mature as you need them to be or may have goals that conflict in some ways with your vision. Perhaps a mayor's office or hospital CEO who might provide donated pharmacy space. Perhaps a church pastor who will bring the congregation to refurbish the space. Perhaps a fund development expert who will bring funding. Perhaps an attorney who will help with your incorporation. The putting aside of your own ego is a discipline you will have the opportunity to cultivate in order to serve the cause of the community charitable pharmacy. You may need to manage the expectations of others, their delays, over promises, and changes in priority in order to get to your goal. Again, some good news, emotional maturity and egoless leadership can be practiced and cultivated.
- Networking Networking is critical in starting up your charitable pharmacy but not like you may think. Golf games, evening dinner parties, and health system networking events are fine. But to launch a community charitable pharmacy, you may need to seek out people who you do not know and who control resources that you need. Don't be discouraged if you are not a natural networker or extrovert. Rather, embrace the challenge of reaching out to others for a purpose, getting known, and creating energy in them to see the launch of a community charitable pharmacy.

Championing a community charitable pharmacy takes character and skill. The good news is that the skills you need can each be practiced and learned. They can even be failed at and restarted. Know that the course of your work is going to establish an important healthcare program for your community, and at the same time will establish an important new enterprise in your heart and mind. Give yourself grace, try, fail, try again, and keep envisioning the opening of your community charitable pharmacy.

Collaborative Building

One of the first steps in your work is to involve a community collaborative, representing the key stakeholders in medication access. While not a complete list, the following leaders, agencies, and businesses are typical suspects in the creation of your community charitable pharmacy. You might consider starting a small group of passionate leaders, at first. But over time, expand your community charitable pharmacy leadership to have engaged the following for assistance, leadership, administrative help, facility space, donations, and staffing:

Health System/Hospital Leadership – Aside from the patients themselves, hospitals have the most to gain in seeing the launch of a community charitable pharmacy. Inpatient care and Emergency Department services to treat otherwise avoidable conditions among the uninsured cost billions of dollars annually for hospitals. This uncompensated care will be greatly impacted by your community charitable pharmacy. Work with your hospital leadership to identify resources and funding. They are often the most willing to help.

Medical Societies – Physicians care about their patients. They get frustrated that patients, particularly the uninsured, may decline in health specifically because the medication needed is unaffordable. Medical Societies offer the administrative organization access to the heart (and wallet) of the physician community. Work early and directly with the medical societies and local physicians. They will champion your work with you.

Boards of Pharmacy – It would be a mistake to assume that the Board of Pharmacy is simply the rule making and rule enforcing structure in a state's pharmacy access system. Rather, the board of pharmacy is composed of smart pharmacist leaders, who care about the uninsured and care about the transformation of the community to serve better health outcomes. Engage the Board of Pharmacy about design questions, but also ask for their expertise as you build your work. They will help you do it efficiently, and correctly.

Public Health – The local health officer is responsible to improve the health of the community. They and their staff can assist you in finding funding, the best facilities, and other resources to serve your work.

Free Clinics – Unless your community is rather small, there is probably at least one free clinic in the area. If there are more than one, they often meet to discuss issues such as funding, operational design, patient care, and other topics. Be sure to engage with the free clinic community to complement their strategies for community health, to align operational systems, and to work together to achieve overall health improvement.

FQHCs – Not unlike the free clinics, federally subsidized clinics (called Federally Qualified Health Centers) exist in almost every community. Be sure to work with them to align operational design and to complement existing services.

Schools of Pharmacy – A ready source of research support and volunteer students exist at local schools of pharmacy. Be sure to work with the leadership of the schools to maximize your integration with their work.

Faith Community – Often, churches, temples, mosques, and synagogues have operational features that support the healthcare of the poor, and which provide funding for good ideas. Often, the faith community in an area has a collaborative structure or ecumenical council that meet to consider new ideas and resources.

Government Leadership – your local mayor's office can be a great help in starting a community charitable pharmacy. The staff at the mayor's office has the networking connections and relationships to identify answers to key questions.

There are a number of partners in a given city or community ready to help you achieve your vision of a community charitable pharmacy. When it is time to educate these and work to launch an operation, start by building relationship and sharing vision. Often partners will want to know you, as well and know your vision. Some other partnership opportunities not listed above include: parish nursing programs, disease specific coalitions, transplant coalitions, for-profit healthcare providers, health coalitions, engaged community leaders, and the chamber of commerce.

Steps

- 1. Preoperational Steps:
 - a. Create the vision and guiding coalition
 - b. Establish a business plan (See Appendices/Business Plan)
 - c. Identify funding seed and ongoing (See <u>Initial Funding for a Community Charitable Pharmacy</u>
 - d. Engage with community partners, regulatory, and operational partners
- 2. Operational Design Steps
 - a. Identify facility and prepare it
 - b. Identify staffing and train them
 - c. Identify supply chain partners
 - d. Begin marketing
 - e. IT Hardware and Pharmacy Operating System
 - f. Soft Launch
- 3. Opening
 - a. Ready the facility
 - b. Stock inventory
 - c. Opening day
- 4. Post opening and ongoing maintenance
 - a. Collect and measure process and outcome metrics

Establish a Business Plan

A business plan defines who you are as an organization, what need or issue is being addressed, how you propose to meet that need (goals and objectives), and how success will be measured. Your business plan is a written document that provides a road map for the future of your charitable pharmacy. Keeping it up-to-date ensures that the focus and mission of the pharmacy continue to be relevant and are being met. Sections include finance, marketing, pharmacy management, limitations or constraints and any supporting documents. A summary of the process of developing a

community charitable pharmacy is found in the appendix. See <u>Appendices\Business</u> <u>Plan</u>

Local Factors for Community Charitable Pharmacy Implementation

With the implementation of the Affordable Healthcare Act, tax exempt hospitals became required to implement a <u>Community Health Needs Assessment</u> (CHNA) every three years. Many of the same assessments are useful in determining where a charitable pharmacy is to be a located based on community need. Factors assessed by CHNA include:

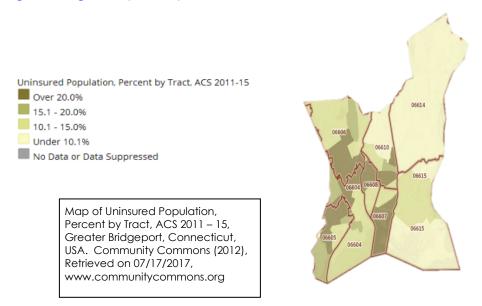
- Demographic Assessment identifying the community the pharmacy will serve
 - Population by age group, sex, language
 - Income, insurance, poverty level
 - Public transportation, housing status, education status
- A community health needs assessment survey of perceived healthcare issues
- Quantitative analysis of actual health care issues
 - Health Behaviors and Outcomes
- Appraisal of current efforts to address the healthcare issues
 - Access to healthcare providers (hospitals, clinics)
 - Locations of hospitals and FQHCs
- Formulate a 3-year plan the community comes together to address those remaining issues collectively, ultimately working towards growing a healthier community
 - Who are potential local collaborators to improve health outcomes through improved medication access?
 - What other agencies exist in the community that are providing similar services (free medication, aid with PAP applications, etc.)?

<u>Geo-mapping</u> allows visualization and analysis of data as it relates to geographical information (zip code, city, county, state). Comparing a possible site for a community charitable pharmacy to health disparities provides insights for the population being served. Disparities include lack of insurance, chronic disease states, transportation to health providers and/or pharmacies, language, and poverty level. Data comparisons with location can be a convincing visual for potential partners and funders.

Figure 1

Uninsured population, Percent for Bridgeport, Connecticut with zip code delineations.

This geo-map can help determine need within the city, where that need is greatest and possible locations that would be nearest the population in need. A comparison to number of patients served and prescriptions filled reflects how well the population's needs are being met. See How Many? and Appendices/Marketing/Building a Map of Impact



Some free online sources for this information are the US Census Bureau, Community Commons, City-Data, and City Health Dashboard.

<u>Censusbureau.com</u>/ACS offers a Fact Finder tool, allowing specific data to be accessed from the previous US census (2010) and the American Community Survey (ACS) which is conducted continually and published annually. Training webinars are available online and ongoing to aid in use of the Fact Finder and their many other tools.

- CommunityCommons.org is a website offering common use of the census bureau data by communities with tools to "improve communities and inspire change." Data can be linked to maps (state, county, city, zip code) to relate data to a specific location. This is useful when determining the location of the charitable pharmacy (See: Location) and in assessing impact of the pharmacy on the community (See: Results-Based Accountability). Sample stories and maps are available to view and adapt to your situation as well as creating maps to fit a specific need. Training tools are available.
- <u>City-Data.com</u> collects and analyzes data from a variety of government and private sources to create detailed, informative profiles of cities in the United States. Though not healthcare related, data relating to income, transportation, born outside United States, population density, unemployment, and poverty status are factors affecting a charitable pharmacy population.
- <u>City Health Dashboard</u> is an interactive tool that provides access to health-related statistics –from housing costs to high blood pressure to premature birth rates in 500 cities across the United States. Data can be broken down into a region within a city and allows comparison of statistics to other cities or the national average.

Pharmacy Deserts

A <u>Pharmacy Desert</u> is a low-income census tract or zip code where a substantial number of residents have low access to a community pharmacy. This definition is based on the USDA definition of a food desert. Patients with chronic diseases living within a pharmacy desert face tough challenges with regards to medication access and information. Several methods can be used to determine a pharmacy desert. An <u>urban pharmacy desert</u> can be defined as a low-income community or neighborhood with no pharmacy within a half-mile for those with limited vehicle access. For low-income communities with adequate vehicle access, the defining radius extends to a mile.

A <u>rural pharmacy desert</u> is defined as any area within a 10-mile radius without ready access to a community pharmacy (for those that have access to transportation).

Another measure used for determining a pharmacy desert is the density of community pharmacies per 10,000 residents in an area with predominately a low-income (or minority) population compared to areas with moderate income (or non-minority) population (See: Evaluation of racial and socioeconomic disparities in medication pricing and pharmacy access and services).

In determining a pharmacy desert, considerations in an urban setting include resident access to individual or public transportation, walking distance to pharmacy from public transportation, and home prescription delivery service. Limited transportation is also a consideration in a rural setting. A survey to evaluate disparities conducted in Shelby County, TN included "out of pocket" costs of three medications, hours of operation, home medication delivery, a generic drug program, immunizations, and MTM services. A community charitable pharmacy may be able to address the issues seen in a pharmacy desert by improving affordable medication access and medication

information. Locating in or near a place already frequented by the population in need reduces transportation barriers. Mail-order charitable pharmacies offer home or close to home delivery for rural populations (See: <u>Location</u> and <u>Models of Community Charitable Pharmacies</u>).

Environmental Factors for Community Charitable Pharmacy Implementation

After considering individual and local factors involved in starting a charitable pharmacy, another assessment is a global look at the environment. **PEST** Analysis is a simple and widely used tool to help analyze the **Political, Economic, Socio-Cultural, and Technological (Legal and Environmental** can also be added) changes in an industry environment. These changes can be opportunities, as in new technologies, new funding streams, changes in government policies. Or they may be threats, as in deregulation that exposes intensified competition, increased interest rates, or a shrinking market. Examples of this type of global influence were the implementation of the Affordable Health Care Act, Medicaid expansion, and e-scribing. The status of 3408 may be a factor in coming years.

A sample PEST (LE) Analysis exercise is in <u>Appendices/Business</u> <u>Plan/CSHP_WhatsYourStrategy2018</u> (See: <u>Environmental Factor Resources</u> for references on concise, current information regarding health, medicine and scientific discovery).

As PEST looks at the "big picture", **SWOT** explores these factors at a business, product-line or product level. **SWOT Analysis** explores **Strengths**, **Weaknesses** (often internal), **Opportunities**, **and Threats** (internal or external). SWOT can be used to evaluate factors that are sustainable and those requiring closer dialogue. (See: <u>Appendices/Business Plan/CSHP_WhatsYourStrategy2018</u>) for a PEST exercise and example of a SWOT analysis.

Detailed information on PEST (LE) and SWOT can be found at Mindtools.

Steps for Starting a Stand-Alone, Mixed-Model Community Charitable pharmacy

Phil Baker of Good Shepherd Medication Management offers these points to starting a stand-alone charitable pharmacy.

Good Shepherd Medication Management is a nonprofit organization of Christian pharmacists dedicated to providing pharmacy services to the under-served in Memphis, Tennessee. This nonprofit was created to be Memphis' first charitable pharmacy, dispensing to low-income uninsured patients for free, specializing in personal patient counseling services.

- Acquire nonprofit status in state where pharmacy will exist (See: <u>501(c)3 Nonprofit Status</u>).
- Develop a three-year **budget** (See: <u>Example of Initial Budget</u>). Start fund development once at least the first year's budget is defined.
- Strive for **funding** from more than one source, a minimum of three. If initial budget is \$450,000 for 3 years and \$150,000 is needed for the first year, seek for "Matching" funds from three different organizations. Example: \$50,000 per year from 3 different sources on an annually recurring grant for three years. Funders may be more amenable to a smaller recurring grant than one large single grant. Securing one grant allows time to pursue the other two.

• Partnerships:

- Hospitals- most nonprofit hospitals have foundations that can (sometimes) be sources of funding. Transitional care programs are a great place to partner for direct reimbursement.
- o **Pharmacy Schools** not sources of funding but essential to a healthy program. Become a preceptor site for local schools as quickly as possible. Precepting fees bring in revenue and students can be utilized throughout the program as they learn various pharmacy processes and develop skills for serving an uninsured population.
- o **Foundations** Connect with local foundations as early as possible. These are great sources of funding, but they are relationships that take a long time build (See: <u>Fund Development and Relationship</u>).
- After securing at least one supporter, the next focus is finding a **location**. Encourage the new "supporter/s" to help find the best location for free (See: Location).
- Once a facility has been acquired, work with the state for licensing as a pharmacy and/or wholesaler/distributor, related to reclamation. The state may require a wholesaler/distributor license if transferring reclaimed meds from the facility to another facility/pharmacy (See: Registrations and Steps to Obtaining a Pharmacy License).
- Initiate contracts with nonprofit distributors: Dispensary of Hope, AmeriCares, Direct Relief, SIRUM and others.
 Determine a starting inventory and place an initial order (See: <u>Developing a Formulary</u> and <u>Vendors</u>).

TIP: Iowa Prescription Drug Corporation is licensed as a distributor and pharmacy. Reclaimed meds are distributed to program participating pharmacies throughout the state as well as directly from the facility.

- Technology: (See: Resources)
 - Website
 - HIPAA Compliant form on website.
 - o Pharmacy Software
 - Billing software
 - Customer Relationship Management (CRM) Software

- o G-suite for email, contacts, drive space
- Publicity: (See: <u>Marketing and Community Outreach</u>)
 Community
 - o Host a grand opening event and maximize publicity.
 - o The first 12 to 18 months are primarily about publicity. Plan on spending at least 50% of time outside the pharmacy speaking to anyone who will listen (primary care providers, other safety net providers, rotary clubs, and anywhere you are invited to speak).
 - o Recruit (or hire) a local PR professional and plan some sort of press release or event every 30 days. Every new partnership (school, foundation, hospital, etc.) is an opportunity for a press release. Publicity builds credibility as quickly as possible. Under a web search for the pharmacy, the more articles that come up, the more credible the pharmacy is seen.

Patients

- Recruit patients through partnerships with hospitals, other safety-net providers and speaking engagements.
- Enroll patients
 - in person (walk-ins)
 - over the phone
 - through pharmacy website



Initial Funding for a Community Charitable Pharmacy

Fund development is a process of letting the best ideas compete for limited resources. Before we talk about funding, let's talk about how we lead. We are leaders. That means that in our work, we must always discern and call others to discern the deepest principles driving the work. In fund development, the principle that should guide us is that the resources at our disposal should always be invested in a way that best serves the patient.

Resources are limited. In small, financially limited free clinics, even to the financially comfortable health system, every dollar is and should be scrutinized. Said in one way, the "idea" of a community charitable pharmacy should be compared against all other good ideas. On their merits. Our role is to let the ideas compete. And ideas that bring the highest value are those which should be funded.

As you and I talk about fund development planning, we are conscious that ideas like a community charitable pharmacy are worth putting forward for funding because they out compete other ideas by their measure of patient health impact. As leaders, it is our job to discern the best ideas, and to strive to gain funding for those that are most effective for the patient.

Fund Development and Relationship

Fund development can be a very frustrating topic for nonprofit leaders, particularly when neighborhood-level charities begin dealing with institutions such as hospitals, and for hospital departments attempting to align funding for department focus. That frustration can be overwhelming.

First and foremost, all business agreements happen through relationships. This may be surprising for those of us new to business, who assume that business agreement is first and foremost transactional. The truth is, most seasoned leaders look for a relationship first (meaning trust, respectfulness, honesty, reasonableness, competency, business acumen, agreeableness) and then work out transactions (who gets what and what it costs) later. For those new in the field of fund development, it does not matter how good your idea is or your execution will be if the relationship is not yet in place. Become known as a reasonable, trustworthy, stable, and considerate leader and know that those qualities will bring your funding 75% the way there. Reputation and relational connection is the seedbed for business partnerships.

The sad news is that this irrefutable principle in business may takes some time to develop if you are a new factor in a community or in the hospital. Get known and get respected. There is always funding for good ideas and a community charitable pharmacy is an exceptionally good idea. Such a model produces sustained improvement in health among the most complex patient populations, and does so at a fraction of the cost of other healthcare programs. But funding happens through trusted relationships, followed by accountability and follow through.

Speaking the Language as you Market your Fund Development Need

Consider your hospital as an island and on that island lives four different tribes. Each tribe has a different language that they speak. Let's say that you have a very good idea that will benefit this island, but you need these tribes to collaborate with you. If you do not become fluent in each of the four languages, there is no way that you can persuade the whole island to do what you wish, even if what you wish is best for them. They can't agree until you answer their questions, and to understand their questions, YOU HAVE TO SPEAK THEIR LANGUAGE.

Think of the following as features of your communication with the hospital, conveyed in meetings, presentation, and your business planning/budget...

Healthcare Funders speak (but not primarily speak) the "Heart" Language – The
Heart Language is actually the least spoken language within the funder's walls
(which may be surprising to hear). It tells how we made the world a better
place. While it is true that everyone in healthcare speaks this language (you do
not go into hospital administration, healthcare foundation management, or
medical school unless you care for people), if you speak only to the heart about

how you can or are making the world a better place, then you will confuse and frustrate those asking questions in other languages.

While it is important that your effort considers the FACE of those impacted and speak the heart language – patient lives, age, gender, numbers in the community, their stories, what those lives are going through, the responsibility of the hospital for those lives, etc. - It is a big and common mistake for people who serve outside of the healthcare funding arena to approach the funder with funding ideas, conveying the concept mostly with heart messaging.

- Healthcare Funders speak the Financial Language this is an important language and it tells what it cost, what was the return, and when that return came. It is spoken primarily by the Chief Financial Officer and the Chief Risk Officer, but every foundation and resource rich environment's executives speak the financial language. This language is fluent in cost, return, probability of savings, and risk associated with failure. Examples budget, performance, ROI, and throughput data.
- Healthcare Funders speak the Health Outcomes Language this language tells us if we improved patient health, where was that improvement, and how we measured that improvement in health outcomes. While this language is primarily spoken by the Chief Medical Officer, Chief Nursing Officer, and Chief Pharmacy Officer, every leader in healthcare funding understands and speaks the health outcomes language. To convey answers in this language, your business plan needs to capture the language. Examples: health impact by disease state, hospital length of stay data, readmissions, etc.
- Healthcare Funders speak the Plumbing Language this is the language that tells us how we improved the health system flow, impacted efficiency, and lowered risk within the healthcare continuum. The language is spoken by the Chief Operations Officer, and Chief Strategy Officer, but again, every leader who controls healthcare resources speaks this language. Those creating a community charitable pharmacy have an amazing story about routing avoidable hospital discharges and ED encounters through the charitable pharmacy and saving money and resources for the local healthcare community. Leaders who speak this language are always looking for ways to impact the three-legged stool of healthcare - reduce cost, improve patient experience, and increase health outcomes.

A charitable pharmacy distribution point has one of the most powerful messages in healthcare that can be conveyed

Tip: Storytelling as Best Practice by Andy Goodman is a helpful resource for telling your organization's story.

Storytelling as Best Practice

Storytelling as Best Practice

The stories at magning poor and story.

through the four languages. If you become fluent in all four, you have one of the most compelling stories to share in your island.

Initial Funding versus Ongoing Funding

There are two types of funding needed to launch a charitable pharmacy: seed funding and ongoing funding. **Seed funding** addresses the initial planning and startup expenses of a project, whereas **ongoing funding** covers the post-implementation, day-to-day costs of a community charitable pharmacy. These two types of funding cover different phases of the nonprofit's organizational life cycle (launching work versus ongoing service delivery work). As such, the needs differ between funding startup and ongoing efforts. Similarly, the character and expectations of seed funders are different than ongoing funders. For reasons outlined below, it would not be uncommon to be declined seed funding by a funder with the profile more akin to supporting regular post-implementation service delivery. This section will attempt to explain the two types of funding, the needs of the funders, and how to approach each on a program's way to sustainability.

Seed funding is the term that represents the initial dollars needed to cover expenses associated with a launch of a program. As such, seed funding is heavy on the kinds of expenses that would count as new, one-time costs (capital expenses to purchase a facility, renovation costs, personnel firm hiring searches, initial marketing design work, initial legal expenses, etc.). More nonprofit programs fail at conception than at adulthood as the most vulnerable days of a new nonprofit are its early development. A seed funder will shoulder the burden of funding the highest risk period for a program (its earliest days of service) and covering the cost of some of the costliest program expenses. The nature of seed funding must be far more tolerant of program risk and the potential for organizational failure. Therefore, seed funders must be cultivated in a way that acknowledges the higher risk to the funder.

Unknowns create risk. Seed funders wish to make sure that the leaders overseeing the creation of the program are as thorough as possible with a plan to manage unknowns. Planning reduces some of that risk and lowered risk means a higher probability of success at a lower cost. Since the risk profile for a new program is much more tenuous than a program with 10 years of operating experience, funders must be cultivated initially that will be tolerant of the risk.

Seed funders have different questions and different expectations than an ongoing funder. A solid business plan is required by most seed funders. For instance, since there will be no program history to provide, program leaders will need to provide benchmarking data and examples of the programs they envision. Replication of proven programs and an actionable plan are desirable for seed funders – who are often eager to confirm that there is a business plan in place for a community charitable pharmacy. A sound business plan demonstrates that the program knows what it will

attempt to create, will know how much money is needed over a given time period to create that program, and will know the way that the program will measure success over time (See: The Fund Development Plan and the Fund Development Planning Process).

Seed funding opportunities differ from ongoing funders in type as well. Funders with a higher tolerance for the increased risk of seed funding typically include those with a closer proximity to a program's work (same community, rather than a federal or national funding concept), and are ones with a more direct potential benefit for the program's successful work. Prospective funders with a close proximity and a greater potential benefit include:

- Local hospitals Next to patients served by the community charitable pharmacy, the local hospitals will have the greatest financial and mission benefit from the work. Seed funding conversations should engage hospitals early and should seek to understand issues such as:
 - What is each hospital's perception of the need for increased medication access among the poor? (Is medication access a topic in the hospital's strategic planning? Has medication access been identified as a strategy for increasing the health of the community? Has medication access registered in the local health department with the Chief Public Health Officer, and/or in the local nonprofit hospital's community health needs assessments?)
 - o Is the hospital looking to save money among the self-pay/uninsured population by improving the health of the uninsured through the provision of stable access to a robust formulary of essential medications? (Where is the Chief Medical Officer on the topic of chronic illness management and medication access? Is the hospital's director of pharmacy amenable to expanding medication access for the poor?)
 - o Is the hospital in a financial position to partner with the leaders of the community charitable pharmacy in the goal of opening a robust and functioning charitable pharmacy? (Where is the Chief Financial Officer and the Business Development Office on the topic of investing into a community-wide solution to lack of medication access?)

These and other questions can be answered through relationships with the local hospital, partnering and communicating the opportunities to move medication access forward in the community.

Local Foundation Grant Investment – Foundations are grantmaking organizations which seek to partner with local charities to achieve a defined mission. That mission is a statement which is publicly available for review, listed in each foundation's annual IRS990PF (an annual tax document available for free to view on Guidestar.org). It is important to approach foundations with a mission that is complementary to the work of your community charity nonprofit.

Most foundations distribute a percentage of an endowment each year. The distribution process is overseen by a board of directors responsible to ensure that the funding distributed aligns with mission. Being caretakers of an endowment, foundations may be a bit more willing to absorb the risk of funding a startup concept, especially when the business case and replication demonstrate the community charitable pharmacy has a solid plan and a lowered risk. For that reason, a foundation may be willing to contribute to a risky startup venture when other funding sources cannot tolerate the potential risk of a funded failure.

It is always best to follow the process for a funding request outlined by the foundation. However, when not explicitly discouraged by the foundation, it is recommended to request a meeting with a foundation to share about the work that the community charitable pharmacy aims to do and to understand:

- Does the foundation accept funding requests solicited by the community, or are funding offers only extended to organizations approached by the foundation?
- o What is the foundation's level of comfort in funding a new effort?
- What kinds of pre-work planning is typically required of a foundation to support a new initiative?
- Corporations and Corporate Foundation Investment Corporations may offer funding to the community, either as a direct support from the revenue of a corporation or through a charitable foundation tied to a corporation. When considering the opening of a community charitable pharmacy, consider the businesses that are at work in the community, and seek to meet with that business to understand:
 - o Does the corporation fund community efforts?
 - o Is the focus of that funding compatible with the work of the community charitable pharmacy?
 - o What is the corporation's level of comfort in funding a new effort?

The Fund Development Plan and the Fund Development Planning Process

Fund Development planning is the exercise of creating an actionable plan to lead fund development efforts. It is a written vision, activities, due dates, and measures around which your fund development work can take place. The goal of the fund development plan is to:

- identify funding opportunities and resource rich relationships,
- prioritize those opportunities by likelihood of success, cost, and return; and
- begin each using project management principles.

It is generally suggested to begin the fund development planning process with a meeting of key leaders. The assignment before and during the meeting is to brainstorm funding opportunities. After the opening remarks, introductions, and discussion of the vision of the meeting, start by brainstorming funding opportunities where every leader in

attendance shares their ideas for funding the work. After all ideas are recorded on a whiteboard or poster paper, allow the room to define the:

- a) cost,
- b) return,
- c) probability of success, and
- d) political or influencing factors related to each idea. See: <u>Environmental</u> Factors.

The goal is to compare each idea on their own merits and assign an objective value to each idea. When completed and the cost, return, probability of success, and influencing factors are defined, allow the room to rate each idea against each other to assign a priority. The goal is to identify the top 5 or 6 ideas and ask for volunteers to lead each idea. When completed, create a project management matrix for the top candidates (goal, measure of success, the top 3-7 activities, due dates for each activity, person responsible for each activity). Then begin the work!

For examples see:

- Figure 1 (below)
- 2018 Sustainability Plan Ozanam
- Fund Development Toolkit
- Fund Development Planning and Brainstorm

Figure 1

Dispensary of Hope Finance	ial and Health In	npact Eval	uation – De	velop Retu	rn on Inves	tment Fund	ding Partne	rship				
Description: Create the busin	ess case, commi	unicate the	business ca	se and clos	e the deal o	n funding fo	r vour Disp	ensary of Ho	ne program	l.		
Measure of Success: \$150,0							you. 2.op	5115ary 51 116	po program			
Task 1		Develop a 1-page business plan which features the four languages.										
Task 2		Identify, schedule and participate in one-on-one meetings with all of the community's hospital decision makers for our three health systems,										
100112			ne CMOs, ar									
	meeting.	10 0000, 11	10 011100, ui	10 1110 011101	1111001011 01	10010/ 001 po	i ato oooiai i	кооролюю	iy oxoodiivo	0. 100(10)	moroot ma	oommanity.
Task 3		and host all	three hospit	al svstems i	n a commu	nity roundtab	ole with the	goal of esta	olishina \$40	0.000 annu	ally in hospit	al funding
			cy Concept.			,		3	3 .	,	,	3
Task 4			th meetings		EO and ho	spital board.						
Task 5	Open the c	harity phari	macy									
Task 6	Take a 1 w	eek vacatio	n in Florida!									
	Jan 1	Feb 1	March 1	April 1	May 1	June 1	July 1	Aug 1	Sept 1	Oct 1	Nov 1	Dec 1
Task 1												
Task 2												
Task 3												
Task 4												
Task 5												
Task 6												
Cost - \$2,000 plus 1,000 hou	rs of staff time.											
Return – \$400,000												
Likelihood of Success – 50%												
Project Owners – Frank and I	Lisa (task 1), Ralj	ph (task 3 –	- facilitate), F	rank and Li	sa and Bob	(task 4 and	5), Frank a	nd his wife (task 6, leav	e the kids at	home with	mom)

Dispensary of Hope, 2015

Funding Resources

Finding funding is the starting point for securing investment. A typical mistake for nonprofit charities is to assume that there are national sources for funding a charitable pharmacy. The reality is that the financial, health, and mission benefits of a community charitable pharmacy are close by, rather than distant. Therefore, funding is more often going to be found close by, rather than distant.

The following as a series of resources that you can use to identify potential funders:

National Resources

- Foundation Center Database This service is a subscription-based database which provides searchable access to every foundation in the United States. Information includes items such as the total endowment of each funder, the annual giving, the members of the board, and the approach process. Further, results can be filtered by foundation location, foundation service area, and types of causes addressed by the foundation. It maintains the most comprehensive database on United States and, increasingly, global grant makers and their grants a robust, accessible knowledge bank for the sector. It also operates research, education, and training programs designed to advance knowledge of philanthropy at every level. The Foundation Center has 5 regional hubs and over 400 funding information centers across the country. An example of the use of the Foundation Center is to conduct a search of every national foundation that might have a presence in your specific city and which are concerned with healthcare access for low income adults. The results of such a search include details on the list of foundations and contact information for each.
- <u>Guidestar</u> –provides free access to the IRS 990s produced by foundations. An IRS 990 is a United States Internal Revenue Service form that provides the public with financial information about a nonprofit organization. Included on this document are fields mandated by the Internal Revenue Service. They include total endowment, annual expenses, vendors, investment portfolio data, board members, and gifts given. Typically, submissions to GuideStar run two years behind the current date. An example of the use of GuideStar might be a search of all of the IRS Form 990s of all of the organizations that are similar in mission and are located in your community, which would give you a feel for what kinds of funders are investing into the health of the uninsured in your community.
- <u>Grantsmanship Training Center State Resource Database</u> This resource provides a searchable list of funders in each state. The information is general in nature (top givers, corporate foundations, community foundations) but it does provide a free starting point for funders.
- <u>Grants.gov</u> This portal provides a central repository for information on federal government grants, as well as tools to support grant applications, grants management, budgeting, and other grant writing activities.

Local, State and National Funding Resources

- Local Hospitals Hospitals have the most to gain in your success. Community charitable pharmacies have a large impact on the health of the uninsured, and can therefore impact the financial position of the hospital (See: Return on Community Investment (ROCI) Funding and relationships).
- **State and Local Government** A smart place to begin your search is to sit with the Mayor's Office or meet with the Governor's staff to understand possible funding to open a community charitable pharmacy.

- Individual Donors Community leaders of considerable financial ability often have a
 deep concern for healthcare. Identifying such leaders may not be easy, but by asking
 other leaders in the community, it is possible to meet with those who have the interest
 and ability to launch a community charitable pharmacy. Funding of this type will
 require a solid business plan and trustworthy leadership. Like all funding, relationship
 comes before transaction.
- Local Corporate Foundations Corporations like to be positive neighbors in the community. An approach to the largest corporations in the region is worthwhile, but not until your initiate has researched the past giving of every corporation. Past giving is a good indicator of current interest and willingness. Know that funding should only be requested after a meeting. Again, relationship and trust come before investment.
- Faith Community Many large denominations have funding programs to serve the low income, vulnerable populations. Speak with area ministers, imams, and rabbis to learn of and access these funding pools.
- Pharmaceutical Manufacturer Foundations Often among the most generous and largest foundations annually in the US, foundations of the largest manufacturing companies may have funding programs to help support the work of a community charitable pharmacy.

Return on Community Investment (ROCI) Funding

Some funding is based on the generation of new revenue, such as a loan that a bank may give to a grocery store in order to help that grocer begin a business that generates revenue. However, with charity efforts that serve those in need, charity investment is often provided in the hope to avoid expensive and less efficient costs. In other words, ROCI funding is an agreement to invest into a charity that will save avoidable expensive costs on the part of the funders. As an example, ROCI funding may solicit \$300,000 in seed funding and \$100,000 in ongoing funding per year in order to avoid \$500,000 annually per hospital in the local healthcare economy's three hospitals. The cost is the startup and ongoing staffing of a charitable pharmacy. The return is that 1,000 patients each per hospital will be served with consistent access to medication. The investment goes into opening the pharmacy, with the benefit provided by the community charitable pharmacy back to the hospital.

An ROCI funding relationship asks the following questions...

- What is the cost of the present system?
- What is the cost of the future system?
- What is the delta of those two financial realities?
- Who pays that cost?
- Who will receive the benefit?
- Is there capital enough to invest into the new system?

Some partner's pain points your community charitable pharmacy could solve for them, and the benefits that the partner would experience include.

Potential ROCI	Current Cost (Pain	Potential Return	Investment Type
Partner	Point)		

Hospitals	Avoidable emergency department and inpatient care	Savings in IP and ED care due to consistent access to primary care medication through a charitable pharmacy	Seed and operating dollars to start and maintain the community charitable pharmacy
Patients	Lowered health status and quality of life Reduced employability Lost work time Presenteeism	Supporting the community charitable pharmacy through donations and service fees	Fees, donations, and service charges
Doctors	Lost time and personal frustration of prescribing meds that a patient cannot afford	An easy, simple answer for patients to get medications, as well as a prescribing formulary for the uninsured	Seed and operating dollars to start and maintain the community charitable pharmacy
Employers	Lowered health status and quality of life for workers Diminished workforce Reduced employability Lost work time Presenteeism	An easy, simple way for workforce to experience improve health outcomes	Seed and operating dollars to start and maintain the community charitable pharmacy
County, State, and Federal Government	Reduced tax income on earnings Lowered quality of life and satisfaction of the population	A low-cost mechanism to improve the health of the low income, and increase the productivity of the workforce, including increased taxable income	Seed and operating dollars to start and maintain the community charitable pharmacy

Local Healthcare	Frustration in	Measurable impact	Seed and	
Foundations	achieving a mission on health operating a		operating dollars	
	of improved health	health improvement to start and		
	outcomes among	among the	maintain the	
	the chronically ill	uninsured	community	
		charitable		
			pharmacy	

Outcomes Measurement in Fund Development Relationships

Research shows that community charitable pharmacies are playing a role in a qualitative and cost savings difference for these patients who are served. In 2015, a pre-post analysis was completed by the Advisory Board Company that looked at the work of a charitable pharmacy. That study demonstrates cost avoidance impact related to medication access, specifically on the costs of hospital care for the uninsured.

Pre-Post Intervention Analysis Focuses on ~400 DoH Patients Enrolled

During 2014 ¹		Inpatient			ED	
	Pre-	Post-	% Change	<u>Pre-</u>	Post-	% Change
Total Encounters	219	137	-37%	212	205	-3%
Average Cost ² per Encounter	\$7.5K	\$6.0K	-20%	\$288	\$132	-54%
Average LOS	7.0 days	5.7 days	-19%	n/a	n/a	n/a
Implied Savings per 1,000 Lives		~\$2.0M			~\$80K	NO THE

Key Takeaways

- Inpatient decreases in utilization driven by 50% fewer encounters for diseases of the circulatory system as well as meaningful decreases in encounters related endocrine & metabolic diseases, Infectious & Parasitic Diseases, and Injury & Poisoning
- Over a 400-patient sample, St. Thomas saved ~\$850K in Direct Variable Costs postintervention through the Dispensary of Hope
- Unique ED visits decreased by 12% post-enrollment

Dispensary of Hope-Advisory Board Evaluation White Paper

Total inpatient encounters decreased 37% from 219 to 137 while average length of stay decreased by 19% from 7 to 5.7 days. Overall cost per encounter was reduced 20% from \$7,500 to \$6,000. The average length of stay decreased from 7 to 5.7 days. Total emergency department visit use decreased 3% from 212 to 205 visits with a 54% reduction in cost per

encounter from \$288 to \$132. The implied savings per 1000 patient lives totals \$2.1M with \$2 million for inpatient visits and \$80,000 associated with emergency department visits. The takeaway is that community charitable pharmacies are playing a role in cost savings difference and outcomes difference.

Since this is a population that represents only cost to a hospital (reimbursement is very low among the poor and uninsured, and sometimes not even worth pursuing for financial and for risk reasons), a healthier uninsured population means savings for a hospital and for insurers.

Fund Development Decision Tree

Please refer to <u>Fund Development Toolkit</u> Tool #1 where it displays decision tree for Fund Development. The decision tree helps think through the process of getting started with an idea (new service line) and evaluate your funding options and opportunities. Notice that every funding model is going to be different based on specific needs and resources available in the community. For best practice, pursue those opportunities that have the greatest likelihood of success.

- **Earned income** Earned income is revenue income from traditional pharmacy services such as prescription, MTM service, and consulting services. Any revenue generated by services served is earned income.
- Subscriptions Subscriptions are a subset of earned income. This is a program where patients pay monthly subscription fee and enables the pharmacy to provide any medication in which the patient qualifies. This is a rare model for pharmacies because most work with pharmacy benefit managers (PBMs) or Medicaid/Medicare insurance. With this new model, pharmacies don't accept insurance and do not operate under a PBM. The pharmacy develops their own model that is very non-traditional. Nevertheless, subscription program allows your pharmacy to generate steady cash flow and increase the value of your pharmacy.
- **Retail** Retail is any revenue generated by filling medications.
- Public & State Funding Public and state funding are very important areas. It's now becoming more relevant. An example of public funding is to operate the pharmacy by getting medications donated from other health care system such as long-term care pharmacy. State funding involves working with your state legislator to operate drug donation program. For some pharmacies, the drug donation program generates the highest revenue and is what keeps the organization sustained. Many charitable pharmacies may not get contracts to operate this program but it's possible through advocacy. Building relationships and communicating the importance of the program to the community with the lawmakers help advocate your cause. Start with the state legislator that is connected to pharmacy or safety net health services; find an advocate for your cause/program and they can go to other members of government and share that story. You can bring in other community leaders such as local hospital CEOs and free clinic administrator as your advocates. When the legislators see the need for charitable pharmacy, it puts pressure on them to try to come up with a way to make it happen. (See: Stakeholders and Funders and How Much Did We Do or How Many?)
- **Foundations** Foundations are a type of funding available from other organizations. This allows for your pharmacy to use funding from different areas as a match from other organizations. Visit <u>Foundation Center</u> to search and apply for foundation organizations.

- For more information go to <u>Fund Development Toolkit</u> Tool #2, to learn how to find and cultivate foundation investment.
- **Hospitals** Hospital funding applies to charitable pharmacies that are part of large health systems. The large health system can see the value of providing free or low-cost access to medication to their patients. If their patient is not able to take medication, their condition could exacerbate resulting in a readmission to the hospital. Therefore, hospitals that have charitable pharmacies help reduce the hospital cost. In many cases, hospitals have revenue streams that are required to be invested in charitable pharmacy. Additionally, revenue generated from 340B program are reinvested into safety net program.
- Grants Grants are typically funded by foundations. The challenge is finding a grant that is a good fit for the charitable pharmacy. A great way to find funding is through the federal grants website www.grants.gov. Refer to Fund Development Toolkit Tool #4 and Grants and Funders to find websites and resources for grant funding. In many instances, it's not about finding a grant that already exists, but you can present the idea to an organization and they can turn around and present your pharmacy a grant to invest in the program. When presenting your idea to potential investors, make sure to include the return on investment advantage that shows the financial impact of the work. Please refer to Fund Development Toolkit Tool #5 for more information. Obtaining grants also depends on advocacy and building relationships within your community. As an example, the Iowa Safety Net Pharmacy noticed a need for a mental health program for inmates in their community. Many inmates do not have access to medical care and their medications upon leaving jail, thus their conditions deteriorate and may result in further incarceration. Iowa Safety Net Pharmacy reached out to their local government official to present the idea which landed them a grant to start the program. They now offer a corrections program that provides immediate primary care services and up to 90 days of behavioral health prescription drug coverage for transitioning offenders released from the county jail (See: Incarceration).
- Fees/Waivers A waiver is a type of voucher program. Different pharmacies operate waivers differently. For instance, the Iowa Safety Net Pharmacy provides uninsured patients with a voucher for the patient can then take it to a pharmacy and have a prescription filled. The pharmacy submits the voucher and get reimbursed for the medication they gave.
- Contract work Contract work is another opportunity to work with the community to help replicate similar programs. For instance, these could include offering consulting services. Contract work is utilizing the expertise from the leaders that are part of the charitable pharmacy.
- Partnerships Forming partnerships is one of the most critical avenues of funding and advocacy. Partnership is a way of creating relationships with other like-minded organization such as the local health system, or community health clinic to provide services (See: Top 10 Ways to Grow Your Charitable pharmacy Volume). This can be a contract service. For instance, there is a Dispensary of Hope pharmacy in lowa that was contracted by their local pharmacy association to dispose of drugs and they get paid for the service (See: Final Incineration).
- Technical School This is a type of funding that utilizes workforce training initiatives. Knowing that there is tremendous shortage of certified pharmacy technicians, and tuition being expensive for employees, some charitable pharmacies create their own pharmacy technician program to generate revenue. Your charitable pharmacy can develop a platform where a pharmacy technician certification program can be provided via online resources in combination with experiential hours in the pharmacy.

In-Kind - In-kind is a type of donation that does not involve cash grant. The donations
provided are contribution of goods or services other than monetary exchange. For
instance, hospitals could offer lease free space or donate certain hours of work to the
pharmacy. Volunteer work is also considered an In-Kind donation (See: <u>Students and Volunteers</u>).



Facility & Location

Tip: Be creative when you think of space. Charitable pharmacies are located in churches and thrift shops as well as departments of health and clinics. Where do the people you plan to serve go?

Facility Needs

Facility needs include any components needed to run and operate a pharmacy. Follow any state board of pharmacy requirements for specifics in terms of space, water supply, security systems, and others.

Location

The location of the pharmacy needs to be easily accessible and as close to the population you are trying to serve as possible. Are there other pharmacies or even charitable pharmacies already in the area? Was the location picked because of the absence of a charitable pharmacy presence or is there a certain patient specific population that is being underserved? Are there enough patients in need of your services in the area? See <u>Local Factors for Community Charitable Pharmacy Implementation</u>. Location is pivotal and must be chosen wisely. Only decide on a location when there is enough data to support that the new facility will be able to operate successfully.

Patient transportation to your facility is key to accessibility. Factors to consider include:

- Convenient:
 - o Proximity to local clinics or other healthcare services
 - Near local bus or public transportation stop
- Adequate parking

Include public transportation information (bus route, subway stop, etc.) on maps and marketing materials.

Size

The new facility must be able to meet the needs of a specific population and area, thereby creating the charitable pharmacy's own unique market. Anticipate growth. Once clinics, hospitals, and patients discover the value of a charitable pharmacy, numbers of new patients and prescriptions will accelerate rapidly. If possible, build this growth into your budget (for staffing as well as purchasing) and space.

Dedicate space for:

Pharmacy

- Inventory: segregated medication from various suppliers (if required)
- Records: prescription files, patient files, pharmacy records
- o Bulk supplies: vials, labels, office supplies
- Med destruction
- Patient Education materials
- Enrollment area: enrollment may take 30-60 minutes for a new patient, 10-15 minutes for re-enrollment
- Dispensing and counselling area: cash register, will call space, etc.
- **Extended services**: MTM, multi-language counselling, device use, immunizations, etc.
 - Space to allow privacy and meet HIPAA regulations
 - Area for students and/or volunteers
 - Office
- Staff eating and break area separate from the medication storage area
- For mail-order, shipping area: both for arrival of donations and for outgoing prescriptions
- Waiting area large enough to accommodate population:
 - o Stand-alone pharmacy sitting and roaming aisles
 - o Shared space if in a clinic, hospital or other shared location

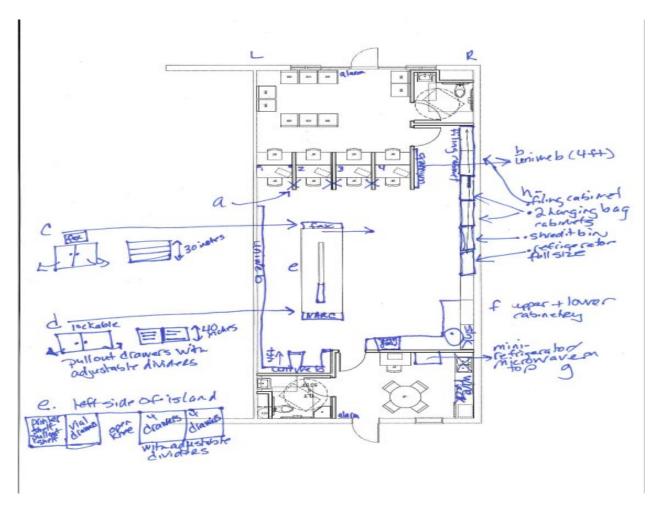
A suggested starting size is 1,000 square feet, designing up or down depending on final size of facility. Here are some examples of the square feet needed compared to the number of prescriptions filled used by St. Thomas Health in Tennessee:

- a. Busy hospital outpatient pharmacy that provides employee prescriptions, retail and discharge prescriptions, and Dispensary of Hope medications. Metrics: 1,507 square feet to fill 6,786 prescriptions during Sept 2017
- b. Hospital outpatient pharmacy that solely provides prescriptions for indigent patients. Metrics: 808 square feet to fill 3,368 prescriptions during Sept 2017
- c. Pharmacy within a clinic that provides employee prescriptions for the hospital nearby, retail prescriptions for the clinic, and Dispensary of Hope prescriptions. Metrics: 1,200 square feet to fill 3,643 prescriptions during Sept 2017
- d. Pharmacy within a rural clinic that provides prescriptions for the hospital nearby, retail prescriptions for the behavioral health clinic, and Dispensary of Hope prescriptions. 559 square feet to fill 115 prescriptions during Sept 2017 (opened August 2017)

Example layout of pharmacy

STH River Park Plaza Pharmacy

TIP: Think where you hope to be in 5 or 10 years. Plan for additional inventory, staff, volunteers, and services. WMDP started with 1,000 square feet for their mail order charitable pharmacy. Ten years later, in 2018, they will move to a 4,000 square feet facility to relieve a very cramped space. What do you plan to add in the future? Who will be helning vou2



Hours of Operation

Startup hours of operation factor in funding, services offered, and size of population to be served. Many stand-alone or community collaborative charitable pharmacies begin with three days per week (21 to 24 hours/week). If the charitable pharmacy is to be affiliated with a clinic or hospital with an established population, five days a week may be feasible.

Limited hours of operation provide time for marketing to community and health care referral sources, funders, and patients. Even with community support, presentations to clinics (social workers as well as providers), and health fairs, church groups, libraries, etc. are needed to introduce your pharmacy and its services to the community and establish your reputation (See: Where to start).

Hours of operation may need to be adjusted to better meet the community need. Examples: Open early or close later one day a week to accommodate patients who are working; closed on Wednesday as clinics do not have specialties open on Wednesdays; open on Friday afternoon to accommodate discharge patients. Check with local health care facilities to determine when their disease state clinics are run to best offer your services to their patients.

Equipment

Follow any state board of pharmacy guidelines for specifics on required equipment.

Office	Pharmacy Specific	Fixtures/Utilities
 Desk Chairs/stools for desk, tasks, waiting area Filing cabinets Counselling area furniture Student/ volunteer area furniture Envelopes, staples, office supplies Packaging supplies if using mail order Shredder Trash receptacles 	 Shelving and fixtures: meds, printer, etc. Refrigerator/freezer Vials/ bottles / caps Labels, including auxiliary Shelving for bulk items Counting apparatus (trays or devices) Measuring devices: solids, liquids Bags or packaging for dispensing Hanging bags or will call supplies Floor mats Safe, if using money or carrying controlled substances Thermometer: refrigerator & room Medical waste container Cash register if doing any retail/or subsidies with co-pays De-blister machine to punch pills from bubble wrap for destruction 	 Bathroom/sink Dispensing sink Security system, if required

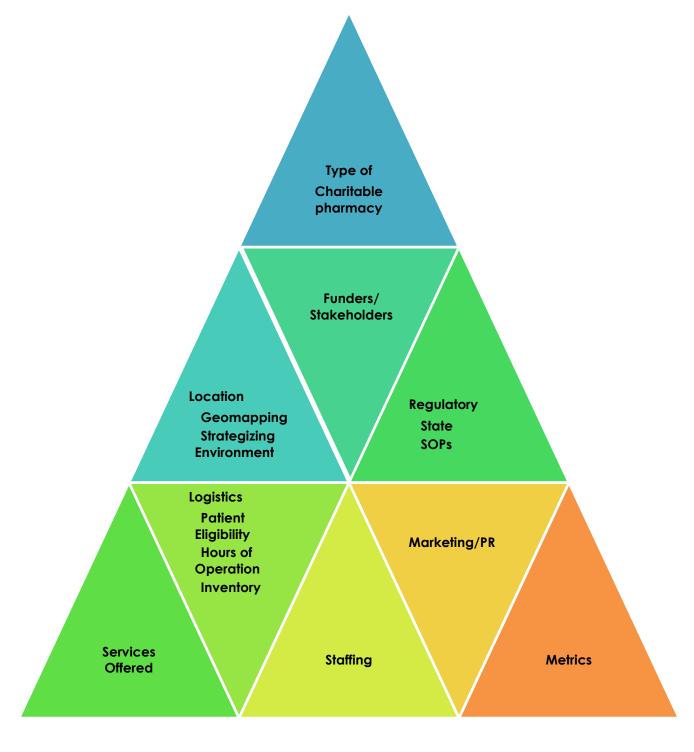
<u>Technology</u>

Listed below are the categories to consider when making decisions regarding types of technology required. Technology matches the unique services offered by the pharmacy to allow smooth and efficient operations. See Pharmacy Management Systems for pharmacy operating systems.

General	Optional	Pharmacy specific	Billing
 Phone Fax machine Printers Computers Register Security System (if required) 	 Language interpretation software (Martti, Language Line Services) See Interpretation. Interpretation Language translation services Pharmacy Translations, Translating TV for waiting room 	 Pharmacy dispensing system Counting machine (Kirby Lester or "robot") Internet access provider Drug information resources (Clinical Pharmacology) Patient assistance program software (RxAssistPlus and others) Microsoft Office or equivalent 	 Reimbursement support Reconciliation services See Operations Software

For <u>Start-Up Costs</u> see <u>Start-Up Costs.</u>

Models of Community Charitable Pharmacies



A charitable pharmacy program serves un-insured or underserved patients with low-income. The charitable program may be a pharmacy's exclusive focus, or it may be incorporated into

pharmacy with a broader business plan with many agendas. Pharmacies dispensing solely to patients under the charity program will be referred to as "Charity-only" pharmacies, whereas pharmacies dispensing to both insured and un-insured patients and engaging in other for-profit activities in addition to the charity program will be referred to as "Mixed-Model" pharmacies. A charitable pharmacy program may be successfully operationalized in many different types of pharmacy models and settings with a stipulation that each must segregate charitable medications from the for-profit medications.

Some charitable pharmacies are independently funded, <u>stand-alone</u>, not fully supported by a hospital or health system. All charitable pharmacy models can be <u>open-door</u>: serving eligible patients from the entire community or state. Clinic or hospital models may or may not limit their patients to those referred from a specific source. Most models limit the geographical population they serve (city, county, state, etc.) due to limited resources.

Model	Funding	Patients	Open-door
Charity-Only	Can be stand alone or not	Dispense solely to eligible charity patients; May limit to geographical area	May be open-door or limit to specific referral source
Mixed-Model	Can be stand alone or not	Serves both insured & uninsured patients; May limit to geographical area; Engages in other for-profit activities in addition to the charitable pharmacy	May be open- door or limit to specific referral source

Charitable pharmacies can take many forms and be operated in a physical location or mail order, at a hospital campus, or out of a collaborative practice site (health department, thrift shop, etc.) The following are examples of existing charitable pharmacies serving the uninsured of their area in a variety of models.

Charity Only

 Stand-a-lone pharmacy providing services for uninsured only patients
 Central fill pharmacy

Mail Order Charity Only

 Comprehensive drug donation, redispensing & disposal programs

Collaboration Mixed Model

Charity pharmacy that serves both insured and uninsured

Clinic Based Mixed Model

 Can be located on a hospital campus or inside a primary care clinic location

Hospital Based Mixed Model

Charity Pharmacy & Retail Pharmacy on hospital campus

Charity-Only Pharmacy



Ozanam Charitable Pharmacy

Shearie Archer, Executive Director

The Ozanam Charitable Pharmacy, Inc. located in Mobile, Alabama was founded as a non-profit 501 (c) (3) organization in 1997 and began serving low-income residents of Mobile County in 1998. The primary goal was to decrease inappropriate ED visits and decrease hospitalizations of seniors 60 years-old plus. Emphasis was to keep in stock maintenance medications- blood pressure, heart, anti-seizure, etc. A policy was established that no controlled substances (narcotics) would be stocked. Initially, medications were to be obtained as samples donated by area physicians and as purchased generics. In the early

stages pharmacists were volunteers and the pharmacy filled prescriptions for roughly 400 patients per month in Mobile County.

Case workers with Catholic Social Services certified individuals as being eligible for pharmacy services. A guideline examined patient sources of income and necessary expenses. Those left with little or no money would be eligible. In subsequent years, service has been extended to residents of Baldwin and Escambia (Alabama) Counties. In the aftermath of Hurricanes Katrina and Rita the pharmacy has filled prescriptions for evacuees of the disaster staying in our community.

In 2001 the growing partnership with Area Agency on Aging and establishment of a partnership with the Escambia County Health Department led to the extension of pharmacy services to patients in Escambia and Baldwin Counties. As a result, the pharmacy's patient base in Escambia County has grown from 150 per month to over 400 per month. Grants to Ozanam Pharmacy include Community Block Grant funding from the City and County of Mobile, South Alabama Regional Planning Area Agency on Aging, Catholic Charities, United Way of South Alabama, local, national foundations, a primary fundraiser, and direct mail.

As funding increased, a full-time pharmacist was hired to handle filling more than 1,000 new prescriptions per month. In subsequent years grants from McMillan Trust and Neal Trust in Escambia County allowed the addition of a part-time pharmacist and the purchase of more generic medications. A staff position was created to assist low-income persons enrollment into manufacturer Patient Assistance Programs (PAPs). This program helps ensure patients a consistent supply of brand-name medications challenging to keep in stock via physician samples. In many cases, these medications come directly to the pharmacy and patients are able to pick them up along with their other prescriptions.

Ozanam became a teaching site for Auburn University Harrison School of Pharmacy with fourth year pharmacy students performing their 5 weeks of rotations at our pharmacy. Due to health literacy issues, our patients needed more disease state education. Students provide patient education, including targeted Medication Therapy Management, device utilization, and motivational techniques. The Mobile County School Commission provides the pharmacy with 4000 square feet of space to accommodate the extensive counseling.

Initial marketing included a partnership with local Medical Alliance Group, Physician Groups (primarily for samples), clinics, local churches, health fairs, and other organizations serving the uninsured population. Today, we use the local print and broadcast media, web site, enewsletters, publish printed newsletter, direct mail and social media to provide information to our patients and health care professionals.

As of 2017, Ozanam pharmacy fills prescriptions for as many as 1,671 persons each month. In fiscal year 2017, 28,000 prescriptions were filled with a retail value of roughly \$2,000.000 on a budget of roughly \$400,000. Funding provided for seven full-time and part-time staff and 22 hours of operation, open 4 days weekly.

Collaboration Charity-Only Pharmacy



HOPE Dispensary of Greater Bridgeport

Christine Toni, BS Pharm, Founding Coordinator Angela Faulhaber, PharmD, Current Coordinator

HOPE Dispensary of Greater Bridgeport was started as a collaboration between health care agencies within the city (Primary Care Action Group (PCAG)) to address recurrent ED visits and hospital admissions by low income, uninsured patients at two hospitals. Medication access for this population was determined as a primary factor. A charitable pharmacy, offering medication access, education, and referring patients to primary care providers would offer the city's uninsured a cost-effective health care option.

Initial funders provided a startup grant (2-year Ascension Health), location and utilities (City of Bridgeport Department of Health building), and fixtures and salary mechanism (St. Vincent's Medical Center). Community groups (rotary, water company, and others) provided funding for software and vendor memberships. Bridgeport Hospital and five area clinics acted as referral sources for patients to and from HOPE. The initial site was chosen to meet state pharmacy regulations and offer familiarity and convenience for patients (on a local bus route with other social services provided in the building). Funding provided for 21 hours of operation, open 3 days weekly. Initial staffing was one pharmacist and one pharmacy assistant. More funding became available as metrics demonstrated the positive impact of the pharmacy on the health of the community. As work volume both for prescriptions and manufacturer patient assistance programs increased, a pharmacy technician was added to the staff.

It was determined for pharmacy safety there would be no fees for patients (therefore no money) and no control medications. A limited formulary provided the maximum use of resources for most of the disease states seen in this population. The initial formulary list was distributed to area providers, utilizing therapeutic interchange as needed with provider consent. With the institution of Collaborative Practice in Connecticut, a collaborative practice agreement for therapeutic interchange was obtained with many physicians, allowing dispensing of prescriptions upon initial visit.

Initial marketing included presentations at physician groups, clinics, local churches, health fairs, and other organizations serving the uninsured population. Though physicians were important, APRNs, PAs, social workers, case managers, and clinic liaisons provided the most patient referrals and constructive feedback. Fliers in multiple languages with a map and hours of operation were made available at all clinics, food pantries and grocery stores. Another

referral source became local pharmacies that had patients who could not afford their medication.

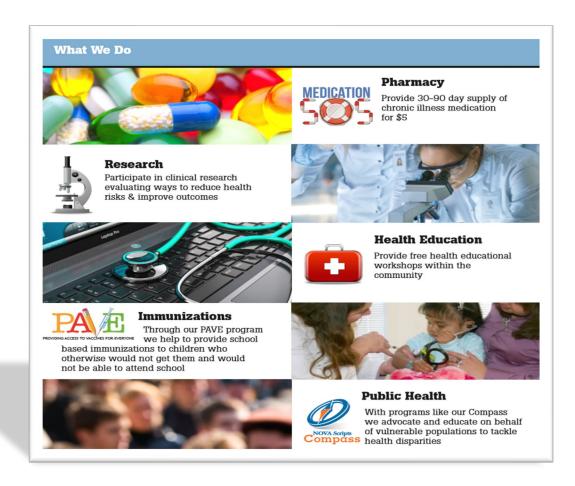
As the primary goal of the PCAG was to decrease inappropriate ED visits and decrease hospitalizations, patient education became as important a service as medication access. Greater than 50% of the patients speak a language other than English so having staff and technology to interpret was essential. Providers soon depended on the pharmacy to compliment what they were not always staffed to offer for patient education, including targeted Medication Therapy Management, device utilization, and motivational techniques. The pharmacy became more of an ambulatory care site, with the city donating another space for patient counselling.

A collaboration with local universities developed as the pharmacy workload increased. Pharmacy students volunteered for service hours as well as IPPE, APPE, and Pharmacy Resident rotations. A program for Experiential Service Learning for nursing, foreign language and social worker students was developed, providing students professional encounters with this population and donating volumes of chart maintenance for the pharmacy.

Nova Scripts Central, Inc.

Donney John, Pharm D. Executive Director 6400 Arlington Blvd, Falls Church, VA 22042

Established in 2007
NOVA ScriptsCentral, Inc. (NSC) is a 501 (c)3 nonprofit collaborative pharmacy.
Mission: Our mission is to provide quality integrated pharmaceutical care and
medication access to low-income uninsured children and adults living in Northern
Virginia.
Vision: Improve the health of the community by empowering patients to take charge or
their health and eliminating barriers to care.



Special services:
Comprehensive Medication Management (link)
Educate before you medicate (link)
Nova Scripts Compass (link)
Medication SOS (link)

Mail Order Charity-Only Pharmacy

Wyoming Medication Donation Program

Natasha Gallizzi, Pharm.D. Program Manager

The Wyoming Medication Donation Program, a program of the Wyoming Department of Health, is a state-wide mail order charitable pharmacy. The program is a comprehensive drug donation, re-dispensing, and disposal program that improves prescription access for Wyoming's low-income patients, up to 200% Federal Poverty Level, who lack adequate prescription coverage while reducing medication waste.



Bubble wrapped medication donations received from extended care facilities and others across Wyoming to be used for prescription filling at the WMDP.

Wyoming has a state-wide donation network that collects sealed, in-date medication donations, excluding refrigerated medications and controlled substances, which are shipped to the central location for processing. After processing, acceptable medications are made available to fill prescriptions for eligible patients throughout Wyoming. Unacceptable medications are disposed of via incineration (See: Medication Destruction). To fill gaps in the donated inventory, additional medications are acquired through the Dispensary of Hope membership.

The Wyoming Medication Donation Program (WMDP) started as a pilot program in Laramie County with a typical retail pharmacy model under a non-profit agency. After showing positive results, the pilot pharmacy continued (under the non-profit) and the statewide mail-order pharmacy branched off under the Wyoming Department of Health (WDH) in a new facility with a new pharmacy license. Both pharmacies are still flourishing.

As of 2017, WMDP serves approximately 3,000 patients annually. More than 700 of these patients are served via mail only, mailing over 1,000 prescriptions per month. The remaining patients are serviced at our Dispensing Sites. The Dispensing Sites are Wyoming clinics or pharmacies registered with WMDP to order donated medications to maintain at their site. Each site is responsible for verifying patient eligibility and dispensing the medication according to prescription. The sites send quarterly reports to the WMDP on the number of patients served and number of prescriptions filled. There are currently six active Dispensing Sites, including two free clinics, a homeless clinic, and the pilot program pharmacy mentioned above. State-wide data is compiled and shared with WDH administration, legislators, and supporters.

Staffing

The WMDP pharmacy is open 30 hours per week. Staffing consists of one pharmacist/program manager (0.75FTE), one fill-in pharmacist (0.25FTE), and three pharmacy technicians (2.25 FTE). Several volunteers help process donations and disposal. Volunteer hours average 35 hours per month. The program was recently approved for expansion that will provide more space and staffing, as well as adding a service to help patients apply for manufacturer prescription assistance programs. This is especially needed for insulin and inhalers.

The Wyoming Department of Health, Division of Healthcare Financing, and Pharmacy Services serves as a rotation site for pharmacy students from the University of Wyoming. The students spend one week of their rotation with WMDP. In the summer, pharmacy student interns volunteer.

Marketing

Local collaborations are very important for success. In the beginning, education of local providers, the hospital, and safety-net services were the most impactful. The program has focused a lot of education and marketing to state networks to spread the word about what we do and increase utilization of the program. Some examples are the Wyoming Hospital Association, Wyoming Primary Care Association, Prevention Management Organization, hospitals, PCMH's, Wyoming Pharmacy Association, Public Health, Nursing Home Association, and various state health advisory groups.

Collaborating and coordinating messages with existing agencies and programs with statewide contacts has been a key to the program's success. Venues include our website, presentations, e-newsletters, vendor booths at conferences, involvement in task forces that have similar goals. For example, the pharmacist is on the Wyoming Prescription Drug Abuse Stakeholders group, making many good contacts during the drug disposal discussions.

Patient Services

Case workers from 45 hospitals, clinics, and mental health centers around the state refer patients to the pharmacy. Enrollment is done via fax or standard mail. Online enrollment is not used due to unknown security of the sender's internet connection for private parties (See: Application Packet 02 27 2017.pdf for example of enrollment forms).

To assist communication via mail, we have several different colored notes that we send along with the patient's prescription to notify them about issues. Notifications include:

- 90-day supply dispensed
- Dose substitution (e.g. lisinopril 20mg 1 orally daily to lisinopril 10mg 2 orally daily)
- Notification that the requested medication is not in stock and we put them on the waitlist
- Additional eligibility information required
- Notice of eligibility renewal needed (sent along with application for renewal)
- Notice to request refills together so we don't have to ship so many packages per month for the same person
- Notice of PAP paperwork (e.g. Eliquis, insulins, etc.)

Notes are color coded, making it easier to find the correct note to send. The prescription vial and notes are placed inside a plastic bag then placed inside the mailing envelope. Patients seem to notice the notes bagged with the prescription separately better than when the notes were included with all of the other prescription paperwork just inside the mailing envelope.

Documentation is placed in the patient profile of the pharmacy software system regarding date eligibility expires, requests for additional information, and other care notes. All notes are dated to facilitate follow-up communication with patients and/or providers. Staff checks the patient profile each time the patient is on the phone to verify any changes in address or phone number to save on returned mail and keep all files as current as possible.

Mail Order Process

Prescriptions are sent to patients free of charge via certified mail. A signature is required, and packages can be tracked. During the holidays we get a lot of mail status questions due to mail delays. Bigger boxes are typically sent via United Parcel Service (UPS). In the very rural towns, UPS has provided the most reliable carrier. Most packages take two days or longer to be delivered. In December and when there are federal holidays more delivery time is allowed. Refills are sent up to ten calendar days prior to due date.

Special equipment is utilized in a mail order practice, including a postage meter, certified mail stickers, and a contract with a courier for incoming donations. Ideally, the pharmacy has a designated shipping area, both for arrival of donations and for outgoing prescriptions. In the shipping area are kept mailing envelopes, package tape, boxes for shipping, and other mailing supplies. Meds for disposal are segregated to their own area as well.

Metrics

In addition to metrics other charitable pharmacies keep, we track the number of cities served. A reporting feature in the software tracks by zip code or city name. This was especially helpful as we were growing our state-wide program to determine if the program was achieving a state-wide reach.

The medication dollar value <u>dispensed</u> to each county as well as the dollar value <u>donated</u> from each county is tracked. State leadership has been interested to see if the incoming donation value correlates with outgoing in each county. Wyoming has 23 counties. See <u>How Much Did We Do or How Many?</u>. We are researching other software options to recalculate more information into county metrics.

Another metric helpful for gaining support has been breaking down the number of prescriptions by therapeutic class, especially to see how many mental health medications are dispensed. See How Many?.

SafeNetRx Charitable Pharmacy

Jon Michael Rosmann, CEO 11100 Aurora Ave, Bldg 13 Urbandale, IA 50322

Clinic Based Mixed-Model Charitable Pharmacies

Saint Thomas Health (STH) operates several different types of charitable pharmacy models. Two are located on metropolitan hospital campuses, while two others are located inside of STH primary care clinics. All models except one dispense medications to charity patients of either the hospital and/or clinic and STH associates. These pharmacies have the ability to process commercial insurance and Tennessee Medicaid (Tenncare) as well. 340B qualifying locations will also layer this program into existing charitable pharmacy models to offer comprehensive service to its patients. Both a charitable pharmacy model and 340B program can work in tandem to provide medication access to patients experiencing affordability issues. Of note, one pharmacy does not dispense to associates due to a non-STH owned pharmacy already contracted to provide this service prior to the introduction of the charitable pharmacy to this campus.

Saint Thomas Health is a family of Tennessee hospitals and physician practices united by a single mission: to provide spiritually centered, holistic care that sustains and improves the health of the communities we serve. As a part of Ascension Health, the largest not-for-profit health care system in the United States, they are committed to healing and dedicated to service, especially to persons who are poor or needy, reflecting the spiritual core of our mission, vision, and values.

The Clinic Model (<u>Mixed Model</u>) is the preferred model for Saint Thomas Health now that campus-based charity models have been established.

- Best suited to capture indigent/sliding scale clinic patients
- Convenient to patients already onsite for appointment decreasing transportation issues
- Onsite support for providers with patients expressing affordability issues, steer prescribers to charity formulary
- Market to associates as an in-house pharmacy to capture revenue and also save health system dollars if self-insured
- Capture retail business from the clinic to offset charity operational costs
- Assist with hospital discharge prescriptions if close proximity to a hospital campus without an onsite outpatient/charitable pharmacy
- Is there space in clinic for a pharmacy?
- Is there a common lobby that can be shared decreasing square footage needs of pharmacy? Patients should be able to access pharmacy even if clinic is closed if hours differ.

Hickman Charitable Pharmacy

Ashley Bennett, Pharm D Saint Thomas Health Outpatient Pharmacy Supervisor Centerville, TN

- Part of a \$1 million-dollar Clinic expansion that included behavioral health services and a charitable pharmacy
- Clinic model chosen as no space available on Hospital proper, Clinic shares a parking lot with Hospital
- 340B reinvestment narrative helped make this happen (25 bed critical access hospital)

- Needs assessment identified behavioral health/medication access as a focus area
- Hickman County has one of the highest suicide rate in the state
- Behavioral Health needs include medication access
- Just started filling employee RX in February 2017

Hickman County Demographics

- Rural community
- Population approximately 25,000
- Median household income \$31,013
- Persons below poverty level 16.3%

<u>Hickman County (Community Health Needs Assessment)</u> See <u>Local Factors for Community</u> Charitable Pharmacy Implementation

- Prioritized Need #3: Access to Care/ Care Coordination
- **Goal:** Improve access to comprehensive, quality healthcare services through increasing availability and affordability of care while advocating for increased health insurance coverage.

Strategy 2: Open a Dispensary of Hope Charitable Pharmacy to provide medication assistance for uninsured and underinsured individuals who experience financial hardship, as well as to assist patients with navigating other community resources as needed

- This strategy's target population is uninsured and underinsured individuals who demonstrate financial hardship and thus are in need of assistance to obtain necessary medications.
- This strategy provides medication access to an underserved patient population, addressing access barriers due to cost of care.
- This strategy is built upon the evidence base that has been generated by the unique Dispensary of
 Hope Distribution Center model, which works with leading drug manufacturers to increase the supply
 of essential medicine to patients in need; the Dispensary of Hope Pharmacy links the medications
 made available from the Distribution Center to the individuals in need of a means to fill a prescription
 affordably.

Anticipated Impact:

- Provide unaffordable medications to qualifying individuals who enroll in Dispensary of Hope through medications obtained through the DOH Distribution Center, Saint Thomas Health Safety Net list, or physician donated samples.
- Assist qualifying individuals with obtaining medication assistance through manufacturer sponsored Patient Assistance Programs

Initial Marketing plan - See Marketing Where to start.

- STH Campus providers
 - Saint Thomas Health Clinic staff
 - Hospitalists
 - Emergency Department
 - Care Management
 - Behavioral Health providers
 - Community resource counselor
- Flyer distribution
 - Local medical & dentist practices
 - Local Health department

- Local Churches
- Helping Hands
- Churches
- Saint Thomas Health At Home Medical Mission
- 211 nationwide local resource listing
- Community Safety Net meeting
- Community newspaper ad & local radio spot
- Open House with Blessing/Ribbon Cutting Ceremony

Saint Louise Pharmacy

Rutherford County, TN

Rutherford County, Tennessee, population 308,251 in 2016 with 10.5% uninsured. Of note, Community Commons 45% uninsured rate for Hispanic and Latinos in the area (2015). Also, 24% of adults 19-25 years old are without health coverage.

- Located in the Saint Louise Clinic in Rutherford County, a clinic that serves
 patients of all ages which includes pediatrics, obstetrics, adult primary
 care, and geriatrics.
- Partners with medical residents and pharmacy students to provide learning opportunities
- Pharmacy dispenses to Saint Thomas Health associates and charity patients from Saint Louise Clinic and community at large
- Saint Thomas Health first charitable pharmacy site, operating 10+ years
- 1 pharmacist, 2 technicians
- Fiscal Year 2017, Pharmacy dispensed over 25,000 prescriptions to 6,149 patients qualifying for charity care.

Hospital Based Mixed-Model Charitable Pharmacy

Davidson County, TN

Population 684,410 (2016)

14% persons without health insurance, under 65 years

- Best suited to capture discharge patients and most convenient to eliminate an extra stop post discharge
- Partner with Care Management to identify patients with medication access issues prior to discharge
- Provide 30 day fills for discharge patients to prevent readmission
- Best aligned with 340B covered entities to fit into the narrative of 340B savings reinvestment
- Marketed to all potential patients: employees, discharge insured and uninsured patients, Meds to Bed program, ED patients, patients of hospital specialty clinics such as transplant, full retail capability to service patients visiting practices in the Medical Office Buildings, Same day surgery sites, and visitors staying with patients in the hospital.
- Is there space on campus with convenient access?

Plaza Pharmacy- Saint Thomas West Hospital campus



- Plaza Pharmacy is a full-service retail pharmacy opened to the public
- Metropolitan hospital campus
- In house pharmacy for hospital associates
- Charitable pharmacy
- Transplant specialty meds
- Located in the Plaza Medical office building adjacent to food court connected to the hospital
- 3 pharmacists, 6 technicians
- Retail Pharmacy 30+ years, Charity program 10 years
- During Fiscal Year 17, Plaza served over 6,000 charity patients by dispensing approximately 24, 000 prescriptions

Saint Vincent Pharmacy - Saint Thomas Midtown Hospital campus



- Located on first floor by registration and Emergency Department
- Serves Charity patients only since October 2014
- does not dispense to associates due to a non-STH owned pharmacy already contracted to provide this service prior to the introduction of the charitable pharmacy to this campus
- Metropolitan hospital campus in close proximity to downtown Nashville and homeless population
- Referrals from hospital discharges, homeless shelter, other safety net providers in area
- 1 pharmacist, 2 technicians
- Saint Vincent served 6,149 charity patients during hospital's last fiscal year which represented 25,327 prescriptions.



Regulatory

<u>Legal Considerations in the Development of Best Practices for Charitable Pharmacies</u>

Thanks to Dorothy Pak, JD, BRADLEY ARANT BOULT CUMMINGS LLP, Birmingham Alabama, for her donations of time and expertise. Presented 2015.

Regulatory Framework

Pharmacy licensing, medication procurement to destruction, professional collaborations, nonprofit status, and more are all highly regulated both on a state and federal level. The pharmacy should comply with federal laws unless the state law is more restrictive, in which case, the state law is followed. A legal partner with expertise in healthcare and general business matters is essential to maintaining best practices.

Regulations include:

- Federal Law
 - o Nonprofit Status See <u>501(c)3 Nonprofit Status</u>
 - Prescription Drug Manufacturing Act (PDMA) See <u>Donation of Prescription Drug</u>
 <u>Samples from Licensed Practitioners</u>
 - Drug Supply Chain Security Act (DSCSA) See <u>DSCSA Track and Trace</u> Legislation
 - Other Food and Drug Administration (FDA) rules and regulations

- (if applicable) Drug Enforcement Agency (DEA) regulations for dispensing narcotics or controlled substances, both federal and state specific.
- o (if applicable) Centers for Medicare and Medicaid Services (CMS) regulations for accepting Medicare or Medicaid payment, both federal and state specific.

State Law

- Boards of Pharmacy rules and regulations
- Nonprofit Status and Charitable Solicitation rules (may need to review attorney general rulings)
- (if applicable) Department of Public Health rules for drug reclamation/donation programs. Some states have drug reclamation/donation rules under Board of Pharmacy.

Local Law

Local/County Business Codes

Refer to state board of pharmacy state regulations in Appendices\Regulatory\Board of

<u>Pharmacy state regulations 1.2017.xlsx.</u> For more up-to-date information, check the individual state board of pharmacy website.

Governing law or contracts with vendors, donors or manufacturers will likely dictate:

- Who is qualified to receive medications (patient eligibility)
- Whether any charge may be made for dispensing
- Any specific requirements on storage, recordkeeping, segregation, etc.

In some instances, these regulations may be very detailed and onerous. It is important to keep track of requirements and follow accordingly. Policies and procedures, staff training and use of software help make processes more manageable and trackable. See <u>Manufacturer Bulk Patient Assistance Programs</u>. Tips for an audit are below under Auditing.

TIP: "Phone a Friend" - make contact and consult with State Board of Pharmacy before beginning a charitable pharmacy to ensure all requirements will be met.

 States vary widely on how detailed their regulations are for charitable pharmacies, medication reclamation, and collaborative practice.

Policies and Procedures

Most states regulating charitable pharmacies will require policies and procedures be filed and approved prior to licensure. See <u>Standard Operating Procedures</u>.

These are similar to regular pharmacy policies and procedures, with unique variations (and possibly some waivers and exceptions), pertaining to the "charity" and nonprofit status of the pharmacy.

State law may dictate policies regarding:

- Qualifying patients, in addition to contractual requirements or simply internal policies
- Determining whether patients may be charged and if so, how much

- Unique record-keeping requirements to track donations
 - o Could vary slightly depending on where medications are sourced
- May have more leniency in staffing and equipment requirements

DSCSA - Track and Trace Legislation

The Drug Supply Chain Security Act (DSCSA) was implemented to facilitate tracing products through the pharmaceutical distribution supply chain. This act requires manufacturers, wholesalers and pharmacies to exchange and track transaction information, transaction history and product tracing information. Tools for compliance are found in Irracking the Medication Supply Chain.

Legal Resources

Many great resources from which to seek help in this highly regulated field include:

- CharityPharmacy.org and other national, regional, and state organizations
- <u>State Boards of Pharmacy</u>
- Legal Counsel
 - <u>Legal and Operational Guide for Free Medical Clinics</u> jointly published by American Health Lawyers Association and American Medical Association Foundation.
 - o www.healthlawyers.org

501(c)3 Nonprofit Status

When starting a nonprofit, there are many legal considerations. A 501(c)3 organization is a nonprofit organization in the federal law of the United States according to 26 U.S.C. § 501 and is one of 29 types of nonprofit organizations which are exempt from some federal income taxes (Wikipedia 3.15.18).

Obtaining 501(c)3 status within the tax code can be a lengthy and challenging process; however, it provides:

- Exemptions from federal and state income and corporate taxes
- The ability for donors to make tax deductible contributions
- Greater fundraising opportunities ability to apply for grants that may be limited to entities with 501(c)3 status

All assets of a 501 (c)3 entity, by law, are permanently dedicated to a charitable purpose. Public charities are held to a strict expectation that their funding be used to run programs directly benefiting the public within their stated mission. In a nonprofit corporation, there are no profits to be distributed, so financial accountability rests with the Board of Directors.

Two options that exist to starting a nonprofit are:

- 1. Form new entity that will qualify as a nonprofit, charitable entity
 - o Provides limited liability and tax-exempt status
 - Most common form is nonprofit corporation

There are many web-based programs to help with the application process, usually for a fee. <u>Legal and Operational</u> <u>Guide for Free Medical Clinics</u> is a legal resource for starting a nonprofit medical establishment including points for 501 (c)3 status and much more. Other resources may be found at <u>Nonprofit Status</u>.

- 2. Be part of an entity that already has 501 (c)3 status.
 - Many operational synergies, but could lose some autonomy
 - Would not segregate liabilities from rest of organization
 - o Requires a fiscal sponsorship agreement

A fiscal sponsorship is a contract between a 501(c) 3 and another nonprofit entity (state-level). The sponsor is responsible for the accounting and the sponsored inherits 501(c) 3 status. Donations, grants, etc. can be made to the sponsor, but specified for the sponsored. The sponsor may take an administrative fee (2018 estimate is 10%). The

TIP: Once state nonprofit status is received, donations can be accepted and will ultimately be tax deductible if federal 501 (c)3 status is approved, as tax exempt status is recognized back to the creation date by the state.

 However, if exempt status is not approved, donations will not be deductible.

contract may be for a specific amount of time (an event) or be left open indefinitely. See <u>Appendices\Regulatory\Sample Fiscal Sponsorship Agreement -Re-Grant Model.docx.</u>

Registrations

Nonprofit status begins at the state level and requires registration as a charitable or nonprofit entity. This process may be online and requires an annual fee with annual renewal. The state will issue a Charter document, used to register with the Internal Revenue Service (IRS), to receive an Employer Identification Number (EIN). Use the EIN to open a bank account for the nonprofit. The bank may provide a discount for a nonprofit organization. The EIN is also used to register with the State Department of Labor for payroll purposes.

Apply for a state sales tax exemption certificate from the State Department of Revenue.

In addition to state registration as a charitable or nonprofit entity, registration may be required for charitable solicitation. Some states require registration for all organizations that solicit money for charitable purposes. Registration is usually annually and requires a fee, submission of a financial report of the entity's most recent fiscal year as well as information about the entity, its personnel, and its purposes. States with county governments may require registration as a nonprofit with the county.

Some business models may require applying for a state/county business license. This may be covered under the pharmacy license.

Registration	Level	Fee	Annual Fee	Annual Renewal
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Register as charitable or nonprofit entity; Receive Charter Document	State	Yes	Yes	Yes
Register with IRS using state Charter Document; Receive EIN	Federal	No if done by self	No	No
Use EIN to open bank account	Local	Discount for nonprofit status?	Varies by bank	Varies by bank
Register with state Dept. of Labor using EIN	State	Varies by state	Varies by state	Varies by state
Apply for state sales tax exemption	State	Varies by state	Varies by state	Varies by state
Register for charitable solicitation if required; required documents may vary by state	State	Yes	Yes	Yes
Register as nonprofit in county if required	County	Yes	Yes	Yes
Register for business/pharmacy license	State/ County/ City	Yes	Yes	Yes

Steps to Obtaining a Pharmacy License

Contract

- Charitable pharmacies
- · Hospital outpatient pharmacies
- Free Clinics
- FQHCs

Board of Pharmacy Inspection

- State decision with Pharmacist in Charge
 - Approval
 - Denial
- · Issuance of state license

Pharmacy Licensure

- DEA (requires state license)
- NPI (independent of state license)
- NCPDP (requires state license)

Set up drug wholesaler

- · Drug wholesaler account
 - Ex: McKesson, Cardinal, etc.

Pharmacy Operating System

- Get capital approved
- May need installation prior to BOP inspection (varies by state)
- Select vendor

Donation of Prescription Drug Samples from Licensed Practitioners

The use of prescription drug samples is governed by the federal Prescription Drug Manufacturing Act (PDMA), 21 C.F.R. 203.39. PDMA sets forth various requirements governing the distribution of drug samples by manufacturers to licensed practitioners. This law permits the donation of samples to charitable institutions, as long as a strong system of controls is in place to minimize diversion.

These requirements are:

- Donations only to "charitable institutions," thus importance of 501(c)3
- Original, unopened packaging with labelling intact
- Received by authorized employee of charitable institution
- Licensed practitioner or pharmacist to examine product
- Unsuitable donations destroyed or returned to manufacturer
- Accurate records of donation, distribution, inventory, return & destruction kept for 3
 vears
- Annual inventory of drug sample stocks
- Samples must be stored properly to maintain integrity
- Significant loss or known theft must be reported to FDA in 5 days

For more information on use of medication samples in a charitable pharmacy, see <u>Donations</u> <u>from Prescribers and Practices</u>.

Drug Reclamation/Donation Regulations

At a global level, the World Health Organization has developed international drug donation guidelines for humanitarian relief as a basis for national and institutional guidelines. At the federal level, the US Food and Drug Administration and other federal regulators such as the Drug Enforcement Agency have not developed regulations specific to drug donation programs. As a result, state drug donation or <u>reclamation</u> programs are largely governed at the state level and vary greatly from state to state. In general, enabling legislation must be passed by a state legislature, and participating entities such as a community pharmacy or wholesale drug distributor are regulated by their respective State Board of Pharmacy. Specific administrative rules for a drug donation program are often developed by the state's Department of Public Health, Department of Health, or Board of Pharmacy.

Most state programs have substantial restrictions on who can donate and what types of prescription products or supplies may be donated. For example, some states only allow certain classifications of medication, such as anti-cancer medications to be donated. In addition, very strict patient safety rules apply to ensure the integrity of medications distributed, as well as income and insurance (or lack of) guidelines to ensure donated medications are provided to the state's most indigent or vulnerable populations.

Most state programs have a number of common provisions including:

- No "controlled substance" medications may be accepted or transferred.
- All prescription drugs or over the counter medications must be inspected by a pharmacist prior to being distributed or dispensed.
- No adulterated, misbranded or mislabeled medication may be accepted or transferred.
- No expired medications may be accepted or transferred. (Many states require a minimum of 6 months beyond use dating)
- All medications must be unopened and in original, sealed, tamper-evident packaging.
- Liability protection for both donors and recipients usually is assured. Patients may be required to sign a statement when completing eligibility forms.
 Appendices\Eligibility\WMDP Application Packet 02 27 2017.pdf (see bottom of page 3).

Some differences in provisions across states include:

- Classes of medication accepted for redistribution. (Such as prescription-only, over the counter, or disease-specific such as anti-cancer)
- Eligible donors (Such as pharmacies, health providers, individuals)
- Eligible recipients (Such as a clinic, pharmacy, or direct to patient)
- Patient eligibility (Income standards, uninsured, or underinsured status)
- Protocol for transfers and repackaging
- Dispensing fee for donated medications (Allowed or not allowed, monetary cap)
- Centralized/decentralized (One statewide entity versus local programs)
- Program funding (State assistance provided or strictly charitable)

Drug donation programs are quickly being established by states. They function as practical channels to connect patients in need of assistance with unused prescription medications, and ensure that obsolete medications are appropriately disposed of. As more states move to make drug donation programs operational, it is imperative that program leaders and stakeholders work with state and federal regulatory agencies to ensure drug donation and reclamation programs flourish.

See the Appendix for **state drug donation rules** adopted by specific states. See Appendices\Regulatory\Sample State Regulations.

Direct Donations from Manufacturers

See Manufacturer Bulk Replacement.

Collaborative Practices

Collaborative practice agreements (CPAs) create a formal practice relationship between a pharmacist and a prescriber. The agreement specifies what functions, in addition to the pharmacist's typical scope of practice, are delegated to the pharmacist by the collaborating prescriber. The collaborating prescriber is most often a physician, but a growing number of states are allowing for CPAs between pharmacists and nurse practitioners or other nonphysicians. The functions provided under the agreement vary from state to state based on the pharmacist's scope of practice and the state's collaborative practice laws. Most often, CPAs are used in the context of authorizing pharmacists to initiate, modify, or discontinue medication therapy. These changes may be as part of a disease management CPA. Functions performed under a CPA may also include ordering and interpreting laboratory tests if those services are not already authorized in the pharmacist's scope of practice. Certain states allow pharmacists to prescribe under protocol for specific conditions such as Lyme Disease. Other states allow pharmacists to enter into a collaborative practice agreement with a provider to managed specific conditions. Check with state board of pharmacy for details. See Appendices\Collaborative Practice for guidelines, sample agreement, and competency.

Sample Types of Collaborative Services

Delays in providing medication	Collaborative	Benefit for community
Limited availability of medications (formulary system) requiring contacting provider for change	Therapeutic Interchange	Prescription fill on initial visit
Patient returning to pharmacy more than monthly for prescriptions	Synchronized refills and 90-day refills	Increased compliance when patient gets all maintenance refills at one time
Lag time between pharmacy request for refill and response from provider; patient without maintenance medication	Short supply dispensed when no refill	Allows time for pharmacist/patient to contact provider and maintain compliance
No appointment availability or conflict with patient schedule	Point of care testing: Checking A1Cs, blood pressure, cholesterol, and evaluating depression	No appointment requirements and on time lab check-ins
Need for additional medical supplies to fully utilize a prescription	Dispensing a glucometer and supplies with an insulin prescription; Dispensing a chamber with an inhaler for pediatrics	Convenience for patient and no lag time in receiving proper care
Lack of disease prevention programs	Environmental approaches to diabetes prevention program managed with lifestyle modifications	Reduces risk of developing diabetes and heart disease
Lack of access to quality community resources for chronic disease management and polypharmacy	Medication therapy review, personal medication record, medication-related action, intervention/referral, documentation, and follow up	Addition or removal of necessary medications

Auditing

Audits, whether state, insurance, or manufacturer, go best when documentation is in order. The best way to go about this are some of the following:

- Reinforce with staff proper day's supply calculation, dosage form, quantity, and correct DAW code.
- Keep signature logs up to date: refrigerator, freezer, pharmacist.
- Directions for "as directed" are clarified and documented on prescription and/or computer.
- Diagnosis codes are included when required.
- Policy and procedure manuals are up to date and being followed.

For more tips see Clinical Resource, <u>Tips to Help Prevent and Survive a Pharmacy Insurance</u> <u>Audit</u>. Pharmacist's Letter/Prescriber's Letter. January 2018.

Pharmacy Technician Status

States vary in the requirements and roles of pharmacy technicians. In <u>Entry-level practice</u> <u>requirements of pharmacy technicians across the United States: A review</u>, Ashlee N. Mattingly, Pharm. D. provides a review of statutes and regulations to determine entry-level requirements as of March, 2017, in the United States and the District of Columbia.

Check with the state board of pharmacy regarding:

- Differentiations between certified and non-certified technicians and their roles
- Differentiations between technician and "clerk" or other pharmacy assistant role
- Pharmacist to technician/certified technician ratio
- How the pharmacist/technician ratio is affected by students, volunteers, and pharmacy residents



Accounting and Finance

Although the primary objective of a charitable pharmacy is not to make money, the organization must be managed and operated like a small business. Charitable pharmacies have revenue streams, operating costs, and other financial obligations. As such, the organization must be responsibly managed and include mechanisms to ensure appropriate oversight is provided.

Separation of Duties

Separation of duties for routine bookkeeping and other accounting functions are imperative. Although a charitable pharmacy may have a small staff size, accounting policies should require that financial tasks be spread across multiple staff members or volunteers. For example, incoming mail may be received and opened by an office manager or administrative designee. Incoming bills and outgoing invoices could be reviewed and signed by the executive director or board treasurer. The bills and invoices will then be posted to the accounting records by an accountant or another staff/volunteer. Any outgoing payments will require the signature of the executive director, board treasurer, or both. Separating financial duties across multiple staff or volunteers eliminates opportunity for fraud or errors, as all as provides a layer of protection to staff or volunteers in the event an error or misdeed is identified. See Appendices/Finance for examples of financial policies adopted by other charitable pharmacies.

Routine Bookkeeping and Payroll

Simple routine bookkeeping entries such as posting incoming bills or generating an invoice may be handled by an office manager or other administrative designee. These day-to-day financial tasks can be easily reviewed by an executive director or board treasurer. As the organization grows and professional, paid staff is brought on board, the organization may choose to outsource its payroll and employee benefit functions. Professional employment organizations (PEOs) can provide payroll, employee benefits, and other human resources services. Outsourcing payroll services ensures that compensation processes are performed accurately, and that state and federal payroll tax obligations are addressed. The PEO can also manage paid time off (PTO) or vacation plans, assist with employment functions such as screening applicants, providing human resource guidance, and file required state and federal employment data. Furthermore, if the charitable pharmacy is able to offer health and retirement benefits, the PEO can generally provide large group health insurance rates to small organizations and administer qualified retirement instruments such as a 401k plan.

Oversight

The organization's Board of Directors should adopt a set of financial policies to ensure that bookkeeping and accounting functions are appropriately assigned, duties are separated, and responsibilities are understood. See Appendices\Finance for examples of financial policies adopted by other charitable pharmacies.

In addition, the Board may choose to elect a treasurer or create a financial committee to review financial reporting and internal processes. The treasurer or financial committee may choose to review the organization's financial statements routinely to offer a financial report that can be discussed and approved by the full Board of Directors on a scheduled basis. Financial oversight of the organization should not be taken lightly. In recent years, board members of charitable organizations have been held responsible when little or no oversight has been provided, and a fraudulent event has occurred. All board members should review the organization's financial policies and understand their personal responsibility and risk exposure. The charitable pharmacy may elect to purchase a directors and officers liability insurance policy that provides protection to individuals supporting the organization in those capacities.

Audit

As the charitable pharmacy grows, conducting a financial statement review or a formal audit is desirable. In its infancy, members of the Board of Directors may choose to conduct a review of financial statements at the end of the year. Board members may choose to examine, a number of accounting entries to ensure the source documents (invoices, bills, etc.) have been reviewed and that the items were entered into the accounting system accurately. In addition, board members may also desire to evaluate bank statements, payroll entries, or other financial documents. At the conclusion of the review, the board members may elect to issue a statement indicating that the financial assessment was conducted and offer additional guidance as necessary.

As the organization grows and sources of funding become larger and more complex, the charitable pharmacy may elect to conduct a formal financial audit by a Certified Public

Accountant (CPA). Financial audits are often conducted annually and require the CPA to issue a statement addressing the accuracy of the organization's financial statements. Some funding sources may require a financial audit as a condition of the grant or contribution. In addition, throughout the year, a CPA can provide guidance to ensure complex accounting issues are accurately posted in a manner that is consistent with industry standards. For example, a CPA may issue professional counsel when a large capital expenditure is made, to ensure the asset is recorded on the organization's depreciation schedule, and that appropriate amount is expensed at year end.

Account or Credit References

New businesses or charitable organizations lacking credit history will need to develop healthy relationships with service providers and vendors. The organization may find it beneficial to identify three to five vendors that may be called upon to provide a credit reference for the organization. Some funding opportunities may require credit references to determine that the organization is not an operating concern and has the operational capacity to execute the proposed project in a reasonable manner.

Start-Up Costs

Costs to open and sustain a charitable pharmacy can vary widely. See Pharmacy Management Systems, Vendors and Operations Software

Costs include:

Facility	Is free or donated space available at a good location that can be made to fit state requirements?	
Utilities	Can some of these be donated with facility?	
Technology	May be available through pharmacy vendor	
Equipment	Used or donated available?	
Legal & License Fees	Vary by state NPI DEA (if applicable)	
Insurance	Property, liability, health	
Staffing	1 Pharmacist and 1 technician to begin	
Start-Up inventory	 Local Donations Reclamation Purchased – decision to provide insulin, inhalers if not available for free Via membership vendors Devices, testing equipment if offering services 	

Vendor Memberships,	 Dispensary of Hope, Reclamation Direct Relief, Manufacturer Bulk Replacement,
non-profit and profit	Americares SIRUM, and others McKesson, Cardinal, and others
Signage and Marketing	 Outside pharmacy Pamphlets/fliers Elevator posters See <u>Marketing and Community Outreach</u>

Referral sources are available at:

<u>Shelving Design Systems</u>
<u>What does it really Cost to Start a Pharmacy?</u>
<u>McKesson Rx Ownership</u>

Starting a Pharmacy: What to Consider

Example of an Initial Budget

Good Shepherd operates a mixed-model, stand-alone community charitable pharmacy in Memphis, Tennessee. His startup plan is offered in the Introduction chapter of <u>Steps for Starting a Stand-Alone, Mixed-Model Community Charitable pharmacy</u>. A sample budget is available, which includes revenues, donations, operating expenses, and debts. Income is divided between revenue from the business and donation from various funders. Expenditures are divided between operational expenses and debt from loans.

Wyoming Medication Donation Program (WMDP) started as a pilot mail order, charitable pharmacy serving one county (population ~100,000). Initial facilities were provided by the Wyoming Department of Health, as well as the pharmacist (salary and benefits). Grant funding provided the remainder of the total budget ~\$240,000. The program has transitioned to all Wyoming Department of Health funding and continues with about \$250,000 budget. Mailing costs, including packaging and postage, are approximately \$24,000 annually. WMDP currently serves the entire state of Wyoming and in 2018 will be located in a new facility. See Wyoming Medication Donation Program

<u>Safety Net Charitable Pharmacy</u>

Points to consider when establishing a fee system:

- Aligned program with state Medicaid program copays (if exist)
- Designed to a break-even or subsidy level (340B) for purchased meds
- Adapt to patient's needs, pharmaceutical pricing, sample/donated drug availability, and donated services budget

TIP: Beacon Charitable
Pharmacy in Canton OH
requests patients to give
a donation toward their
medication. This
donation is not required
but allows patients the
dignity to "pay" for their
medication at their
affordable level. These
donations are then used
for Beacon operating
expenses.

- Implement Quantity Restrictions on some items (such as Hydralazine #60, Nifedipine ER #30, Isosorbide mononitrate #60) when dictated by purchase price
- Whenever possible maintain predominately \$1 fee (with some \$3, \$10, etc.) to make program more affordable (especially when aligning with stakeholder disease state initiatives (CHF, HT, etc.)
- Budget for Safety Net Drugs
- Never charge for medications from a "free" vendor (DOH, SIRUM, manufacturer bulk assistance program, etc.)



Human Resources

Even a small organization benefits from having guidelines regarding mission, hiring, training, staffing, and other employee practices. Training becomes more efficient and standardized. There is a reference for policies and questions. Employees who understand the pharmacy mission are empowered to incorporate this mission into all aspects of their work. Clear guidelines demonstrate to potential employees, communities, stakeholders, and donors that the organization has a commitment and policies for treating all persons with dignity and against discrimination.

Staffing

Staffing consists of pharmacists, pharmacy technicians, student pharmacists, and volunteers. Other healthcare professionals, such as social workers, may work with patient eligibility and enrollment. Staff needs to be adaptable, empathetic, patient focused, and willing to accept new challenges as they unfold throughout the workday. Patients in need often time have complex prescription needs that require staff to have patience and persistence in helping them to navigate a complex health care system for the poor and vulnerable. Cross-training, when possible, allows all the duties of the charitable pharmacy to be performed with flexibility. Staffing depends on the amount of prescriptions filled, counseling needs, other clinical services provided, and administrative tasks.

TIP: An Employee
Handbook is an
effective tool to verify
the employee is
informed of policies
and understands what
is expected with
employment. Ozanam
Charitable Pharmacy
shares theirs. Examples
in Appendices\Human
Resources.

Adding an **Executive Director** to the staff allows fund development, marketing, and other roles to be provided by a trained professional. One individual concentrating on these aspects of the business, whether full or part-time, benefits the entire organization.

Staffing Policies

Staffing policies should consider federal and state requirements. There should always be a licensed pharmacist working, typically with at least one technician. The pharmacist/technician ratio varies from state to state and may change if the technician is certified.

Certified technicians may also be allowed additional responsibilities beyond that of non-certified technicians.

Policies should be in place regarding:

- Attire, including badge display with name and position
- Attendance, tardiness, absences, lead time for calling out, and sick day verses personal day
- Confidentiality/HIPAA
- Corrective action, including progressive discipline

- Licensure and certification, including terms for updating
- Position descriptions, including limitations
- Reporting suspected abuse (when patient appears to be in an harmful situation)

See Appendices\Standard Operating Procedures

More details regarding policies can be found in <u>Standard Operating Procedures</u>.

Job Descriptions

Job descriptions for all positions include:

- A general statement regarding position, skills required, role expectations, and licensing or certifications.
- Essential Functions: giving detail to the roles involved in the position
- Organizational Requirements: for the organization in addition to the specific department
- Knowledge, skill, and ability requirements or competencies
- Education/Licensure/Certification/Registration
- Core Competencies: list and define behaviors expected of employee
- Additional Requirements: skills, knowledge, and abilities regarding language (multilingual?), communication, problem solving/reasoning, technology
- Physical Requirements
- Exposure to harmful substances or situations

Sample descriptions for various pharmacy positions can be found in <u>Appendices\Human</u> <u>Resources</u>.

Orientation to the Organization and the Position

Initial orientation includes a review of the community charitable pharmacy Standard
Operating Procedures (see Appendices\Human Resources\HUPE Orientation.pptx) as well as becoming acclimated to the position. An orientation checklist and sign off ensures the employee has been introduced or trained in the various responsibilities of the position. This can also document confidentiality (HIPAA), safety, policy, and procedure training.

Appendices\Human Resources\Orientation sign-off-pharmacy assistant_2012[1][1].docx

<u>Review</u>

See <u>Standard Operating Procedures</u> for evaluation of competencies for annual reviews and implementation of new processes and procedures.

Students and Volunteers

Students can be a valuable addition to the charitable pharmacy team. With students performing pharmacy tasks, staff is freed up for other needs. Students will encounter the uninsured population, perhaps for the first time, developing skills specific to the poor and

vulnerable. Compassion, communication, social justice, and a broader global view are gifts a charitable pharmacy offers in exchange for developing pharmacy skills. Students may leave inspired to incorporate these gifts into their future positions and volunteer work.

Developing and providing an educational program is time consuming but can be a win-win for all involved. Precepting pharmacy and other students usually requires additional training or certification. Check with a local universities or schools of pharmacy to investigate requirements. Beyond pharmacy students, consider precepting other health professions, foreign language, small business, marketing, social services, and other majoring students.

Volunteers are a valuable resource for many non-pharmacy tasks within the pharmacy. Retired or volunteer pharmacists may be able to assist with pharmacy related tasks depending on licensure and liability. Non-pharmacy or healthcare volunteers can help with non-direct patient tasks. Students volunteering for Experiential Service Learning (ESL) may be able to interact with patients depending on the program. Pharmacist volunteers may require liability insurance if volunteering as a licensed pharmacist and not covered by a parent organization.

All volunteers should be oriented to pharmacy and pharmacy operations. Training may include HIPAA and privacy regulations, orientation to dealing with the patient population, pharmacy logistics, safety precautions, best practices, and media release if information will be used for marketing or reporting. Software products are available to manage and track volunteers.

TIP: Check with state board of pharmacy to verify pharmacist ratio for students and technicians, and whether volunteers are included in this ratio.

Sources for Volunteers

1. Retired Senior Volunteer Program (RSVP)

RSVP is a program specially designed for seniors over the age of 55. With this program, there is a huge variety of volunteer positions available. Pharmacy chooses the hour to be put in, where volunteer will serve, and the type of work to do. Volunteer will successfully join over 500,000 senior citizens across the United States.

2. <u>United Way Volunteer Program</u>

As a partner agency, the pharmacy can sign up with the Volunteer Program. List as looking for a development volunteer to assist with newsletter and other projects or whatever the volunteer need is.

3. The National AmeriCorp Vista Volunteer Program

AmeriCorps VISTA (Volunteers in Service to America) is a national service program that focuses on projects aiming to alleviate poverty in communities across the country. VISTA members make a year-long, full-time commitment, to build the capacity for programs to efficiently and effectively reach their goals of bringing individuals and communities out of poverty. AmeriCorps VISTA primarily works on projects and tasks that are considered indirect service. Their focus is working to assure projects are sustainable and can reach a larger population of people.

4. <u>Local University Pre and Pro Pharmacy Students and other Students</u>

Become a teaching organization and preceptor for both IPPE and APPE pharmacy students as well as volunteers. Use Pre-Pharmacy and Post-Pharmacy students from the local schools for daily operations and community outreach at local health fairs and workshops. Other university students to consider are nursing, other health sciences, foreign language, business, marketing, technology, depending on the needs of the pharmacy (interpretation/translation, newsletter, website, marketing materials, other).

5. <u>Workforce Development Services - Senior Community Service Employment Program (SCSEP)</u>

The Senior Community Service Employment Program (SCSEP) offers training opportunities to low-income adults age 55 and older in 16 states who wish to re-enter the workforce. The program allows participants to overcome barriers to employment by gaining real world work experience at community service organizations called "host agencies" in the community. Participants are assigned to host agencies for about 20 hours per week. The objective is to provide current hands-on training that can lead to unsubsidized employment in the private sector. Assignments vary and range from six to twelve months. Participants can be assigned to more than one host agency in order to provide them with enhanced experiences and a broader range of skills.

Productivity Metrics (Throughput)

Productivity for a pharmacy is typically measured by how many prescriptions the pharmacy fills a day and the total accumulated in a week. It is best to closely align the volume of prescriptions to the number of staff working. Be patient as building volume takes time when beginning a new pharmacy. In general, the maximum pharmacist/technician ratio is achieved before adding an additional pharmacist.

Sample measures from Saint Thomas Health:

How many prescriptions added per day?

- Start up
 - 1 pharmacist/1 tech for new operation
 - 20 25 patient encounters/day which = ~100 – 175 prescriptions/day
 - o 1 pharmacist/2 techs when increase volume
 - 35 40 patient encounters/day = 125 -150 prescriptions/day
- One existing retail model had the capacity to handle an additional 50 prescriptions/day prior to starting up a charity program. Within a few months, demand exceeded projection and the pharmacy was filling up to 100 prescriptions/day exceeding capacity.
 - Have a plan ahead of time so if volume expands quicker than anticipated there will already be buy-in from stakeholders/funders/administrators to add additional staff.
 - Consider automation (tablet counter, robot, etc.) as expansion tools.

As healthcare moves away from the fee-for-service model, more focus will be on outcomes and services compared to the quantity of prescriptions. Services include:

- Medication Therapy Management (MTM) and targeted MTM
- Monitoring therapeutic outcomes (A1c, lipids, blood pressure, etc.)
- Device education (glucometer, insulin injectors, inhalers, etc.)
- Collaborative practice <u>Appendices\Collaborative Practice</u>
- Medication and disease interventions
- Counseling in non-English languages
- Transitional Care Appendices\Transitional Care

Clinical services require more pharmacist time and perhaps specially trained staff. Example, a technician may serve both as a pharmacy technician and an interpreter, requiring time away from pharmacy tasks. Develop metrics to demonstrate how these services effect staffing as well as benefit patient outcomes. (See Measurements/ Evaluation/Outcome and <u>Appendices\Metrics</u> for sample studies and metrics).

Example measures from a community charitable pharmacy offering PAPs, targeted MTM, collaborative practice, and counselling in non-English:

- 1 pharmacist/2 pharmacy technicians. The technicians work three 7 hour shifts per week.
 - 25-27 patients encounters/day
 - 100 prescriptions/day
 - o 2-3 PAPs/day
 - 4-6 clinical interventions/day
 - 4-5 therapeutic interchanges/day

Example productivity metrics for a drug donation/reclamation program are found in Drug Reclamation/Donation Performance Metrics.



Standard Operating Procedures

Standard Operating Procedures (SOPs) are established or prescribed methods to be followed routinely for the performance of designated operations or in designated situations (Merriam-Webster Dictionary). In healthcare, the aim of SOPs is to achieve efficient, quality, safe, and uniform performance in compliance with state and federal regulations and in accordance with established best practices. They serve all employees as a reference for clear performance of processes and procedures, especially those used infrequently, and a defined standard of expectations. Documentation of training employees in facility SOPs acts as a

safety guideline, performance review standard, and legal grounds in case of accident or violation.

Examples of SOPs from multiple sites and states, including various forms, are included in the <u>Appendices\Standard Operating Procedures</u>.

Procedures and processes should be reviewed and updated regularly, adjusting to changes in regulations, technology, efficiency, therapeutic guidelines, and best practices. Updates can reflect feedback on quality improvement, safety, cost savings, improved productivity, and reduction in error rate. Use of flowcharts and examples in process explanation act as visual aids to add clarity. See <u>Flowchart for external referral</u> for an example.

Types of Standard Operating Procedures

Site

Policies are established for federal and state **licensing** of the facility (pharmacy), and staff (pharmacist, technician, other). They may include frequency of renewal, methods of documentation, and consequences of non-compliance. Policies may include **regulations** including signage, language, or notifications to patients. E.g. state phone number to call to report an error, dispensing prescription in patient language, etc.

Security and safety procedures and policies protect employees, patients, and products. They include:

- Environmental: fire, disaster, hazmat, etc.
- Technology access and privacy
- Patient confidentiality and privacy, HIPAA
- Media Release

Records

Retention and destruction of records including:

- Pharmacy and patient related; regulations may vary by state See Record Keeping
- Governance, Tax, Intellectual Property (copyrights, etc.)
- Financial
- Pension and benefits
- Government Relations (lobbying, etc.)

See <u>Appendices\Standard Operating Procedures\2009Record</u>RetentionPolicy.doc.

Employee

Employee policies may include:

- Compliance with Core Values and Mission of organization
- Education or certifications needed for positions See <u>Appendices\Human Resources</u> for job descriptions.
- Procedure documentation including orientation to position, training in new or changed procedures, and ongoing compliance - See <u>Appendices\Standard Operating</u> <u>Procedures\Competencies</u> and <u>Competency</u>
- Employee standards for attire, attendance, behavior, etc.

• Steps for leadership or career advancement

Pharmacists, and in some states technicians, are required to complete annual or bi-annual continuing education. Some states differentiate between certified and non-certified technicians.

An employee handbook serves as a record for the employee of applicable policies and documentation for the employer of employee education. Examples of employee handbooks may be found in <u>Appendices\Standard Operating Procedures</u>.

Financial

Financial policies relate to business practices (bribes/collusion, etc.). Patient financial policies relate to prescription payment (no charge, safety-net, etc.) Topics include:

- Conflict of interest
- Financial planning and reporting
- Budgeting Process
- Recording and Audits
- Revenue

A sample financial SOPs is in <u>Appendices\Standard Operating Procedures\2017 Financial</u> Policy and ProcedureOCP.docx.

Medication

Policies, procedures and processes covering medication from acquisition to destruction ensure compliance with government regulations, safety for patients and handlers, and established best practices. See Appendices\Inventory Management. Formulary\Forms for examples of policies and forms.

- Formulary management: restrictions (no controlled substances, birth control, pain medication, other therapeutic classes, devices); use of therapeutic interchange and restrictions.
- Medication ordering and receiving procedure, especially if vary by vendor
- Medication storage: temperature sensitive products, logs, procedure when storage temperature is violated (alternative storage arrangement, shortening of expiration/beyond use date, disposal).
- Medication segregation: by vendor, therapeutic class (oncology, inhalers, topical, etc.).
- Sample Medications See <u>Donations from Prescribers and Practices</u>
- Returns and recall procedures, usually vary by vendor
- Inspection for expiration: who (volunteer, tech, pharmacist) and frequency (monthly, quarterly)
- Medication destruction procedures See <u>Medication Destruction</u>

Prescriptions

Policies, procedures, and processes covering prescriptions ensure uniformity, safety, and compliance with government and vendor regulations. Regular review of processes adjusts for changes in technology, efficiency, therapeutic guidelines, and best practices.

- Prescription processing: information needed for processing, system for waiting/returning/next day/provider call back
- Day supply and incentives for adherence
- Medication information resources for pharmacist and for patients
- Labeling: multiple languages, samples, eligibility, counselling or other alerts
- Dispensing: patient counseling, use of interpreter
- Return to stock: frequency, process for specific vendors
- Adverse Event and Quality Complaints Reporting

Patients

Patient enrollment may be paper, electronic, or both. Processes may vary if enrolling for medication available at charitable pharmacy or through a manufacturer patient assistance program. Types of acceptable documentation for identification, lack of insurance, residency, income, and other requirements need to be made clear to staff and patients.

See chapter on **Eligibility and Enrollment** for more details.

Assistance Programs

Vendors and bulk assistance programs require practices that meet with their established policies and procedures. These include, but are not restricted to, patient eligibility, acceptable forms of documentation, refill requirements, and prescriber and prescription documentation. SOPs may be required regarding:

- Manufacturer Patient Assistance Programs
- Manufacturer Bulk Assistance Programs
- Facility Audits
- Notification of Regulatory Inspections

See chapter on **Inventory Management** for more details.

<u>Competency</u>

With new staff orientation, implementation of a new process or procedure, and at regular intervals, usually annually, competencies are administered to review and measure employee compliance and maintenance of understanding. For annual review, topics such as safety, financial and privacy compliance, and core values are sometimes offered with a pre-test. A pre-test score of 100% accuracy allows the employee to skip the review.

Clinical and technical skills usually require a proficiency exam annually and at implementation of a change.

 A math test may be used to demonstrate calculations of day-supply, units/volume as in an insulin pen or drops in eye dropper, pediatric dosing, and conversion of measures (pounds to kilograms, milliliters to ounces). See example <u>Appendices\Standard</u> <u>Operating Procedures\Competencies\Math Competency 10.15.docx.</u>

- Equipment: cleaning and use, e.g. a counting machine or robot
 Therapeutic Interchanges: insulins, inhalers, within classes See <u>Appendices\Standard</u> Operating Procedures Competencies and Appendices Collaborative Practice
- Collaborative Practice



Inventory Management

Inventory Management is one of the keys to a successful charitable pharmacy. Devolving and maintaining inventory processes will allow the pharmacy to maximize the use of limited resources and to serve patients to the best of their ability.

This chapter will cover concepts that may be considered when developing and managing an inventory including: developing a formulary, sourcing medications which may include donated medications, prescription assistance programs, developing standing orders for therapeutic substitution, proper drug disposal, computer systems, and routine inventory management tactics.

Developing a Formulary

As defined by the American Society of Health-System Pharmacists (ASHP), a drug formulary is a continually updated list of medications and related information, which represents the clinical judgment of physicians, pharmacists, and other experts for the treatment of disease and promotion of health. In a community setting, a formulary addresses the therapeutic, economic, educational, and rational evidenced-based drug use of the population being served.

In a community pharmacy, a formulary is a list of medications available at the pharmacy to meet patients' needs. It can be shared with prescribers explaining medications that are available at the pharmacy and to reduce or restrict the inventory of the pharmacy.

The formulary will likely be comprised of the most commonly used medications to treat chronic conditions such as hypertension, diabetes, hyperlipidemia, asthma, mental health, and others affecting patients across the United States. Medication can be selected from each therapeutic class to help manage chronic conditions based on clinical evidence from nationally supported disease state treatment guidelines and medication monographs (adverse reactions and interactions). See <u>Dispensary of Hope Formulary Development and Utilization</u>. Factors that affect the formulary include availability of medication along with class changes (new drugs that become available, brand to generic switch, and generic to OTC changes), medication shortages, patient allergies and/or adverse events, prescribing changes, guideline changes, adverse effects and alerts, and pharmacoeconomic shifts.



Considerations

- **Start small and with a lean** inventory, knowing that pharmacy volume can take a while to build up at first. This reduces waste, staff time, and inventory space.
- Set up an inventory by identifying drugs currently dispensed to the uninsured patient population, and target these drugs first when ordering. Ordering one of each medication is not recommended as it would require additional shelf space (which may be limited), and these additional drugs may go unused and destroyed.
- **Share your formulary** with prescribers regularly (monthly, quarterly) so they may generate prescribing habits to use what is available through the your "free" vendor inventory first.
 - Site example: Embed the formulary in the EMR, if possible, or print copies of the most recent formulary to share in discharging patient medical records.
- If getting requests for drugs not available, communicate and educate the prescribers.
 - First Share the formulary with them and ask which medications they will likely be needing, then order those.
 - Second Ask the prescribers if there are any medications they may need that are not on the formulary. Look for ways to source these if possible.
 - Third Keep track of what is available at your pharmacy. Share this available inventory list on a regular basis so prescribers know what is on hand and can be filled.
 - Fourth Utilize therapeutic interchange to recommend alternative medications to prescribers. For instance, the prescriber asks for fexofenadine and only

- cetirizine is available at your pharmacy. Recommend a change to cetirizine to prevent the patient going without medication.
- o Fifth Consider developing a <u>collaborative practice agreement</u> (CPA) with practitioners, allowing the pharmacist to automatically dispense medication from an approved protocol. Therapeutic interchange, with approved parameters, fits well within a CPA. Several states already have collaborative practice agreements in place.

Pharmacy Management Systems

Many software programs are available that receive prescriptions and aid in dispensing medications for use in community pharmacies. These programs help manage inventory, workflow, accounts, and assist in record keeping. Beyond those necessary for running a pharmacy, there are features that are especially suited for a community charitable pharmacy. Most systems are adaptable but may require creativity on the part of the pharmacist and the software provider to develop. Features that may be available or adapted involve labeling, patient records, counselling, reporting, and billing. See <u>Dispensary of Hope</u>
Pharmacy Software Webinar.

TIP: Some pharmacy software resources offer deep discounts for charitable pharmacies. Be sure to ask.

Patient Enrollment Criteria and Documentation Data

Patient eligibility for charity services frequently varies from that normally used when filling a routine prescription. See <u>Eligibility Guidelines</u>. This may require creating customized fields. Additional information needed beyond demographics and allergies/sensitivities include:

- Income/Federal Poverty Level (FPL)
- Size of household: adults/children
- Preferred language
- Ethnicity (if required)
- United States residency status
- Insurance status (uninsured, pending, ineligible)
- Eligibility for other assistance programs
- Referral source
- Veteran

Additional software may screen patients for insurance.

Maintain patient database by removing patients who have not filled a prescription within a set period of time as determined by the site.

Systems are upgrading to accommodate documentation of patient interactions and health information. Exchange of health information allows pharmacists to improve their clinical services—especially medication therapy management (MTM). Hospitals and clinics may allow a view-only link to access patient data. Access to lab values and other trackable measures (blood pressure, weight, etc.) may allow opportunities for <u>collaborative practice agreements</u>. Documentation of clinical interventions within the patient profile allows for metrics collection

and tracking outcomes even when this is not a billable service. By 2018, pharmacy systems should be Centers for Medicare and Medicaid Services (CMS) compliant, allowing trackability of outcomes pertaining to reimbursement by Medicaid and Medicare.

Bidirectional systems allow other healthcare providers access to pharmacy information and vice versa. Some systems accommodate linking multiple systems for information exchange. Following control substance prescriptions is an example of many healthcare providers, including prescribers and pharmacists, having access to pertinent patient data across a geographical area. Connecting systems may allow pharmacist documentation of a medication problem or recommendation to be transmitted directly to the prescriber. See Health information technology in the community pharmacy.

Label and Patient Information Capability

Specialty labeling for the prescription, bag, signature log and patient information may be useful and necessary in a community charitable pharmacy.

- Features for multiple languages. The ideal patient label system uses numerals rather than alpha characters (2 instead of two) as these are usually more legible across languages. Written patient education information also available in multiple languages. See Pharmacy Translations.
- Pictograms for patients who do not read and to enhance understanding across languages. See <u>Illiteracy</u>, <u>Pharmacy Translations</u>, and <u>Appendices\Transitional</u> Care\Pictograms.
- Pricing of "0" for medication dispensed at no charge to patient.
- Alerts for information needed prior to dispensing including renewal of eligibility, missing documentation, and special patient counselling.

Tracking Product from Multiple Vendors

In compliance with the Drug Supply Chain Security Act (DSCSA), pharmacy management systems help track product to the patient level. See <u>Tracking</u>.

Options include:

- Establish a separate billing code (even though not billing) for each vendor for compiling reports.
- Set patient cost based on specific billing codes: "0" for no copay or a set price for safety net products.
- Adapt NDC codes for products provided by more than one vendor (check with system provider on best way to do this).
 - Change product description to differentiate vendor
 - o Program system to pull product from nonprofit vendor first
 - Creating a "dummy" NDC eliminates Drug Utilization Review (DUR) function, removing safety features of system.
- Use Wholesale Acquisition Cost (WAC) cost rather than Average Wholesale Price (AWP)
 when determining value of product from a non-profit vendor. The WAC price is based
 on what a pharmacy would pay for a product if purchased from a pharmacy
 wholesaler.

- Manually add inventory received from a nonprofit vendor to allow reporting when automatic ordering is utilized
- Drug recall report are based on vendor billing code and specific NDC.
- When in a mixed-model pharmacy serving both charitable and billable patients, having "virtual" facilities helps create a less manual process and makes tracking nonprofit vendors easier.

Reports and Metrics

In addition to inventory, pharmacy management and state required reports, vendors may require specialty reporting. These reports may need to be built specifically for the data being captured. System providers and other charitable pharmacies using similar systems are two resources to check when developing a new report. Reports exported as excel spreadsheets can be adapted using excel formulas.

Example

Total number of 30-day prescriptions:

Create an excel report that looks at the day supply.

=IF(L6<31,1,IF(L6<61,2,IF(L6<91,3,IF(L6<121,4,IF(L6<151,5,(IF(6<181,6))))))

Number of Unique Patients:

Create an excel report that looks at patient name.

=IF(C6=C7,0,1)

Number of Patient Encounters:

Create an excel report that looks at the patient name and the date the prescription was filled.

=IF(C7=C6,IF(B7=B6,0,1),1)

<u>Dispensary of Hope Link to Webinars</u> Best Practices in Technology and Pharmacy Software Webinar

Adapting fields within a pharmacy system is an option to create a specific report or a report with additional information. This can be done by adding the following:

- A prescriber state license number to a pull-able, non-used prescriber field to be used in a report that requires state license but not DEA number.
- A pull-able blank patient field populated with the patient Federal Poverty Level (FPL).

Clinical Reporting

Systems such as <u>Outcomes MTM</u> and <u>Mirixa</u> are platforms for collecting and measuring the impact of clinical data and interventions. They allow disease specific medication management, track adherence, or if additional medication is needed for patient.

<u>RxAssistPlus</u> is a clinic-friendly system adaptable for collecting and reporting many types of clinical data. Patient enrollment criteria can be collected and is useful for demographic reporting, including language, referral source, income compared to FPL, and more.

These systems can track the clinical impact of services on patients served. Outcomes can be measured in severity, type, and number of interventions performed. As well as the total estimated cost avoidance to other healthcare systems (hospitalizations, ED visits, etc.) and total service worth if the services were billable to insurance.

TIP: Good Shepherd Health uses <u>Prosperworks</u> to keep patients informed and expand the practice.

See the chapter on <u>Measurements, Evaluation and Outcomes</u> and <u>Appendices Metrics</u> for more reports and how they can be used. <u>Implementation of performance metrics to assess pharmacists' activities in ambulatory care clinics</u> presents measurable pharmacist functions that impact patient outcomes and mechanisms used to document these services.

Customer Relationship Management (CRM)

Patient engagement and keeping patients informed is important to the growth of a charitable pharmacy. CRM covers a broad set of applications for business management, workflow, productivity, marketing, and more. These software systems help manage relationships and expectations with patients, funders, stakeholders, colleagues and others who have a relationship with your charitable pharmacy. Patient interactions and other contacts are documented giving team members access to current information and managers the ability to track productivity. Patientriciti is specifically for healthcare providers, allowing personalized engagement with patients based on demographics and clinical/behavioral data to improve outcomes. See Marketing for resources.

Volunteers and Scheduling

See Human Resources/Volunteers and Volunteers for resources.

Routine Inventory Management

Medication Storage

Some meds may require **segregated storage** (and <u>destruction</u>). Vendors may require segregation of the products they supply. Many will also require separation of the virtual inventory in the pharmacy software system. Be sure to check with your software vendor on this

capability. Oncology and other hazardous medications may be segregated as well (warfarin, estrogen and progestin products, finasteride, lindane, nicotine, nitroglycerin). See <u>CDC</u>
<u>Antineoplastics</u> and <u>Healthcare Environmental Resource Center</u> for current listings.

Many medications are **temperature sensitive**. Document refrigerator temperatures twice daily or as required by state regulations. Medications stored at room temperature may also be affected by extreme temperatures (inhalers, nitroglycerin, capsules, etc.). Develop a plan should extreme temperatures occur (loss of air conditioning or heat). See example of temperature log.

Beyond Use Dates

Medications are labeled with a <u>beyond use</u> date (expiration date); beyond which they should not be used or dispensed for use. These dates are subject to change depending on storage conditions and repackaging. Products should be reviewed regularly for outdates. The following are suggested procedures:

- When a new product is shelved, ensure the product soonest to outdate is in front (rotate stock).
- Regularly, usually quarterly, all products should be reviewed, and outdated product removed to a quarantined area for destruction.
- Product whose beyond use date has been changed due to storage considerations should be stored separately from regular stock and clearly labeled to prevent confusion.
- When repackaging medication, use the actual beyond use date up to 1 year from repackaging.

Cycle Counts

Instead of counting the entire inventory once a year, WMDP does "Cycle Counts". Fast movers are counted quarterly and the whole inventory over the course of the year. The top fast movers are divided up over a 12-week cycle. Usually about 10 drugs are counted per week. For the full inventory, one to two letters of the alphabet are assigned per month. For instance, all "A & Z drugs" are counted in January. If an inventory count is significantly off, counts are checked and adjusted more frequently. Inventory counts on all drugs that show a negative inventory are verified at the end of each month. With the bubble packs and so many NDC's in stock, a full year inventory was not manageable, but this process made it manageable. The inventory is posted online to assist with patient referrals. Cycle Counts keeps the inventory more accurate.

Overstock Medication

For charitable pharmacies accepting direct donations, there may be an abundance of donated medications that have a low demand. This can increase workload significantly when adding into inventory, maintain storage, include in cycle counts, and then subtract when reach beyond use date. To improve efficiency, a list is kept of medications that are currently in overstock. When donations are sorted, items on the overstock list are automatically disposed. The list is updated every 2 weeks. This process has proven to improve program efficiency.

Medication Recalls

When using directly donated medications, there may not be a routine recall notice received at the pharmacy. FDA provides a weekly <u>report</u> regarding recalled medications. To use the report:

- Narrow the report to drugs only
- Check report for NDC's that are on file at the pharmacy
- Check inventory for recalled Lot/Expiration numbers

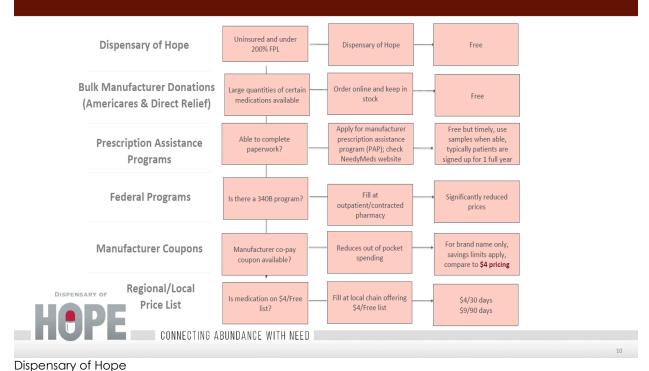
Pharmacies who provide donated medication to dispensing sites must notify those sites regarding any recalls that affect medication received from the source pharmacy.

Sources for Medications

As a community charitable pharmacy, a primary goal is to provide medication to uninsured and underinsured patients for free or as economically as possible. Various sources exist to supply medications for this population.

Figure 1.

FINDING COST EFFECTIVE OPTIONS FOR PATIENTS



, ,

Vendors

Many vendors exist for "free" medication. Some charge an annual fee for membership which includes ordering available medications and shipping to your facility. Some vendors allow enrollment without a fee, allowing pharmacy to order from available products. Products may include medical devices (e.g. glucometers, test strips, etc.) as well as over-the-counter meds (OTC), but products and medications are not always available. (Direct Relief, Americares, Dispensary of Hope, SIRUM, etc.) Seek legal advice when entering into a contract to ensure meeting all state and local regulations.

Possible medication resources:

- Americares
- Direct Relief
- Dispensary of Hope
- NeedyMeds
- Partnership for Prescription Assistance
- RxOutreach
- SIRUM
- Xubex

Some pharmacy wholesalers and distributors are listed in <u>Vendors</u>. Pharmacy management software may be available through a wholesaler as well. Contracting with another pharmacy may be possible if within state and local regulations and follow <u>DSCSA</u>. See <u>Tracking the Medication Supply Chain</u>.



Not all vendors offer next day delivery. Many are weekly or monthly. Plan ahead!

Each medication source may have its own procedures for storage, record keeping and handling of expired meds. Ensure careful attention and documentation as per vendor's policies.

340B

The **340B** Drug Discount Program is a US federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. Covered entities that participate in the 340B program may contract with pharmacies to dispense drugs purchased through the program on their behalf. Two useful resources regarding <u>340B</u> as used in an outpatient pharmacy are:

<u>The Bridge to 340B Comprehensive Pharmacy Solutions in Underserved Populations</u>. This resource is from 2004 and there have been significant regulation changes since that time but provides information regarding the intent of the 340B program and applications to pharmacy.

<u>Understanding 340B and Contract Pharmacy</u>. This resource is from McKesson wholesaler, 2015, and presents a business approach to utilizing 340B with a contract entity.

Considerations:

- If a charitable pharmacy works with a covered entity registered under the 340B program, then they should be set up as a contract pharmacy. Inventory is virtually tracked through a split billing system and replenished with 340B drugs based on appropriate accumulations in eligible patients of the covered entity or child sites.
- Free or donated drugs must be kept as separate inventory (and are not part of the 340B program).
- The Virtual Inventory is mixed between purchased medications and 340B replenished medications but can NEVER be mixed with free or donated drugs.
- If the charitable pharmacy is part of the 340B covered entity then segregated 340B inventory could be maintained (if the covered entity chooses not set the charitable pharmacy up as a contract pharmacy) but must follow the rules of the covered entity type to prevent duplicate discounts, adhere to the Group Purchase Organization (GPO) prohibition (if applicable) or adhere to the orphan drug exclusion (if applicable) and can only be used in an eligible patient based on the 340B statute.
- Proper auditing MUST occur to make sure 340B drugs and free or donated drugs are completely separate and are not part of the 340B records.

Vouchers

Vouchers can be manufacturer coupons, where medication dispensed is reimbursed by the manufacturer, or from a healthcare facility which contracts with the pharmacy for reimbursement, usually at a discounted rate. Medication dispensed using a voucher cannot be taken from free or donated stock.

Another type of voucher used to supplement gaps in stock is between pharmacies. A contract is established with a retail pharmacy who is able to fill prescriptions for approved patients at an agreed upon rate. The voucher is provided by the charitable pharmacy to the patient or faxed to the contracted retail pharmacy. The patient picks up the prescription from the retail pharmacy. The retail pharmacy submits a report monthly or as contracted for prescriptions filled. Reimbursement occurs once the invoice/report is verified. Grant funds may provide for the cost of these vouchered prescriptions.

Manufacturer Bulk Replacement

Some manufacturers offer a bulk replacement program allowing the pharmacy to stock the medication and act as the PAP program manager. Manufacturer programs require their own eligibility requirements, policies, monthly and annual metrics, auditing and volume of med dispensed. See <u>Manufacturer Bulk Patient Assistance Programs</u>

Direct Donations

Legal regulations regarding donated sample medications can be found in Appendices\Regulatory\Sample State Regulations.

Upon receipt, **donations should be inspected** by pharmacist or qualified pharmacy technician. Inspection includes:

- 1. Donation record accurately describes drug samples
- 2. Beyond Use Date (expiration) is within limits
- 3. Sample labeling is not mutilated, obscured, or detached from packaging (primarily donations previously dispensed as in reclamation.)
- 4. Sample does not show evidence of storage or shipping condition that might have affected it stability, integrity, or effectiveness.
- 5. Sample is still on the market and not subject to recall
- 6. Sample shows no evidence of contamination, deterioration, or adulteration
- 7. If the sample does not pass the inspection, it is destroyed or returned to the donor and documented on the donation record.

Donations from Prescribers and Practices

Branded samples including insulin and inhalers may be available from providers and practices that are willing to donate directly to your charitable pharmacy. <u>NovoMedLink</u> has an online service to order sample insulin. Hospitalists at local hospitals may be willing to donate sample insulin to provide for their uninsured patients at discharge. Clinics may be willing to donate excess sample medication or may have eliminated medication cabinets and be willing to

acquire donations for a charitable pharmacy. Internists and other providers who prescribe insulin in their practice may be willing to order and donate samples. Pulmonologists may have access to excess inhalers; cardiologists to antithrombolitics and heart failure meds. See Insulin and Inhalers for a presentation regarding possible sources. Irack and Trace compliance is mandatory.



Sample Medications

Samples come with their own set of regulations. To stay compliant, check with individual state. In general:

- Samples require <u>DSCSA Track and Trace</u> compliance when donated from a healthcare practice or facility.
- Samples are dispensed in the original container. Do
 not open containers to dispense a partial quantity in an
 original container or combine samples into a separate
 vial.
- Each sample container requires an individual patient label.
 - Boxes of blister pack samples may have one label attached to several boxes.



TIP: Find Physician Practice Champions

willing to donate samples monthly. Celebrate them at an annual Medical Association meeting and in newsletters.

- Quantities dispensed are in multiples of sample original container, not usually 30, 60, 90.
- Samples beyond the use date are not returned to manufacturer or vendor for credit or destruction. Record of destruction (See <u>Track and Trace</u>) still needs to be maintained per policy and/or state regulations.
- Oncology and hazardous waste samples and meds have specific destruction regulations. Follow the direction of disposal vendor.

State Drug Donation Programs

Across the country and beyond, drug donation programs are quietly emerging as a practical channel to connect patients in need of assistance with unused prescription medications. The World Health Organization has developed international guidelines for humanitarian relief as a basis for national and institutional guidelines. The National Conference of State Legislatures (NCSL) reports that 42 states have legislatively created drug donation programs, of which 20 states have operational programs.

Tip: At WMDP, we have enough medication donations to fill about 2/3 of our prescriptions. The other 1/3 is filled using product ordered from a nonprofit vendor or purchased using grant funds.

Direct donations from patients and institutions (skilled nursing facilities, prisons, etc.) vary by state. Check with state

pharmacy regulations to determine if donations are allowed and any restrictions that exist. (See Figure 2 (below) and <u>Appendices\Regulatory\Board of Pharmacy state regulations</u> 1.2017.xlsx)

State Rx Reuse Snapshot

State Prescription Drug Return, Reuse and Recycling Laws

10/1/2018



Pharmaceutical donation and reuse programs are distinct prescription drug programs providing for unused prescription drugs to be donated and re-dispensed to patients. Such drug <u>repository</u> programs began with state legislative action in 1997. As of fall 2018 there are **38 states and Guam** with enacted laws for donation and reuse.

STATE REUSE PROGRAMS: Four Spotlight Examples (as of mid-2018)

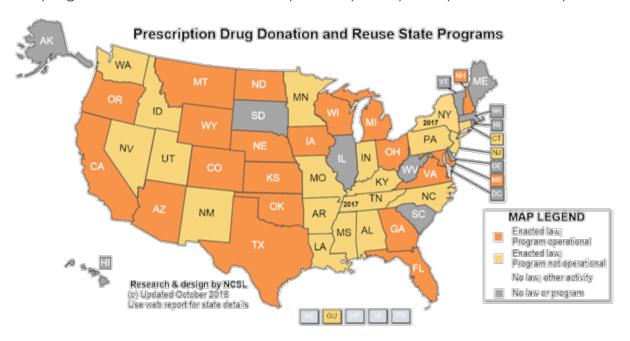
- <u>lowa</u> created its program in 2007 and has served 71,000 patients and redistributed \$17.7 million in free medication and supplies donated to people in need (taken from <u>2016</u> <u>Performance Update</u>).
- Wyoming's Medication Donation Program was created in 2005 and has helped Wyoming residents fill over 150,000 prescriptions, adding up to over \$12.5 million.

- Oklahoma created its program in November of 2004 and has filled 227,603 prescriptions, worth about \$22,518,462 based on the average wholesale price of medication, through the end of May 2018.
- Georgia's return and reuse repository, despite being a newer program, has quickly grown
 into one of the nation's more successful programs.

See: Medicine donation program helps many Georgians who can't afford what they need - GA news article, Aug. 7, 2018

Pharmaceutical donation and reuse programs are distinct prescription drug programs providing for unused prescription drugs to be donated and re-dispensed to patients. Such drug repository programs began with state legislative action in 1997.

Although many states have passed laws establishing these programs, almost half of these states do not have functioning or operational programs. "Operational programs" are those states that have participating pharmacies, charitable clinics, and/or hospitals collecting and redistributing donated drugs to eligible patients. Some common obstacles are the lack of awareness about the programs, no central agency or entity designated to operate and fund the program, and added work and responsibility for repository sites that accept the donations.



Nationwide Rx Reuse Snapshot

- As of mid-2018, 38 states and Guam had passed laws establishing drug redistribution programs. Many of these programs are not operational or small, but successful programs are growing. A few measures have been repealed.
- Twenty-one states currently have enacted laws with operational repository programs.
- At least a dozen and a half additional states are categorized as having non-operational enacted laws. New York's Nov. 2016 law is the latest.

• Filed legislation: In 2015-2016 there were 19 bills regarding this topic introduced throughout the states and the District of Columbia.

Cancer-Specific Programs: The enacted laws in 13 states—Colorado, Florida, Kentucky, Michigan, Minnesota, Montana, Nebraska, Nevada, Ohio, Pennsylvania, Utah, Washington, and Wisconsin—allows them to accept and distribute cancer-related prescription drugs.

NOTE ON SAFE DISPOSAL:

This NCSL report does not include the numerous programs that coordinate disposal and safe destruction of unwanted drugs, either legal or illegal. Such disposal programs are designed to prevent re-use, rather than aid the health of needy patients. Disposal policies and laws are handled by the NCSL Environmental Health Program (link).

Comparison of Provisions in Enacted Legislation

- Most state programs have a number of provisions in common:
 - o No "controlled substances" medication is allowed to be accepted or transferred.
 - o No adulterated or misbranded medication is allowed to be accepted or transferred.
 - o All pharmaceuticals must be checked by a pharmacist prior to being dispensed.
 - All pharmaceuticals must not be expired at the time of receipt.
 - o All pharmaceuticals must be unopened and in sealed, tamper-evident packaging.
 - Liability protection for both donors and recipients usually is assured.
- Some current differences in legislation across states include:
 - Drugs accepted for re-distribution: Prescription only vs. Over the Counter vs. Drug specific (i.e. only cancer drugs)
 - Eligible donors, recipients and patients.
 - o Minimum number of months before expiration date.
 - Protocol for transfers and repackaging.
 - Maximum dispensing fees
 - Centralized / decentralized
 - Programs funded or unfunded

Sources of <u>Repository</u> Medication

Drug donation regulations are governed at the state level and contrast greatly from state to state. Most state programs have substantial restrictions on who can donate and what types of prescription products or supplies may be donated. Very strict safety rules also apply, intended to protect the patient that ultimately obtains and takes the medication.



Bubble wrapped medication donations received from extended care facilities and others across Wyoming to be used for prescription filling at the WMDP.

Contributed medications that do not meet the donation criteria must be incinerated or destroyed. Because of the donation criteria, any medications dispensed in an amber vial or dispensed in a manner that does not use sealed, tamper-evident packaging is strictly prohibited. As a result, many operational programs rely on long-term care dispensing pharmacies as the primary source for donated medications. The 31-day or less blister packs that are used in long-term care settings allow for easy visual inspection for drug identification and tampering. Dispensing pharmacies for long-term care have welcomed drug donation repository programs as an economical option to dispose of previously dispensed but unused medications.

Example:

Wyoming state law allows **Wyoming Medication Donation Program** (WMDP) to collect donations from any source having sealed, in-date medication (within 5 months of beyond us/expiration date.) Donations can be from the public or a facility that has unused medications, including nursing homes, detention centers, prisons, hospice, samples from offices, and other facilities with patients in their care that have bubble pack meds.

Excluded medications include: refrigerated, controlled substances, broken or half tablets, packets with multiple pills in the bubble, beyond use or expired, short-date (5-month expiration from the date of donation or beyond use date), and medical supplies.

All donated medications should be inspected as described above. See Direct Donations

Patients Served

Drug donation programs are designed to aid uninsured and underinsured patients with limited incomes. These programs are not intended to provide medication assistance in lieu of state or federal programs, but do serve patients who need short-term assistance, such as an insured, low-income patient who cannot afford a prescription co-pay, an individual who has lost employer-provided insurance, or a senior who has reached the Medicare coverage gap. In many cases, a drug donation program provides critical medication access in instances where the patient would otherwise go without.

Although some states allow the drug donation program to dispense directly to the patient in need, many programs are licensed in their state as a wholesale distributor. As distributors, the drug donation programs supply community pharmacies or medical facilities such as a free

medical clinic or a federally qualified health centers with donated medications that will be dispensed to patients in need. Once the donated medications are received by the pharmacy or medical facility, the medications are dispensed to the patient in its donated form; however, some states also allow the dispensing medical facility to repackage the donated items in a format that is consistent with retail pharmacies.

National Conference of State Legislatures Staff. State Prescription Drug Return, Reuse and Recycling Laws. National Conference of State Legislatures. (2017, March 31). Rosmann J. <u>Drug Donation Repositories: State Programs to Leverage Scarce Health Resources. Inside Pharmacy.</u> 2013;1:13-14.

Reclamation Resources

The **National Conference of State Legislatures** (NCSL) is the best resource to see what is happening across the country regarding medication <u>reclamation</u>, however the information is a little outdated since it largely relies on states self-reporting new updates and changes. See <u>NCSL for updates</u>. New York and other states may be added to the list with enacted laws.

A recent story in ProPublica, December 1, 2017, highlights the work of several states to make programs operational. See <u>More States Hatch Plans to Recycle Drugs Being Wasted in Nursing Homes</u>.

Consider medication destruction as part of a reclamation program or any program largely based on donations. Of all the medication donated to WMDP, about 25 per cent ends up in disposal, based on pounds of disposal versus pounds of donation collected. This can influence space, staffing and volunteering, and provide opportunities for partnering with the community. See Medication Destruction

<u>Filling Gaps in Free Medication</u>

Create a Unique Safety Net List

Creating your own formulary and finding affordable sources for those medications is necessary to support low income patients. For example, provide a "safety net list" of medications

available for a small fee (\$1, \$3) or no charge to provide patients in need when medications are not available for free.

For example, Saint Thomas Health hospital in Nashville, TN, offers these goals for inventory for a **Safety Net Program**:

- Offer at least one or two medications in most therapeutic drug classes since some brand & generic meds are not always available through "free med" vendors
- Provide a drug formulary that would be more stable and affordable than other community programs (including \$4 lists)
- Fill in any therapeutic gaps not provided by "free med" vendors, \$4 lists, etc.
- Provide a one-stop shop (since transportation can be an issue)
- Guidelines for fee schedule

Tip: What therapeutic gaps exist in the formulary you want to provide? (Antibiotics, ophthalmics, dermatologics, inhalers, cardiac, neurologic or psychotropic meds, insulins, diabetic supplies, spacers for inhalers, others?) What have other charitable pharmacies done to fill these gaps? What options can you utilize?

Low Cost Mail Order

Vendors such as <u>RxOutReach</u>, <u>Xubex</u>, <u>GoodPill</u>, and <u>HoneyBee Health</u> offer eligible patients discounted pricing on their formulary medications. Prescriptions are mailed and usually for a 90 day supply. A credit or debit card or check may be required for payment.

Utilization of <u>manufacturer Patient Assistance Programs (PAPs)</u> may be able to supply the long term needs of eligible patients for medications not available or in short supply at your pharmacy (e.g. inhalers, insulin).

Options for Insulin

The Dispensary of Hope team frequently hears from safety net providers across the country about the need for access to **insulin**. Caregivers for vulnerable populations often struggle to meet all the medication needs for their diabetic patients. Due to the high cost of insulin therapy, many patients still struggle to control their blood sugar levels and either skip doses or do without which ultimately leads to poor health outcomes. ¹ Offering the most vulnerable patients, those who could not afford even a \$25 vial, access to donated insulin can impact their health and reduce their risk of heart attack, blindness, and amputations. Providing donated insulin See <u>Direct Donations</u> for those patients most in need can save communities and health systems billions of dollars in uncompensated medical care. ^{1,2} Diabetes can be controlled if managed properly. Providing medication for those most in need can help those patients lead healthier lives and can change a diabetes diagnosis from a terminal one to a manageable disease.

The "CINCI" study was published in 2017 by St. Vincent de Paul Charitable Pharmacy of Cincinnati after they followed patients switched from basal/bolus to twice daily dosed OTC insulin. This choice to switch to twice daily insulin reduced costs for St. Vincent de Paul (who was covering the insulin cost) but yielded similar outcomes to the basal/bolus therapy.

References:

- 1. <u>Business Insider</u>. Novo Nordisk and CVS offer 25 per vial insulin.
- 2. Office of Disease Prevention and Health Promotion. <u>Healthy People 2020:</u> <u>Diabetes</u>. Washington, D.C.: US Department of Health and Human Services; 2014.

Over-the Counter (OTC) Insulins

The OTC insulins included are the older generation of insulin (R, N, 70/30 Mix, 75/25 Mix.) These are available without a prescription for as low as \$25 for a 10 ml vial. Some Charitable Pharmacies have been able to work with suppliers to purchase OTC insulins in a limited quantity for patients.

The OTC insulins have a dissimilar action profile than prescribed insulins. However, as shown in the CINCI study, the different profile does not indicate a lower quality.

Though a prescription may not be required, ensure providers know what insulin their patients are using. Patients converting from a basal/bolus regimen to the older insulins require education as to insulin timing, mixing and storage.

Low cost Insulin Wholesale Distributors

<u>Sterling Distributors</u> has been providing diabetic supplies to pharmacies, nursing homes, home care agencies and other medical supply companies for ten years. Charitable Pharmacies are able to purchase Novolin 70/30 vial 10ml (an OTC insulin) as well as diabetic supplies.

For more information on insulin, refer to the Dispensary of Hope's Insulin & Inhaler Savings.

Diabetic Supplies



Various suppliers offer lower cost diabetic supplies for patient purchase. <u>ReliOn</u>, through Walmart, offer meters, test strips, and a wide selection of other diabetic supplies. *True Matrix* brand meters and strips are available at many pharmacies and on-line. Patients should check expiration dates when purchasing.

Vendors such as <u>Independence Medical</u>, <u>Sterling</u>, and <u>Bionime</u>, among others, offer discounted pricing and "free" offers for pharmacies purchasing products.

For information on diabetic supplies, refer to the <u>Dispensary of Hope's Diabetic Supplies</u> <u>Webinar</u>. If affiliated with a hospital or clinic, the cost of these supplies can be utilized in Community Benefit reporting.

Manufacturer Patient Assistance Programs (PAPs)

Many pharmaceutical manufacturers offer programs for eligible patients to receive free or discounted medication. Eligibility for these programs varies significantly depending on income, residency, insurance status, diagnosis and other factors. For eligible patients these programs supply life-saving medication for up to one year, with possible re-enrollment.

Factors to consider when offering a PAP service

As a charitable pharmacy, improving medication access is of prime importance. Access to PAPs can be managed by the patient or by the pharmacy and patient cooperatively. When managed by the pharmacy with patient cooperation, additional staff will be necessary for enrollment and follow-up. The staff does not necessarily need to be pharmacy trained as a technician, though cross training is helpful and clear role delineation must be maintained if PAP staff is not pharmacy trained. Non-technician position possibilities include an enrollment specialist, social worker, or pharmacy navigator.

Factor	Record Keeping – Patient	Record Keeping – Pharmacy
Staff	Does not require pharmacy technician status for position	Does not require pharmacy technician status for position

Staff time	 Limited staff time to determine if PAP is available Enrollment software available for patient use Patient takes responsibility for enrollment, refills, eligibility changes, tracking issues 	 Requires significant staff time for processes Determine eligibility Follow-up with patients: signatures, pick-up, refills Follow-up with providers: signatures, refills, directions Properly labeling and education
Clinical Considerations	 Pharmacy unaware of adherence, continuing or discontinuing med, dosage adjustments No tracking for metrics 	Assures:

PAP Software Options

Software options vary depending on whether the program is patient or pharmacy managed. Programs such as <u>Needy Meds</u> and <u>Partnership for Prescription Assistance</u> link manufacturer PAP sites and applications. If a PAP program exists for a specific medication, the application is printed, completed, then mailed or faxed directly to the manufacturer. Patient specific data is not stored with these sites so copies must be retained either by the patient or, if managed this way by the pharmacy.

Additional software options exist when PAP programs managed by the pharmacy. Spreadsheets can be developed to track patients, enrollment, documents missing, refills, etc. RxAssistPlus offers a web-based software that allows for patient enrollment, PAP application fill based on enrollment information, refill and new application report notifications, and privacy compliant data storage. Completed applications are printed for signatures (patient and provider) then faxed, scanned or mailed to manufacturer. Programs such as RxAssistPlus provide record keeping and reports, and can be utilized for extensive metrics including but not limited to patient demographics, location, referral site, dollar value of applications processed, PAP meds dispensed, FPL, and clinical interventions. Experience with Word Access helps when creating specialized reports, but the reports are built by the software provider.

<u>Comparison of patient assistance program software</u>, though dated, offers key points when reviewing software options including features of programs, logistic information, support and training, and program costs.

Steps for Processing PAPs

1. Initial Medication Supply

As PAPs require shipment, the first step is providing medication until the shipment arrives. Manufacturer or discount coupons, product samples, or a therapeutic interchange may fill the gap. Some manufacturers offer coupons which provide medication for up to one year for eligible patients. This option eliminates shipping and provides immediate dispensing – a win-win for patient and pharmacy. Providers who carry samples (e.g. cardiologists, pulmonologists, etc.) may be willing to donate directly to a charitable pharmacy even if the patient is not part of their practice. (See <u>Direct Donations</u>)

2. Eligibility

Each manufacturer has individual qualifications. Variables include:

- Residency requirements and documentation,
- Social Security or Tax ID number
- Income requirements, documentation, and processes (some companies do a soft credit check for initial enrollment),
- Insurance eligibility status,
- Age or diagnosis restrictions.

<u>Therapeutic Interchange</u> may allow patients to be eligible for a similar product when not qualified for the product prescribed.

See Eligibility for general details and documentation.

3. Enrollment

As with eligibility, applications and documentation vary with manufacturers. Attention to detail is paramount in reviewing each application to ensure all signatures and documentation is complete and provided prior to submission. Application variables include:

- Patient signature (some allow caregiver, spouse, parent or guardian),
- Provider signature ensure matches provider used on application; hospital residents may lack credentials (state license, DEA number),
- Signatures to be original versus faxed,
- Acceptable photo identification, residency and income documentation,
- Original prescription versus application becomes prescription.

TIP: HOPE Dispensary adapted a patient specific section to record clinical interventions and associated potential dollar values. Metrics are then shared with stakeholders and funders, documenting services provided beyond med access.

When providing this service at the charitable pharmacy, create guidelines and deadlines for patients and providers to provide documents and signatures. A reasonable guideline is two follow-up phone calls or requests within a four to six-week period. Document follow-up. Software is helpful for documentation and scheduling.

Once all application signatures and documents are procured, submit to manufacturer. Some require original documents/signatures necessitating mailing applications. Others accept faxes or allow scanning to a website. If a reply is not received, follow-up with manufacturer probably ten days after submission to confirm receipt of application, proper documentation, and verify patient eligibility

4. Shipping and Providing to Patient

Shipping from the manufacturer directly to the patient is convenient for the patient but may not be best practice. Although the medication has already been dispensed from the manufacturer to the patient it may not be labeled in compliance with state laws. As clinical pharmacists, we know that a state-approved label should be attached to container(s). Some manufacturers do this; others send just a packing slip and medication information sheet. When servicing a patient with PAP medication, ensure the product is properly labeled with accurate directions (not "as directed"), patient is counselled and any questions are answered. Dispensing from the pharmacy provides opportunity for both proper labeling of prescription vials and patient counseling.

	Patient	Pharmacy
Prescriptions mailed to Patient	 Saves patient trip to pick-up prescription Frequent changes in patient address and contact information may delay delivery Patient must call pharmacy for counselling or questions 	 Requires follow-up with patient to confirm delivery and questions or counselling Proper prescription label may be missing Metrics and trackability not always available

<u>Prescriptions mailed to</u> Pharmacy

- Patient required to pick-up and sign for prescription
- Patient receives properly labeled Rx and has opportunity for counselling and questions
- Ensure delivery of medication and patient receipt
- Follow-up for delayed delivery
- Ensure patient pickup
- Verify proper labeling, patient education
- Obtain metrics
- Follow-up for meds not picked up
- Delivery challenges from manufacturer if pharmacy has limited hours, especially for refrigerated items

For PAP meds picked-up at the pharmacy, guidelines are helpful.

- Call patient for medication pick-up
 - Document call: spoke with patient or name of other person, left voicemail, phone number not accurate, no voicemail
 - Limit number of documented phone calls or attempts (e.g. 2 attempts/30 days or less)
- At pick-up, remind patient to call for refill between 21 and 30 days prior to needed to allow time for contacting manufacturer, shipping, and obtaining a new prescription if this is the last refill.
- If patient no longer needs, would they be willing to donate to the charitable pharmacy for use by another patient? Document on packing slip and in other records with reason not given to patient.
- If patient does not pick-up within set guidelines, document as above.

5. Refills

When a patient calls the pharmacy or is contacted for a refill, check for possible changes in eligibility, contact information, provider, and directions. Contact the provider to verify any changes in directions. Contact the manufacturer and relay any changes (may require new prescription for direction changes.)

Follow-up phone calls may be made to verify patient's need for refill, usually 30 days prior to next fill. As well as being proactive, this is an opportunity to check adherence.

Document all communications with patients, providers and manufacturers.

6. PAP Medication Destruction

Product dispensed as PAP from a manufacturer cannot be returned to another vendor or wholesaler for destruction. Destroy beyond use meds as per pharmacy policy. See: Medication Destruction and Standard Operating Procedures

7. PAP Metrics

Measures used to evaluate a PAP program can include:

- Number and dollar value of PAPs processed (this quantifies time spent processing whether patient is not eligible, not all documentation is returned, or med is not pickedup
- Number and dollar value of PAPs dispensed (this includes new and refilled PAPs)
- Manufacturer and/or product or therapeutic class of PAPs

Manufacturer Bulk Patient Assistance Programs

A manufacturer bulk replacement program or PAP allows the pharmacy to maintain a segregated bulk supply of product(s) available for immediate dispensing. The program is largely governed by individual contracts with specific manufacturers. Contract with manufacturer will determine patient eligibility requirements.



From a patient standpoint, the shipping time is eliminated when product is in stock at the pharmacy. On the pharmacy side, the pharmacy, rather than the manufacturer, accepts responsibility for verifying patient eligibility. Policies approved by the manufacturer include patient eligibility, acceptable forms of identification and income documentation, product receipt, storage, recall and destruction, and adverse event reporting. (See PAP policies) Patient and product dispensed information are usually reported monthly. Audits are annually, usually with one to two months preparation time to collect data for the auditor.

Though time consuming to manage, a bulk replacement program may be a valuable source of branded medication for charity patients, filling therapeutic gaps not available with generic meds.

Helpful tips for incorporating a bulk replacement program:

- Record keeping and documentation are paramount
- Trained staff following manufacturer-accepted policies and processes make reporting and auditing easier

- Product labeling and dispensing are the same as other prescriptions from the pharmacy
- Add the manufacturer as a third party in pharmacy software for reports
- Adapt pharmacy prescription software to provide other information needed for monthly reports, including provider state license number and patient FPL
- Segregate prescription pick-up or use other designation to ensure collection of all necessary signatures for monthly reporting and audits
- Add alerts in pharmacy software and on prescription pick-up label for communicating with the patient about missing documentation or in need of renewing for next fill
- Tag and store charts for patients utilizing the bulk program separately, reducing time tracking charts for eligibility documentation
- Use well trained students and/or volunteers in audit preparation.

<u>Tracking the Medication Supply Chain</u>

The Drug Supply Chain Security Act (DSCSA) tracks medications from the manufacture to the patient. This feature is a safety feature to protect patients from counterfeit medications entering into the supply chain. Currently there is no exemption for sample drug donation programs. A <u>Donation Tracking</u> form or software record may be used for direct donations. Both the pharmacy and the donor retain copies of the transaction.

Required information includes:

- Donor and contact information
- Pharmacy or recipient contact information
- Date of donation
- Drug name, strength, quantity in package(s), lot number, NDC if available, beyond use date (expiration) and quantity of packages

Bulk repackaging (e.g. converting bottle of 1000 to 90s, etc.) also falls under the DSCSA. Bulk repackage medications (sample meds may not be eligible for repackaging) and labeling requirements may be affected by state regulations:

Med name/ Strength/ Quantity in Package

NDC

Lot#

Beyond Use Date (Max. 1 year from packaging)

Beyond Use Date is the actual beyond use date to a maximum of 1 year from packaging. See Example of Bulk Repackaging record.

Medication Destruction

Medication that is beyond the use date (expired) or has been stored such that the beyond use date has shortened (Example: refrigerated product left at room temperature) must be destroyed appropriately.

Medication should be <u>destroyed per pharmacy policy</u>. A log is maintained regarding all med destruction in compliance with the EPA, DSCSA, and your destruction vendor. The <u>medication destruction log</u> should include:

- Date of destruction or placing in Regulated Medical Waste Bin
- Medication name, strength and dosage form
- Lot number
- Expiration Date (from container; may add note if different due to storage conditions)
- Quantity destroyed (units not containers) Example: Tablets, milliliters, grams, etc.

Remove external packaging as described in **Figure 3** (below) to decrease weight and destroy only medication waste. Remove patient identifying information from packaging by removing patient labels and shredding them or covering with stickers such as an <u>Identi-Hide</u> sticker. A de-blister machine is a time saver for removing tablets and capsules from blister packaging.



Hazardous Products

Controlled Substances and products considered **hazardous** (<u>Hazmat</u>) **or p-waste** such as oncology medications, warfarin, estrogen and progestin products, finasteride, lindane, nicotine, and nitroglycerin **may require segregation for destruction**. See <u>CDC Antineoplastics</u> and <u>Healthcare Environmental Resource Center</u> for current listings.

- Segregation may be required in a **red bag or container** or container provided by the destruction vendor.
- These products, unlike regular waste, require the destruction of the empty container, lid, cotton, seal, etc. (all packaging that has touched the product.)
- Wear gloves and work in a well ventilated area or wear a face mask.

When storing and preparing meds for destruction follow guidelines provided by destruction vendor. See **Figure 3** (below) for general guidelines. Vendors may require separation of control substances, hazmat, aerosols and other items.

Figure 3.

	Where?	How to destroy
Bulk Containers	Return to vendor/wholesaler when possible	

Bulk Containers NOT eligible for return	Regulated Medical Waste bin	Dispose of paper packaging and container in regular trash
Oral Samples	Regulated Medical Waste bin	Dispose of paper packaging and container in regular trash
Inhalers	Regulated Medical Waste bin or separated as per vendor requirements	Dispose paper packaging and removable plastic mouth piece in regular trash. Discard only inhaler in Regulated Medical Waste Bin or as per vendor
Injectables: Pens, Vials, Ampules, etc.	Regulated Medical Waste bin	Dispose of paper packaging and plastic caps in regular trash. Do NOT open container to empty. Discard with container or vial intact. Discard only medication in container in Regulated Medical Waste Bin.
Oncology/ <u>Hazmat</u> Bulk Containers	Return to vendor/wholesaler when possible	
Oncology/ <u>Hazmat</u> Samples, empty bulk containers	Regulated Medical Waste bin Or Hazmat Waste bin	Samples, empty containers including lids, cotton, etc. discard in Regulated Medical Waste bin or as per vendor Wear protective clothing
Other	Regulated medical waste bin	Remove paper packaging. Discard with container or vial intact.

Adapted from HOPE Dispensary of Greater Bridgeport

Final Incineration

Incinerating medications that are beyond use/expired may be completed economically by collaborating with law enforcement departments and manufacturing companies such as steel mills. In some states or communities, the DEA or law enforcement agency will permit charitable pharmacies to drop expired medications at the Drug Take Back Days or Drop of

Sites. It is also possible that a law enforcement agency will share a "burn" at a manufacturer's furnace when they are burning guns and other evidence. The law enforcement and security staff at the incineration company will coordinate the burn. The companies may work directly with the charitable pharmacy to permit them to have their own burn, with or without charge.



Reference: https://www.elastec.com/products/portable-incinerators/smartash/ Accessed 4.21.18

There is usually not a charge for the service when combined with law enforcement; however, the charitable pharmacy may have an expense of renting a vehicle if there is not access or pharmacy ownership of a van or truck. The cost is well worth it. A licensed pharmacist from the charitable pharmacy will accompany the medications to the furnace area and will observe the medications being thrown into the furnace. The pharmacist will wait the brief period of time it takes for the drugs to be destroyed. The company's security department will give the pharmacy guidance on protocols for participating in a burn and clothing requirements.



Patient Eligibility/ Enrollment

A goal to improving medication access is to help patients without insurance become eligible for charitable pharmacy services. This may involve providing medication directly, enrolling patients in a manufacturer patient assistance or bulk program, or directing them to a mailorder or other discount program. There are transitions of care involved. Frequently special services are required such as translation, interpretation, dealing with illiteracy, arrangements for homeless or those who have been incarcerated. The charitable pharmacy is in a unique position to address these needs and create reasonable options for their patients.

Record Keeping

For patients to receive medications at the pharmacy, record keeping measures for eligibility and required documentation should be in place. Records need to be securely stored according to state and federal guidelines (e.g. Adults: 7 years; Under 18, 7 years past 18th birthday.) Records may be stored as paper or electronically depending on state and federal guidelines.

Flowchart for external referral

Uninsured patient identified at hospital or ED Discharge

Case Management or Discharge Planning Team identifies that patient is uninsured and may have difficulty filling their prescriptions

Care Navigator or Social Worker may check if patient is eligible for Charitable pharmacy and/or Dispensary of Hope meds

Patient is eligible for Dispensary of Hope (DOH) meds,

IF 1) UNINSURED (pharmaceutically uninsured)

AND 2) < 200% FPL

*If possible, document patient eligibility in EMR for patient to be pre-qualified when they arrive at the pharmacy

For eligible patients, fill as many Rxs as available from free inventory

Prescriptions may be filled and delivered to patient's bedside (if med-to-bed program is in place), **OR** direct the patient to the hospital's outpatient pharmacy that has a free inventory, **OR** local Charitable pharmacy. The pharmacy will try to fill as many Rxs at \$0 that are available in the pharmacy.

If the patient is not eligible for DOH or free meds OR if some meds are not available in inventory, THEN see if one of the following strategies will work to obtain affordable medication access

THEN	If not, THEN	If not, THEN	If not, THEN	If not, THEN	If not, THEN
If possible, make therapeutic interchange to med that is available for free	Use manufacturer drug card Sign the patient up for Patient Assistance if applicable	Use the 340B drug price if hospital is 340B eligible	Use a limited safety net formulary where certain medications are only \$1 or \$3 for the patient price to fill any gaps	Use a Rx discount card (i.e. Family Wize, GoodRx, etc.)	If the hospital has a charity fund, then fill any remaining Rxs out of this fund

Adapted from Dispensary of Hope Flowchart for external referral

Eligibility Guidelines

Key elements to determine when developing eligibility guidelines include demographics of the population being served and any guidelines from referral sources, funders, vendors or state drug donation programs. Work with referral sources (case management, etc.) to determine how they track and determine eligibility. When possible, utilize pharmacy point of service software to check patient insurance status.

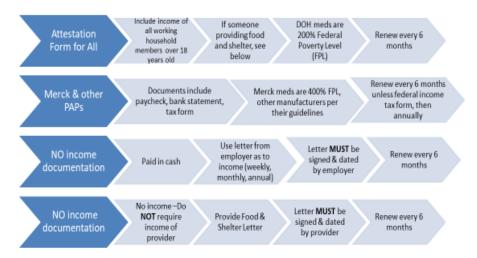
- Develop criteria for patients to meet to receive new and refill medications. Criteria can include:
 - Household income
 - Income usually includes that of entire household, not just patient
 - Size of household: adults, children under 18
 - Program criteria may vary: Children over 18 may not be counted as part of household by some programs
 - Romantic partner may count but someone just staying may not
 - o Difference in household income versus expenses
 - Where patient resides: zip code, city, state
 - Patient age
 - Provider network or referral source
 - United States residency status
 - Veteran
 - Eligibility for other assistance programs (social security, disability, state, etc.)
 - Prescription drug insurance status: uninsured, gap in insurance, donut hole, spend down, etc.
- Do these guidelines fit the demographics of the patient population to be served?

- Do these guidelines fit the eligibility requirements of the medication suppliers used?
 (Manufacturer bulk replacement, patient assistance programs, non-profit vendors, purchased distributors, state drug donation program, etc.)
- Some vendors require all documentation to be acquired prior to dispensing of any medication, even first fill.
- Acceptable proof of eligibility and guidelines for documentation.
 - Photo ID. Exceptions: discharge from a facility, mail order, patient not able to be present (age, illness, disability), minors
 - Types of acceptable photo ID: State/government issued, school issued, credit/debit card, other
 - o Residency: USPS mail, utility bill, rent receipt, or copy of lease
 - Residency, others: homeless, shelters, rehabilitation center, facility, staying with another person: See <u>Appendices\Eligibility\Sample Letter of Cash Income or</u> <u>Food & Shelter STA.docx</u> for form letter.
 - Insurance: denial letter, lack of coverage criteria (not US resident, etc.), attestation
 - Some software programs can screen for prescription insurance status
 - Income: pay stubs (how recent, how many?), bank statement, letter from employer (notarized may be burdensome for patient), attestation, Social Security, child support, previous year tax form
 - For those paid in cash, sample letter for income documentation is in <u>Appendices\Eligibility\Sample Letter of Cash Income or Food & Shelter STA.docx</u>. A phone number of employer may be added. This may not be acceptable for manufacturer <u>PAPs</u>.
 - A formalized letter of support from family members, friends, organizations that help support the patient's bills may be required.
 Appendices\Eligibility\Sample Letter of Cash Income or Food & Shelter STA.docx
 - Are food stamps considered income in your state, for eligibility for meds from the vendor or manufacturer program?

Example Algorithm for acceptable income documentation:

Income Algorithm

Size of family unit	200 % of Poverty 2017
1	\$23,760
2	\$32,040
3	\$40,320
4	\$48,600
5	\$56,880
6	\$65,160
7	\$73,460



HOPE Dispensary of Greater Bridgeport

- Determine timeline for patient to provide documents needed for initial eligibility
 - Prior to dispensing
 - o Prior to refill, 30 days, 60 days, 90 days
 - Exceptions: emergency medication, other
- Criteria for refill
 - All documentation provided
 - For mail order, 10 business days prior to refill needed. This may be adjusted for shipping holidays and delays (weather, etc.)
- Criteria for 90-day supply refill verses 30 or 60-day fill
 - Some pharmacies restrict all refills to 30-day supply to monitor adherence
 - Another option is monitoring patient 30-day refills. When 3 refills in a row are timely (+ or – 3 days of due date), the patient is congratulated for adherence, a note made in patient chart, and future refills will be for 90 days. This may require a collaborative practice agreement in some states.
 - For shipping of maintenance meds, a 90-day supply following first fill may be set as a policy for the program.

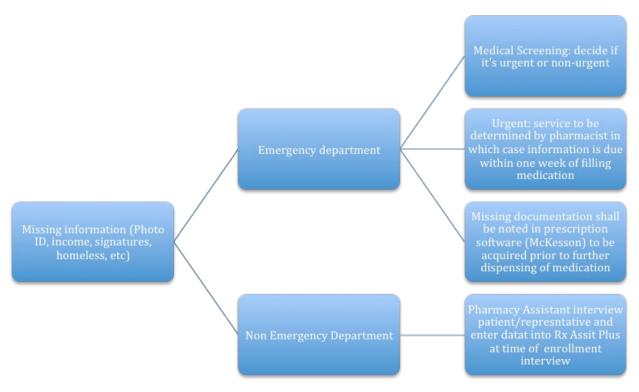
Enrollment

Allow for extra time for new patient enrollment (30-60 minutes) and re-enrollment (10-15 minutes). Patient enrollment processes may vary based on suppliers of medication (vendor requirements, prescriptions being filled in-house or via PAPs) and software systems being used.

- Develop method of enrollment:
 - Form(s), paper chart
 - Electronic: pharmacy system or another system.
 Software for enrollment and/or PAPs may be separate than that used for prescriptions.
 - Alert for missing documentation
 - System should be capable of providing metrics for patient demographics including but not limited to age, sex, language and/or ethnicity, income, insurance status, referral source, location, and contact information. (See Chapter on <u>Measurements/ Evaluation/Outcome</u> for more information.)
- HIPAA/Privacy form(s) for (original) patient signatures
 - Possible exceptions for original signature
 - Discharge from facility, minor, patient unable to be present (age, illness, etc.), other
 - Give copy to caregiver to return(?)
- When using state drug donation medication, a <u>liability protection</u> for both donors and recipients form is signed by patient (bottom of page).
- All forms and patient materials may need to be translated into multiple languages depending on the population being served.
 Interpretive services are discussed below.
 - . An interpreter may be needed to ensure patient understands what documentation is needed for enrollment
- Some patients may not read and may require oral completion of forms.
- Determine re-enrollment period and criteria
 - Semi-annual or annual
 - o All new proofs of eligibility or limited (income, residency, insurance, etc.)
 - Alerts for re-enrollment

Example: Patient enrollment forms can be found in Appendix/Eligibility.

Example: Algorithm when information is lacking



Adapted from Saint Thomas Health

Further Assistance with Medication

When a medication is not available at your pharmacy, options include:

- Changing medication to a therapeutically equivalent medication carried
- Referring to a discount pharmacy for a \$4 or discounted med or equivalent
- Providing a manufacturer coupon
- Checking with a specialty provider who may have access to medication until supply is available
- Referring to another outreach provider (<u>Rx OutReach, Xubex</u>, <u>GoodPill</u>, <u>Honeybee</u>
 Health or a community- based provider)
- Enrollment in manufacturer <u>Patient Assistance Program</u>

See more details in Filling Gaps in Free Medication

Transitions of Care/Handoffs

An important service required of pharmacies is assistance in <u>transitions of care</u> (TOC). The <u>National Transitions of Care Coalition</u> defines transitions of care (TOC) as "the movement of patients between health care locations, providers, or different levels of care within the same location as their conditions or care needs change". Patients move to and from hospital or ED to outpatient to clinic or primary care practice to pharmacy (s), labs, homecare agencies,

and other providers. Each of these transitions is an opportunity for pertinent information to be missed or misinterpreted by patients and or healthcare providers. Lack of insurance may influence access to healthcare, including medications, and ultimately, the ability to adhere to a new discharge plan.

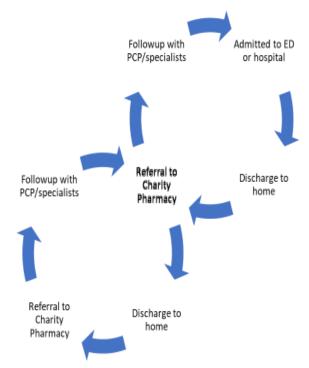
(Development and validation of a transitions-of-care pharmacist tool to predict potentially avoidable 30-day readmissions.)

Charitable pharmacies are in a unique position to provide medications for the uninsured, allowing them to be key members of the TOC team. As with other pharmacies, they can provide medication history, including allergies and adverse reactions, and reconciliation at time of hospital admission or ED visit. Working with hospital providers (inpatient pharmacists, case managers, physicians and other prescribers), the charity pharmacist can help develop a free or affordable medication regimen for the patient, ideally prior to

TIP: Good Shepherd Health offers a unique service. We do a transitional care program with a local for-profit (hospital). We fill their indigent patients' discharge meds all at once as a 90day supply. The hospital has to approve med charges if they exceed \$400. We follow up via telephone with the patient at 30, 60, 90 days. The patient gets a 90-day membership with us which means they can get their prescriptions for free or at cost. Eventually we hope to show decreased readmissions... We sell the discharge meds to the hospital at cost as well. This hospital doesn't have an outpatient pharmacy and we bear the full cash price from the nearest (local chain pharmacy.)

discharge. Check with state board of pharmacy for pharmacist scope of practice. (See <u>Collaborative Practices</u> and <u>Appendices Collaborative Practice</u> <u>Regulations</u> for additional information. See example forms for referrals and delivery in

- Appendices\Transitional Care\Articles & Resources
- DOH referral form for Case Manager
- DOH Completed <u>Referral Form for Patients</u> See: <u>Eligibility Guidelines Missing Information</u>



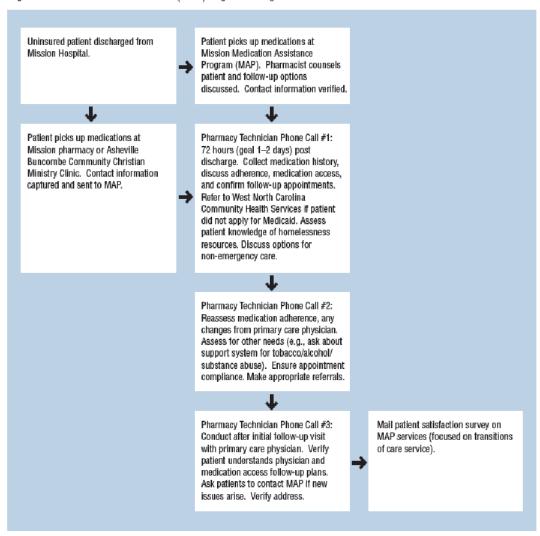
Adapted from Pharmacists implementing transitions of care in inpatient, ambulatory and community practice settings [UPDATED], 2014, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4161412/ accessed 2.12.18

<u>Transitions of Care: Case Examples Resource</u>, published by APhA, provides examples of pharmacy personnel roles, successes and barriers from six clinical settings.

ASHP and APhA collaborated to provide a TOC best practice report, **ASHP-APhA** <u>Medication</u> <u>Management in Care Transitions Best Practices.</u> Each of eight best practice cases presents processes, barriers, cost justification and metrics for their various locations. Mission Hospitals discuss their safe transitions for an uninsured population. Their **M**ission **U**ninsured **S**afe **T**ransitions (MUST) program includes referral at discharge from hospital and followup from pharmacy personnel. A sample technician phone call script is included in the article (ibid pg. 32).



Figure 5. Mission Uninsured Safe Transitions (MUST) Program Discharge Process



See Medication Management in Care Transitions Best Practice,

University of Pittsburgh School of Pharmacy and University of Pittsburgh Medical Center (UPMC) prepared a follow-up checklist for outpatient pharmacists: (ibid, pg. 43) The outpatient care transitions follow-up activities of the pharmacist include:

- Reviewing the patient's discharge medication list and home medications.
- Identifying and resolving any medication discrepancies.
- Communicating any medication-related changes to the appropriate outpatient pharmacist.
- Identifying and resolving any ongoing medication-related problems.
- Contacting other health care professionals, where appropriate, to convey and resolve any issues identified during the post-discharge follow-up call.
- Updating the patient's outpatient home medication list in the outpatient EHR.
- Sending a follow-up note to the patient's primary care physician.

Transitions and Mail Order

As a mail order charitable pharmacy, Wyoming Medication Donation Program (WMDP) uses colored notes, packaged in a zip lock bag with the prescription to alert patients. The notes notify patients of dose substitution, 90-day supply, missing information for proof of residency and/or income, eligibility renewal notice and notice that medication was not in stock. See <u>Mail Order Charity-Only Pharmacy.</u>

Pharmacy Translations

Miscommunication in the healthcare field can lead to poor health outcomes and can potentially even be life-threatening. There are a rising number of migrant patients as well as a high number of foreign-trained healthcare practitioners in the United States. This can lead to increased communication barriers between a healthcare practitioner and patient when one or both are speaking English as a second language. The lack of thorough understanding of one's own medical condition, as well as poor understanding of the treatment and follow-up plan can lead to a number of problems. These problems may include but are not limited to poor adherence to treatment plans consisting of medications and/or diet and lifestyle recommendations, which can lead to uncontrolled health conditions, poor health outcomes, and increased morbidity and mortality. Patients with low health literacy are often associated with poor health outcomes, increased hospitalizations, and an overall decreased quality of life¹. Taking the time to ensure a patient's proper understanding of points discussed with the healthcare team can result in better outcomes and decreased costs to the individual patient, clinic, and health system. Patients with language barriers are also less likely to have a consistent provider of medical care leading to a poor continuity of care further contributing to the array of health problems a patient may face. Language barriers can deter patients to ask questions about their treatment and prevent them from taking an active role in managing their overall health. It is important to overcome these language and communication barriers so we can have a positive effect on patients and support them in becoming champions of their own health.

The resources provided below can be used to overcome these language barriers:

Resource	Description	Languages Available for Patient Materials	Cost
RxTran	RxTran offers pharmacies the service of providing prescription drug labels, auxiliary labels, and patient medication guides in different languages. Currently they offer SIG translation into 17 different languages. The also offer over the phone interpreting in over 150 languages available 24/7. http://www.rxtran.com/	English, Arabic, Bengali, Chinese (traditional & simplified), French, German, Greek, Haitian Creole, Hindi, Korean, Italian, Polish, Portuguese, Russian, Spanish, Tagalog, Vietnamese	\$80-100/ month dependi ng on number of locations, pharmac y software, and languag es needed
Meducation	Meducation is a cloud-based solution, accessible to healthcare providers within their clinical workflow via their EMR system or as a standalone solution, which delivers medication instructions. http://www.fdbhealth.com/meducation-overview/	Over 20 languages	Contract specific pricing
VUCA Health	VUCA Health is an organization that gives patients the ability to quickly and conveniently access thousands of medication-specific videos in the MedsOnCue library by clicking on a link in an email or text message, or by scanning a QR code printed on prescription labels and patient information sheets. http://www.vucahealth.com/	Videos available in English and Spanish	Contract specific pricing

Lexicomp	Lexicomp is a drug information resources that also gives you access to patient medication hand outs http://www.wolterskluwercdi.com/lexicomp-online/ *Figure 9	English, Arabic, Chinese (traditional & simplified), French, German, Greek, Creole, Japanese, Korean, Italian, Polish, Punjabi, Portuguese, Russian, Spanish, Tagalog, Turkish Vietnamese	- \$285/yea r for mobile app -\$795 for mobile app and online
Micromedex	Micromedex is a drug information resources that also gives you access to patient medication hand outs https://www.micromedexsolutions.com/home/dispatch	English, Spanish	Contract specific pricing
Access Pharmacy	AccessPharmacy is an online pharmacy resource designed to meet the demands of pharmacy education and practice today. AccessPharmacy gives instant access to videos, games, Q&A, leading pharmacy textbooks, information about drugs, herbs and supplements, as well as patient drug handouts. https://accesspharmacy.mhmedical.com/	English, Spanish	\$595/yea r
Clinical Key	Clinical Key is a clinical search engine that gives access to drug monographs, guidelines, journals, books, and patient education handouts. https://www.clinicalkey.com/#!/	English, Spanish	\$499/yea r for internal medicine package
Medline Plus	MedlinePlus is the National Institutes of Health's website for patients and their families and friends. It provides information about diseases, conditions, drugs, supplements and wellness issues in patient friendly information. https://medlineplus.gov/	English, Spanish	Free

English, Albanian, Amharic, Arabic, Armenian, Bengali, Bosnian, Burmese, Cape Verdean Creole, Chinese (traditional and simplified), Chuukese, Dari, Dzongkha, Farsi, French, German, Gujarati, Haitian Creole, Hakha Chin, Hindi, HealthReach offers easy access to Hmong, Ilocano, FREE quality multilingual, Indonesian, Italian, multicultural public health Japanese, Karen, information including documents, Karenni, Khmer, HealthReach audio, and videos for those Free Kinyarwanda, Kirundi, working with or providing care to Korean, Kurdish, Lao, individuals with limited English Levantine, Malay, proficiency. Marshallese, Nepali, https://healthreach.nlm.nih.gov/ Oromo, Pashto, Pohnpeian, Polish, Portuguese, Punjabi, Russian, Samoan, Serbo-Croatian, Somali, Spanish, Sudanese, Swahili, Tagalog, Thai, Tibetan, Tigrinya, Tongan, Turkish, Ukranian, Urdu, Vietnamese

Recognizing language barriers in healthcare as a significant issue, some states have also started to require pharmacies to provide labeling in multiple languages to patients. The following table lists states that have requirements for multi-language labels:

State Requirement

California*

All pharmacies or facilities which dispense medication are required to provide translation of the 15 SIG codes on the Board of Pharmacy of California website. The board has interpretations of these in 5 languages which include Spanish, Chinese, Korean, Russian, and Vietnamese.

New York*

Chain pharmacies are required to provide free competent oral interpretation and written translation services of prescription drug labels, auxiliary warning labels, and other written materials to limited English proficiency patients. The primary languages required are Chinese, Spanish, Russian, and Italian.

Texas*

Whenever possible the directions of use on a prescription container label should be provided in the patient's preferred language. Drug name shall be in English. Translations of prescription medication labels should be produced using high quality translation process.

North Carolina

The NC Board of Pharmacy provides signs for pharmacies to put up for Spanish speaking patients informing patients they can obtain their prescription medication instructions in Spanish.

^{*}These states legally require pharmacy label translation.



Below are some examples of patient labels and handouts from these services.

Figure 1: RxTran translated SIG



Figure 2: RxTran Integrated into Pharmacy Software



Figure 3: NOVA Scripts use of Meducation Rx label



Figure 4: NOVA Scripts use of Meducation Rx label



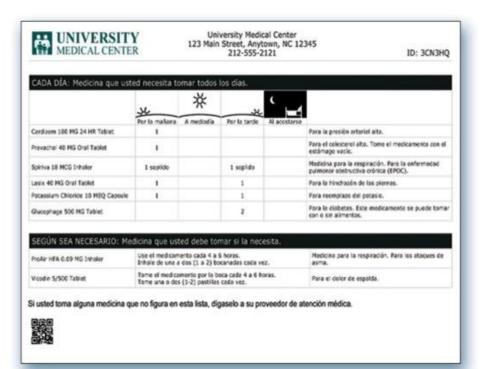


Figure 6: Meducation Instruction Sheet

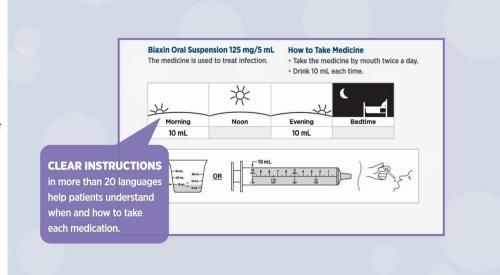


Figure 7: Meducation Handout



Figure 8: VUCA Health QR Code

Patient Education

米国のブランド名 Norvaso カナダのプランド名 Accel-Amlodipine; ACT-Amlodipine; Amlodipine; Amlodipi この薬は、高血圧を治療するために使用されます。 この葉は、胸痛あるいは胸部圧迫感を治療するために使用されます。 ・ 本剤を突発性の胸痛の治療に使用しないでください。 本剤は助けになりません。主治医に相談してください。 ・ この薬は、他の理由で投与される場合があります。主治医に相談してください。 本剤を服用する前に、主治医に何を伝える必要がありますか? アムロジビンか、または本剤のその他成分にアレルギーがある場合。 ・ 本剤と阿頚の薫剤、他の薫剤、食品、またはその他の物質に対するアレルギーがある場合。アレルギーとその症状(発疹、アレルギー反応として掻痒、思切れ、喘噌、咳、肺・唇・舌・味の腫れなど)につい 本剤は、他の薬剤や健康問題とも相互作用することがあります。 服用している医薬品(処方薬、市販菓、自然薬、ビタミン剤)について主治医と薬剤師に伝えてください。 服用しているすべての医薬品およびお持ちの健康問題にとって、この医薬品が安全であることを確認 してください。主治医に相談することなく医薬品の服用を開始または停止したり、服用方法を変更したりしないでください。 この薬を服用するに当たっての注意事項は? 医療従事者全員に本剤を服用していることを伝えてください。これには主治医、担当医師、香護師、薬剤師、および歯科医が含まれます。 本剤の影響が分かるまで、注意が必要な運転やその他の作業または活動を避けてください。 ・ 目眩を感じたり気絶したりする可能性を低下させるために、座ったり横になったりしている時はゆっくりと起き上がってください。階段の上がり降りには注意してください。 ・ 血圧検査を頻繁に受けてください。主治医に相談してください。

Figure 9: Lexicomp Pateint Education Handout on Amlodipine in Japanese

1. https://www.ahrq.gov/downloads/pub/evidence/pdf/literacy/literacyup.pdf

Authors:

Onkur Lal, Pharm.D. Candidate 2018 Virginia Commonwealth School of Pharmacy Zeshan Mahmood, PharmD, Clinical Pharmacist NOVA ScriptsCentral

Interpretation

As with translations, miscommunications through an interpreter can lead to poor health outcomes. Interpretation is a skill requiring practice both by the interpreter and the healthcare professional. See Appendices\Transitional Care\Articles & Resources\How to use an Interpreter.docx Family members and friends may not be accurate in interpreting. There also may be information exchanged that would violate patient privacy with a family member or friend. Interpretation could be altered to "protect" the patient or reflect the interpreter's perspective rather than the patient's. Do not use a minor for interpretation. Ideally a qualified interpreter is used for the most accurate interpretations. When the community charitable pharmacy is likely to serve multilingual patients, hiring multilingual staff and training them as an interpreter is a cost effective, privacy compliant option.

Whether using technology (tablet or phone based) or a live qualified interpreter, communication needs to be clear and personal.

- Maintain eye contact with patient, not interpreter. This will give nonverbal clues to patient understanding.
- Use language that is easily interpreted and non-technical when possible.
- Speak directly to the patient, not "Tell her..."
- Be patient. What in English is a short sentence may be multiple sentences in another language. The interpreter may need to think what the best way to interpret what was said by patient or healthcare provider.

Use of technology for interpretation takes practice. See <u>Interpretation</u> for resources. Before ending the session, verify the patient clearly understands and has had questions answered and the pharmacy has all the information needed.

Illiteracy

Illiteracy, especially in English, may be a factor in adherence contributing to readmissions. Offering labels, (See Pharmacy Translations) counselling and education in patient's first language is a best practice in service, appreciated by patients and healthcare referral sources. Picture handouts for use of devices and pictograms for medication directions may provide clarity. They can be posted at home as a reminder for compliance and/or shared with caregivers. They can be photographed to keep on a patient's phone. (Example handouts are in Appendices\Translitional Care\Pictograms)

Example: pictogram for H. pylori Treatment (HOPE Dispensary of Greater Bridgeport, 2019)

Medication	Manana	Noche	
Clarithromycin 500 mg	1	1	Por 14 dias For 14 days
Amoxicillin 500 mg	2	2	Por 14 dias For 14 days
Omeprazole 20 mg	1	1	Por 14 dias For 14 days
Yogurt	1	1	Por 14 dias For 14 days

<u>Services Offered and Special Populations</u>

Besides medication reconciliation and dispensing, other services can be offered to complement those available at referral sources.

- Delivery to patient prior to discharge
- Follow-up phone call to patient
- Targeted MTM
- Therapeutic Outcomes monitoring (A1c, blood pressure, lipids, etc.)
- Medication and disease management through a <u>collaborative practice</u> agreement
- Device training
- Motivational training
- Smoking cessation

• Immunization evaluation (and administration if available)

Referring patients to their primary care provider for regular appointments may help to maintain compliance and assess health status. Issues of adherence (too much or too little), behavioral health, ineffectiveness of treatment or device utilization are all opportunities to alert and work with providers and, ideally, keep patients out of the hospital.

Charitable pharmacies often recognize patient needs for community services that may not be being met. Example: a diabetic patient without access to a stable food source. United Way 211 may offer a list of local community services including:

- Food banks and pantries
- Clothing
- Diapers
- Shelter/housing
- Transportation

NOVA Scripts Compass offers a search for free and reduced cost services like medical care, food, housing and more in your immediate area by zip code.

Establishing reciprocal referral relationships with other community providers is a win-win for patients and lists #4 on the <u>Top 10 Ways to Grow Your Charitable pharmacy</u>.

<u>Incarceration</u>

"For people discharged from prison, managing chronic illness is often a lower priority than finding housing, employment, and food." *Transitions Clinic Network: Challenges and Lessons In Primary Care For People Released From Prison*. In this study, approximately 40% of those released from incarceration reported being uninsured, though some were eligible. A referral relationship with correctional agencies (prisons and parole and probation officers), as well as recovery and other community service providers offers an opportunity to connect this population to medication access and a charitable pharmacy. See <u>Fund Development Decision Tree</u>.



Measurements/ Evaluation/Outcome

<u>Metrics</u>, evaluation and outcomes are essential to measuring and sharing your successes and opportunities, and demonstrating what is actually being done. They are useful to:

- 1. **Attract funding** If your idea is successful as determined by evaluating metrics, it will attract potential funders who want to support good ideas.
- 2. **Spread the vision** Great outcomes from established programs encourage new programs to start and existing programs to improve and expand.
- 3. **Deepen integration locally** Sharing outcomes with free clinics, Federally Qualified Health Centers (FQHCs), hospitals, departments of health and others help them understand the impact of your work.
- 4. **Credibility** Your credibility establishes trustworthiness for the charitable pharmacy and the services provided.

Success depends not only on the right "product": improved medication access to the uninsured and improving health outcomes. Being truly successful in achieving a charitable pharmacy mission includes ensuring a proper "supply chain": staff adequately trained in pharmacy skills and for the particular population being served. Equally important is a relationship of trust and education:

- Patients understand how and when to use medication, common adverse effects, and access to and provision of other resources that promote health and stability (food, housing, social services, etc.)
- Providers who act as referral sources to your pharmacy and are collaborators with the services they provide
- Community government, hospitals, clinics, churches, and all who can collaborate with your charitable pharmacy to build a healthier community

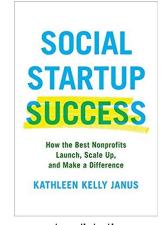
Gathering qualitative and quantitative data as you go establishes standards and allows for adapting processes frequently. Staffing can be shifted to areas of most demand. Services with the most impact, such as disease or service specific education (CHF, diabetes, MTM, device utilization, smoking cessation), may be expanded. Other services that have less impact or are a service that can be offered from another resource, for example types of PAPs, may be reduced or eliminated. Evaluation allows for funding to funnel to what has the greatest impact and encourages gains in funding for practices that show the positive impact. Measures of variability provide opportunities to train best practices across the supply chain.

Benchmarks for Community Charitable Pharmacy Testing

- Do you have an internal process for testing ideas? How will you know you are successful?
- ✓ Do you have strong relationships with your patients and regularly ask them for feedback on services offered and impact on their health and economic wellbeing?
- ✓ Do you solicit patients input when introducing new processes or teaching techniques?
- √ Have you developed a list of all stakeholders who can influence your work, directly or indirectly?
- ✓ Do you provide spaces in staff meetings, reports and/or fund meetings to have open conversations about failure?
- ✓ Do you have a mechanism to incorporate lessons learned from failure?
- ✓ Do you regularly assess programmatic priorities to ensure focusing on areas of greatest impact?
- ✓ Do you have a process to discontinue programs or activities when they are not having an expected impact?

Adapted from Social Startup Success

TIP: Funders may offer training to grantees on measures and models of measuring. Example: Fairfield County Community Foundation offers their grantees seminars on Results Based Accountability, the tool they use to measure organization impact.



After collecting data, measuring, and evaluating your charitable pharmacy and validating the impact it is having on patients and the community, communicate these results both internally – with staff and board members through meetings and dashboards- and externally – to supporters, funders, stakeholders via newsletter, webinar, input call, or presentation. Consider presenting your model or findings to professional organizations (local, state, national) to help other charity and ambulatory care pharmacies to better serve the uninsured. (See: Share Results below).

Dispensary of Hope Results

The Dispensary of Hope has a set of metrics that it asks partners to share which includes number of 30-day fills, number of unique patients, and total number of patient encounters. Health system outcomes may be measured as a percentage decrease in 30-day hospital readmissions which can be very difficult to measure from an outpatient pharmacy standpoint. These outcomes can be measured readily at neighboring hospitals that share patients with charitable pharmacies. To show continued measures of success, some useful metrics that can evaluate program utility include: emergency department utilization for preventable visits related to lack of primary care and potentially preventable disease complications, inpatient visits, length of stay, and cost savings associated with the reduction of these visits.

Evaluation of the cost-effectiveness or **return on investment** (ROI) of the Dispensary of Hope program at your pharmacy can be calculated by measuring the number of doses dispensed through the program and the cost savings of a subscription to the service. A 2015 study conducted by the Advisory Board Company on a study hospital in Nashville, TN showed an average cost savings of \$645K for a large hospital or an ROI of \$3:1. (See: <u>ROCI</u> and <u>Dispensary of Hope Advisory Board White Paper.</u>)

Results-Based Accountability

Results-Based Accountability (RBA) is a model used to organize the metrics you collect and demonstrate their impact. RBA is used by state governments, grant funders, and others as an accountability tool for their programs. Measures can be used to improve programs and make them more effective. Another metric tool is Theory of Change), which helps demonstrate causal links between program activities (providing medication access, MTM services, etc.) and the organization vision (fewer ED visits and hospitalizations, increased primary care visits and improved community health.) "It's about following the flow of activity to the ultimate impact. The activity itself is not enough to measure; it's the impact of that activity which makes the metric so meaningful." Natalie Bridgeman Fields, Accountability Counsel, Social Startup Success, pg. 63)

The three kinds of performance measures are "How much did we do?", "How well did we do it?", and "Is anyone better off?" Most of the measures you collect fall into one of these categories.

How Much Did We Do or How Many?

- Patients new, returning, demographics
- Prescriptions (Rxs) new, refills, synchronized refills
- PAPs total PAPs submitted, approved
- Interactions/interventions
- Glucometers/spacers dispensed
- Dollar value dispensed as prescriptions, PAPs, Safety Net

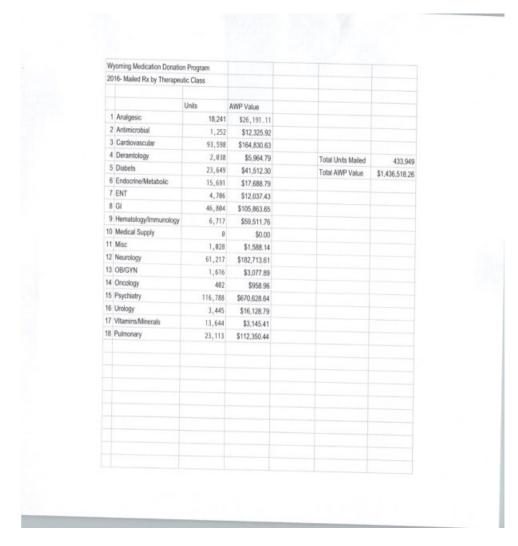
Example: **How Many**:

Dashboard of metrics regarding patients, prescriptions and dollar value for prescriptions

	Number of Patients Served		
	Patients with prescription filled		
	Patients with PAPs dispensed		
	Total patients served		
	Number of New Patients		
	New Pts NOT eligible for Assistance		
How Many	Prescriptions		
	Number of RX filled		
	Average # Prescriptions/day		
	Number of PAPs submitted		
	Value of Meds(Based on WAC)		
	HDGB Meds		
	Dispensed as PAP		
	Total Meds Value Dispensed		

HOPE Dispensary of Greater Bridgeport (HDGB)

Dashboard from Wyoming Medication Donation Program measuring the number of units (tablets) dispensed and the medication dollar value for 2016. The pharmacy is operational 30 hours per week. Staffing includes 1 full time pharmacist, 1 fill-in pharmacist as needed, and 3 pharmacy technicians.



Natasha Gallizzi, Pharm.D, Program Manager, Wyoming Medication Donation Program, 3.29.2018

How Well

How Well Did We Do It? (% of common measures or activity-specific measures). A "How Well" measure evaluates the degree to which a goal/population has been met. When possible compare data from your charitable pharmacy to a reference – from literature, hospital or clinic data, patients with Medicaid or insurance other insurance.

Goals established for measurement need SMART indicators:

Specific: clearly defined

Measurable: objective measurement- "How Many", "How Much"

Attainable/Achievable: goal is realistic

Relevant: there is a connection between the activity and the intended outcome

Time-Bound: there is a realistic timeframe to achieve the goal

Did we serve patients:

- From all the area clinics
- o Within the zip codes covered by our service area
- Within the income levels established
- Not eligible for other types of assistance
- o Using multi-lingual services for patients needing them
- Did we meet goals or best practices:
 - Average % of patient prescriptions filled on initial visit
 - Increase patient compliance as measured refill rate
 - Counselling impact on compliance of a complicated regimen
- Did we need: (workload measures)
 - o overtime
 - extra staff
 - o changes in software

TIP: Measuring impact is a critical focus of an organization.

The presentation of data helps to tell a great story well.

by

Example: **How Well**:

Dashboard of metrics regarding referral sources served and patients meeting income (FPL) requirements

	Referral Sources to HDGB
	Bridgeport Hosp/Clinic
	Optimus Care
	Private Practice
	SVMC Hosp/Clinic
How Well	Southwest Community Health
	Other
	Federal Poverty Level (FPL)
	FPL < 100%
	FPL 100-199%
	FPL 200%+

HOPE Dispensary of Greater Bridgeport (HDGB)

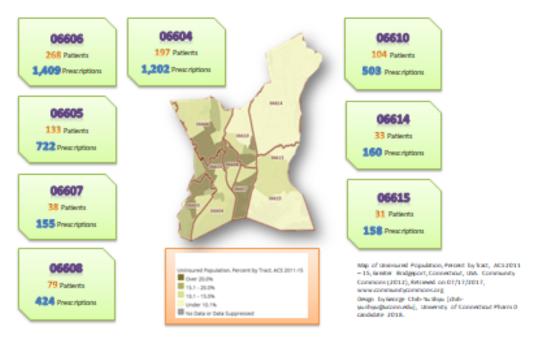
Tracking referral sources helps measure the effectiveness of marketing and partnerships with other stakeholders or partner safety-net organizations in our community. It also allows monitoring if re-education needs to occur to a particular referral site (internal or external).

Map of density of uninsured patients in area served with number of patients served and prescriptions filled by Zip Code. (See: Geo-mapping in <u>Local Factors for Community Charitable Pharmacy Implementation</u> and <u>Appendices\Marketing\Building a Map of Impact.docx</u>).

HOPE Dispensary of Greater Bridgeport Medication Dispense Distribution by Zip Code

January-June, 2017

72% of newly enrolled patients in FY17 were not eligible for insurance.



HOPE Dispensary of Greater Bridgeport 7.17

Is Anyone Better Off? or Benefit/Impact

Is Anyone Better Off? (skills, knowledge, attitude, behavior, circumstances) "Better Off" measures demonstrate the **benefit or impact** of services on the patient or the institution/community. Impact measurements may include intermediate outcomes or goals that lead to achieving the final vision of the charitable pharmacy. An intermediate goal could be improved or stable number of patient primary care visits and the vision or success goal is to decrease ED visits and hospitalizations.

Patients

- Measurable clinical outcomes if available (A1C, blood pressure, lipids, etc.)
- Regular use of maintenance meds in comparison to rescue meds (inhalers)
- Proper use of devices
- Interventions
- Renewed applications (patient perceived benefit of program)

- Patient dollars saved by coupons, vouchers, therapeutic interchanges
- A patient satisfaction survey can be a tool to measure patient's perceived impact of pharmacy services on their health, economic, or other areas of their life

Institutions or Community

- Cost avoidance
- Potential billable amounts
- Referrals
 - o ED visits, hospitalizations, primary care visits

Example: **Better Off**:

Dashboard of metrics regarding measures of benefit to patients and the community

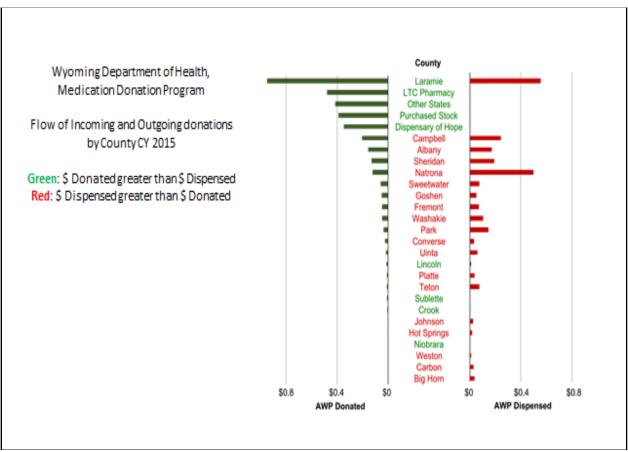
	Patient Impact
	Interventions and referrals
	Collaborative Practice
Better Off	Therapeutic Interchanges
beller Oll	Community Impact
	Cost Avoidance
	Potential Billable Amount
	Volunteer/Education Hours

HOPE Dispensary of Greater Bridgeport (HDGB)

Wyoming Medication Donation Program (WMDP) relies heavily on county donated medication as their source for dispensing. The formulary is supplemented by reclamation of meds from Long Term Care facilities and pharmacies (LTC), purchasing meds, and non-profit vendors. The following chart is used to encourage counties to donate medication samples and quantifies the value of medication dispensed to patients within the counties.

In RAB terms:

- How Many dollars of donated medications (value) by Wyoming counties versus amount spent to acquire meds from vendors and reclamation
- How Well is the WMDP serving the state of Wyoming and its counties based on the value of medication dispensed and number of counties being served
- How Well is each county contributing donated medication samples to WMDP
- Better Off: by county, dollar value of patients benefiting through medication access



Natasha Gallizzi, Pharm.D, Program Manager, Wyoming Medication Donation Program, 3.29.2018

WMDP reports a Return on Investment (ROI) to communities consistently above 5 (value of Rx's dispensed (AWP)/program cost). In 2015 the value was \$10.77. See Return on Community Investment (ROCI) Funding.

Drug Reclamation/Donation Performance Metrics

Performance metrics for drug donation and reclamation programs will vary greatly depending on:

- Donation source (long-term care, health system, or individuals)
- Types of medications accepted (prescription only, over the counter, or disease specific, durable medical supplies)
- Program model (centralized repository, logistics only, dispensing or wholesale)
- Staff structure (professional staff, volunteer based, or mixed)

The following metrics were gathered from a state drug donation program in lowa that utilizes a centralized repository for the state, collects medications from long term care facilities, clinics, pharmacies and individuals, and distributes medications to participating pharmacies and clinics utilizing a wholesale distribution pharmacy license. The table shows the shows the volume (one tablet = one unit) and value of incoming medications that were donated, inspected and accepted into the program, the volume and value of medications that were distributed to participating clinics and pharmacies, and the professional staff utilized each year to achieve the results.

	Staffing (Full Time Equivalent)				Produ	etivity				
Year	Pharmacist	CPhT	Admin	Program / Outreach	Student / Part time	Driver	Units Donated	Donated Value	Units Shipped	Shipped Value
1	1.50	1.50	1.00		0.00	0.05	768,311	\$ 786,400	492,686	\$ 475,592
2	1.25	1.50	1.00		0.25	0.05	890,986	\$ 1,316,052	629,573	\$ 935,698
3	1.00	2.00	1.00		0.25	0.08	1,106,003	\$ 1,492,565	850,559	\$ 1,234,450
4	1.00	2.00	1.00		0.25	0.08	1,166,447	\$ 1,634,593	931,431	\$ 1,430,735
5	1.00	2.00	1.00		0.50	0.10	1,075,950	\$ 1,924,488	1,095,934	\$ 1,877,496
6	1.30	2.00	1.00		0.50	0.12	1,230,200	\$ 2,593,314	1,147,464	\$ 2,477,716
7	1.30	2.00	0.50	1.00	0.25	0.12	1,395,640	\$ 2,605,366	1,105,153	\$ 2,319,464
8	1.30	2.00	0.50	1.00	0.25	0.15	1,199,643	\$ 2,545,372	1,124,404	\$ 2,418,984
9	1.50	2.00	0.50	1.00	0.50	0.15	1,500,749	\$ 3,807,618	1,417,630	\$ 3,478,690
10	1.50	2.00	0.50	1.00	0.50	0.15	1,271,790	\$ 5,132,757	1,318,373	\$ 4,909,595

SafeNetRx.org April, 2018

Drug donation programs are complex operations. The operating procedures, program design, staffing structure, and services offered may require significant adjustment in the initial years of operation. The program will become more efficient over time as various components of the program are evaluated and refined every year.

These measures are used internally and externally to shareholders to demonstrate growth, efficiency, and value of outreach (<u>footprint</u>).

TIP: Be creative with indicators of progress.

SIRUM measures not only how many pounds of medication they redistribute but also the reduction of medication waste they prevent.

Data Collection

The key to data collection is keeping it as simple as possible.

Data collection that fits with normal workflow	Satisfaction surveyLimit time frameUtilize technology if possible
Utilize residents, students and volunteers	 Students: pharmacy, healthcare, foreign language, business, pastoral care Volunteers: retirees, service hours for professional programs
Adapt techniques from literature	 Trial what has worked in literature into present setting Provides comparison when presenting data

Many pharmacy **software products** are adaptable and/or vendors will work with you to create reports to demonstrate your metrics. (See Pharmacy Management Systems; Dispensary of Hope Software Webinar; Resources.) Software products are also available to manage and track volunteers.

Implementation of performance metrics to assess pharmacists' activities in ambulatory care clinics presents measurable pharmacist functions that impact patient outcomes and mechanisms used to document these services.

Example of software (<u>RxAssist Plus</u>) method for collecting clinical intervention data with assigned dollar value:

TIP: Is there something you do exceptionally well or is unusual? Find a way to measure it and promote your excellence. Example: student volunteers conducted a patient survey but also helped hugely with filing. The volume of files was correlated to a case of paper to show 500 pounds of charts managed.

Intervention	Potential CMS Billable Value	Estimated Cost Avoidance
Add Medication	\$20	\$92.95
Adverse Drug Event	\$20	\$276.12
Allergy Detect/Clarification	\$20	\$187.37
Drug Information or Therapeutic Consult	\$20	\$47.89
Discontinue Med	\$20	\$80.24
Dosage Form Change	\$20	\$63.88
Dose Change	\$20	\$82.25
Med Reconciliation/ Transition of Care	\$20	\$30.12
Medication Change	\$20	\$40.88
Patient Education	\$10	\$35.21

(Values referenced from <u>Outcomes MTM</u> and <u>Implementation of performance metrics to assess pharmacists' activities in ambulatory care clinics)</u>

Schools of pharmacy and other programs, such as business management and statistics, are a great resource for evaluating outcomes. The schools need to conduct research and publish, providing a win-win scenario for the charitable pharmacy and a school of pharmacy to partner.

Outside Experts may be recruited or found at Volunteer Match and Taproot Foundation

A satisfaction survey is usually subjective but demonstrates the patient perspective which can influence compliance and perhaps other outcomes.

- Questions can reflect objective data, e.g. over previous 6-12 months number of visits to primary care provider, visits to emergency department, hospitalizations.
- Subjective questions demonstrate patient satisfaction with services provided, perceived health, economic or other benefits to using the charitable pharmacy, and can act as an education point to reveal options to services offered. See examples in satisfaction survey and Implementation of performance metrics to assess pharmacists' activities in ambulatory care clinics

Example of Survey Results Conducted by Fairfield University Students for HOPE Dispensary of Greater

Bridgeport



World map of those countries represented by **HOPE** population

Students don't always realize there are poor in the United States or that immigrants come from across the globe.

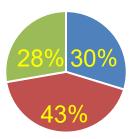
"Before this class and our time at HOPE. I did not know about the population in the US that does not have health insurance or access to health services."

Fairfield University/HOPE Dispensary Experiential Service Learning Program Fall Semester 2017, Dr. Michelle Farrell, Dr. Jessica Planas, Christine Toni, BS Pharm,

How would you get your medicine if you did not have access to HOPE?

Results from a patient survey: 43% of patients interviewed would not get their medicine and another 30% did not know what they would do.

Fall 2017



Try via other pharmacy Would not get medicine Do Not Know

December 13, 2017, Fairfield University.

Development of a community-based, multi-disciplinary research project

Determine focus of study: What will the study address? How is this different from previous research, in the literature or your organization?

Establish concrete goal(s) for the study: What is trying to be accomplished? (not the outcome, but what will be measured.)

Three factors for a successful research project include recruiting and sustaining a qualified research workgroup, addressing financial needs, and developing a solid research plan.

Develop a research workgroup based on:

- What is the goal of the research?
- What systems/organizations/providers are impacted by this project? Include prescribers, departments of health, hospitals and/or clinics, healthcare providers, academia, community organizations, other pharmacies, transportation providers, community leaders, board members, etc.
- Workgroup should include members familiar with the subject being addressed, including front-line workers, administrators, providers, volunteers, students and any others involved with the processes.
- Have an executive sponsor or principal investigator who takes responsibility for the study.

Inclusion in research workgroup

- Contribution of skills needed to complete the study. Interest in goal, statistics, administrative, professional
- Review curricula vitae, resumes and biographies of potential interested members
- Availability and willingness to dedicate time for conducting research. Develop an approximate ask time for specific tasks for study – hours/week, number of weeks. Will time be voluntary or paid, available as regular or additional staffing hours?

Responsibilities of workgroup members

- Establishing study design and goals; consider use of Stages of Change Model
- Identify benefits and risks to participants and community
- Investigate need of Investigational Review Board (IRB) (usually through hospital or academic institution) See Determining if IRB approval is needed

Develop a research team

This is the team who will be conducting the research and the ongoing analysis. Key will be determining those within the organization (volunteers, staff, students) with the appropriate skills and abilities to conduct and/or support the study. See <u>Inclusion in research workgroup</u>

Training those conducting research:

 Health Insurance Portability and Accountability Act (HIPAA) including signed agreement with organization(s) involved

- National Institute of Health (NIH) <u>Protection of Human Subjects Education</u> Note: tutorials are no longer updated as of September 2018, but site includes informatics defining Human Subject Research and tutorial prior to September 2018 with quiz.
- If you think your study does NOT constitute research involving human subjects, consult Comparison: Characteristics of Human Subject Research Versus Other Project Types
- Develop training materials that include clear procedures and processes (as in <u>Standard Operating Procedures</u>) to ensure consistency of tasks by all team members.
 Competency with performing tasks should be measured.
- A check list verifying training and competency is beneficial for analysis, liability and stakeholders. Materials should be signed and dated by both researcher and trainee to be kept with research materials.

Develop a Research Plan

- This is a business plan for the project
- Create a budget based on direct (e.g. office and medical supplies) and indirect costs (space, utilities, technology, staff compensation).
- Other factors besides financial include legal, Investigational Review Board (IRB) processes, facility or designated space requirements, and time limits and expenditures.

Steps for Research Project

Not required to be completed in sequential order, but all items should be completed prior to implementation of project.

- 1. <u>Define focus and goal of project</u>. Can your research provide evidence to change practice within the scope of practice (Evidence Based)? Is there a pattern of evidence emerging from the organization's practice that may not be described in current literature? Is there a gap in current literature that this research may fill?
- 2. Develop a research statement based on the question the study will address. Statement should be specific, not be too general, too vague, or too ambitious. Example: Impact of pharmacist-led Medication Therapy Management in collaboration with healthcare providers on patient reported health outcomes.
- 3. Review relevant literature. Does project meet a gap? Are there methodologies that could be used for this project?
- 4. Develop <u>study design</u>: randomized or non-randomized; control or no-control; double blinded.
- 5. Develop subject participation criteria (age, disease state, length or severity of illness, literacy, income, language, other).
- 6. Establish <u>ethics of research</u>. Participants should not be coerced to participate. Consent is obtained. Written or verbal information is in language and literacy level appropriate to participants. Risks are minimized and there is a potential for benefits (risk benefit ratio). HIPAA permission is obtained, stored and compliance is maintained.
- 7. Determine <u>methods and data to be collected</u> From this, design policies and procedures for research team.
- 8. Construct research proposal based on <u>Research Plan</u>. This is used for community and organization support, collaboration and funding.
- 9. Receive IRB approval if needed.

Project Implementation

- Those conducting research are trained in their roles, methodologies, data to be collected, etc. Methods should be clear, repeatable and consistent by all researchers.
- Data should be collected clearly and accurately, utilizing technology whenever possible.
- As well as clinical data, monitor: subject recruitment process, time commitments, followup, and dropout rate.
- Pilot study may be used evaluate processes, collection of data relevant to project, time commitment, and quality and quantity of data
- Team meets frequently to evaluate processes See <u>Improving Care Delivery through</u> Lean for a model of implementation.
- Utilize <u>Plan, Do, Study, Act</u> (PDSA) to refine processes, such as setting upper limits of participants/team member, reasons for non-participation or return for follow-up, etc. Review study documentation for accuracy, streamlining, and compliance with local health officials, external sponsors, ethics committees or academic institutions.
- Research Workgroup oversees project.

Analysis and Interpretation

- As much as possible, determine data points prior to beginning study or as soon as points become apparent to ensure necessary quantity and quality of data.
- Minimum of 50 study participants are required to achieve statistical significance
- Clear and accurate interpretation of data can be done by a statistician or using medical statistics software.
- Analysis is a time-consuming process; allow time for this.

Share Results

Sharing results that establish social justice requires a two-pronged approach. First, to establish meeting the social need: as a charitable pharmacy improves medication access for the uninsured. The second is education to others, including stakeholders and funders but also the next generation, professional colleagues, and the community.

Who might want to see the results?

- Stakeholders: sponsors, funders, community, healthcare providers, patients (See: <u>Stakeholders and Funders</u> for use of sharing your results with stakeholders).
 - Methods such as dashboard, PowerPoint, or newsletter work well to share results with internal stakeholders or external stakeholders who are familiar with the work.
- Professional Organizations: local, state, national, CharityPharmacy.org
 - For professional education, use of an oral presentation, PowerPoint, webinar, poster, or published article is recommended.

The pharmacy professional organizations, American Society of Health-Systems Pharmacists (ASHP) and American Pharmacists Association (APhA), offer guidelines to create a professional poster presentation. If you consider a formal research project, clinical research involving patients requires approval by an institutional review board (IRB) and, if appropriate, informed consent from patients. Example abstracts are provided.

For example, HOPE Dispensary offers some sample topics that do not require IRB review:

- Establishing and evaluating a charitable pharmacy collaborative practice agreement
- An overview of charitable pharmacy for urgent care and emergency department physicians
- Evaluation of verbal counseling, written directions, and a visual aid to affect adherence in a culturally and linguistically diverse urban population
- Implementation of a Medication Therapy Management intervention in ambulatory care settings: experiences and lessons learned
- Transitions of care
- Utilization of therapeutic interchange to improve access to medication in a low income uninsured population demonstrating patient dollar savings

Educational webinars offer education to the participants and can be saved for referral. Topics presented by Dispensary of Hope include: <u>Dispensary of Hope Link to Webinars</u>

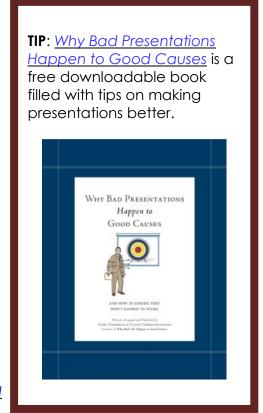
- Diabetic Supply Resources Overview
- Dispensary of Hope Formulary Development and Utilization
- Pharmacy Software Webinar
- Utilizing Outcomes to Help Fund Development

Topics presented by CharityPharmay.org members in a Communities Joined in Action webinar series include:

- <u>Charitable pharmacies Volunteer and Student</u> Staffing
- Charitable pharmacies Evaluations and Outcomes

Educational documents created by Dispensary of Hope include:

- <u>Dispensary of Hope Advancing Medication Access</u>
 Tool
- <u>Dispensary of Hope Marketing to Internal and External</u> <u>Audiences</u>





Marketing and Community Outreach

Community outreach is a great way to reach to more patients within the community, county, or state. Partnerships with other healthcare facilities, whether clinics with hospitals, pharmacies with clinics, or other combinations can help to promote a charitable pharmacy allowing more patients to learn about the services available to them. Promoting the program through community outreach can help to spread the word, serve more patients, and generate a better return on investment. Healthcare doesn't stop at the four walls of the hospital, clinic, or pharmacy; it extends into homes, schools, and neighborhoods.

Where to start

- Many communities have coalitions in place to address issues such as improving healthcare. Develop contacts and create a planning committee of key stakeholders from the community to develop a coordinated plan to serve the uninsured, including medication access. Connect with others to help meet the common goal of improving the community's health.
- Partner with community facilities with different types of services to a vulnerable population, sharing skills and/or resources. For example, some hospital sites fill prescriptions and deliver them to nearby safety-net clinic patients. See Appendices\Marketing\Partnerships Framework for working together.pdf.
 - o Partner with other organizations within the community to help form a network of services to care for the indigent patients. Think through the social determinants of health and how organizations in your community fill needs that you do not.

- Potential partners may include: FQHCs, other safety-net providers, the Health Department, other hospitals, homeless shelters, thrift shops, food pantries, etc.
- ➤ Decide what you want to accomplish with your outreach efforts and set a SMART goal (Specific, Measurable, Achievable, Relevant, Time-bound) such as, "we will recruit 50 new patients this quarter."
- ➤ Partner with your organization's communications team or community partners to help create internal and external marketing pieces to tell others about the program. Sites for marketing include:

Internal to a Healthcare System

- Clinics and medical providers
- Medical Office Building providers (physician practices)
- Hospitalists and providers involved with discharges, ED providers
- Hospital Associates care management, financial counselors, ED staff, nursing, pharmacists, patient navigators, and any staff involved with discharging patients

External to a Healthcare System

- Charitable care clinics/hospitals
- Behavioral Health providers
- Medical and Dental providers
- Shelters & Recovery programs
- Nursing homes and Assisting Living Facilities
- Local pharmacies and pharmacy organizations
- Health Department
- Medical Mission at Home

Social and work settings

- Churches and other places of worship
- Community resource providers
 - o Soup kitchens, food pantries, etc.
- Thrift shops and grocery stores
- Civic organizations
- Kitchens of restaurants, landscaping businesses
- Community groups health and safety net organizations in the community or state
- > Share your program with the local newspaper, television stations, community newsletters, and social networking sites to build awareness in the community about the program to allow for more low-income, uninsured patients to learn of the access opportunity available to them.
 - For example, a site that opened in September 2017 near a rural hospital filled 115 prescriptions within the first 30 days of opening due to successful marketing of the program through the local newspaper and other methods.
 - A feature story in the local newspaper or on the local radio or television news is very effective and is free! Research health care issues in your state or services area and relate the research to how your organization is making a difference.
 - "Half of our referrals come from current patients or doctor's offices"

TIP: Where does the population served congregate, receive healthcare, work, make purchases? What media tools do they use? What languages do they use to converse? How can your marketing reach them?

Communication Systems

- Local newspaper ad and radio spots with Google tracking phone number to monitor success of advertisement
- <u>United Way's Info-211</u> system

- Community Newsletters and Church Bulletins
- Open House and Ribbon Cutting

 invite the media
- Social Media
- Internet Links

Tools

- Posters placed in patient elevators at hospitals and clinics, on buses, at thrift shops
- Brochures provided to clinics and placed in patient waiting areas in the hospital, soup kitchens, food pantries
- Informational meetings with local clinics
- Referrals at Medical Missions at Home (provide applications) if held in your community

- Updated information with <u>United</u> <u>Way's Info-211</u> referral system
- Include language(s) of population being served
- Customized brochures for some clinics with specific needs (behavioral health, cardiac, respiratory, diabetes, etc.) with transportation options in directions to pharmacy,
- <u>Internet Links</u> on other provider sites

See Marketing Appendix for examples of fliers, posters, etc.

What to include in materials:

Direct to Patients:

- Definitions:
 - Name of charitable pharmacy and purpose
 - Population served (uninsured, underinsured, income requirements, location restrictions, other)
- Eligibility requirements and what to bring to initial visit
- Pharmacy location(s), directions, hours of service (closed for lunch, holidays?)
- Contact information: phone, fax, email, social media, website
- Translation if population does not read English
- Services: interpreter services provided, no appointment necessary, or call for an appointment, fees for Safety-Net meds

Direct to Providers:

- Above patient information plus:
- Formulary information:
 - What is available
 - o What is not available (control meds, birth control, immunizations, etc.)
 - Meds that are specific for that type of practice
 - How to access formulary (on website, faxed to provider)
- How providers can help: direct donations, enroll for insulin samples to donate to pharmacy

• Check with individual state regulations regarding types of donations your pharmacy can receive and from whom. (See: Appendices\Regulatory\Board of Pharmacy state regulations 1.2017.xlsx)

Example:

How Can Your Practice Help?

- We need practices that are willing to enroll to receive free insulin samples to donate to our charitable pharmacy – insulin is one medicines that is in great demand.
- Donate to the HOPE Dispensary. Many of the medications we dispense, particularly those for behavioral health, are not available except through purchase. Costs of generics continue to rise and many have been removed from the \$4 programs. A gift of \$100 provides approximately \$600 worth of medication to patients.

HOPE Dispensary of Greater Bridgeport

Directions

When designing a map to reach the charitable pharmacy, points to consider:

- Can your population read a map?
- Do directions need to be in more than English?
- Include driving and public transportation directions from a specific hospital or clinic if helpful
- Include bus or public transportation routes and directions from stop to pharmacy

Example from Saint Thomas Health:

MTA BUS DIRECTIONS TO PLAZA PHARMACY

From Siloam Family Health Center, walk north to Kirkwood Ave & Franklin PK - East Bound.

Take bus 8 towards downtown to 8th Ave S & Broadway Ave - North Bound.

Walk to 8th Ave S & Broadway Ave - South Bound.

Take bus 5 towards Bellevue. Get off at Harding
Pike & Bosley Springs Rd - West Bound.

Walk to Saint Thomas West Hospital.

DRIVING DIRECTIONS TO PLAZA PHARMACY Head north on Gale Ln. toward Franklin Pike. Turn right onto Franklin Pike. Take the Woodmont Blvd. W. exit. Merge onto Woodmont Blvd. Turn right onto Harding Pike. Turn left at the light just passed Woodlawn Dr. Take an immediate left and park in the garage on your right directly below the Medical Plaza East. Park on any level of the garage and take the elevators to the 2nd floor. We are located next to the Food Court on the 2nd floor of the Medical Plaza West. Hours of Operation: Monday - Friday | 8AM - 4PM

<u>Saint Thomas Health's Best Practices and Lessons Learned from their Dispensary of Hope program.</u> Jennifer Belue, Social Worker Ashley Bennett, Outpatient Pharmacy Manager David Neu, Executive Director of Pharmacy April 27, 2017

Internet Accessibility

For many of the uninsured/underinsured, their phone is their only computer. Being internet linked to other resources patients use makes a charitable pharmacy easier to find.

Internet links to a charitable pharmacy could include:

- Local hospitals
- Clinics and FQHCs
- Department of Health
- Safety Net providers: food pantries, soup kitchens, shelters, recovery centers, social service providers (diapers, behavioral health, others), thrift shops, and entities who serve immigrants

Track the impact of marketing

When possible, develop a metric to measure the impact of the marketing tool.

- Google tracking phone number or visitors to website
- Monthly metrics (number of Rx, new patients, patient encounters, etc.) prior to and after advertising
- Referral sources for new patients
 - From a specific location or provider
 - o Where did you hear about pharmacy?
 - Helps measure the effectiveness of marketing and partnerships with other stakeholders or partner safety-net organizations in community
 - Allows monitoring if re-education needs to occur to a particular referral site (internal or external). See <u>Results-Based Accountability</u> "How Well did we do it?"

Stakeholders and Funders

Marketing your charitable pharmacy is simply informing your potential and current donors or key stakeholders about their investment or potential investment in your organization. Encourage your philanthropic team to see themselves as partners working for the same goal of serving the uninsured and improving health outcomes as opposed to just donors of funds. When developing your plan, share outcome measurements that reflect your mission (See: Results-Based Accountability). Include a timeline and set financial goals which include income and expenses. What is your total budget and what are your marketing and fundraising goals? Ozanam Charitable pharmacy, serving for more than 20 years, offers 15 steps that will get you on the path to marketing ideas and approaches that could make a significant difference in reaching the goals of your organization.

- 1. Research similar non-profit organizations and learn from successes.
- 2. Understand your mission and develop a clear and concise mission message.
- 3. Define who are you wanting to reach with your message or mission. What is your target audience? (hospitals, independent pharmacies, pharmaceutical companies, etc.)
- 4. Develop a strategy and create a plan to determine the desired outcome of your marketing efforts. Examples based on your fiscal year develop a 12-month calendar of marketing goals and projected outcomes.
- 5. Once you have determined your message and marketing plan develop brochures and other <u>marketing materials</u> that describe the benefits, services, donation opportunities and values that represent your organization.
- 6. Develop a <u>social media marketing strategy</u>. <u>Social media</u> such as <u>Twitter and Facebook</u> can provide an avenue for reaching a large number of people interested in your organization and do it in an inexpensive way. Manage your social media marketing plan by developing the number of post per week on your chosen platform or platforms. Tool such as <u>Hootsuite</u> can help you manage all your social media accounts from one central website.
- 7. Create and maintain a professional <u>internet marketing presence</u> by developing a website that moves your message forward and represents who you are as a charitable pharmacy. You can use your website as a portal for sharing important information such as the history of your organization, breaking news items, monthly newsletters, upcoming events and as a way to create a sense of community. Use your Facebook platform to drive your potential donors to your website. Use your website to increase online donations. Some examples of donation platforms include <u>Just Give</u>, <u>Donate Now</u>, and <u>Paypal</u>. Remember, all platforms have an administrative fee. Research the giving platform that works for you.
- 8. Develop and maintain a current and prospective donor database. Use your databases for special mailings, follow-up phone calls, event invitations, to develop alliances, for research profiling and <u>market segmentation</u>. There are many donor platforms to use such as <u>Frontstream</u>, <u>Donor Perfect</u> and <u>Donorquest</u>. Research the donor software that will work for you. These donor

- management databases can be expensive. Develop an account with **<u>Techsoup</u>** to find reduced or free donor management tools.
- 9. Use e newsletters and quarterly printed newsletters to showcase the objectives of your organization as well as successes. Insert a donation envelope in each printed newsletter and a <u>Donate Now</u> on each e newsletter. You'll also want to showcase patients, volunteers, board members, staff, students, programs and specials projects.
- 10. Develop and implement at least four direct appeals to your current donor base by creating a mailer that tells your story. This would be a good time to write about one of you patients and how your mission has assisted them. Have at least one acquisition mailer to acquire new donors in your donor base. You may have to purchase a mailing list for this direct ask. Research proven mailing houses for accurate mailing list based on your needs.
- 11. Create an e-fundraising like <u>GoFundme</u>, <u>Amazon Smiles</u> and <u>CaringCent.com</u> platform. You can use these platforms to raise money from e commerce.
- 12. Always be on the lookout for opportunities to collaborate with other nonprofits, government, media, corporations, academia and community leaders. This step alone will develop your circle of support.
- 13. Write grants for programs and general operations. Research community foundations, corporate giving, United Way, government contracts and grant research organizations like <u>Grant Station</u>. Grant Station is a national research grant opportunity tool. There is a fee to join Grant Station and it varies. Check <u>Techsoup</u> for annual discounts on Grant Station. Another great resource to look at is the <u>Foundation Center</u> which maintains the most comprehensive database on U.S. and, increasingly, global grantmakers and their grants (See: <u>National Resources</u>). Develop a timeline and set realistic goals.
- 14. Develop at least one primary fundraising event and a secondary. Fundraising event are great sources of unrestricted income. Grants are restricted in many cases. Develop a fundraiser that will work in your community. Do something different and set a budget for projected expenses and income. Some development pros like to develop detailed timelines that list not only big picture goals, but also all of the small goals that go into making that big goal a reality. For example, instead of just listing that we're having an event, also list entertainment needs, when venue decisions need to be made, when sponsors will be solicited, when invitations will go out, etc.
- 15. Develop a major gift plan. The definition of what constitutes a **major gift** differs from organization to organization. A small nonprofit might deem a **major gift** as anything over \$1,000 while a large, established organization might call \$50,000 a **major gift**. Outside of planned giving, **major gifts** are the largest donations that a nonprofit receives. Major gifts include donations from stocks, real estate, and wills. Often this donation is stimulated by a board member or friend of the organization. It may also include donations from trust and foundations. It takes time to cultivate this type of gift.

Wyoming Medication Donation Program uses the <u>Mail Chimp</u> e-newsletter service. It is easy to use and free. :) It is used for specific communication with our reclamation donation and dispensing sites as well as general communication like a newsletter or

special notice. Our Wyoming Department of Health yearly invites each program to do a Health Stat report to division leadership providing program mission, description, budget, ROI, outcomes, efficiencies, etc. Periodically, the report may be accompanied by a presentation. The report is a useful document when educating legislators and others to explain the program and demonstrate the outcomes. This process enabled program expansion funding for 2018. (See Appendices\Metrics\Dashboards & Reports\WMDP Performance_Template.doc)

What to include in a Newsletter

A newsletter can be directed to referral sources, donors and potential donors, partners in the community and beyond. When preparing a newsletter determine the audiences then "speak their language". Languages include Heart, Financial, Healthcare Outcomes and Plumbing or improvement in processes (See: Speaking the Language as you Market your Fund Development Need). Newsletters may be printed and mailed or distributed via or email. Some resources for developing a newsletter are listed in Resources and examples are in Appendices\Marketing\Fliers and Newsletters.

Items may include:

- New: new staff, new outreach, new partners, new milestones, new outcome measures
- "In the News": recognitions, publications, awards, articles
- Ways to help: donation button, volunteer button, website button
- Events and fundraisers
- Thank you: sponsors, donors, partners, volunteers, students
- Photos: get a <u>media release</u> signature
- Financial Statement (usually annually): include "<u>How your dollars help</u>", return on investment (Example: Every \$1 donated provides \$6 in medication)
- Sponsors and board Members
- Pharmacy contact information



Funding and Sustainability

After opening the doors to your community charitable pharmacy, mechanisms need to be put in place to ensure your continued involvement for the health of the patients and community you serve. Develop an informed, dedicated, and dynamic governance board. Plan for implementation of growth and sustainable funding. Build relationships and collaborations with healthcare providers and others who are mission-minded within the community and beyond. Be a voice for those you serve and the impact of the service.

Governance Board

A "nonprofit corporation" is a legal term. This status is given by state and federal government to a corporation that fits a specific set of criteria. When credited with the term "nonprofit corporation", the company then exists for the benefit of, and is theoretically owned by, society. The community owns the nonprofit company, and the company exists to serve the community. Charitable pharmacies are always organized as a nonprofit corporation.

But companies require leadership if they are to be successful. Standing in the place of the community's ownership of a nonprofit is an acting governing board. Therefore, the governing board is the legal "caretaker" of nonprofits, serving on behalf of its owner, society. A governing board has the responsibility to manage a nonprofit corporation, its vision, its daily work, its finances and the completion of its outcomes. Typically, members of a nonprofit board are volunteers and not paid for their volunteer services.

Instead, they meet, decide, serve, and operate as community volunteers, for the benefit of the community, responsible to the community.

A governing board works with the staff to achieve the mission of a community charitable pharmacy. While the Board of Directors, or Governance Board, is the final authority over a nonprofit corporation, the board does delegate a specific set of activities to the staff and the staff relies on the board for its critical leadership role. That delegation can be summarized as the board behaving as the legislative, judicial and strategy role of a company (setting policy, establishing vision and creating clarity when there is disagreement). In turn, the staff should behave as the executive branch, executing the work of the company.

A governing board is responsible for all activities of a nonprofit corporation; however a few roles stand out with particular focus for board members as the primary role of a board of directors:

- Mission It is the role of the governance board to make sure that the community charitable pharmacy is working toward and achieving its mission, and doing so in a way that ensures efficient stewardship of resources. That means setting goals, reviewing progress on goals, and holding the community charitable pharmacy accountable to the work. The mission of the organization is a legal statement, with the nonprofit status awarded in part due to that mission. The board protects the organization and serves society by working toward the completion of that mission.
- **Compliance** Good organizations keep their promises and do the work in the right way. It is the role of the board to make sure that the community charitable pharmacy is behaving in a way that is ethical, that all staff members are working under the authority, and within the ethical guidelines, of the organization. This is a critical role for all healthcare organizations, especially those that deal with expensive medications, valuable patient medical histories, and large sums of vendor and funder resources.
- Policy It is the role of a governance board to establish and then memorialize
 policy for a community charitable pharmacy. Policies can be organized as
 formal statements, such as a Standard Operating Procedure or a staffing policy.
 But policy can also refer to best practice or mundane management decisions,
 such as the practice of holding a monthly board meeting on a certain recurring
 date and time. Sound policy creates safety, efficiency, and risk reduction for a
 community charitable pharmacy.
- Relationship network manager Community charitable pharmacies require a
 massive network to run. Vendors, suppliers, patients, donors, volunteers a
 typical community charitable pharmacy requires many hundreds of contributors
 if it is to be successful. It is the role of the board of directors to cultivate
 relationships with the community, and to honor each member of the network in
 the appropriate way. Tools used in network management include annual
 reports, on-time IRS filings, board minutes, events to celebrate successes, and
 outreach. The board of directors operate as ambassadors to the community,
 bringing in resources and maintaining connection.
- **Funding** It is the role of the board of directors to ensure that the funding for the enterprise is available for the work to happen. Often staff members are hired to assist with the work of fund development (e.g. grant writers, event planners,

development coordinators). However, it is the responsibility of the board of directors to plan for the cost of the work, and to make sure there are enough dollars to do the work. And if there are not enough dollars, it is the responsibility of the board to address closure, mergers and dissolution.

- **Volunteers** While it is the volunteer role of the board of directors to guide a community charitable pharmacy, the board of directors also serves as a volunteer base of support, assisting the company in day to day operations, and filling gaps where the staff cannot.
- **Strategy** Finally, it is the role of the governing board to identify strategic direction and to move toward that strategy in a way that is plausible and efficient. Key to the success of a community charitable pharmacy is the ability of a board of directors to identify strategy and then work to accomplish that strategy.

Accepting a role on a board of directors for a community charitable pharmacy has consequence. Not only are all the roles listed above requirements for a board member as they serve in their collective leadership capacity. Board members also have requirements for their individual behavior, which is: to act in a way that has fidelity with the role of caretaker of a community-owed effort. Outlined by the National Council of Nonprofits, board membership includes the following individual duties:

- **Duty of Care:** Take care of the nonprofit by ensuring prudent use of all assets, including facility, people, and good will.
- Duty of Loyalty: Ensure that the nonprofit's activities and transactions are, first and
 foremost, advancing its mission. Recognize and disclose conflicts of interest.
 Make decisions that are in the best interest of the nonprofit corporation, not in
 the best interest of the individual board member (or any other individual or forprofit entity).
- **Duty of Obedience:** Ensure that the nonprofit obeys applicable laws and regulations, follows its own bylaws, and that the nonprofit adheres to its stated corporate purposes/mission.

Creating a Governing Board:

Building a board of directors is as much art as science. Most nonprofits create their board over the course of several years, concurrently building strong relationships while they grow the capacity for effective board management. The goal is to quickly have in place a small community of capable leaders (7 to 19 members, depending on the need of the community charitable pharmacy) who are a joy to work with, and who effectively adjudicate their responsibilities as a board.

Building a board of directors is difficult work. It requires a great number of responsible and ambassadorial leaders to come together for a clear goal, and to be ready to compromise their own interests for the benefit of the community. While creating a board is complex, a key success factor is to have in place a leader who is adept at balancing vision for the creation of the effort, with effective people skills. The champion of the board will be responsible not only for bringing a group of like-minded leaders

together, but also to create the kind of vision focus and behavioral norms for the group to be effective as a collaborative body. Some key roles include:

- Board members as non-experts Board members have a role. Place board members who can fulfill that role. Do not be bashful to insist that board members are committed to the work, follow through on assignments, and are pleasant to work with. Board leadership means working with people over the course of months and years in complex projects. Emotional maturity, reasonableness, and communication skills are required of board members if they are to complete such difficult work in a way that is satisfying to the culture of the group. A board member does not need to be expert in the details of pharmacy management. However, they should be a learner a learner of the organization, a good listener when working with others, and a leader humble enough to ask questions when they do not understand detail. A learner is a person who can behave in a way that promotes excellence, even when they are not excellent at such a specific topic as pharmacy operations.
- Board members as experts It is standard practice for board members to behave as topic experts. Since the board of directors operates in a role as experts, the placement of high quality leadership onto the governing board is a top concern. Specific valuable assistance for a community charitable pharmacy includes filling roles such as: attorneys, financial experts, CPAs, human resources and management experts, lobbyists, and industry leaders. Finally, consider placing leaders who are skilled in the topics important to a pharmacy, such as formulary design, pharmacy operations, and business management.

When building a board of directors for a community charitable pharmacy, consider using the process of filling the officer positions as an opportunity to empower colaborers of specific skill and integrity into places of influence. A specific concern in creating a board of directors is to place the best board officers in their respective roles of Chair, Secretary, and Treasurer. Some suggestions for each include:

• Board Chair – The role of the board chair is specifically to serve the needs of the board. This means that the Chair is responsible to cultivate the effectiveness of the board of directors, and to manage decision making. Rather than being the sole driver of strategy and action, a board chair's role is more defined as being the ambassador among the board, and the leader of board effectiveness in creating and defining strategy. Some keys for the board chair roles include: setting and chairing meetings, surfacing the values and vision within the board, setting the agenda that will identify strategy, and reviewing and addressing the behavior of the CEO and other board members.

In a statement, the board chair is responsible for the board's effectiveness, as the CEO is responsible for the staff's effectiveness. Therefore, selection of the board chair should consider questions like: Is this person responsive and able to fulfill the duties of the board chair? Does this person have the necessary balance between mediation and management, with the skills to create bridges to others, while moving the group forward? Is this person capable of taking responsibility

for themselves and that of the board? Is this person pleasant and easy to work with?

Secretary – The role of the secretary is to help create, and then safeguard, the decisions of the board and to be responsible for all filings required of a board of directors. More than taking minutes, the secretary can be helpful to the board chair and the CEO in moving a board to definitive, actionable decisions. The secretary is also central in communication and notices, issues likely addressed by a community charitable pharmacy's bylaw. Finally, the secretary is responsible for keeping records, presenting, and getting approval of the decisions which have been made.

In placing a secretary, some questions to consider are: Is this person organized? Is this person ethical? Is this person equipped with the necessary abilities to move a room to a clear decision, actionable for the staff? Is this person pleasant and easy to work with?

• Treasurer – The primary role of the treasurer is to oversee the financial position of a community charitable pharmacy, being the representative of the governing board on all matters that are financial. In day to day practice, this duty may include assessment and presentation of the finances of the company (for a large nonprofit), or may be as detailed as completing the actual company bookkeeping for smaller organizations. The role of the treasurer varies by corporation and is likely outlined in the corporation's bylaws. However, it is the role of the treasurer in assuring that all dollars are stewarded in an effective and ethical way.

In placing a treasurer, some questions to consider are: Is this person organized? Is this person ethical? Is this person equipped with the necessary abilities to assess and communicate the financial position of a community charitable pharmacy? Is this person pleasant and easy to work with?

Governance Board Self-Assessment

Once the board is in place, it is helpful to regularly (annually) assess the board members understanding of the mission of the charitable pharmacy, the by-laws, their roles as board members, and contributing to the needs of the organization, financial, and other. The self-assessment tool is used to determine gaps and strengths in knowledge and expertise of the board in order to address any issues that are revealed. Future strategies for the board itself and/or the organization can be adjusted based of the results of the assessment.

Ozanam Charitable Pharmacy offers a sample of their Board Self-Assessment.

Funding Sustainability

Though the approaches are different, many of the principles used in seed funding are useful for ongoing sustainability (See: Initial Funding for a Community Charitable Pharmacy). Building relationships, Speaking the Language as you Market your Fund Development Need, and communication systems (See: Stakeholders and Funders) apply to all types of sustainability. Encourage your philanthropic team to see themselves as partners working for the same goal of serving the uninsured and improving health outcomes as opposed to just donors of funds.

Developing a sustainability plan provides the board and the organization a framework to maintain the longevity of the pharmacy. The plan includes existing and anticipated funding opportunities, engagement with the community, and networking opportunities. Ozanam Charitable Pharmacy offers a sample of their Sustainability Plan.

In conjunction with a sustainability plan is a fundraising or fund development plan (See <u>The Fund Development Plan and the Fund Development Planning Process</u>). Defined are resources and potential resources, marketing for fundraisers, distribution of tasks, and a timeline for each task. Short and long-term goals are set. Ozanam Charitable Pharmacy shares a <u>fundraising plan</u>.

In a Dispensary of Hope <u>webinar on funding</u>, Angie McLaughlin of Community Healthcare Clinic answers "We could never afford it!" with "We can't afford Not to!" She offers suggestions of bundling grants and including vendor memberships with chronic disease management grants. Justin Coby, Health Partners Free Clinic, suggests using "best practices who don't know best" to build collaborations, local to national.

Growing the Charitable Pharmacy Practice

Within the area the charitable pharmacy practice serves (neighborhood, community, county, state) a need has been determined that you, as a charitable pharmacy, are meeting. Affordable medication access is a major need, but you as well as healthcare, government and other leaders in your area, may have identified other needs for which your charitable pharmacy is in position to help address. **Patient self-management** programs for chronic diseases include hypertension, diabetes, obesity, and mental and behavioral health. Healthy living programs include smoking cessation, nutrition, physical activity, and social/emotional wellness. **Collaboration with free clinics** offers a multi-disciplinary approach to healthcare, allowing the pharmacist to offer clinical services, either as a volunteer or as part of the healthcare team. Providing medication to <u>discharge patients</u>, delivering to patient bedside or home, helps hospitals ensure patients have the medication needed to decrease readmissions. Data collection may lead to grant opportunities as well as improving the lives of patients. See <u>Collaborative</u> Practice for establishing a collaborative practice and Services Offered and Special

<u>Populations</u> and <u>Transitions of Care/Handoffs</u> for services pharmacists offer at charitable pharmacies to better meet the needs of their patients and the community.

David Neu, Pharm D and Saint Thomas Health offer:

Top 10 Ways to Grow Your Charitable Pharmacy Volume

#10 Educate referring providers (depending on location):

- ED practitioners
- Hospitalists
- Any other practices that could benefit (ambulatory infusion, dialysis, oncology, etc.)

#9 Marketing Materials

 Pamphlets, posters, handouts, flyers, both for direct to providers and direct to patients

#8 Educate decentralized and ambulatory care Pharmacists to educate/refer patients

- When verifying home meds or allergies
- When providing patient education (CHF, COPD, etc.)
- Ask the question of medication affordability

#7 Educate case management, social workers

- Ask patients early in their hospital stay if they can afford medications
- Review income criteria/application/qualification process
- Invite to spend time or tour the pharmacy
- www.needymeds.org
- Free coupon until med available at charitable pharmacy, changed to one that is accessible, or acquired through PAP
- For insured patients, coupon and copay reduction <u>vouchers</u>

#6 Educate financial counselors in hospitals and clinics

- Income criteria/application/qualification process
- These counselors are talking to self-pay patients prior to discharge and regularly at clinics

#5 Associated AND Non-Associated Clinics

Any in proximity?

#4 Community agencies

(Helping Hand, Community Helper, Housing Authority, Immigration services, thrift shops, food pantries, etc.)

- Create mutual referrals
- Community agencies may be able to pay for utility bills or rent but not help a patient with medication needs
- A charitable pharmacy can help a patient with Medication Access but can't pay utility bills or rent

#3 Area Hospitals

Network with social workers, case managers, financial counsellors

#2 Local Churches and Places of Worship

#1 Word of Mouth

- Charitable pharmacy patients are one of the best referral sources for new patients
- They know firsthand the benefit of services
- They know friends, family, neighbors, parishioners that could be helped
- Ask patients to tell others, and their places of worship, the story of how they were helped by the charitable pharmacy.

For more ideas to help grow, check Fund Development Decision Tree

Challenges and Opportunities

"Free Drug" concept and other Safety Net Program patients

- Other local programs began sending patients to our program without notification
 - **Solution**: Meet with local clinics & safety net programs to anticipate potential added volume.
- Consider options to address revenue not secured in dispensing purchased medication.
 - **Solution**: Institute a <u>Safety Net Drug program</u> at \$3.00 (?) per prescription. Apply for grant funding for purchased meds/supplies (diabetic supplies, etc.)

• Physicians Not Aware of Available Inventory

- o Prescribers unaware of charitable pharmacy and formulary were not prescribing meds that were available.
- o Increase in patient wait time results in the pharmacist needing more time to resolve therapeutic changes.
 - Solution: Partner with medical leaders across the systems to educate physicians, hospitalists and other key providers
 - Educate prescribers that stock is for short term use until eligible patients receive medication from PAP
 - Distribute current formulary to prescribers who frequently send
 - Establish Collaborative Practice Agreement with prescribers to make changes then notify prescriber

Staffing and Stress of Staff (paid staff)

o Patient and prescription volume grow quicker than anticipated and not initially able to hire additional staff due to budget constraints.

TIP: "Patient referrals are

sources outside patient

discharges." David Neu,

Pharmacy, STH

Pharm D, Executive Director of

one of the biggest referral

Solution: Seek short term (1 year) grant to add additional full time or part time staff (social worker, technician. Introduce an automated robot or counting machine to help manage workflow better.

• Staffing (volunteer staff)

- Not enough volunteers to help break down incoming samples, process the inventory, complete paperwork, and maintain patient's files.
 - <u>Solution:</u> Volunteering for charitable pharmacy was placed on the hospital pharmacy employee evaluation as a way to exceed expectations related to the mission of the hospital.
 - Partner with local university for healthcare and foreign language students for Experiential Service Learning to interact with patients and help maintain pharmacy tasks.

• Language and Literacy Barriers

- o Patients whose language is not English without an interpreter
- o Difficulties explaining the program or requirements (proof of income)
- Forms only in English or patient unable to read English or their primary language
 - <u>Solution</u>: Challenging—but use of the <u>AT & T Language line</u>, <u>Martti</u>, <u>https://www.freetranslation.com/</u>, or other interpretive services.
 - Hire multilingual staff when possible
 - Print prescription labels and other forms in multiple languages and use pictograms to supplement. (See <u>Transitions of Care/Handoffs</u> and Appendix <u>Transitional Care</u> for samples)

• Validating Proof of Income

- o Patients with no income
- Undocumented workers (paid in cash, no social security number, can't have a bank account)
- o The number of people in the in household (who should be responsible?)
 - <u>Solution</u>: Require a formalized letter of support from family members, friends, and organizations that help support the patient's bills
 - Require a letter from the patient's employer that includes the amount that the patient is paid per week (month or year) and a phone number to call and verify the amount paid for patients who are paid in cash
 - Letter of support does not require a notary as the process was burdensome for the patients
 - Verification of food stamp benefits by using the state benefit website instead of requiring patients to bring in paper copy as proof of income
 - Example of processes in <u>Patient Eligibility/ Enrollment</u>
 - Example forms in <u>Appendices/Eligibility/HDGB Enrollment Forms</u>

Undocumented Workers (proof of income/PAP programs)

- Patients not eligible for Manufacturer PAP programs but have long term need
- Documenting proof of income

- Solution: Some PAPs use soft credit tool to determine income which may work for some patients
- Use therapeutic interchanges to provide medication from manufacturer with best fit for eligibility
- If patient meets residency requirements, some programs will accept letter from employer
- Direct donations do not require supplemental income documentation
- Some coupons provide discounted med for up to one year if patient can afford low copay

• Coordinating physician donations of samples and Pick ups

- Need a sustainable supply of medications
- Supply and demand- donations do not always match what is needed the most
 - <u>Solution</u>: Specify to physician donors what is needed and only accept those donations
 - Complete Track and Trace documentation for all donations. (See: Tracking the Medication Supply Chain)
 - Use therapeutic interchange when possible to dispense from present inventory

• Maintaining a retail pharmacy environment

- o The program is integrated into a working retail pharmacy
- Employees and other customer wait times increased to get prescriptions filled/check out
 - <u>Solution</u>: Designate a specific window or area for patient enrollment that stocks enrollment paperwork and clipboards for patients who can read and write to begin enrollment process independently
 - Use various colored bins to designate newly enrolling patients, who expect a longer wait time, versus other patients.

Keep in touch with other charitable pharmacies that may have solved a challenge or are facing the same dilemma.

Charitable pharmacy organizations, as well as other pharmacies and organizations, are a wealth of information: from staffing issues to setting up a collaborative practice, finding volunteers to med destruction. Be involved, and be willing to share your experiences with those who want to learn from you.

Make your voice heard, Advocate!

It is very important for you to stand up, show up and be present for your mission. Nonprofit advocacy groups are often known as special interest groups, citizen organizations, mobilizing groups, multi-issue organizations, or social movement organizations. The activities in which they participate may be called **grassroots action**, civic voice, public action, organizing, and empowerment.

Yes, nonprofits organizations are allowed to advocate. Advocating for your mission matters. When done right, advocacy influences public policy by providing a way for individuals and organizations to have a voice. However, it is important to learn the difference between advocacy and lobbying.

Advocacy is the process of stakeholders making their voices heard on issues that affect their lives and the lives of others at the local, state, and national level. It also means helping policymakers find specific solutions to persistent problems. Most nonprofits can and do engage in as much advocacy as possible to achieve their goals. For example, informing a member of Congress how a federal grant your organization received has helped your mission is considered advocacy.

Lobbying, on the other hand, involves activities that are in direct support of or opposition to a specific piece of introduced legislation. While nonprofits can engage in some lobbying, the IRS has strict rules about what portion of their budget can go toward these activities. There are also prohibitions on any use of federal funds for lobbying. For example, asking your member of Congress to vote for or against, or amend, introduced legislation is considered lobbying.

How can you be an advocate?

You can be an advocate by educating policymakers about the needs of your organization and the people you serve, and developing a relationship where you act as trusted voice on policy issues. You also can organize supporters on issues of importance and educate a wider audience on your accomplishments. Some examples include:

- Emailing or calling your elected officials
- Organizing meetings or site visits with your legislators and their staff
- Making your views known to policymakers and your community through traditional and social media

Understand the rules of your state in regard to inviting policy makers to your organization or event, for example if you have to have approval from the State Board of Ethics. Make sure you don't cross the line. Keep in mind that activities are considered lobbying if they call for action on introduced legislation or a pending regulation.

See <u>Share Results</u> for ideas on presenting the impact of your charitable pharmacy and its services to groups local to national.



Resources

Resources	Description	Phone	Other	
Reference to a p	Reference to a program does not constitute			
endorsement of	product or services. Websit	tes		
accessed March, 2018				
Not all references contain primary references		es		
or have them available.				
<u>Vendors</u>				

	Dooksaina Colutions	
Altium Healthcare	Packaging Solutions including vials	
-	Nonprofit distributor	
	of donated	
	medications for	
	domestic and	
	international	
<u>Americares</u>	distribution	
AmerisourceBergen	Pharmacy wholesaler	
Milensourcebergen	Thurmaey wholesaler	1-909-781-
<u>Bionime</u>	Diabetic Supplies	6969
Cardinal Health	Pharmacy wholesaler	
	Nonprofit distributor	
	of donated	
	medications for	
	domestic and	
	international	
<u>Direct Relief</u>	distribution	
	Nonprofit distributor	
<u>Dispensary of Hope</u>	of generic medication	
<u>Independence</u>	Diabetic & Medical	
<u>Medical</u>	Supplies	1-800-860-8027
	Distributor for generic	
Key Source	meds	1-800-842-5991
	Nonprofit distributor	
	of donated	
	medications for	
	international	
Kingsway Charities	distribution	
	Nonprofit distributor	
	of donated	
	medications for	
	international	
<u>MAP</u>	distribution	
McKesson	Pharmacy wholesaler	
	A national cooperative	
	group purchasing	
	organization for	
	government facilities	
	that provide	
MMCAP/Infuse	healthcare services	
A. A. H. L.	Insulin and other	4 000 727 6500
<u>NovoMedLink</u>	diabetic samples	1-800-727-6500
	Nonprofit distributor	
CIDLINA	of reclaimed	
SIRUM	medications	4 000 442 7004
Canadia - Distanti III	Insulin, diabetic and	1-800-443-7081
Sterling Distributors	medical supplies, OTCs	or 954-340-8210
	Nonprofit distributor of donated	
Twolve Backets Full		
Twelve Baskets Full	medications for	

	international	
	distribution	
77' 1	Distributor of vials &	
<u>Vials</u>	caps	
A41		
<u>Med</u>		
Destruction		
<u>DC3IIOCIIOII</u>		
	Incinerator for	
GEI Works	purchase	772-646-0597
	Nationwide biohazard	
	collection and	
<u>SteriCycle</u>	destruction	(888) 926-5967
<u>Manufacturer</u>		
Rulle		
<u>Bulk</u>		
<u>Replacement</u>		
-		
<u>AstraZeneca</u>		
AZ&ME		1-800-292-6363
<u>Bristol-Myers Squibb</u>		1-800-736-0003
	Bulk replacement	
Direct Relief	medications from	
Replenishment	AbbVie, Novartis,	
Program	Johnson & Johnson and Eli Lilly	
Johnson & Johnson	and Lit Lilly	
Patient Assistance		
Foundation, Inc.		1-800-652-6227
Merck Bulk		1 000 002 0227
Replacement		
Program		1-855-842-0539,
PfizerRxPathways		1-800-984-1500
_ Indian anna, b		
<u>Patient</u>		
<u>Assistance</u>		
<u>Programs</u>		
	Search free and	<u> </u>
	reduced cost services	
	like medical care, food,	
	housing and more in	
NOVA Scripts	your immediate area	
Compass	by zip code	

	DAD annallmana		
Davis Assistant	PAP enrollment	900 607 4060	
<u>Drug Assistant</u>	software	800-697-4060	
	Mail order generic		
	meds at discounted		
	prices; useful for meds		
	not on formulary;		
	licensed in many		
	states; Discount for		
	CharityPharmacy.org		
<u>Honeybee Health</u>	patients		
	Forms for PAP		
<u>NeedyMeds</u>	enrollment	800-503-6897	info@needymeds.org
Partnership for	_		
<u>Prescription</u>	Forms for PAP		
<u>Assistance</u>	enrollment		
		info (888) 593-	
		1085 ext. 110	
		support (888)	
	PAP enrollment	593-1085 ext.	
<u>RxAssistPlus</u>	software	122	info@rxasssistplus.com
	Mail Order pharmacy		
	for eligible patients at		
<u>RxOutReach</u>	discounted rate	1-888-796-1234	
	Mail Order pharmacy		
	for eligible patients at		
<u>Xubex</u>	discounted rate	1-866-699-8239	
0			
<u>Operations</u>			
Software			
<u> </u>			
<u>Chargify</u>	Billing Services	1 (800) 401-2414	
	Prior Authorization		
CoverMyMeds	platform		
DOH Webinar	Webinar		
	Prescription fill and		
<u>QS1</u>	enrollment, metrics		
	Pharmacy, prescription		
<u>Rx30</u>	management system		
	<u> </u>	info (888) 593-	
		1085 ext. 110	
	Enrollment, PAPs,	support (888)	
	clinical documentation,	593-1085 ext.	
RxAssist Plus	metrics	122	info@rxasssistplus.com
Stripe	Billing Services		info@stripe.com
<u> saripe</u>	Discounted or free		oe surpercom
<u>TechSoup</u>	software products		
<u>,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,</u>	Prescription fill,		
	enrollment,		
	counselling		
WinRx	documentation		

Clinical Pharmacist **Collaborative Practice** Agreements and **Ambulatory Care** Review and APhA Recertification courses Patient care resources and continuing education modules for <u>APhA</u> CMM elements Collaborative practice and Ambulatory Care **Basics and Certification** <u>ASHP</u> Review National learning experience to help healthcare providers and organizations integrate Comprehensive Medication Management into their A 3 Collaborative strategic plan Online resource center designed to help healthcare stakeholders find the best in evidencedbased and promising approaches to improving care for people with complex Better Care Playbook health and social needs Comprehensive Medication Management in Team-**Based Care Collaborative Practice** Agreements: **Explaining the Basics** Clinically integrated, nationwide organization of pharmacy networks organized to advance community-based **CPESN** pharmacy practice

	Pharmacy:	
	Collaborative Practice	
CDC	<u>Agreements</u>	
	Webinars and training	
	regarding	
	Comprehensive	
Get The Medication	Medication	
Right	Management	
	Improving Patient	
	Health Through	
	Medication	
	<u>Management</u>	
	The Patient Care	
	Process for Delivering	
	Comprehensive	
	Medication	
	<u>Management</u>	
	Optimizing Medication	
	Use in Patient-	
	Centered, Team-Based	
	Care Settings	
	Resource for	
	those struggling	
	with addiction	
	and their families	
	to find	
	the information,	
	support, and	
	resources needed	
	to get help.	
	Provides	
	ways to recognize	
	the <u>warning signs</u>	
<u>RehabSpot</u>	of addiction	
	Used with Hospital	
	Formularies for	
	collaborative &/or	
<u>Therapeutic</u>	formulary	
<u>Interchanges</u>	development	
N B CI		
<u>NonProfit</u>		
Status		
<u>Status</u>		
Foundation Group	What is a 501©(3)	
	Step by Step through	
<u>IRS</u>	application process	
Legal and		
Operational Guide	Legal resource for	
for Free Medical	starting a nonprofit	
Clinics	medical establishment	

340B

<u>Understanding 340b</u> <u>and Contract Status</u>

Donor Perfect

DonorQuest

platform

platform

Donor management

The Bridge to 340B Comprehensive Pharmacy

Services Solutions in Underserved Populations

4 - 1-1			
<u>Metrics</u>			
	Census Bureau data,		
<u>American Fact Finder</u>	some down to zip code		_
Census Bureau: Small	Health Insurance		
<u>Area Health</u>	coverage maps by		
Insurance Estimates	county		
	City profiles and		
<u>City Data</u>	statistics, maps		
City Health	City profiles and		
<u>Dashboard</u>	statistics		
Community	Build maps based on		
<u>Commons</u>	Census Bureau data		
	Free Spreadsheets and		
Google Sheets	templates		
<u>Mirixa</u>	Clinical Metrics		
Outcomes MTM	Clinical Metrics	877.237.0050	info@OutcomesMTM.com
<u>Marketing</u>			
	Donations collected for		
<u>AmazonSmile</u>	free		
	Message delivery		
Callin - Darat	service for phone calls,		
<u>CallingPost.com</u>	emails or texts		
	Message delivery		
CallMultiplier	service for phone calls,		
<u>CallMultiplier</u>	and texts Donations from		
	rounding up on debit/credit card		
CaringCent	purchases		
CarringCent	Newsletters, emails,		
Constant Contact	etc.		
Constant Contact	Adds donation button		
DonateNow	to a website		
DONACTION	Donor management		
5 5 6 1	1 if		

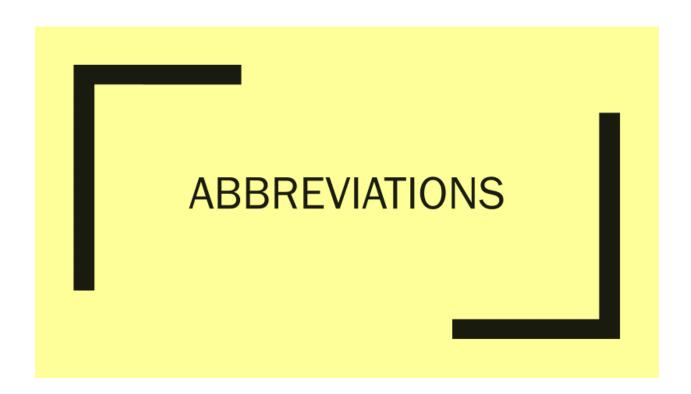
	Fron conforcing sell-		
Free Conference	Free conference calls		
<u>Call.com</u>	and online meeting		
F 161	Donor management		
<u>FrontStream</u>	platform		
0.5.104	Donations collected for		
<u>GoFundMe</u>	free		
	Donations collected for		
<u>JustGive</u>	a small fee		
<u>MailChimp</u>	Email newsletters, etc.		
	Marketing and care		
	management for		
<u>Patientriciti</u>	providers		
	Donations collected for		
<u>PayPal</u>	a small fee		
	Customer		
	Relationship		
Droomomusedes	Management and G-	(445) 004 0000	
<u>Prosperworks</u>	Suite	(415) 231-6360	sales@prosperworks.com
	Customer Relationship		
Calactarea	Management and G- Suite		
<u>SalesForce</u>			
Victorrint	Templates and design		
<u>Vistaprint</u>	your own materials		
<u>Volunteers</u>	A year-long, full-time		
	commitment to assure		
	projects are		
	sustainable and can		
	reach a larger		
	population of people in		
Americorps VISTA	poverty.		
/iciicoips visiA	One of the largest		
RSVP - Retired	volunteer networks in		
Volunteer Senior	the nation for people		
Program	55 and over.		
SCSEP - Senior	Offers training		
Community Service	opportunities to low-		
Employment	income adults age 55		
<u>Program</u>	and older		
	Match experts as		
	highly qualified		
Taproot Foundation	volunteers		
United Way	Must be a partner with		
Volunteers	United Way		
	Tracking volunteers		
<u>Volgistics</u>	and hours		
	Match experts as		
	highly qualified		
Volunteer Match	volunteers		

<u>Translating</u>			
	Dhawara ay adyyaatia a		
Access Pharmasy	Pharmacy education,		
Access Pharmacy	videos, games		
	Drug monographs,		
Clinical Key	patient education handouts		
Cillical Key	Free public health		
Health Reach	information		
<u>nearth Reath</u>	Med information with		
	access to patient		
Lexicomp	handouts		
<u>Lexicorrip</u>	Patient friendly		
	information on		
Medline Plus	diseases, drugs		
viculiic Flus	Prescription label		
Meducation	translation		
*icaacation	Med information with		
	access to patient		
<u> Micromedix</u>	handouts		
VIICI OTTICUIX	Prescription label		
RxTran	translation		
tx rrun	Medication-specific		
VUCA Health	videos		
Interpretation			
<u>Interpretation</u>			
nterpreter	Phone App for		
nterpreter (Google Play)	interpretation		
nterpreter Google Play) .anguage Line	interpretation Ondemand phone		
nterpreter Google Play) Language Line	interpretation Ondemand phone interpretation		
nterpreter Google Play) Language Line	interpretation Ondemand phone interpretation Tablet based		
nterpreter Google Play) Language Line Services	interpretation Ondemand phone interpretation		
nterpreter (Google Play) Language Line Services	interpretation Ondemand phone interpretation Tablet based		
Interpreter (Google Play) Language Line Services Martti	interpretation Ondemand phone interpretation Tablet based		
Interpreter (Google Play) Language Line Services Martti	interpretation Ondemand phone interpretation Tablet based		
Interpreter (Google Play) Language Line Services Martti Reclamation	interpretation Ondemand phone interpretation Tablet based		
Interpreter (Google Play) Language Line Services Martti Reclamation National	interpretation Ondemand phone interpretation Tablet based interpretation		
nterpreter (Google Play) Language Line Services Martti Reclamation National Conference of	interpretation Ondemand phone interpretation Tablet based interpretation state self reported		
Interpreter (Google Play) Language Line Services Martti Reclamation National Conference of	interpretation Ondemand phone interpretation Tablet based interpretation		
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Interpretation Interpreter (Google Play) Language Line Services Martti Reclamation National Conference of State Legislatures Grants and	interpretation Ondemand phone interpretation Tablet based interpretation state self reported		
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Interpreter (Google Play) Language Line Services Martti Reclamation National Conference of State Legislatures Grants and Funders	interpretation Ondemand phone interpretation Tablet based interpretation state self reported information Non-profit		
Interpreter (Google Play) Language Line Services Martti Reclamation National Conference of State Legislatures Grants and	interpretation Ondemand phone interpretation Tablet based interpretation state self reported information		

	nractice and nationt	
	practice and patient	
	care delivery through	
	grant funding and	
	resource sharing	
	Manage donors and	
<u>DonorPerfect</u>	funding	
	Manage donors and	
<u>DonorQuest</u>	funding	
	Foundations and	
- Lu	applications for	
Foundation Center	grants	
Formatatoria	Manage donors and	
<u>Frontstream</u>	funding	
	Grants and grant	
Crant Station	writing, fee but	
Grant Station	coupons available	
	Information on	
	federal government	
Grants gov	grants and grant writing	
Grants.gov Grantsmanship	writing	
Training Center State	List of funders in each	
Resource Database		
Resource Database	state Funders investing in	_
	health of uninsured in	
Guidestar	your community.	
Guidestai	Discounts for Grant	
<u>Techsoup</u>	Station	
Insurance		
<u>III30IGIICE</u>		
	Healthcare Providers	
	Service Organization	
<u>HPSO</u>	Liability Insurance	
	Risk Management	
	coverage for	
Pharmacy Mutual	pharmacies	(855) 989-1813
Proliability	Liability Insurance	877-353-5801
- 	<u>,</u>	
Environmental		
LITVIIOIIIIEIIIGI		
Factor		
100101		
Resources		
	amail and the state of	
APhA e-mail	email current topics	(202) 520 4440
newsletters	that affect pharmacy	(202) 628-4410
ASHP Pharmacy	Strategic planning	
<u>Forecast</u>	advice for pharmacy	
	for the year	

Drug Topics	email current topics	
newsletter	that affect pharmacy	(866) 295-2505
	Analysis tools for	
Mind Tools	environmental factors	
	email current topics	
Stat News	that affect healthcare	
	that affect fleatificare	
D. f		
References		
	Links to individual	
National Association	state boards of	
of Boards of	pharmacy for laws and	
Pharmacy (NABP)	regulations	
Filatiliacy (NADF)	regulations	2014 Columbia
Croative Strategy A	Stop by stop guido to	Business
Creative Strategy: A	Step-by-step guide to	
Guide for Innovation,	innovate using global	School
William Duggan	past success models	Publishing
Social Startup	Steps for Nonprofits to	
Success, Kathleen	launch, scale up and	2017 Da Capo
Kelly Janus	make a difference	Press
	Tool to map casual	
	links detailing	
	intermediate steps	
	from program activities	
Theory of Change	to vision and impact	
Why Bad	How to improve your	
Presentations	presentation delivery	
Happen to Good	skills, connect with the	
Causes	audience, use body	
Andy Goodman	language and more.	
- may Goodman	How stories strengthen	
	your organization,	
Storytelling	engage your audience,	
As Best Practice	and advance your	
Andy Goodman	mission.	
Timuj Geeuman	mission.	
Dispensary of		
Hope Link to		
<u>Webinars</u>		
Advison, Desert		
Advisory Board		
Research Webinar	1 151	
Best Practices in Techr	nology and Pharmacy	
Software Webinar		
Diabetic Supply		
Resources Webinar		
Formulary		
Development and		
Utilization Webinar		
Funding Webinar		
Tallaling Weblilai		

Innovative Strategies
For Caring For The
Uninsured
Mental Health
Webinar
Network Update
Webinar, 2015
Prescription for
Collaboration
Webinar
Adapting Global
Health Experiences
to Solve Local
Healthcare Issues
Webinar

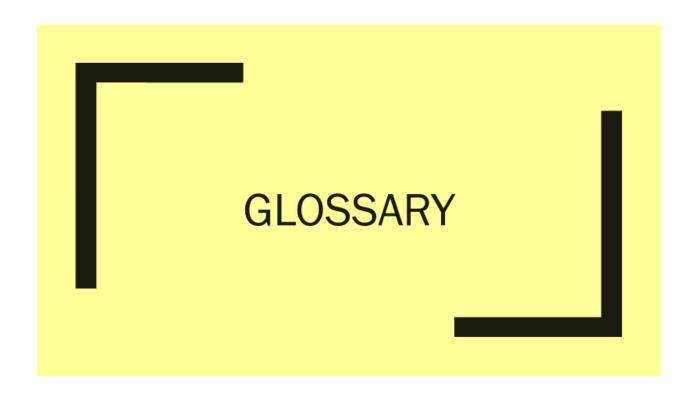


Abbreviations

211	United Way Helpline
340b	Federal government program that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices.
501c3	Type of federal non-profit status.
A1C	Blood test that provides information regarding the average blood glucose level.
ACA	Affordable Care Act
ACS	American Community Survey (Census Bureau)
APhA	American Pharmacist Association
APPE	Advanced Pharmacy Practice Experience
ASHP	American Society of Health-Systems Pharmacists
AWP	Average Wholesale Price-price used for insurance reimbursement
CEO	Chief Executive Officer

CHF	Congestive Heart Failure
CHNA	Community Health Needs Assessment
CMM	Comprehensive Medication Management
CMS	Centers for Medicare and Medicaid Services
СРА	Certified Public Accountant
CRM	Customer Relationship Management
DAW	Dispense as written
DEA	Drug Enforcement Agency
DOH	Dispensary of Hope
DSCSA	Drug Supply Chain Security Act
DUR	Drug Utilization Review
ED	Emergency Department
EIN	Employer Identification Number
EMR	Electronic Medical Record - usually used at hospitals and clinics.
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FLP	Federal Poverty Level
FQHC	Federally Qualified Health Center
GPO	Group Purchase Organization
G-Suite	Google Integration
HDGB	HOPE Dispensary of Greater Bridgeport
HIPAA	Health Insurance Portability and Accountability Act
нт	Hypertension
IP	Inpatient
IPPE	Introductory Pharmacy Practice Experience
IRB	Institutional Review Board
IRS	Internal Revenue Service
IT	Information Technology

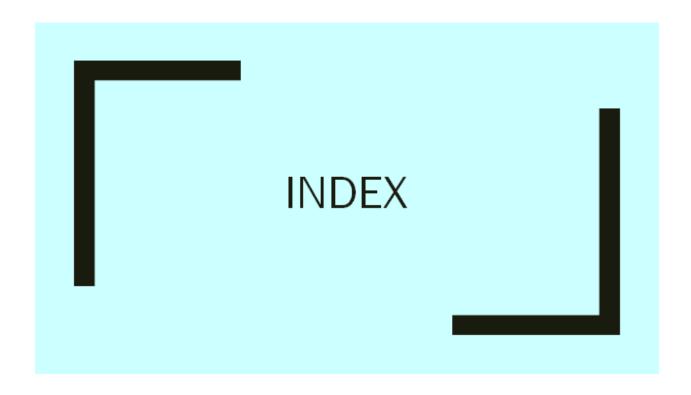
LTC	Long Term Care (facilities)
MTM	Medication Therapy Management
MUST	Mission Uninsured Safe Transitions
NCSL	National Conference of State Legislatures
NDC	National Drug Code
NPI	National Provider Identifier - a unique health identifier for facilities (pharmacies) and providers (pharmacists and prescribers).
ОТС	Over-the-Counter medication, those not requiring a prescription.
PAP	Manufacturer Patient Assistance Program
PCP	Primary Care Provider
PDMA	Prescription Drug Manufacturing Act
RAB	Results Based Accountability
ROCI	Return on Community Investment
ROI	Return on Investment
RSVP	Retired Senior Volunteer Senior Program
Rx	Prescription
SCSEP	Senior Community Service Employment Program
SMART	Specific, Measurable, Achievable/Attainable, Relevant, Time-bound
SOP	Standard Operating Procedure
STH	Saint Thomas Health
SVdP	Saint Vincent de Paul
тос	Transitions of Care
UPS	United Parcel Service
USDA	United States Department of Agriculture
VISTA	Volunteers in Service to America
WAC	Wholesale Acquisition Cost - the price a pharmacy would actually pay a wholesaler for a product.
WDH	Wyoming Department of Health
WMDP	Wyoming Medication Donation Program



Glossary

340b	US federal government drug discount program that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices.
501(c)3	Type of non-profit status.
Beyond Use	Date after which product should not be dispensed or used. This could be due to improper storage (as with insulin at room temperature) or beyond package expiration date.
Charity-Only	Pharmacies dispensing solely to patients under the charity program.
Charly-Only	marmacles dispensing solely to patients order the charity program.
Footprint	Area served or area of impact.
	, , , , , , , , , , , , , , , , , , , ,

Metrics	Standards of measurement by which efficiency, performance, progress, or quality of a plan, process, or product can be assessed and evaluated and outcomes determined.
Mixed-Model	
71117.04 711.0401	Pharmacies dispensing to both insured and un-insured patients and engaging in other for-profit activities in addition to the charity program
Open Door	Pharmacy serving eligible patients from the entire community or state, not limited to a specific clinic or referral site.
Pharmacy Desert	A low-income census tract or zip code where a substantial number of residents have low access to a community pharmacy. Definition varies by urban or rural population.
Reclamation	Dispensing of donated, previously dispensed medications; regulations vary by state as to donation sources, usually medical facilities but may include personal donations.
Repository	With regards to medication, places where excess or unused medications are being stored that may be available for donation. Example: skilled nursing facilities, prisons, etc.
Stand Alone	Pharmacy is independently funded, not fully funded by a hospital or health system.
Transitions of Care	The movement of patients between health care locations, providers, or different levels of care within the same location as their conditions or care needs change.
Vendor	Medication supplier. It can be for profit (commercial distributor), non-profit (e.g. DOH, Americares, SIRUM, Direct Relief), or manufacturer (bulk assistance programs, PAPs).



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