Amy J. Rinehart *Legislative Service Commission*

Sub. H.B. 283

127th General Assembly
(As Passed by the General Assembly)

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**

Sens. **Schuring, Seitz, Wagoner, D. Miller, Morano, Cafaro, Cates, Fedor, Harris, Kearney, Mason, Mumper, Niehaus, Sawyer, Schaffer, Spada, Coughlin**

Effective date: *

ACT SUMMARY

- Exempts from the terminal distributor of dangerous drugs licensing requirement a business entity that is a corporation, limited liability company, partnership, or professional association 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.

- Authorizes a wholesale distributor of dangerous drugs to sell dangerous drugs to a business entity described above.

- 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 a business entity described above.

* 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.

- 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 act 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.

- Permits a pharmacist to administer immunizations to individuals over 18 years of age that are approved by the State Board of Pharmacy in consultation with 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] Continuing law provides that

[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).

with few exceptions, a person must have a terminal distributor of dangerous drugs license to possess, have custody or control of, or distribute dangerous drugs.[2] Prior law prohibited a wholesale distributor from selling dangerous drugs to any person other than, among others, a licensed terminal distributor of dangerous drugs[3] or a licensed health professional authorized to prescribe drugs.[4]

Exemption from license requirement

(R.C. 4729.51, 4729.54, and 4729.541)

The act creates an exemption from the licensing requirement. It permits a business entity to possess, have custody or control of, and distribute dangerous drugs without a license as a terminal distributor of dangerous drugs if the entity 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.

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

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

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

Category III--any controlled substance 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).

[3] R.C. 4729.51.

[4] "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, or (6) a veterinarian.

The act authorizes a wholesale distributor of dangerous drugs to sell dangerous drugs to the business entities described above.

Investigation costs

(R.C. 2947.23 and 2947.231)

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

The act 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 "***Exemption from 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 act permits any manufacturer, terminal distributor, or wholesale distributor of dangerous drugs to donate a dangerous drug, including a dangerous drug that has expired,[5] to a pharmacy school.[6] It permits a pharmacy school to accept a donation of a dangerous drug to be used for instructional purposes if the drug is not a controlled substance and requirements described below regarding storage, labeling, and confirmation of delivery are met.

Storage, labeling, and delivery requirements

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

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

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[5] The act (R.C. 3715.88(A)) defines "expired," by reference to Ohio's pure food and drug law (R.C. 3715.55). It means that the date on the drug, specified under a federal regulation on expiration dating of drugs (21 Code of Federal Regulations 211.137), has passed.

[6] The act (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.

(1) Each container in which a dangerous drug is donated must contain a single drug indicated by a single national drug code number.[7]

(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 entity 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) Donated drugs cannot be used for a clinical use (21 C.F.R. 201.125). "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 act 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 act.

Criminal, civil, and professional immunity

(R.C. 3715.92)

The act 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, in the absence of bad faith, subject to any of the following for matters related to the donation or acceptance of

[7] The act 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 United States Code 360, as amended (R.C. 3715.88(B)).

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 act 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))

Continuing law prohibits a person from selling, offering to sell, or delivering at retail or to the consumer a drug that is expired (21 C.F.R. 211.137). The act 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 continuing 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. Continuing 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 act specifies that when expired drugs are donated to a pharmacy school in accordance with the act, the above provisions do not apply.

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

Continuing 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 a number of reasons, including that the drug has expired.

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

Immunizations

(R.C. 4729.41)

Continuing law authorizes a licensed pharmacist to administer certain vaccinations specified by statute.

The act expands this authority by allowing 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. The Pharmacy Board must consult with the State Medical Board prior to adopting the rules.

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	05-21-08
Passed Senate (33-0)	05-22-08
House concurred in Senate amendments (96-0)	05-28-08

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