CORRECTED VERSION

Bill Analysis

Jeffery A. Bernard *Legislative Service Commission*

Am. Sub. H.B. 283*

127th General Assembly

(As Reported by S. Health, Human Services, and Aging)

Reps. Webster, Setzer, Stebelton, Wagner, S. Williams, Schindel, J. McGregor, Fessler, Evans, Seitz, Latta, Yuko, Koziura, Coley, Combs, Collier, Fende, Peterson, Heard, Ujvagi, Hughes, Reinhard, Letson, Otterman, B. Williams, Uecker, Aslanides, Bacon, Batchelder, Brown, Budish, Chandler, Daniels, DeBose, Dodd, Domenick, Dyer, Flowers, Gibbs, Goodwin, J. Hagan, Huffman, Luckie, Patton, Schlichter, Schneider, Wachtmann, Wagoner, Yates, Zehringer

BILL SUMMARY

- Provides that a business entity that is a corporation, limited liability company, partnership, or professional association that is required to be composed solely of individuals who are licensed health professionals authorized to prescribe drugs and authorized to provide the professional service provided by the business entity is not required to hold a terminal distributor of dangerous drugs license to possess, have custody of, and distribute a dangerous drug.

- Authorizes a wholesale distributor of dangerous drugs to sell dangerous drugs to a business entity that is a corporation, limited liability company, partnership, or professional association that is required to be composed solely of individuals who are licensed health professionals authorized to prescribe drugs and authorized to provide the professional service provided by the business entity.

- Provides that, in any criminal offense, a judge or magistrate is to include in the defendant's sentence any investigation costs incurred by the State Board of Pharmacy in investigating certain business entities.

* This analysis was prepared before the report of the Senate Health, Human Services, and Aging Committee appeared in the Senate Journal. Note that the list of co-sponsors and the legislative history may be incomplete.

- Permits a manufacturer, terminal distributor, or wholesale distributor of dangerous drugs to donate a dangerous drug, including a dangerous drug that has expired, to a pharmacy school.

- Places restrictions on the storage, labeling, delivery, and use of the drugs donated and prohibits donation of controlled substances.

- Grants limited immunity to the State Board of Pharmacy, any manufacturer, terminal distributor, or wholesale distributor of dangerous drugs that in good faith donates a dangerous drug, and any pharmacy school that accepts a drug donation from criminal, civil, or professional liability for matters related to the donation or acceptance of the drug.

- Exempts drug donations made in accordance with the bill from restrictions and prohibitions applicable to the sale, delivery, and labeling of expired and adulterated drugs.

- Requires the State Board of Pharmacy to adopt rules governing donation of dangerous drugs to pharmacy schools.

- Provides that a pharmacist may administer immunizations to individuals over 18 years of age that are approved by the State Board of Pharmacy, with consultation of the State Medical Board.

CONTENT AND OPERATION

Terminal distributor of dangerous drugs

Background

Possession and distribution of dangerous drugs, including controlled substances, is strictly controlled under state law.[1] With few exceptions, a person

[1] A dangerous drug is a drug that: (1) under the "Federal Food, Drug, and Cosmetic Act," 21 U.S.C. 301, 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 on a prescription, (2) may be dispensed under Ohio law only upon a prescription, (3) any drug that contains a schedule V controlled substance, or (4) any drug intended for administration by injection into the human body other than a natural orifice of the body. Controlled substances are dangerous drugs placed in a schedule based on their use and potential of being abused (R.C. 4729.01).

must have a terminal distributor of dangerous drugs license to possess, have custody or control of, or distribute dangerous drugs. A wholesale distributor is prohibited from selling dangerous drugs to any person other than, among others, a licensed terminal distributor of dangerous drugs[2] or a licensed health professional authorized to prescribe drugs.[3]

Terminal distributor of dangerous drugs license requirement

(R.C. 4729.54 and 4729.541)

The bill provides that a business entity that is a corporation, limited liability company, partnership, or professional association that is required by the Revised Code to be composed solely of individuals who are licensed health professionals authorized to prescribe drugs and authorized to provide the professional services being offered by the business entity is not required to hold a terminal distributor of dangerous drugs license to possess, have custody of, and distribute the dangerous drugs described under the law governing terminal distributors of dangerous drugs.[4]

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[2] R.C. 4729.51.

[3] A licensed health professional authorized to prescribe drugs means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice, including only the following:

(1) A dentist;

(2) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a certificate to prescribe;

(3) An optometrist licensed to practice optometry under a therapeutic pharmaceutical agents certificate;

(4) A physician authorized to practice medicine and surgery, osteopathic medicine and surgery, or podiatry;

(5) A physician assistant who holds a certificate to prescribe;

(6) A veterinarian.

[4] A terminal distributor may, with exceptions, receive a category I, II, or III terminal distributor of dangerous drug license.

Category I means single-dose injections of intravenous fluids, including saline, Ringer's lactate, 5% dextrose and distilled water, and other intravenous fluids or parenteral solutions included in this category by rule of the Board of Pharmacy, that have a volume

Wholesale distributors of dangerous drugs

(R.C. 4729.51)

The bill authorizes a wholesale distributor of dangerous drugs to sell dangerous drugs to the business entities described above (see "***Terminal distributor of dangerous drugs license requirement***").

Investigation costs

(R.C. 2947.23 and 2947.231)

Under current law, a judge or magistrate, in any criminal offense, is to include in the sentence the costs of prosecution of the defendant.[5]

The bill provides that a judge or magistrate, in any criminal offense, is to also include any investigation costs incurred by the State Board of Pharmacy related to the offense if the defendant is one of the business entities described above (see "***Terminal distributor of dangerous drugs license requirement***"). Investigation costs include staff salaries, administrative costs, travel expenses, attorney's fees, and any other reasonable expense incurred by the Board.

Donation of dangerous drugs to pharmacy schools

Who may donate and receive drugs

(R.C. 3715.89(A) and 3715.90(A))

The bill permits any manufacturer, terminal distributor, or wholesale distributor of dangerous drugs to donate a dangerous drug, including a dangerous drug that has expired,[6] to a pharmacy school.[7] It permits a pharmacy school to

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of one hundred milliliters or more and that contain no added substances, or single-dose injections of epinephrine.

Category II means any dangerous drugs not included in category I or III.

Category III means any controlled substance that is contained in schedule I, II, III, IV, or V. (R.C. 4729.54.) Schedule I, II, III, IV, and V drugs are categories of dangerous drugs that are scheduled based on their potential for abuse (R.C. 3719.41).

[5] R.C. 2947.23.

[6] The bill (R.C. 3715.88(A)) defines "expired," consistent with the definition of this term in Ohio's pure food and drug law (R.C. 3715.55), to mean that the date on the drug,

accept a donation of a dangerous drug to be used for instructional purposes if the drug is not a controlled substance and requirements regarding storage, labeling, and confirmation of delivery are met (see "***Storage, labeling, and delivery requirements***," below). (See **COMMENT**.)

Storage, labeling, and delivery requirements

(R.C. 3715.89(B) and (C) and 3715.90)

The bill places the following restrictions on drug donations to pharmacy schools:

(1) Each container in which a dangerous drug is donated must contain a single drug indicated by a single national drug code number.[8]

(2) If the dangerous drug is of a type that deteriorates with time, the container in which the drug is contained must be plainly marked with the drug's expiration date.

(3) Each drug donation must be accompanied by a form, signed by both a representative of the manufacturer, terminal distributor, or wholesale distributor donating the drug and the pharmacy school accepting the drug, that confirms (a) the acceptance of the donation by the pharmacy school, and (b) that both parties understand the immunity provisions applicable to donations (see "***Criminal, civil, and professional immunity***," below).

(4) Donated drugs can be used only for instructional purposes.

(5) Donated drugs cannot be sold or transferred for consideration of any kind.

(6) In accordance with a federal regulation on the exemption of certain drugs from the labeling requirements of the Federal Food, Drug, and Cosmetic Act

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specified under a federal regulation on expiration dating of drugs (21 C.F.R. 211.137), has passed.

[7] The bill (R.C. 3715.88(C)) defines "pharmacy school" as a school, college, university, or other educational institution that operates a pharmacy program recognized and approved by the State Board of Pharmacy.

[8] The bill defines "national drug code number" as the number registered for a drug pursuant to the listing system established by the U.S. Food and Drug Administration under the federal Drug Listing Act of 1972, 21 U.S.C. 360, as amended (R.C. 3715.87(B)).

(21 C.F.R. 201.125), donated drugs cannot be used for a clinical use. "Clinical use" includes furnishing the drug to a human or animal with the intent or understanding that the human or animal will ingest or otherwise absorb the drug into the human's or animal's body.

Rulemaking authority

(R.C. 3715.91)

The bill requires the State Board of Pharmacy to adopt rules in accordance with the Ohio Administrative Procedure Act (R.C. Chapter 119.) to give effect to the bill.

Criminal, civil, and professional immunity

(R.C. 3715.92)

The bill provides that the State Board of Pharmacy, any manufacturer, terminal distributor, or wholesale distributor of dangerous drugs that in good faith donates a dangerous drug as described above, and any pharmacy school that accepts a drug donation as described above is not subject to any of the following for matters related to the donation or acceptance of the drug: criminal prosecution; liability in tort or other civil action for injury, death, or loss to person or property; or professional liability.

Conforming amendments

The bill amends the following sections of Ohio's current Pure Food and Drug Law (R.C. Chapter 3715.) to make them consistent with the provisions, described above, that permit the donation of dangerous drugs to pharmacy schools.

1. Prohibition on sales of expired drugs (R.C. 3715.521(A))

Current law prohibits a person from selling, offering to sell, or delivering at retail or to the consumer a drug that is expired as required under a federal regulation on the expiration dating of drugs (21 C.F.R. 211.137). The bill exempts from this prohibition expired drugs that are donated in accordance with the provisions on pharmacy school drug donations described above.

2. Detention or embargo of adulterated, misbranded, or expired drugs (R.C. 3715.55(B))

Under current law, when the State Board of Pharmacy finds or has cause to believe that a drug or device is adulterated, so misbranded as to be dangerous or fraudulent, or expired, the Board must affix to the drug or device a tag or other

appropriate marking that does both of the following: (a) gives notice that the drug or device is, or is suspected of being, adulterated, misbranded, or expired, and has been detained or embargoed, and (b) warns all persons not to remove or dispose of the drug or device by sale or otherwise until permission for removal or disposal is given by the Board or the court. Current law also prohibits a person from removing or disposing of a detained or embargoed drug or device by sale or otherwise without permission of the Board.

The bill specifies that when expired drugs are donated to a pharmacy school in accordance with the bill, the above provisions do not apply.

3. Exclusion from meaning of "adulterated drug" (R.C. 3715.63; R.C. 3715.52 (not in the bill))

Current law prohibits, among other things, the manufacture, sale, delivery, holding or offering for sale of a drug or device that is adulterated or misbranded; the adulteration or misbranding of any drug or device; the receipt in commerce of any drug or device that is adulterated or misbranded; and the delivery or proffered delivery of an adulterated or misbranded drug or device. A drug is "adulterated" for purposes of this law for any of a number of reasons, including that the drug has expired.

The bill specifies that an expired drug is not adulterated if the drug is donated to a pharmacy school in accordance with the bill.

Immunizations

(R.C. 4729.41)

Current law provides that a licensed pharmacist may administer certain vaccinations specified by statute.

The bill allows a licensed pharmacist to administer any immunizations to individuals over 18 years of age that are approved under rules adopted by the State Board of Pharmacy, with the consultation of the State Medical Board.

COMMENT

In contrast to this bill, the drug repository program the State Board of Pharmacy must establish under current law[9] does not permit pharmacy schools to receive or use donated drugs. Under the drug repository program, pharmacies,

[9] The drug repository program is governed by R.C. 3715.87 through 3715.873.

hospitals, and nonprofit clinics can receive and dispense drugs donated by any person to Ohio residents who meet eligibility standards adopted by the Board in rules. The repository program also prohibits the acceptance and dispensing of drugs that bear an expiration date that is less than six months from the date the drug is donated.

HISTORY

ACTION	DATE
Introduced	07-05-07
Reported, H. Health	10-25-07
Passed House (95-0)	12-04-07
Reported, S. Health, Human Services, and Aging	---

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