

135M.4 Prescription drug donation repository program requirements.

1. A prescription drug or supplies may be accepted and dispensed under the prescription drug donation repository program if all of the following conditions are met:

a. The prescription drug is in its original sealed and tamper-evident packaging. However, a prescription drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit dose packaging remains intact.

b. The prescription drug bears an expiration date that is more than six months after the date the prescription drug was donated. However, a donated prescription drug bearing an expiration date that is six months or less after the date the prescription drug was donated may be accepted and distributed if the drug is in high demand and can be dispensed for use prior to the drug's expiration date.

c. The prescription drug or supplies are inspected before the prescription drug or supplies are dispensed by a licensed pharmacist employed by or under contract with the medical facility or pharmacy, and the licensed pharmacist determines that the prescription drug or supplies are not adulterated or misbranded.

d. The prescription drug or supplies are prescribed by a health care practitioner for use by an eligible individual and are dispensed by a pharmacist or are dispensed to an eligible individual by the prescribing health care practitioner or the practitioner's authorized agent.

2. A prescription drug or supplies donated under this chapter shall not be resold.

3. *a.* If a person who donates prescription drugs under this chapter to a medical facility or pharmacy receives a notice from a pharmacy that a prescription drug has been recalled, the person shall inform the medical facility or pharmacy of the recall.

b. If a medical facility or pharmacy receives a recall notification from a person who donated prescription drugs under this chapter, the medical facility or pharmacy shall perform a uniform destruction of all of the recalled prescription drugs in the medical facility or pharmacy.

4. A prescription drug dispensed through the prescription drug donation repository program shall not be eligible for reimbursement under the medical assistance program.

5. The department shall adopt rules establishing all of the following:

a. Requirements for medical facilities and pharmacies to accept and dispense donated prescription drugs and supplies, including all of the following:

(1) Eligibility criteria for participation by medical facilities and pharmacies.

(2) Standards and procedures for accepting, safely storing, and dispensing donated prescription drugs and supplies.

(3) Standards and procedures for inspecting donated prescription drugs to determine if the prescription drugs are in their original sealed and tamper-evident packaging, or if the prescription drugs are in single-unit doses or blister packs and the outside packaging is opened, if the single-unit dose packaging remains intact.

(4) Standards and procedures for inspecting donated prescription drugs and supplies to determine that the prescription drugs and supplies are not adulterated or misbranded.

b. Eligibility criteria for individuals to receive donated prescription drugs and supplies dispensed under the

program. The standards shall prioritize dispensing to individuals who are indigent or uninsured, but may permit dispensing to other individuals if an uninsured or indigent individual is unavailable.

c. Necessary forms for administration of the prescription drug donation repository program, including forms for use by individuals who donate, accept, distribute, or dispense the prescription drugs or supplies under the program.

d. A means by which an individual who is eligible to receive donated prescription drugs and supplies may indicate such eligibility.

e. The maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated prescription drugs and supplies under the program.

f. A list of prescription drugs that the prescription drug donation repository program will accept.

2005 Acts, ch 97, §4; 2007 Acts, ch 159, §24; 2008 Acts, ch 1058, §6