641—109.4(135M) Standards and procedures for accepting donated prescription drugs and supplies.

109.4(1) Any individual who is 18 years of age or older may donate legally obtained prescription drugs or supplies to the centralized repository or a local repository if the drugs or supplies meet the requirements of this rule, as determined by a pharmacist who is employed by or under contract with a drug repository.

109.4(2) No drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or United States Pharmacopoeia shall be donated or accepted as part of the prescription drug donation repository program. Drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or USP shall not be donated or accepted because of the increased potential for these drugs to become adulterated. Excluded from this restriction are drugs donated directly from a drug manufacturer.

109.4(3) Controlled substances shall not be donated or accepted. Pursuant to federal and state laws, a controlled substance cannot be returned or reused once the drug has been dispensed to a patient.

109.4(4) The centralized repository or a local repository may accept a prescription drug only if all of the following requirements are met:

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

b. The drug has been stored according to manufacturer or USP storage requirements;

c. The packaging contains the lot number and expiration date of the drug. If the lot number is not retrievable, all specified medications will be destroyed in the event of a recall, pursuant to Iowa board of pharmacy rules;

d. The drug has an expiration date that is more than six months after the date that the 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;

e. The drug does not have any physical signs of tampering or adulteration, and there is no reason to believe that the drug is adulterated;

f. The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity or adulteration; and

g. All drugs shall be inventoried at the centralized repository or a local repository. The inventory shall include the name of the drug, strength of the drug, quantity of the drug, and the date of donation if the drug has been continually under the control of a health care professional. If the drug has not been continually under the control of a health care professional, the repository shall collect a donation form provided by the prescription drug donation repository program that is signed by the person making the donation or that person’s authorized representative.

109.4(5) A repository may accept supplies necessary to administer the prescription drugs donated only if all of the following requirements are met:

a. The supplies are in their original, unopened, sealed packaging;

b. The supplies are not adulterated or misbranded; and

c. All supplies shall be inventoried at the centralized repository or a local repository. The inventory shall include a description of the supplies and the date donated. Such inventory shall be recorded on a form provided by the prescription drug donation repository program.

109.4(6) Drugs and supplies may be donated on the premises of a participating centralized repository or a local repository to a person designated by the repository. A drop box may not be used to deliver or accept donations.