

AN ACT

To enact sections 3715.87, 3715.871, 3715.872, and 3715.873 of the Revised Code to establish under the direction of the State Board of Pharmacy a drug repository program to accept and dispense donated prescription drugs.

Be it enacted by the General Assembly of the State of Ohio:

SECTION 1. That sections 3715.87, 3715.871, 3715.872, and 3715.873 of the Revised Code be enacted to read as follows:

Sec. 3715.87. (A) As used in this section and in sections 3715.871, 3715.872, and 3715.873 of the Revised Code:

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

(2) "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.

(3) "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 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 limitation specified in this division, unused drugs dispensed for purposes of the medicaid program may be accepted and dispensed under the drug repository program.

Sec. 3715.871. (A) Any person, including a drug manufacturer or any health care facility as defined in section 1337.11 of the Revised Code, may donate prescription drugs to the drug repository program. The drugs must be donated 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 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 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 drugs a handling fee established in accordance with rules adopted by the board under section 3715.873 of the Revised Code. Drugs donated to the repository may not be resold.

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) The state board of pharmacy; the director of health; any person, including a drug manufacturer, or government entity that donates drugs to the repository program; any pharmacy, hospital, nonprofit clinic, or health care professional that accepts or dispenses drugs under the program; and any pharmacy, hospital, or nonprofit clinic that employs a health care professional who accepts or dispenses drugs under the program shall not, in the absence of bad faith, be subject to any of the following for matters related to donating, accepting, or dispensing drugs under the program: criminal prosecution; liability in tort or other civil action for injury, death, or loss to person or property; or professional disciplinary action.

A drug manufacturer shall not, in the absence of bad faith, be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a drug manufactured by the drug manufacturer that is donated by any person 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 donated drug.

Sec. 3715.873. 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 donated drugs under the program;

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

(C) Standards and procedures for inspecting donated drugs 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 donated drugs may demonstrate eligibility to the pharmacy, hospital, or nonprofit clinic dispensing the drugs;

(F) A form that an individual receiving a drug from the repository 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 to the repository by individuals:

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

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

(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 repository.

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

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

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

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

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

SECTION 2. Sections 3715.87, 3715.871, and 3715.872 of the Revised Code as enacted by this act shall take effect one year after the effective date of this section.

SECTION 3. The State Board of Pharmacy shall adopt the rules required by section 3715.873 of the Revised Code not later than nine months after the effective date of this section.

Speaker _____ of the House of Representatives.

President _____ of the Senate.

Passed _____, 20____

Approved _____, 20____

Governor.

Sub. H. B. No. 221

6

The section numbering of law of a general and permanent nature is complete and in conformity with the Revised Code.

Director, Legislative Service Commission.

Filed in the office of the Secretary of State at Columbus, Ohio, on the
____ day of _____, A. D. 20____.

Secretary of State.

File No. _____ Effective Date _____