



Operating a Drug Repository Program

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[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 have no reasonable financial means to pay for the drug or who are patients of a nonprofit clinic.

All rules governing drug repository programs are located in Chapter 4729:5-10 of the Administrative Code (select the rule number in the table to access a copy of the rule):

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.
4729:5-10-05	Eligibility requirements to receive drugs.
4729:5-10-06	Donor and recipient forms.
4729:5-10-07	Record keeping and handling fee.

NOTE: Drug repository rules in [OAC 4729-35](#) are no long applicable, as they have been rescinded. Licensees should comply with the requirements in OAC 4729:5-10.

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>.

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

The general operation of a drug repository program has not changed substantially in OAC 4729:5-10. However, rule [4729:5-10-04](#) does expand the type of drugs that may be collected by a repository to include the following:

- Orally administered cancer drugs that are not in original sealed and tamper-evident unit dose packaging. "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. Orally administered cancer drugs do not include controlled substances or drugs that require refrigeration, freezing, or storage at a special temperature.

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

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 in order 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. "Nonprofit clinic" does not include a hospital as defined in section 3727.01 of the Revised Code, 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 eligible drugs to a pharmacy, hospital, or nonprofit clinic that elects to operate a drug repository program:

- A licensed terminal distributor of dangerous drugs.
- A licensed drug distributor (i.e. manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider, repackager of dangerous drugs, or wholesale distributor of dangerous drugs).
- A person who was legally dispensed a dangerous drug pursuant to a patient-specific drug order. **IMPORTANT:** Except for orally administered cancer drugs, the person must not have taken custody of the drug prior to the donation. The person must direct the donation through a terminal distributor of dangerous drugs. This may include drugs maintained by an institutional facility that are not in the possession of the ultimate user. 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:

1. The packaging must 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. If the drugs were packaged by a pharmacy, the name of the pharmacy and any other pharmacy identifiers must 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.

2. The drugs have been in the possession of a licensed healthcare professional, terminal distributor of dangerous drugs, or drug distributor and not in the possession of the ultimate user (i.e. patient or caregiver).
3. The drugs have been stored according to federal and state requirements. The drugs must have an expiration date of six months or greater.
4. The repository program has developed and implemented standards and procedures to determine, based on a basic visual inspection, that the drugs appear to be unadulterated, safe, and suitable for dispensing.
5. The packaging must list the lot number and expiration date of the drug.
6. The drugs must not have any physical signs of tampering or adulteration.
7. The drug packaging must not have any physical signs of tampering.
8. All confidential patient information must have been removed from the drug packaging.
9. Except for controlled substances in a long-acting or extended-release form used for the treatment of opioid dependence or addiction, the drugs must not be controlled substances.
10. The drugs must not be samples.

For orally administered cancer drugs that are not in original sealed and tamper-evident unit dose packaging:

1. The repository program has developed and implemented standards and procedures to determine, based on a basic visual inspection, that the drugs appear to be unadulterated, safe, and suitable for dispensing.
2. The drugs have been stored according to federal and state requirements.
3. The drugs must have an expiration date of six months or greater.
4. The packaging must list the expiration date of the drug.
5. The drugs must not have any physical signs of tampering or adulteration.
6. The drugs must not be controlled substances or drug samples.

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.

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, and either:

1. Has no reasonable financial means to pay for the drug prescribed; or,
2. Is a patient of a nonprofit clinic (see Q2 for a definition of a non-profit clinic).

NOTE: Residency is not defined. It is up to the program to set standards on who is considered an Ohio resident.

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

Each donor must sign a 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 that owns the drugs.
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 wellbeing 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. 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: 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.

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

Prior to receiving donated drugs from a drug repository program, each recipient must sign a form stating 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 donating, giving, accepting, or dispensing drugs under the drug repository program, all of the following apply:

(1) Any person, including a pharmacy, drug manufacturer, or health care facility, or any government entity that donates or gives drugs to the drug repository program shall not be subject to liability in tort or other civil action for injury, death, or loss to person or property.

(2) A pharmacy, hospital, or nonprofit clinic that accepts or dispenses 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.

(3) A health care professional who accepts or dispenses drugs under the program on behalf of a pharmacy, hospital, or nonprofit clinic, 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.

(4) The state board of pharmacy and the director of health 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 or director constitutes willful and wanton misconduct.

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?

[Rule 4729:5-10-07 of the Ohio Administrative Code](#) includes all the record keeping requirements for the operation of a drug repository program.

NOTE: This rule references requirements that pharmacies and prescribers document the dispensing or personally furnishing of a repository drug in accordance with division 4729:5 of the Ohio Administrative Code. Until such rules governing dispensing/personally furnishing are finalized in OAC 4729:5, licensees should adhere to current requirements governing the dispensing/personally furnishing of dangerous drugs.