

**Charitable Pharmacy Rule Intent  
July 13, 2010**

**855-044-0001  
Purpose**

This section defines the purpose of the Charitable Pharmacy rule.

**855-044-0005  
Definitions**

Defines terms used in these rules

**855-044-0010  
Registration**

The applicant must develop and submit policies and procedures for the operation of the Charitable Pharmacy. The applicant must also submit a description of the organizations structure and operational work flow for the charitable pharmacy. This would also include job descriptions. The Charitable Pharmacy will name a person who will be a Point-of-Contact (POC) for each location.

**855-044-0020  
Personnel**

The Charitable Pharmacy (CP) must have a pharmacist as the POC or a consulting pharmacist. The CP is required to have a POC for the purpose of responding to Board inquiries. The CP may appoint a pharmacist as the POC if the CP is co-located with an existing pharmacy. This section establishes required policies and procedures. The pharmacist must inspect the medications and determine if they meet the requirements for drugs which may be donated and drugs which do not qualify for donation.

**855-044-0030  
Drug Donation**

This section of rules identifies the medications which can be donated to the CP. These medications would include unit-of-use medications in the manufacturer's packaging which are tamper evident. This includes individual doses sealed in unit dose packaging and medications packaged for use in Long Term Care facilities in sealed bubble packs. The section also defines who may donate to the CP. The donor must certify on a form provided by the Board the drugs have been stored in accordance with manufacturer's requirements.

**855-044-0040  
Storage and Security**

This rule requires proper storage and security of the drugs and patient records.

**855-044-0050**  
**Drug Distribution**

This section defines drugs that may not be distributed under this program. The pharmacist must make a visual inspection of the donated drugs and must approve the drug for distribution. No repackaged medications may be donated with the exception of drugs packaged by a long-term care pharmacy. The drug must have a minimum expiration date of nine months. A recipient of the donated drug must have a valid prescription and be an Oregon resident. The CP may establish policies and guidelines for the eligibility of the recipient based on under-insured status or inadequate health insurance coverage. The CP must make a reasonable effort to establish the eligibility of the recipient. The drug must be dispensed by a properly licensed practitioner with dispensing privileges. A Registered Nurse who receives an order from an authorized prescriber may dispense the medication under the authority granted by the Board for this program. The pharmacist or dispensing practitioner must provide the patient with appropriate medication counseling. The recipient must sign a form attesting to notification of elements of the donation and program.

**855-044-0060**  
**Labeling**

This section outlines proper labeling of the drug to be distributed.

**855-044-0070**  
**Records**

The CP must maintain records of donation, distribution and dispensing which includes the recipient form. The CP must cross-reference the donation record with the distribution, dispensing record and recipient form. The purpose for this cross-reference is to provide a tracking system for the lot number and expiration date of the drug. The CP must complete and submit a report provided by the Board with each renewal of registration.

**855-044-0080**  
**Fees**

This section defines and establishes guidelines for the dispensing fee allowed by this rule. This fee is intended to help cover the cost of dispensing but the cost of the drug can not be included in the fee. Prior to charging a dispensing fee, the CP will need to calculate the fee based on the formula (two and one-half times current Oregon Medicaid dispensing fee) set forth in rule.

**855-044-0090**  
**Liability**

This section restates that the person who accepts or distributes the donated medications for the CP is not subject to criminal prosecution or civil liability as stated in the ORS 689.780.