



Am. Sub. H.B. 221

124th General Assembly

(As Passed by the House)

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

BILL SUMMARY

- Requires the Director of Health 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 Pharmacy 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 or nonprofit clinic that has elected to participate in the program.¹
- Prohibits the resale of drugs donated to the repository program.

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).

- 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 Pharmacy Board to adopt rules governing the repository no later than nine months after the bill's effective date.

CONTENT AND OPERATION

Creation of the drug repository program

(secs. 3701.79 and 3701.793)

The bill requires the Director of Health 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 Pharmacy 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) Standards and procedures for accepting, safely storing, and dispensing donated drugs;
- (2) 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;
- (3) Eligibility standards based on economic need for individuals to receive drugs;
- (4) A means, such as an identification card, by which an individual who is eligible to receive donated drugs may demonstrate eligibility to the pharmacy or nonprofit clinic dispensing the drugs;
- (5) 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;
- (6) A formula to determine the amount of a handling fee that pharmacies and nonprofit clinics may charge to drug recipients to cover restocking and dispensing costs;

- (7) Lists of drugs, arranged either by category or by individual drug, that the repository will accept from individuals and from health care facilities;
- (8) 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;
- (9) 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;
- (10) Any other standards or procedures the Board considers necessary.

Donation and distribution of drugs

(sec. 3701.791)

The bill 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 or nonprofit clinic that has elected to participate in the repository program.² Participation in the repository program by pharmacies and nonprofit clinics is voluntary. The bill 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 Pharmacy 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.

² For the purposes of the bill, "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 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. 3701.79).

The bill requires that the participating pharmacies and nonprofit clinics distribute donated drugs to individuals who 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 bill 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 and nonprofit clinics may charge recipients a handling fee to cover restocking and dispensing costs in accordance with a formula established by the Pharmacy Board. Before receiving a drug from the repository program, the recipient must sign a form established by the Pharmacy Board in rules to confirm that the recipient understands the program's immunity provisions.

Liability

(sec. 3701.792)

The bill 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 Director of Health; any person, including a drug manufacturer; government entity; pharmacy; nonprofit clinic; or health care professional that accepts or dispenses drugs under the repository program and any pharmacy or nonprofit clinic that employs a health care professional who accepts or dispenses drugs under the program.

Date of effect

(Sections 2 and 3)

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

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)).*

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

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