Operating a Drug Repository Program

Updated 5/25/2023

Section 3715.87 of the Revised Code permits a licensed terminal distributor of dangerous drugs (TDDD) to operate a drug repository program. A drug repository program is a program that receives eligible donated drugs to provide to patients who are uninsured, underinsured, or who meet any other eligibility requirements determined by the repository program's eligibility policy.

Effective May 27, 2023, charitable pharmacies, hospitals, and non-profit clinics are now permitted to accept or distribute donated drugs that are not in their original sealed and tamper-evident unit dose packaging.

To reflect these changes, the Board updated its rules governing drug repositories (effective 5.27.23). Select the rule number in the table below to access a copy of the rules:

Rule Number	Rule Title
4729:5-10-01	Definitions - drug repository programs.
4729:5-10-02	Eligibility requirements for a pharmacy, hospital, or nonprofit.
4729:5-10-03	Donating drugs.
4729:5-10-04	Eligible drugs and storage requirements.
4729:5-10-05	Eligibility requirements to receive drugs.
4729:5-10-06	Required forms and record keeping.
4729:5-10-07	Occasional sales and handling fee.
4729:5-3-09	Occasional sale and drug transfers.

For questions regarding the operation of a drug repository program, please review this document. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

Frequently Asked Questions

Q1) Are there any significant changes in the updated rule chapter?

Yes. The rules are being updated to reflect passage of HB 558 of the 134th General Assembly, which allows charitable pharmacies, hospitals, and nonprofit clinics to accept or distribute donated drugs that are not in their original sealed and tamper-evident unit dose packaging. Additionally, the law authorizes participating charitable pharmacies, hospitals, and nonprofit clinics to make occasional sales of donated drugs at wholesale.

Q2) Who is permitted to operate a drug repository program?

An Ohio pharmacy, hospital, or nonprofit clinic licensed as a terminal distributor of dangerous drugs (TDDD) may elect to operate a drug repository program. **NOTE:** A TDDD does not have to make any modifications to its license to operate a repository program.

Per section 3715.87 of the Revised Code, a "nonprofit clinic" means a charitable nonprofit corporation organized and operated pursuant to Chapter 1702. of the Revised Code, or any charitable organization not organized and not operated for profit, that provides health care services to indigent and uninsured persons, as defined in section 2305.234 of the Revised Code, or to underinsured persons, as defined in rules adopted under section 3715.873 of the Revised Code. "Nonprofit clinic" does not include a hospital, a facility licensed under Chapter 3721. of the Revised Code, or a facility that is operated for profit.

Q3) Who may donate eligible drugs to a drug repository program?

The following may donate or facilitate the donation of a drug, pursuant to the eligibility requirements of rule 4729:5-10-03 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.

See OAC 4729:5-10-03 for more information.

Q4) What types of drugs are eligible to be donated to a drug repository program?

For drugs contained in their original sealed and tamper-evident unit dose packaging (applicable to pharmacies, hospitals, and non-profit clinics):

(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 (REMS), that the patient be registered with the drug's manufacturer.

(e) Compounded drugs.

See OAC 4729:5-10-04 (A) of the Administrative Code.

For orally administered cancer drugs that are not in original sealed and tamper-evident unit dose packaging (applicable to pharmacies, hospitals, and non-profit clinics):

(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 (REMS), that the patient be registered with the drug's manufacturer.

(e) Compounded drugs.

NOTE: The rule does not prohibit 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.

REMINDER: Orally administered cancer drugs mean 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. Orally administered cancer drugs do not include controlled substances or drugs that require refrigeration, freezing, or storage at a special temperature.

See OAC 4729:5-10-04 (B) for more information.

For all other drugs that are not in original sealed and tamper-evident unit dose packaging, including drugs that may require storage at a special temperature (applicable to charitable pharmacies, hospitals, and non-profit clinics):

(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.

[See OAC 4729:5-10-04 (C)]

Q5) Who is eligible to receive drugs from a repository program?

A person must meet the following requirements to receive drugs from a drug repository program:

Is a resident of Ohio or currently resides in this state, and either:

1. Is uninsured or underinsured as defined in rule 4729:5-10-01 of the Administrative Code.
2. Meets any other eligibility requirements, as determined by the repository program's eligibility policy.

[See OAC 4729:5-10-05]

REMINDER: "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. [see OAC 4729:5-10-01 (N)]

Q6) What type of documentation is necessary for a person to donate a drug to a drug repository program?

Each donor must sign 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 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; or
    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.

4. The date the form was signed.

NOTE: A repository program may opt to have a patient sign a donor form in advance of receiving treatment in the event the patient discontinues treatment or misses a certain number of appointments.

IMPORTANT REMINDERS:

- The donor forms may be signed physically or by electronic signature. [See OAC 4729:5-10-06 (C)].
- Donor forms shall be maintained for a minimum of three years in a readily retrievable manner by the repository program. [See OAC 4729:5-10-06 (C)].
- The Board does not offer sample forms, nor does it approve forms. It is up to the repository program to comply with this requirement.

Q7) Is any additional information required to be maintained regarding a donor?

Yes. The following donor information must also be documented:

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.

This information may be documented on the original signed donor form or on an alternate record. If an alternate record is used, the record must include the name of the donor.

IMPORTANT: The Board does not offer sample forms, nor does it approve forms. It is up to the repository program to comply with this requirement.

Q8) What type of documentation is necessary for a person to receive a donated drug from a drug repository?

The recipient must attest that they understand the immunity provisions of the program pursuant to division (B) of section 3715.872 of the Revised Code, which states the following:

> *(B) For matters related to activities conducted under the drug repository program, all of the following apply:*
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> *(1) A pharmacy, drug manufacturer, health care facility, or other person or government entity that donates or gives drugs to the program, and any person or government entity that facilitates the donation or gift, shall not be subject to liability in tort or other civil action for injury, death, or loss to person or property.*
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> *(2) A pharmacy, hospital, or nonprofit clinic that accepts or distributes drugs under the program shall not be subject to liability in tort or other civil action for injury, death, or loss to person or property, unless an action or omission of the pharmacy, hospital, or nonprofit clinic constitutes willful and wanton misconduct.*
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> *(3) A health care professional who accepts, dispenses, or personally furnishes drugs under the program on behalf of a pharmacy, hospital, or nonprofit clinic participating in the program, and the pharmacy, hospital, or nonprofit clinic that employs or otherwise uses the services of the health care professional, shall not be subject to liability in tort or other civil action for injury, death, or loss to person or property, unless an action or omission of the health care professional, pharmacy, hospital, or nonprofit clinic constitutes willful and wanton misconduct.*
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> *(4) The state board of pharmacy shall not be subject to liability in tort or other civil action for injury, death, or loss to person or property, unless an action or omission of the board constitutes willful and wanton misconduct.*
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> *(5) In addition to the civil immunity granted under division (B)(1) of this section, a pharmacy, drug manufacturer, health care facility, or other person or government entity that donates or gives drugs to the program, and any person or government entity that facilitates the donation or gift, shall not be subject to criminal prosecution for matters related to activities that it conducts or another party conducts under the program, unless an action or omission of the party that donates, gives, or facilitates the donation or gift of the drugs does not comply with the provisions of this chapter or the rules adopted under it.*
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> *(6) In the case of a drug manufacturer, the immunities from civil liability and criminal prosecution granted to another party under divisions (B)(1) and (5) of this section extend to the manufacturer when any drug it manufactures is the subject of an activity conducted under the program. This extension of immunities includes, but is not limited to, immunity from liability or prosecution for failure to transfer or communicate product or consumer information or the expiration date of a drug that is donated or given.*

[see OAC 4729:5-10-06 (C)]

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

IMPORTANT: The Board does not offer sample forms, nor does it approve forms. It is up to the repository program to comply with this requirement.

Q9) What type of records must be maintained by a drug repository program?

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. [see OAC 4729:5-10-06 (F)]

- For pharmacies, this means compliance with all standard record keeping requirements of Chapter 4729:5-5 of the Administrative Code.

- For clinics, this means compliance with all standard record keeping requirements of Chapter 4729:5-19 of the Administrative Code.

Q10) Are there limitations on types that can be collected by a drug repository program?

Yes. Drug repository programs are prohibited from collecting the following:

1. Controlled substances, except for controlled substances in a long-acting or extended-release form used for the treatment of opioid dependence or addiction. **[NOTE: This only applies to long-acting or extended release medications that have not been in the possession of the patient]. (See Q4 of this document for more information)**

2. Drug samples, unless the repository is operated by a charitable pharmacy.

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

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

5. Compounded drugs.

Q11) Is a repository program required to quarantine donated drug prior to inspection?

Yes. 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. [see OAC 4729:5-10-04 (E)]

Q12) Am I required to notify the Board if my organization operates a drug repository program?

Yes. A pharmacy, hospital, or nonprofit clinic that operates a drug repository program that receives donations or dispenses medications to the public shall notify the board, in a manner determined by the board, within thirty days of establishing a repository program. [see OAC 4729:5-10-02 (C)]

Conversely, a pharmacy, hospital, or nonprofit clinic that no longer operates a drug repository program that receives donations or dispenses medications to the public shall notify the board, in a manner determined by the board, within thirty days of discontinuation. [see OAC 4729:5-10-02 (D)]

The one-page notification form can be accessed here: www.pharmacy.ohio.gov/repnotify.

NOTE: The information provided will be made publicly available to ensure that patients and potential donors can locate active repository programs.

Q13) I am a drug repository program, am I permitted to transfer drugs collected by the program to a different repository program?

Yes. 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) 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.

[see OAC 4729:5-10-07 (B)]