Ohio Administrative Code

Rule 4729:5-10-04 Eligible drugs and storage requirements.

Effective: May 27, 2023

(A) Except as provided in paragraphs (B) and (C) of this rule, drugs donated to a repository program shall be in the original sealed and tamper-evident unit dose packaging and shall meet all of the following requirements:

(1) The packaging shall be unopened except that the drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed.

(2) If the drugs were packaged by a pharmacy, the name of the pharmacy and any other pharmacy identifiers shall be removed from the packaging prior to dispensing or personally furnishing to a recipient patient. This may be accomplished by removing the drug from the pharmacy packaging or by removing the name from the outside packaging of a multiple dose, unit dose packaging system.

(3) The drugs have not been in the possession of the patient and are under the control of the pharmacy, drug manufacturer, government entity, or health care facility.

(4) The drugs have been stored according to federal and state requirements.

(5) The drugs shall include an expiration date on the label or packaging. If the prescription container is the manufacturer's original sealed packaging, the expiration date is the expiration date listed on the packaging. A repository program shall not dispense or personally furnish a donated drug that is beyond the expiration date.

(6) The repository program shall develop and implement standards and procedures to determine, based on a basic visual inspection by a licensed pharmacist or prescriber, that the drugs appear to be unadulterated, safe, and suitable for dispensing or personally furnishing.

(7) The drugs shall not have any physical signs of tampering, misbranding, or adulteration.

(8) The drug packaging shall not have any physical signs of tampering.

(9) Pursuant to division (J) of section 3715.873 the following drugs and drug types are prohibited from being donated to a repository program in accordance with this paragraph, as they are prohibited from donation by federal or state law or may pose a significant health risk to employees or patients of a repository program:

(a) Controlled substances, except for controlled substances in a long-acting or extended-release form used for the treatment of opioid dependence or addiction.

(b) Drug samples, unless the repository is operated by a charitable pharmacy.

(c) Radiopharmaceuticals as defined in rule 4729:5-8-01 of the Administrative Code.

(d) A drug for which the United States food and drug administration requires, as a risk evaluation and mitigation strategy, that the patient be registered with the drug's manufacturer.

(e) Compounded drugs.

(B) A drug repository program operated by a pharmacy, hospital, or non-profit clinic may accept donations of orally administered cancer drugs, as defined in rule 4729:5-10-01 of the Administrative Code, that are not in the original sealed and tamper-evident unit dose packaging if all of the following requirements are met:

(1) The repository program shall develop and implement standards and procedures to determine, based on a basic visual inspection by a licensed pharmacist or prescriber, that the drugs appear to be unadulterated, safe, and suitable for dispensing or personally furnishing.

(2) The drugs have been stored according to federal and state requirements.

(3) The drugs shall include an expiration date on the label or packaging. If the prescription container is the manufacturer's original sealed packaging, the expiration date is the expiration date listed on the

packaging. A repository program shall not dispense or personally furnish a donated drug that is beyond the expiration date.

(4) The drugs shall not have any physical signs of tampering, misbranding, or adulteration.

(5) The drugs do not require refrigeration, freezing, or storage at a special temperature.

(6) Pursuant to division (J) of section 3715.873 the following drugs and drug types are prohibited from being donated to a repository program in accordance with this paragraph, as they are prohibited from donation by federal or state law or may pose a significant health risk to employees or patients of a repository program:

(a) Controlled substances.

(b) Drug samples, unless the repository is operated by a charitable pharmacy.

(c) Radiopharmaceuticals as defined in rule 4729:5-8-01 of the Administrative Code.

(d) A drug for which the United States food and drug administration requires, as a risk evaluation and mitigation strategy, that the patient be registered with the drug's manufacturer.

(e) Compounded drugs.

(7) Nothing in this paragraph prohibits a drug repository program operated by a pharmacy, hospital, or non-profit clinic from accepting donations of orally administered cancer drugs that are in the original sealed and tamper-evident unit dose packaging if the program complies with the requirements of this paragraph.

(C) A drug repository program operated by a charitable pharmacy, hospital, or non-profit clinic may accept donations of drugs, including any such drugs that are orally administered cancer drugs or that may require storage at a special temperature, that are not in the original sealed and tamper-evident unit dose packaging if all of the following requirements are met:

(1) The repository program shall develop and implement standards and procedures to determine, based on a basic visual inspection by a licensed pharmacist or prescriber, that the drugs appear to be unadulterated, safe, and suitable for dispensing or personally furnishing.

(2) The drugs have been stored according to federal and state requirements.

(3) The drugs shall include an expiration date on the label or packaging. If the prescription container is the manufacturer's original sealed packaging, the expiration date is the expiration date listed on the packaging. A repository program shall not dispense or personally furnish a donated drug that is beyond the expiration date.

(4) The drugs shall not have any physical signs of tampering, misbranding, or adulteration.

(5) Pursuant to division (J) of section 3715.873 the following drugs and drug types are prohibited from being donated to a repository program in accordance with this paragraph, as they are prohibited from donation by federal or state law or may pose a significant health risk to employees or patients of a repository program:

(a) Controlled substances.

(b) Drug samples, unless the repository is operated by a charitable pharmacy.

(c) Radiopharmaceuticals as defined in rule 4729:5-8-01 of the Administrative Code.

(d) A drug for which the United States food and drug administration requires, as a risk evaluation and mitigation strategy, that the patient be registered with the drug's manufacturer.

(e) Compounded drugs.

(6) Nothing in this paragraph prohibits a drug repository program operated by a pharmacy, hospital, or non-profit clinic from accepting donations of drugs that are in the original sealed and tamper-evident unit dose packaging if the program complies with the requirements of this paragraph.

(D) In the case of recalls, any donated drugs affected by the recall shall not be dispensed or personally furnished unless the lot number can be determined.

(E) A repository shall quarantine the donated drugs separately from all dispensing stock until the donated drugs have been inspected and approved in accordance with this rule.

(F) No drugs may be dispensed or personally furnished by a drug repository that contain any confidential patient information from the original donor.