



**AFFORDABLE PRESCRIPTION DRUG PROJECT  
COMMUNITY CHARITABLE PHARMACY Q&A SESSION  
MEETING RECORD**

**JULY 11, 2007**

Record: Deb Helber, Consultant

## **Welcome & Framing**

Jeff Biehl welcomed everyone to the Community Charitable Pharmacy Q&A session. In continuing to engage the community in exploring strategies on how we bring more affordable prescription drugs into Franklin County, Access HealthColumbus is inviting “content” experts to come and engage in conversations with us around the questions that emerged from the Kick-Off Meetings.

Kevin Hilvert, an attorney with Schottenstein, Zox, & Dunn, Co., L.P.A. joined us to explore our questions around Community Charitable Pharmacies. We would like to extend our appreciation to Kevin, who has donated his professional time and energy in researching, preparing, and participating in today’s meeting.

## **Background**

Kevin shared with the group some background information around the laws applicable to Community Charitable Pharmacies.

**Charitable Pharmacy** – Any existing pharmacy could have a Community Charitable Pharmacy license. If the existing pharmacy is a for-profit entity it would have to have a not-for-profit subsidiary to hold the Charitable Pharmacy.

### **- *What is a charitable pharmacy?***

- A pharmacy that is charitable (and that is not a hospital) – defined by the Ohio Board of Pharmacy. According to the Ohio Board of Pharmacy a pharmacy is a: "terminal distributor of dangerous drugs" licensed by the Board. Charitable is defined as a 501(c) (3) organization (in its own right or operated by one) – with the ability to submit evidence showing this.
- License application process
  - Application and timeframe (may include on-site survey of pharmacy, usually takes two weeks to process).
  - Application itself is fairly straightforward – a two-page document.
  - Must be signed by an officer of the entity that owns/operates the pharmacy and by a doctor or pharmacist who acknowledges responsibility for supervision and control of the drugs handled by the pharmacy.
  - The licensure process may include an on-site survey of the pharmacy location, but this can occur after the license has been issued. Applications can take two weeks to a month to process.
- Categories of Licensure (Type I, II or III)
  - Type I – single dose injections of IV fluids (very limited – not useful)
  - Type II – all prescription drugs which are not controlled substances (most common)
  - Type III – all prescription drugs and schedule II-V controlled substances. If controlled substances will be dispensed, DEA registration is required.
- Requirements for Licensure – Held to the same standard as any other Pharmacy
  - Appropriate facilities, equipment and space to carry on business of a pharmacy

- Appropriate supervision of drugs by pharmacist or authorized prescriber to ensure drug supply is properly used and accounted for.
- Appropriate safeguards and security to ensure secure drug supply. A pharmacy must adopt controls and procedures to protect against theft or diversion of drugs. The level of security required depends upon the amount and nature of the drugs it handles.
- Record keeping (prescriptions, dispensing, refills etc.)
  - Who dispensed the drug
  - When was it dispensed
  - To whom was it dispensed
  - How much (quantity and strength) was dispensed
  - Refills, etc.
  - Records must be kept on-site, unless otherwise approved by Board
- Confidentiality of Patient Records
- Patient profiling system – immediate retrieval of patients receiving prescriptions including – full name, address, telephone number, date of birth, gender, drug allergies, drug reactions, chronic conditions
- Drug Labeling (including name and address of pharmacy, name of patient, directions for use, date dispensed, etc.)

- **What Can a Charitable Pharmacy do?**

- Receive & Dispense Sample Drugs. Sample drugs are any drug that would be hazardous to health if used without the supervision of a licensed prescriber that has been placed in a container and plainly marked as a sample by a manufacturer. The requirements a Sample Drug must meet in order to be dispensable are:
  - Be in the original container from manufacturer and clearly marked as a sample.
  - Stored in proper conditions to prevent contamination
  - Marked with Expiration Date and Lot Number
  - Must not have expired.
  - Not a controlled substance
- Who can provide sample drugs to a Charitable Pharmacy?
  - Drug Manufacturer
  - Wholesale Distributor acting on behalf of a Manufacturer
  - Prescriber in Location Licensed as Terminal Distributor (which means as doctor, if his/her practice location is licensed as a terminal distributor) – If a drug is furnished by a Prescriber:
    - A record must be created by the prescriber documenting the sample drug transfer.
      - Name & Address (of Prescriber and Charitable Pharmacy)
      - Name, Strength & Quantity
      - Date of Transfer
  - A Prescriber must also furnish a copy of the record it received from Manufacturer/Wholesale Distributor Record documenting the transfer of the sample drug to the Charitable Pharmacy

- These records must be maintained for three years in a readily retrievable manner.
  - No Signs of Tampering to drug or drug packaging
- Requirements for Dispensing a Sample Drug
  - Valid Prescription
  - Patient Meets Eligibility Requirements determined by Charitable Pharmacy
  - Free of Charge – no handling or dispensing fee
  - May be Dispensed:
    - In Original Container; or
    - by removing the sample drug from original container only if the Prescription Label on the substitute container clearly indicates that the drug is a Sample Drug
- What else can a Charitable Pharmacy Do?
  - Purchase drugs from Wholesale Distributors
  - Occasionally purchase of drugs for resale from a pharmacist licensed as a terminal distributor or is employed by a terminal distributor.
  - Receive drugs via Karon's Law

### **Karon's Law**

#### **- Who may donate drugs under Karon's Law?**

- Licensed Terminal Distributors
- Licensed Wholesale Distributors
- Person who has been legally dispensed a drug, but who has not taken custody of the drug prior to the donation.
  - Donation can be made through a licensed terminal distributor; or
  - an Institutional Facility (if the person resides in such facility)
    - Hospital
    - Convalescent Homes
    - Developmental Facilities
    - Long Term Care Facilities
    - Nursing Homes
    - Psychiatric Facilities
    - Rehabilitation Facilities
    - Mental Retardation Facilities

#### **- Donor Documentation Requirements**

- The person donating must complete a form indicating:
  - ownership, intention to donate drugs, name of donor and signature
  - Name of the drug donated (brand or generic) and name of manufacturer or national drug code number.
  - Strength
  - Quantity
  - Date donated
- Donor forms must be maintained for three years by terminal distributor, wholesale distributor or institutional facility.
- Donor Invoices
  - Donor locations (terminal distributors, wholesale distributors and institutional facilities) must create an invoice which includes:

- Donor name and address
  - Name of the drug donated (brand or generic) and name of manufacturer or national drug code number.
  - Strength
  - Quantity
  - Date sent
  - Name and address of recipient pharmacy, hospital or nonprofit clinic.
- Copy of invoice must be maintained for a minimum of three years by both the donor location and the recipient location.
- **What kind of drugs may be donated?**
  - All drugs, except controlled substances and drug samples
  - Requirements of donated drugs
    - Must be in original sealed and tamper-evident unit dose packaging
    - Must have been in possession of a licensed health care professional and not in the possession of the ultimate user
    - Must be stored in accordance with applicable legal requirements
    - Must have an expiration date of 6 months or greater
    - Packaging must list lot number and expiration date
    - No physical signs of tampering or adulteration (to drugs themselves or drug packaging)
    - All confidential patient information is removed from the drug packaging
- **Who can receive drugs donated via Karon's Law?**
  - Must be an Ohio resident; and
  - Must not have third-party prescription drug reimbursement coverage for the drug prescribed or be a patient of a free clinic
- **Recipient Documentation Requirements**
  - The Pharmacy dispensing a Karon's Law drug must obtain, from the recipient of the drug:
    - Signature of recipient on form stating that they understand the immunity provisions Karon's Law (recently modified by Ohio Senate Bill 33). Expanded the immunity from civil and criminal prosecution, but deleted the immunity from professional disciplinary actions.
    - Date form was signed by recipient
    - Name of drug received and name of manufacturer or national drug code number.
    - Strength
    - Quantity
  - Recipient forms must be maintained for a minimum of three years by a pharmacy, hospital or nonprofit clinic.
  - The invoice from the donor location must be maintained for a minimum of three years by a recipient location.
- **Handling Fee**
  - A pharmacy may charge recipients of donated drugs a handling fee.
  - Maximum handling fee that may be charged is 200% of the Medicaid professional dispensing fee.

## Q&A Session

A summary of the Q&A session conversation is outlined in the following chart. Some potential strategies we that emerged that the community could explore are:

- Policy
  - If we try to reshape policies, what change would it be?
  - Could an umbrella be built to cover groups of pharmacists so that individual pharmacists would not have to go through the entire process?
  - Should we advocate for some change that would allow an established pharmacy to receive and dispense samples, if they have a contract with a charitable entity?
  - Are there other institutions that should become eligible for Karon's Law?
  - What other opportunities are there to obtain necessary drugs that the Charitable Pharmacy Law and Karon's Law do not address? Are there excess supplies of drugs in other places in the community that go unused and wasted?
- Working Across Communities
  - Could we have a state-wide repackaging center for medications donated under Karon's Law?
  - Should we convene communities around the state that are working on this issue?
  - How could we design a community/state-wide process for a coordinated, community charitable approach?
- Learning From Other Communities
  - What can we learn from other states and communities?
    - In Virginia, six large companies are donating bulk drugs to the charitable pharmacies (distributors) – an administrative arm handles all the eligibility paperwork.
  - How can Charitable Pharmacies be utilized most effectively and efficiently?
- Acute vs. Maintenance Medications
  - How do we help people get medications for acute needs? For maintenance needs? What are the most efficient ways to do this?

## Announcements

*Prescription Access can help individuals that are at or below 200% poverty with the purchase of prescription medications - especially seniors that have reached the donut hole, have medications that are not covered by their health plan, or other circumstances in which insurance will not cover the medications. They provide service to all ages. You can contact Prescription Access at (614) 645-5556 or at 1-888-299-3615.*

### Q&A Session

Theme	Question	Response/Discussion
<b>Charitable Pharmacies</b>	If you have a network of pharmacies that want to do this, do they each have to become a 501(C) (3)? Can we have an umbrella? Can we do something similar to the 340B process (purchaser/distributor)?	- Yes, each would need to become a 501C 3. If one of the organizations has this status there may be something that could be done? They cannot operate as a 501(C) (3) and under their regular status at the same time.
	Do anti-anxiety drugs fall under the heading of controlled substances?	- The DEA website has a list
	Can a charitable pharmacy take samples in different quantities and repackage them together to fill a prescription?	- They must indicate that it is a sample and they indicate lot numbers, expiration date, etc.
	If an organization like Medshare purchased drugs at a discounted price and those drugs are coming close to expiring, can they donate them?	- No. That process is more similar to Karon's Law, although a Medshare like organization would not be covered under Karon's law.
	Are there sources of drugs going currently unused because the law doesn't allow them to be donated?	- Yes.
	Can you charge a fee for drugs that are purchased by a charitable pharmacy from a wholesaler or distributor?	- Yes
	If a Health Center's physician is licensed as a terminal distributor, can they donate samples to a charitable pharmacy?	- Yes.
	Could Health Center's sell expiring medications to a charitable pharmacy?	- No, there are 3 ways charitable pharmacies can receive medications.
	If a pharmacist in a retail pharmacy has a terminal distributor license, can a charitable pharmacy purchase drugs from them?	- The language says occasionally but is vague about what occasionally means.
	What are the limitations of charitable	- The resources needed – is there a way to operate them in a more efficient

	pharmacies?	<p>manner?</p> <ul style="list-style-type: none"> <li>- The distribution method – is there a way to do this so the charitable pharmacy does not have to be the one to go out and find the drugs?</li> <li>- Finite supply of drugs – requires community collaboration, there can't be a bunch of competing charitable pharmacies in a community.</li> </ul>
	What is the extent of the charitable pharmacy's to meet the needs of patients in a community? Are they intended to be a source for chronic, ongoing medication needs? Acute needs?	<ul style="list-style-type: none"> <li>- It can be what the resources allow</li> <li>- Other communities bill their charitable pharmacy as the pharmacy of last resort – the intent is to get individuals the medication they need while linking them to other sources of assistance.</li> <li>- Some providers are subsidizing the acute needs</li> </ul>
<b>Karon's Law</b>	What is a "free clinic"? Is it being used in the broadest sense of the work?	<ul style="list-style-type: none"> <li>- The statute uses the language, non-profit clinic, which is defined as a clinic that provides indigent care, free of charge.</li> </ul>
	What is 200% of the Medicaid professional dispensing fee?	<ul style="list-style-type: none"> <li>- \$7.60</li> </ul>
	Is there anything limiting automating the paperwork?	<ul style="list-style-type: none"> <li>- There are programs that help you access the programs – one stop shops.</li> <li>- No</li> </ul>
	Is the expiration date requirement of 6 months or greater from at the time of donation?	<ul style="list-style-type: none"> <li>- Yes</li> </ul>
	How stringent do you have to be in verifying that somebody does not have 3 <sup>rd</sup> party coverage?	<ul style="list-style-type: none"> <li>- Having an attestation form with their signature would probably suffice?</li> </ul>
	If you are in the Medicare donut hole does that mean you don't have coverage?	<ul style="list-style-type: none"> <li>- You could argue that they don't have coverage if the out-of-pocket expense doesn't count towards the donut hole.</li> </ul>
	Could this be used with Medicaid spend down? Could this help?	<ul style="list-style-type: none"> <li>- Yes.</li> </ul>
	How widely do routine medications get donated as opposed to the more esoteric medications?	<ul style="list-style-type: none"> <li>- Not sure.</li> <li>- Those currently working with Karon's Law stated they receive many medications that they cannot use – they don't see as many medications used by younger patients. They are getting fewer things that they can use yet incur the expense of destroying expired/unused drugs.</li> </ul>

		- One clinic is limiting what they are taking – seems to be working well
	What are the challenges with the sorting, repackaging of donated meds?	<ul style="list-style-type: none"> <li>- Length of time it takes</li> <li>- Number of people handling the drugs</li> <li>- There are organizations that will sort and rebundle for a small fee – it is actually cheaper than using staff/volunteers to do this because of the time involved</li> </ul>
	There are organizations that destroy medications – they may receive medications that are up to 12 months out from their expiration date. Can they donate these?	
	Can disparate donations with disparate expiration dates, etc. be repackaged together? What if they recall a certain lot number?	- Yes – you would have to list the closest date as the expiration date.
<b>Policy</b>	Is this all Ohio Law?	- Yes. Federal law only applies if you are distributing controlled substances.
	Under Senate Bill 33, do the provisions cover somebody who repackages medications?	- No, they would not comply with Karon’s Law so they would not have immunity.

## **Participants**

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