4729:5-10-01 **Definitions - drug repository programs.**

As used in Chapter 4729:5-10 of the Administrative Code:

(A) "Charitable pharmacy" has the same meaning as in section 3719.811 of the Revised Code.

~~(A)~~(B) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

~~(B)~~(C) "Distributor of dangerous drugs" or "drug distributor" has the same meaning as in rule 4729:6-1-01 of the Administrative Code.

~~(C)~~(D) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

~~(D)~~(E) "Drug repository program" means a program authorized to accept prescription drugs donated or given for the purpose of being dispensed or personally furnished to individuals who are residents of this state and meets eligibility standards established in this chapter.

~~(E)~~(F) "Hospital" has the same meaning as in section 3727.01 of the Revised Code.

~~(F)~~(G) "Institutional facility" has the same meaning as defined in agency 4729 of the Administrative Code.

~~(G)~~(H) "Licensed health care professional" has the same meaning as in section 3715.872 of the Revised Code.

~~(H)~~(I) "Nonprofit clinic" has the same meaning as in section 3715.87 of the Revised Code.

~~(I)~~(J) "Orally administered cancer drug" means either of the following:

(1) An orally administered dangerous drug that is used to treat cancer or its side effects; or

(2) An orally administered dangerous drug that is used to treat the side effects of a dangerous drug used to treat cancer.

~~(J)~~(K) "Original sealed and tamper-evident unit dose packaging" includes single unit dose packaging of oral medications from a manufacturer or a repackager registered with the federal food and drug administration, or from a pharmacy ~~licensed as a terminal~~

~~distributor of dangerous drugs,~~ and includes injectables, topicals, and aerosols in the manufacturer's or repackager's unopened original tamper-evident packaging.

~~(K)~~(L) "Prescription drug" has the same meaning as in section 3715.87 of the Revised Code.

~~(L)~~(M) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer or inspector of the board.

(N) "Underinsured" means any of the following:

(1) Having health care coverage or prescription drug coverage but having exhausted these benefits or being unable to afford any associated deductible, coinsurance, copayments, or similar charges for the drug prescribed; or

(2) Not having prescription drug coverage for the drug prescribed.

4729:5-10-02 **Eligibility requirements for a pharmacy, hospital, or nonprofit.**

A pharmacy, hospital, or nonprofit clinic may elect to participate in a drug repository program, pursuant to sections 3715.87 to 3715.873 of the Revised Code, if all of the following requirements are met:

(A) Must be licensed as a terminal distributor of dangerous drugs pursuant to section 4729.54 of the Revised Code.

(B) Must comply with all applicable federal and state laws, rules, and regulations.

(C) A pharmacy, hospital, or nonprofit clinic that operates a drug repository program that receives donations or dispenses medications to the general public shall notify the board, in a manner determined by the board, within thirty days of establishing a repository program.

(D) A pharmacy, hospital, or nonprofit clinic that no longer operates a drug repository program that receives donations or dispenses medications to the general public shall notify the board, in a manner determined by the board, within thirty days of discontinuation.

4729:5-10-03 **Donating drugs.**

(A) The following may donate or facilitate the donation of a ~~dangerous~~ drug, pursuant to the eligibility requirements of rule 4729:5-10-04 of the Administrative Code, to a pharmacy, hospital, or nonprofit clinic that elects to participate in a drug repository program:

(1) Any pharmacy, drug manufacturer, or health care facility, or other person or government entity may donate or give drugs to a drug repository program.

(2) Any person or government entity may facilitate the donation or gift of drugs to the program.

~~(1) A licensed terminal distributor of dangerous drugs.~~

~~(2) A licensed drug distributor~~

~~(3) A person who was legally dispensed or personally furnished a dangerous drug pursuant to a patient-specific drug order.~~

~~(B) Except for orally administered cancer drugs described in paragraph (B) of rule 4729:5-10-04 of the Administrative Code, a person electing to donate an eligible dangerous drug shall not have taken custody of the drug prior to the donation. The person may direct the donation through a terminal distributor of dangerous drugs.~~

(B) Except as provided in paragraph (C) of this rule, a person electing to donate an eligible dangerous drug shall not have taken custody of the drug prior to the donation. The person may direct the donation through any entity or person authorized in paragraph (A) of this rule.

(C) The restriction in paragraph (B) of this rule does not apply to the following:

(1) Orally administered cancer drugs described in paragraph (B) of rule 4729:5-10-04 of the Administrative Code;

(2) Drugs described in paragraph (C) of rule 4729:5-10-04 of the Administrative Code donated to a charitable pharmacy, hospital, or nonprofit clinic.

~~(C)~~(D) A person who resides in an institutional facility and was legally dispensed a dangerous drug pursuant to a patient-specific order may elect to sign and date a donor form prior to donating a drug, which shall state "from this day forward I wish to

donate all my remaining unused drugs that are eligible, pursuant to rule 4729:5-10-04 of the Administrative Code, to a drug repository program."

(E) The following may make the decision to donate an eligible drug on behalf of a patient:

(1) A person designated by durable power of attorney, a guardian, or other individual responsible for the care and well-being of a patient; or

(2) An executor, administrator, or trustee of the estate of a deceased patient.

~~(D) A person designated by durable power of attorney, a guardian, or other individual responsible for the care and well-being of a patient may make the decision to donate an eligible dangerous drug.~~

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

(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.

4729:5-10-05 **Eligibility requirements to receive drugs.**

A pharmacy, hospital, or nonprofit clinic that elects to participate in a drug repository program must determine if a person is eligible to receive drugs. A person must meet the following requirements to become an eligible recipient of drugs from a drug repository program:

(A) Is a resident of Ohio or currently resides in this state; and

(B) Meets any of the following criteria:

(1) ~~Has no reasonable financial means to pay for the drug prescribed~~Is uninsured or underinsured as defined in rule 4729:5-10-01 of the Administrative Code; or

(2) ~~Is a patient of a nonprofit clinic~~Meets any other eligibility requirements, as determined by the repository program's eligibility policy.

4729:5-10-06 **~~Donor and recipient forms~~Required forms and record keeping.**

(A) Each donor must sign ~~a~~an electronic or physical form stating that the donor is the owner of the drug and intends to voluntarily donate the drug to the drug repository program. The donor form must be completed prior to any donation and include at least the following:

(1) The name of the person that was originally dispensed the drugs or the name of the ~~terminal distributor of dangerous drugs or drug distributor~~entity that owns the drugs.

(2) The full name, contact phone, and signature of the donor, which may include any of the following:

(a) The person designated by durable power of attorney, a guardian, an individual responsible for the care and well-being of a patient;

(b) The executor, administrator, or trustee of the estate of a deceased patient;

(c) The responsible person or the responsible person's designee of a terminal distributor of dangerous drugs or a drug distributor;

(d) The licensed prescriber or pharmacist responsible for the oversight of the entity donating the drug.

(3) The address of the donor or the entity donating the drug.

~~(2) The signature of the donor, which may include the person designated by durable power of attorney, a guardian, an individual responsible for the care and well-being of a patient, or the signature of the responsible person or the responsible person's designee of a terminal distributor of dangerous drugs or a drug distributor.~~

~~(3)~~(4) The date the form was signed.

(B) The following donor information must also be documented. This information may be documented on the original signed donor form or on an alternate record created by the repository program. If an alternate record is used, the record must include the name of the donor in addition to the required information in this paragraph.

(1) The brand name or generic name of the drug donated and either the name of the manufacturer or the national drug code number (NDC#).

(2) The strength of the drug donated.

(3) The quantity of the drug donated.

(4) The date the drug was donated.

(C) Prior to receiving donated drugs from a drug repository program, each recipient must sign ~~a~~ an electronic or physical form stating they understand the immunity provisions of the program pursuant to division (B) of section 3715.872 of the Revised Code.

(D) Donor forms shall be maintained for a minimum of three years in a readily retrievable manner by the repository program.

(E) Recipient forms shall be maintained for a minimum of three years in a readily retrievable manner by the repository program.

(F) A prescriber shall document the distribution of a personally furnished donated repository program drug to the prescriber's patient pursuant to the applicable record keeping rules of division 4729:5 of the Administrative Code and a pharmacy shall document the dispensing of a donated repository program drug pursuant to the applicable record keeping rules of division 4729:5 of the Administrative Code. Such records shall indicate that the drug distributed to a patient was from a repository program. If recipient forms are used with each dispensing or personal furnishing, this information may be documented on the recipient form.

4729:5-10-07 **Occasional sales and handling fee.**

(A) A pharmacy, hospital, or nonprofit clinic may charge the recipient of a donated drug a handling fee up to twenty dollars to cover restocking and dispensing costs. If a drug repository program chooses to charge a handling fee, then the fees collected in any given year shall not exceed the program's total restocking and dispensing costs for that given year.

(B) A charitable pharmacy, hospital, or nonprofit clinic that operates a drug repository program may conduct occasional sales at wholesale of drugs that have been donated or given to the program if all of the following apply:

(1) The receiving location is a charitable pharmacy, hospital, or nonprofit clinic that operates a drug repository program in this state or an entity participating in a drug repository program operated by another state subject to the laws of that state.

(2) The seller maintains a record of or sale that contains the following information:

(a) The name, strength, dosage form, national drug code, and quantity of the dangerous drug transferred or sold, the address of the location where the drugs were transferred or sold, the date of transfer or sale; or

(b) In lieu of the requirements listed in paragraph (B)(2)(a) of this rule, a hospital may document the transfer of the drug within the hospital system in accordance with paragraph (F) of rule 4729:5-9-02.3 of the Administrative Code.

(3) The seller provides a copy of the record of sale as outlined in this paragraph to the receiver.

(4) The seller and receiver maintain a record of the sale for three years from the date of creation in a readily retrievable manner.