
OHIO STATE BOARD OF PHARMACY
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DRUG REPOSITORY PROGRAM

ORC - <i>Ohio Revised Code</i> OAC - <i>Ohio Administrative Code</i>
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Karon's Law

Summary of Laws and Rules

3715.87 Drug repository program for donated prescription drugs - definitions.

(A) As used in this section and in sections 3715.871, 3715.872, and 3715.873 of the Revised Code:

(1) "Health care facility" has the same meaning as in section 1337.11 of the Revised Code.

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

(3) "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.

(4) "Prescription drug" means any drug to which the following applies:

(a) Under the "Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear a label containing the legend, "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only upon a prescription.

(b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription.

(B) The state board of pharmacy shall establish a drug repository program to accept and dispense prescription drugs donated or given for the purpose of being dispensed to individuals who are residents of this state and meet eligibility standards established in rules adopted by the board under section 3715.873 of the Revised Code. Only drugs in

their original sealed and tamper-evident unit dose packaging may be accepted and dispensed. The packaging must be unopened, except that 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. Drugs donated by individuals bearing an expiration date that is less than six months from the date the drug is donated shall not be accepted or dispensed. A drug shall not be accepted or dispensed if there is reason to believe that it is adulterated as described in section 3715.63 of the Revised Code. Subject to the limitations specified in this division, unused drugs dispensed for purposes of the medicaid program may be accepted and dispensed under the drug repository program.

Effective Date: 04-07-2004; 2007 SB33 08-22-2007

3715.871 Drugs must be donated at pharmacy, hospital, or nonprofit clinic participating in program.

(A) Any person, including a pharmacy, drug manufacturer, or health care facility, or any government entity may donate or give prescription drugs to the drug repository program. The drugs must be donated or given at a pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program and meets criteria for participation in the program established in rules adopted by the state board of pharmacy under section 3715.873 of the Revised Code. Participation in the program by pharmacies, hospitals, and nonprofit clinics is voluntary. Nothing in this or any other section of the Revised Code requires a pharmacy, hospital, or nonprofit clinic to participate in the program.

(B) A pharmacy, hospital, or nonprofit clinic eligible to participate in the program shall dispense drugs donated or given under this section to individuals who are residents of this state and meet the eligibility standards established in rules adopted by the board under section 3715.873 of the Revised Code or to other government entities and nonprofit private entities to be dispensed to individuals who meet the eligibility standards. A drug may be dispensed only pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs, as defined in section 4729.01 of the Revised Code. A pharmacy, hospital, or nonprofit clinic that accepts donated or given drugs shall comply with all applicable federal laws and laws of this state dealing with storage and distribution of dangerous drugs and shall inspect all drugs prior to dispensing them to determine that they are not adulterated. The pharmacy, hospital, or nonprofit clinic may charge individuals receiving donated or given drugs a handling fee established in accordance with rules adopted by the board under section 3715.873 of the Revised Code. Drugs donated or given to the repository may not be resold.

Effective Date: 04-07-2004; 2007 SB33 08-22-2007

3715.872 Immunity.

(A) As used in this section, "health care professional" means any of the following who provide medical, dental, or other health-related diagnosis, care, or treatment:

(1) Individuals authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery;

(2) Registered nurses and licensed practical nurses licensed under Chapter 4723. of the Revised Code;

(3) Physician assistants authorized to practice under Chapter 4730. of the Revised Code;

(4) Dentists and dental hygienists licensed under Chapter 4715. of the Revised Code;

(5) Optometrists licensed under Chapter 4725. of the Revised Code;

(6) Pharmacists licensed under Chapter 4729. of the Revised Code.

(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.

(C) In addition to the immunity granted under division (B)(1) of this section, any person, including a pharmacy, drug manufacturer, or health care facility, and any government entity that donates or gives drugs to the program shall not be subject to criminal prosecution for the donation, giving, acceptance, or dispensing of drugs under the program, unless an action or omission of the person or government entity does not comply with the provisions of this chapter or the rules adopted under it.

(D) In the case of a drug manufacturer, the immunities granted under divisions (B)(1) and (C) of this section apply with respect to any drug manufactured by the drug manufacturer that is donated or given by any person or government entity under the program, including but not limited to liability for failure to transfer or communicate product or consumer information or the expiration date of the drug donated or given.

Effective Date: 04-07-2004; 2007 SB33 08-22-2007

3715.873 Adoption of rules.

In consultation with the director of health, the state board of pharmacy shall adopt rules governing the drug repository program that establish all of the following:

(A) Eligibility criteria for pharmacies, hospitals, and nonprofit clinics to receive and dispense drugs donated or given under the program;

(B) Standards and procedures for accepting, safely storing, and dispensing drugs donated or given;

(C) Standards and procedures for inspecting drugs donated or given to determine that the original unit dose packaging is sealed and tamper-evident and that the drugs are unadulterated, safe, and suitable for dispensing;

(D) Eligibility standards based on economic need for individuals to receive drugs;

(E) A means, such as an identification card, by which an individual who is eligible to receive drugs under the program may demonstrate eligibility to the pharmacy, hospital, or nonprofit clinic dispensing the drugs;

(F) A form that an individual receiving a drug under the program must sign before receiving the drug to confirm that the individual understands the immunity provisions of the program;

(G) A formula to determine the amount of a handling fee that pharmacies, hospitals, and nonprofit clinics may charge to drug recipients to cover restocking and dispensing costs;

(H) In addition, for drugs donated or given to the program by individuals:

(1) A list of drugs, arranged either by category or by individual drug, that the program will accept from individuals;

(2) A list of drugs, arranged either by category or by individual drug, that the program will not accept from individuals. The list must include a statement as to why the drug is ineligible to be donated or given.

(3) A form each donor must sign stating that the donor is the owner of the drugs and intends to voluntarily donate them to the program.

(I) In addition, for drugs donated to the program by health care facilities:

(1) A list of drugs, arranged either by category or by individual drug, that the program will accept from health care facilities;

(2) A list of drugs, arranged either by category or by individual drug, that the program will not accept from health care facilities. The list must include a statement as to why the drug is ineligible to be donated or given.

(J) Any other standards and procedures the board considers appropriate.

The rules shall be adopted in accordance with Chapter 119. of the Revised Code.

Effective Date: 04-07-2003; 2007 SB33 08-22-2007

DEFINITIONS

Rule 4729-35-01 [Update effective 01/01/2006]

As used in Chapter 4729-35 of the Administrative Code:

(A) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code and in rule 4729-9-01 of the Administrative Code.

(B) "Drug repository program" has the same meaning as in sections 3715.87 to 3715.873 of the Revised Code.

(C) "Hospital" has the same meaning as in section 3715.87 of the Revised Code.

(D) "Institutional facility" has the same meaning as in rule 4729-17-01 of the Administrative Code.

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

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

(G) "Original sealed and tamper-evident unit dose packaging" includes single unit dose packaging of oral medications from a manufacturer or a repackager licensed 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.

ELIGIBILITY REQUIREMENTS FOR A PHARMACY, HOSPITAL, OR NONPROFIT CLINIC

Rule 4729-35-02 [Effective 01/01/2004]

A pharmacy, hospital, or nonprofit clinic may elect to participate in the 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 federal and state laws, rules, and regulations.

DONATING DRUGS

Rule 4729-35-03 [Effective 01/01/2004]

(A) The following may donate a dangerous drug, pursuant to the eligibility requirements of rule 4729-35-04 of the Administrative Code, to a pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program:

(1) A licensed terminal distributor of dangerous drugs.

(2) A licensed wholesale distributor of dangerous drugs.

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

(B) 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.

(C) 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 4729-35-04 of the Administrative Code, to the drug repository program".

(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.

ELIGIBLE DRUGS

Rule 4729-35-04 [Update effective 01/01/2006]

All dangerous drugs, except controlled substances and drug samples, may be donated to a pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program if the drugs meet all of the following requirements:

(A) The drugs are in their original sealed and tamper-evident unit dose packaging. 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 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.

(B) The drugs have been in the possession of a licensed healthcare professional and not in the possession of the ultimate user.

(C) The drugs have been stored according to federal food and drug administration storage requirements.

(D) The drugs must have an expiration date of six months or greater.

(E) The packaging must list the lot number and expiration date of the drug.

(F) The drugs must not have any physical signs of tampering or adulteration.

(G) The drug packaging must not have any physical signs of tampering.

(H) All confidential patient information must have been removed from the drug packaging.

ELIGIBILITY REQUIREMENTS TO RECEIVE DRUGS

Rule 4729-35-05 [Effective 01/01/2004]

A pharmacy, hospital, or nonprofit clinic that elects to participate in the 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 the drug repository program:

(A) Is a resident of Ohio, *and*

(B) (1) Has no active third party prescription drug reimbursement coverage for the drug prescribed; *or*,

(2) Is a patient of a nonprofit clinic.

DONOR FORM

Rule 4729-35-06 [Effective 01/01/2004]

(A) 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 wholesale distributor of dangerous drugs 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 well-being of a patient, or the signature of the responsible person or his/her designee from a terminal distributor of dangerous drugs or a wholesale distributor of dangerous drugs.

(3) 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. 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 of the drug donated, or the generic name and list 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.

RECIPIENT FORM

Rule 4729-35-07 [Effective 01/01/2004]

Each recipient of a donated drug from the drug repository program 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. The recipient form must also include at least the following:

(A) The signature of the recipient of the donated drug.

(B) The date the form was signed by the recipient.

(C) The brand name of the drug received, or the generic name and list either the name of the manufacturer or the national drug code number (NDC#).

(D) The strength of the drug received by the recipient.

(E) The quantity of the drug received by the recipient.

RECORD KEEPING

Rule 4729-35-08 [Update effective 02/01/2005]

(A) Donor forms must be maintained for a minimum of three years by a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or an institutional facility.

(B) Recipient forms must be maintained for a minimum of three years by a pharmacy, hospital, or nonprofit clinic.

(C) An invoice must be created by the donor location, which includes a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or an institutional facility where the donor resides. The invoice must include at least the following information:

(1) The name and address of the donor location.

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

(3) The strength of the drug.

(4) The quantity of the drug.

(5) The date the drug was sent to a pharmacy, hospital, or nonprofit clinic.

(6) The name and address of the recipient pharmacy, hospital, or nonprofit clinic.

(D) A copy of the invoice must be maintained for a minimum of three years by both the donor location, which includes a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or an institutional facility, and the recipient location, which includes a pharmacy, hospital, or nonprofit clinic.

HANDLING FEE

Rule 4729-35-09 [Effective 01/01/2004]

A pharmacy, a hospital, or a nonprofit clinic may charge the recipient of a donated drug a maximum of two hundred per cent of the medicaid professional dispensing fee to cover restocking and dispensing costs.