



S.B. 228

126th General Assembly
(As Introduced)

Sen. Schuring

BILL SUMMARY

- Requires terminal and wholesale distributors of dangerous drugs to give to the drug repository program established by the State Board of Pharmacy any unsold or unused dangerous drugs or provide an explanation for each unsold or unused drug not given to the program.
- Requires the board to adopt rules governing the duties of terminal and wholesale distributors of dangerous drugs under the bill.

CONTENT AND OPERATION

Background: Drug Repository Program

(R.C. 3715.87 and 3715.871)

Current law 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.¹ The Board has authority to adopt rules specifying the drugs that may be accepted under the program. These donated drugs are to be dispensed by program participants to individuals meeting eligibility standards established by the Board.

Under the program, persons, including drug manufacturers and health care facilities, may donate drugs. These donations must be made at a pharmacy, hospital, or nonprofit clinic that participates in the program and meets eligibility requirements of participation as established by the Board. Accepting and dispensing drugs by pharmacies, hospitals, and nonprofit clinics is voluntary.

¹ The Board has adopted rules governing the program. They are sections 4729-35-01 through 4729-35-09 of the Ohio Administrative Code.

Willing recipients of the donated drugs may dispense them to eligible individuals pursuant to a prescription, or dispense the drug to other government entities and nonprofit private entities. While the pharmacy, hospital, or nonprofit clinic may charge a handling fee established in accordance with board adopted rules, participants are not allowed to resell donated drugs.

Terminal or wholesale distributor participation in the drug repository program

(R.C. 3715.871)

The bill requires terminal and wholesale distributors² of dangerous drugs³ to participate in the program by giving it any unsold or unused drugs the distributor cannot sell or otherwise use that qualify for the program. In the event a

² The terms "terminal" and "wholesale" distributor of dangerous drugs are defined in R.C. 4729.01. "Wholesale distributor of dangerous drugs" means a person engaged in the sale of dangerous drugs at wholesale and includes any agent or employee of such a person authorized by the person to engage in the sale of dangerous drugs at wholesale (R.C. 4729.01(O)).

"Terminal distributor of dangerous drugs" means a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a wholesale distributor or a pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption, and includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist or licensed health professional authorized to prescribe drugs (R.C. 4729.01(Q)).

³ The term "dangerous drug" is defined in R.C. 4729.01 and means any of the following:

(1) Any drug to which either of the following applies:

(a) Under the "Federal 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.

(2) Any drug that contains a schedule V controlled substance and that is exempt from Chapter 3719. of the Revised Code or to which that chapter does not apply;

(3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body.

terminal or wholesale distributor does not give eligible drugs to program participants, the distributor must submit to the Board a statement for each drug as to why the distributor will not give the drug to the program.⁴

Eligibility requirements

(R.C. 3715.873)

The Board, in consultation with the Director of Health, is required by current law to adopt rules under Revised Code Chapter 119. (the Administrative Procedure Act) governing the program. The bill requires that these rules also include the following:

(1) Standards and procedures for terminal and wholesale distributors to give drugs to the repository program, including a procedure whereby a distributor may submit a statement as to why the distributor will not give a particular drug to the program;

(2) For drugs given to the repository program by terminal or wholesale distributors of dangerous drugs, both of the following:

(a) A list of drugs, arranged either by category or by individual drug, that the repository program will accept from terminal or wholesale distributors of dangerous drugs;

(b) A list of drugs, arranged either by category or by individual drug, that the repository program will not accept from terminal or wholesale distributors of dangerous drugs. The list must include a statement as to why the drug is ineligible.

Immunity from liability

(R.C. 3715.872)

In the absence of bad faith, certain entities are not subject to criminal prosecution, civil liability, or professional discipline for matters related to the acceptance or dispensing of donated drugs under the program. These include the Pharmacy Board; Director of Health; any person that accepts or dispenses drugs under the program; and any pharmacy, hospital, or nonprofit clinic that employs a

⁴ Under the bill, drugs are "given" rather than "donated" by a terminal or wholesale distributor; therefore, the term "donated" is removed from Revised Code sections describing the drugs that a pharmacy, hospital, or nonprofit clinic accepts and dispenses in participation in the program.

health care professional who accepts or dispenses drugs under the program. The bill adds terminal or wholesale distributors of dangerous drugs to those granted partial immunity from liability for actions related to participation in the program.

HISTORY

| ACTION | DATE |
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| Introduced | 11-16-05 |

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