

BOARD OF PHARMACY

DIVISION 44

Charitable Pharmacies

855-044-0001

Purpose

The purpose of the program is to provide a process to make donated prescription drugs available to needy or uninsured individuals and those with limited access to pharmaceuticals. Under the rules in this Division, a Charitable Pharmacy that is registered with the Oregon Board of Pharmacy (Board) may accept donated drugs for distribution when the pharmacist can reasonably be assured of the purity and integrity of the drug. The program may not include categories of drugs specified by the Board as excluded from the program.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.772 and 689.774

855-044-0005

Definitions

(1) “Charitable Pharmacy” means a facility registered with the Oregon Board of Pharmacy for the purpose of receiving and distributing donated drugs.

(2) “Point-of-Contact” means an individual designated by a charitable pharmacy who serves as the primary contact person for the charitable pharmacy and who is responsible for managing the charitable pharmacy at that location.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.774

855-044-0010

Registration

(1) A facility may not operate as a charitable pharmacy unless it is registered as such with the Board and has paid the fee specified in Division 110 of these rules.

(2) The application for registration must be on a form provided by the Board and must include proposed policies and procedures and a description of the organization.

(3) Each location must be registered separately.

(4) An applicant for registration as a charitable pharmacy must name a point-of-contact for each registered location.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.774

855-044-0020

Personnel

(1) A charitable pharmacy must have a licensed pharmacist. The pharmacist may also be the Point-of-Contact.

(2) A charitable pharmacy that is co-located with an existing registered pharmacy may name a pharmacist employed by the existing pharmacy as its pharmacist.

(3) A charitable pharmacy that is not co-located with an existing registered pharmacy and does not have a pharmacist on staff must employ a consultant pharmacist.

(4) The pharmacist must develop policies and procedures for:

(a) Receiving donated drugs;

(b) Security;

(c) Drug storage;

(d) Distribution of drugs;

(e) Record keeping;

(f) Disposal of unusable drugs; and

(g) Staff training.

(5) The pharmacist must conduct a visual inspection of each donated drug to ensure that the drug has not expired, been adulterated or misbranded and is in its original, sealed packaging, and that based on this inspection and on the accuracy of the Donor's Form, the drug is safe to distribute.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.774

855-044-0030

Drug Donation

(1) A charitable pharmacy may not accept:

(a) Any controlled substance or any kit, package or blister pack that contains any controlled substance;

(b) A non-prescription drug;

(c) A drug in a container or package that does not contain a product identification label (PIL), except that a drug in a manufacturer's original container or a manufacturer's blister pack does not need to bear a PIL.

(2) A charitable pharmacy may accept:

(a) A prescription drug received in original, sealed, tamper-evident packaging that displays the lot number and expiration date of the drug; and

(b) Sealed single unit dose packages received in opened packages containing multiple single unit doses.

(3) The following are examples of acceptable packaging:

(a) Manufacturer's original container;

(b) Single-dose blister packs in sealed outer package;

(c) Single-dose blister packs in opened outer package;

(d) Tamper-evident hospice kit containing manufacturer's original containers.

(4) Donated drugs that do not meet the above criteria or are judged by the pharmacist to be unsafe for re-dispensing must be stored separately from the drug supply until they can be destroyed.

(5) A charitable pharmacy may accept a drug from:

(a) An individual;

(b) A long-term care facility;

(c) A pharmacy;

(d) A practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice;

(e) Another registered charitable pharmacy;

(f) A medical clinic;

(g) A drug manufacturer or wholesaler;

(h) A Medication Assistance Program (MAP) such as those supported by drug manufacturers.

(6) The donor must certify on a Donor Form provided by the Board that the donated drug has been properly stored, in accordance with manufacturer's recommendations, and has never been opened, used, adulterated or misbranded.

(7) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.772 and 689.774

855-044-0040

Storage and Security

(1) A charitable pharmacy must store all donated drugs securely and physically separate from any existing inventory.

(2) All charitable pharmacy records must be secured to comply with HIPAA and all state and federal regulations.

(3) Outdated and unusable drugs intended for destruction must be quarantined and stored securely.

(4) A charitable pharmacy co-located with an existing pharmacy must use storage and record keeping procedures that maintain separation of charitable pharmacy records and drugs from other pharmacy records and inventory.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.774

855-044-0050

Drug Distribution

(1) A charitable pharmacy may not distribute a donated prescription drug that:

(a) Fails to meet the requirements of the program;

- (b) Has not been stored in accordance with manufacturer's recommendations;
 - (c) Has been repackaged, except that a drug that has been repackaged for a long-term care pharmacy may be distributed;
 - (d) Bears an expiration date that is less than nine months from the date the drug is donated;
 - (e) Is adulterated or misbranded;
 - (f) Is a controlled substance;
 - (g) Is a drug that requires a special registration for dispensing;
 - (h) Is an over-the-counter drug;
 - (i) Requires specialty storage or handling;
 - (j) Requires refrigeration;
 - (k) Is a compounded drug; or
 - (L) In the pharmacist's professional judgment, may be unfit for dispensing.
- (2) A charitable pharmacy may only dispense a drug to a person who:
- (a) Has a valid prescription for the drug; and
 - (b) Is a resident of Oregon; and
 - (c) Is underinsured or does not have adequate health insurance coverage for the prescription drug requested; or
 - (d) Is enrolled in a program of public assistance as defined in ORS 411.010;
- (3) A drug may only be dispensed by a pharmacist or by a practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice, or by a registered nurse subject to the following:
- (a) A registered nurse who is an employee of a charitable pharmacy may dispense a drug to a client of the charitable pharmacy; and
 - (b) Such dispensing by a registered nurse shall be pursuant to the order of a person authorized to prescribe the drug.
- (4) The dispensing practitioner must provide the patient with appropriate counseling on the use of the drug and any potential side effects, and may provide written drug information;

(5) A recipient of a drug under this program must sign a Recipient Form, provided by the Board, that attests that the recipient has been notified that:

(a) The prescription drug was donated to the program;

(b) A visual inspection was conducted by a pharmacist to ensure that the drug has not expired, been adulterated or misbranded, and is in its original, sealed packaging;

(c) A pharmacist has determined that the drug is safe to distribute based on the accuracy of the Donor's Form and the visual inspection by the pharmacist;

(d) Participants in the program are immune from liability as provided in ORS 689.780; and

(e) That they are qualified to receive the drug as specified in section (2) of this rule.

(6) Upon written request the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.772 and 689.774

855-044-0060

Labeling

(1) The label on a drug dispensed or distributed from a charitable pharmacy must meet all federal rules and laws and must contain:

(a) The name, address and telephone number of the pharmacy;

(b) The name of the prescribing practitioner;

(c) The initials of the dispensing practitioner;

(d) Date dispensed;

(e) The name of the patient;

(f) Name and manufacturer of drug, drug strength, the quantity dispensed;

(g) Direction for use;

(i) The expiration date;

- (j) A unique identifier; and
 - (k) Any further cautionary information required for patient safety.
- (2) All original patient identification must be removed.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.774

855-044-0070

Records

- (1) A charitable pharmacy must maintain a donation record of all drugs received that includes:
- (a) Donor's name and address;
 - (b) Drug manufacturer, lot number, name and strength;
 - (c) Drug quantity;
 - (d) Expiration date of the drug;
 - (e) Date donated; and
 - (f) The unique identifier.
- (2) A charitable pharmacy must maintain a distribution and dispensing record that includes:
- (a) Drug name and strength;
 - (b) Quantity distributed;
 - (c) Name of manufacturer;
 - (d) Lot number and expiration date;
 - (e) Date of distribution or dispensing;
 - (f) Name and address of recipient.
- (3) A charitable pharmacy must maintain a record of all drugs that are destroyed.
- (4) In addition to the above records, a charitable pharmacy must cross-reference the donation record and the distribution and dispensing record with the appropriate donor and recipient forms.

(5) A charitable pharmacy must make an annual report to the Board by completing a form provided by the Board and submitting it with their application for renewal of registration.

(6) All records required by these rules must be retained for three years and made available to the Board upon request.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.774

855-044-0080

Fees

(1) A charitable pharmacy may not charge a fee for accepting a donation.

(2) A charitable pharmacy may not sell a donated drug.

(3) A charitable pharmacy may charge a dispensing fee that does not exceed two and a half times Oregon's current Medicaid dispensing fee.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.772 and 689.774

855-044-0090

Liability

In accordance with ORS 689.780, a person who accepts or distributes donated prescription drugs through the charitable pharmacy program is not subject to criminal prosecution or civil liability for any injury, death or loss of or damage to person or property that results from the acceptance or distribution of the donated prescription drugs if the participant accepts or distributes the donated prescription drugs in good faith.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.774 and 689.780