

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

109.4(1) A licensed pharmacist employed by or under contract with the centralized repository or a local repository shall inspect donated prescription drugs and supplies to determine, to the extent reasonably possible in the judgment of the pharmacist, that the drugs and supplies are not adulterated or misbranded, are safe and suitable for dispensing, and are not ineligible drugs or supplies. The pharmacist who inspects the drugs shall sign an inspection record stating the above and attach it to the copy of the inventory or donor record provided with the drugs. If a local repository receives drugs and supplies from the centralized repository, the local repository does not need to reinspect the drugs and supplies.

109.4(2) The centralized repository and local repositories shall store donated drugs and supplies in a secure storage area under environmental conditions appropriate for the drugs or supplies being stored. Donated drugs and supplies will not be stored with nondonated inventory. When donated drugs are not inspected immediately upon receipt, a repository shall quarantine the donated drugs separately from all dispensing stock until the donated drugs have been inspected and approved for dispensing under the program.

109.4(3) Repositories shall destroy donated noncontrolled substances that are not suitable for dispensing and make a record of such destruction according to rules of the board of pharmacy. The destruction record shall be made in the same manner as prescribed for the record of return or destruction of a controlled substance in subrule 109.4(4).

109.4(4) Controlled substances shall not be accepted for donation.

a. Controlled substances submitted for donation shall be documented and returned immediately to the donor or the donor's representative that provided the drugs.

b. In the event controlled substances enter the centralized repository or a local repository and it is not possible or practicable to return the controlled substances to the donor or the donor's representative due to inability to identify the donor or the donor's representative or due to refusal by the donor or the donor's representative to receive them, abandoned controlled substances shall be documented and destroyed beyond reclamation pursuant to rules of the board of pharmacy. Such destruction shall be performed by a pharmacist or other person who has authority to dispense controlled substances and shall be witnessed by another responsible adult employee of the repository.

109.4(5) If a repository receives a recall notification, the repository shall perform a uniform destruction of all of the recalled prescription drugs in the repository and complete the destruction information form for all donated drugs destroyed. If a recalled drug has been dispensed, the repository shall immediately notify the recipient of the recalled drug pursuant to established drug recall procedures.

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