



Sub. H.B. 221

124th General Assembly
(As Passed by the General Assembly)

- Reps.** Schuring, Jolivette, Hollister, Hagan, Cates, D. Miller, Calvert, Hartnett, Patton, Seitz, Britton, Willamowski, Otterman, Ogg, Perry, Allen, Collier, DePiero, Webster, Jones, Boccieri, Schaffer, Redfern, Damschroder, Metelsky, Coates, Aslanides, Lendrum, Kearns, Raga, Kilbane, Mason, Cirelli, Beatty, Williams, Schneider, Flowers, Buehrer, Metzger, Niehaus, Carey, Rhine, Flannery, Barrett, Sulzer, Krupinski, Carano, Key, Latta, Carmichael, Strahorn, Hoops, Stapleton, Fedor, DeBose, Clancy, Driehaus, Manning, Peterson, Core, G. Smith, Reidelbach, Faber, Widowfield, Hughes, McGregor, Young, Olman, Brown, Oakar, Sykes, Wolpert, Salerno, Setzer, Womer Benjamin, Roman, Woodard
- Sens.** Prentiss, Wachtmann, Randy Gardner, Nein, Mead, Amstutz, Spada, White, Harris, Robert Gardner, Austria, Jacobson

Effective date: *

ACT SUMMARY

- Requires the State Board of Pharmacy to establish a drug repository program for the collection and redistribution of unadulterated prescription drugs in their original sealed and tamper-evident unit dose packaging.
- Requires the Board, in consultation with the Director of Health, to adopt rules governing the drug repository program.
- Permits the program to receive drugs from any person, including a drug manufacturer or health care facility, provided that the drugs are donated at a pharmacy, hospital, or nonprofit clinic that has elected to participate

* *The Legislative Service Commission had not received formal notification of the effective date at the time this analysis was prepared. Additionally, the analysis may not reflect action taken by the Governor.*

in the program and meets certain eligibility requirements established in rules adopted by the Board.¹

- Prohibits the resale of drugs donated to the repository program.
- In general, grants program participants immunity from criminal and civil liability and professional discipline for matters related to donating, accepting, or dispensing drugs under the program.
- Requires the Board to adopt rules governing the repository no later than nine months after the act's effective date.

CONTENT AND OPERATION

Creation of the drug repository program

(secs. 3715.87 and 3715.873)

The act requires the State Board of Pharmacy to establish a drug repository program for the collection and redistribution of unadulterated prescription drugs that are in their original sealed and tamper-evident unit dose packaging. The Board, in consultation with the Director of Health, is required to adopt rules pursuant to the Administrative Procedure Act (Revised Code Chapter 119.) that govern the program and establish all of the following:

- (1) Eligibility criteria for pharmacies, hospitals, and nonprofit clinics to receive and dispense donated drugs under the program;
- (2) Standards and procedures for accepting, safely storing, and dispensing donated drugs;
- (3) 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;
- (4) Eligibility standards based on economic need for individuals to receive drugs;

¹ As used in the Revised Code, unless otherwise specified, "person" includes an individual, corporation, business trust, estate, partnership, and association (Revised Code § 1.59).

- (5) 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;
- (6) 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;
- (7) 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;
- (8) Lists of drugs, arranged either by category or by individual drug, that the repository will accept from individuals and from health care facilities;
- (9) Lists of drugs, arranged either by category or by individual drug, that the repository will not accept. The lists must include a statement as to why each drug or category of drug is ineligible for donation;
- (10) A form each individual donor must sign stating that the donor is the owner of the drugs and intends to voluntarily donate them to the repository;
- (11) Any other standards or procedures the Board considers necessary.

Donation and distribution of drugs

(secs. 3715.87 and 3715.871)

The act permits the drug repository program to accept drugs from any person, including a drug manufacturer, or any health care facility, provided that the donation takes place at a pharmacy, hospital, or nonprofit clinic that has elected to participate in the repository program and meets eligibility requirements established in rules adopted by the Pharmacy Board.² The act specifies that

² For the purposes of the act, "hospital" has the same meaning as in Revised Code provisions providing for hospital classification (R.C. 3727.01, not in the act). "Hospital" means an institution classified as a hospital under Ohio law in which are provided to inpatients diagnostic, medical, surgical, obstetrical, psychiatric, or rehabilitation care for a continuous period longer than 24 hours or a hospital operated by a health maintenance organization. Certain facilities, such as nursing homes and outpatient clinics, are specifically excluded from this definition of "hospital." "Nonprofit clinic" means a charitable nonprofit corporation organized and operated in accordance with Ohio law, or any charitable organization not organized and not operated for profit, that

participation in the repository program by pharmacies, hospitals, and nonprofit clinics is voluntary. The act permits unused drugs dispensed for purposes of the Medicaid program to be accepted and dispensed by the repository program. Individuals who donate drugs to the repository program must sign a form established by the Board in rules that states that the individual is the owner of the drugs and intends to donate them to the program.

To be accepted by the repository, the drugs must be in their original sealed and tamper-evident unit dose packaging. The packaging must be unopened, except that drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened, provided that the single unit dose packaging is undisturbed. A drug cannot be accepted or dispensed by the program if there is reason to believe that it is adulterated. Drugs donated by individuals bearing an expiration date that is less than six months from the date the drug is donated cannot be accepted or dispensed by the repository program.

The act requires that the participating pharmacies, hospitals, and nonprofit clinics distribute donated drugs to individuals who are Ohio residents and meet eligibility standards established by the Pharmacy Board in rules. Drugs may be dispensed from the repository program only pursuant to a prescription issued by a health care professional authorized to prescribe drugs.³ The act also requires that the dispensing of donated drugs comply with all applicable federal and state laws dealing with storage and distribution of prescription drugs.

Drugs donated to the repository program may not be resold, but pharmacies, hospitals, and nonprofit clinics may charge recipients a handling fee to cover restocking and dispensing costs in accordance with a formula established by the Board. Before receiving a drug from the repository program, the recipient must sign a form established by the Board in rules to confirm that the recipient understands the program's immunity provisions.

provides health care services to indigent and uninsured persons. "Nonprofit clinic" does not include a hospital, a facility licensed as a nursing home or residential care facility, or a facility that is operated for profit (R.C. 3715.87).

³ *The following health care professionals licensed under Ohio law are authorized to prescribe drugs: dentists; nurses who hold a certificate to prescribe; optometrists licensed to practice optometry under a therapeutic pharmaceutical agents certificate; physicians authorized to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery; and veterinarians (R.C. 4729.01(I)).*



Liability

(sec. 3715.872)

The act provides that, in the absence of bad faith, the following are not subject to criminal prosecution, civil liability, or professional discipline for matters related to the acceptance or dispensing of donated drugs: the Pharmacy Board; Director of Health; any person, including the manufacturer of a donated drug regardless of who donated the drug, government entity, pharmacy, nonprofit clinic, or health care professional, that accepts or dispenses drugs under the repository program; and any pharmacy, hospital, or nonprofit clinic that employs a health care professional who accepts or dispenses drugs under the program.

Effective date

(Sections 2 and 3)

The act requires the Pharmacy Board to adopt the rules to govern the repository program no later than nine months after the act's effective date. The other provisions are to take effect one year after the act's effective date.

HISTORY

| ACTION | DATE | JOURNAL ENTRY |
|---|----------|---------------|
| Introduced | 04-18-01 | p. 305 |
| Reported, H. Health & Family Services | 03-20-02 | pp. 1595-1596 |
| Passed House (94-0) | 04-24-02 | pp. 1706-1711 |
| Reported, S. Health, Human Services, & Aging | 11-14-02 | p. 2125 |
| Passed Senate (32-0) | 11-14-02 | p. 2130 |
| House concurred in Senate amendments (91-0) | 11-20-02 | pp. 2069-2070 |

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