



Sub. H.B. 283

127th General Assembly
(As Reported by H. Health)

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BILL SUMMARY

- 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.

CONTENT AND OPERATION

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,¹ including a dangerous drug that has expired,² to a pharmacy school.³ 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 regarding storage, labeling, and confirmation of delivery are met (see "Storage, labeling, and delivery requirements," below). (See COMMENT.)

¹ Current law (R.C. 4729.01(F)) defines "dangerous drug" as:

(1) Any drug that the Federal Food, Drug, and Cosmetic Act requires 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 that the drug be dispensed only upon a prescription;

(2) Any drug that state law requires be dispensed only upon a prescription;

(3) Any drug that contains a Schedule V controlled substance and is exempt from the controlled substances law or to which that law does not apply;

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

² 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, specified under a federal regulation on expiration dating of drugs (21 C.F.R. 211.137), has passed.

³ 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.

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.⁴

(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 (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.

⁴ 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)).

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.

COMMENT

In contrast to this bill, the drug repository program the State Board of Pharmacy must establish under current law⁵ does not permit pharmacy schools to receive or use donated drugs. Under the drug repository program, pharmacies, 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

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⁵ The drug repository program is governed by R.C. 3715.87 through 3715.873.