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Bill Analysis
Legislative Service Commission

Sub. H.B. 454

125th General Assembly
(As Reported by H. Health)

Reps. White, Seitz, Clancy, McGregor, Raga, Schmidt, Setzer, Chandler, Kearns, Schaffer, Webster, Miller, Perry, Distel, Strahorn, Hollister, Price, Cirelli, G. Smith, Reidelbach, Hoops, Harwood, Slaby, Combs, Beatty, Barrett

BILL SUMMARY

- Requires any sample drug furnished by a manufacturer of controlled substances, manufacturer's representative, or wholesale dealer in pharmaceuticals to a licensed health professional authorized to prescribe drugs or by such a professional to a patient to be furnished free of charge.
- Authorizes, under certain conditions, a manufacturer of dangerous drugs or wholesale distributor of dangerous drugs to furnish a sample drug that is not a controlled substance to a charitable pharmacy and a pharmacist working, whether or not for compensation, in a charitable pharmacy to dispense such a sample drug to a person.
- Requires the State Board of Pharmacy to adopt rules governing furnishing sample drugs to charitable pharmacies and authorizes the Board to adopt rules permitting a manufacturer's representative or a licensed health professional authorized to prescribe drugs to furnish to a charitable pharmacy, under certain conditions, a sample drug as long as the drug is not a controlled substance.
- Establishes a qualified immunity from civil or criminal liability or professional disciplinary action in connection with the donation, acceptance, or dispensing of sample drugs under the bill.

CONTENT AND OPERATION

Prohibition against furnishing a sample drug

Continuing law prohibits a person from knowingly furnishing another with a sample drug. Whoever violates the prohibition is guilty of illegal dispensing of

drug samples.¹ A sample drug is a drug² or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs,³ or a drug of abuse,⁴ and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer.⁵

Current exceptions to prohibition against furnishing a sample drug

(R.C. 2925.36(B) and 3719.81)

There are exceptions to the prohibition against furnishing a sample drug. The prohibition does not apply to licensed health professionals authorized to prescribe drugs, pharmacists, owners of pharmacies, or manufacturers and wholesalers of controlled substances as long as the conduct of these persons complies with the laws governing these professionals and entities.⁶

With respect to manufacturers of controlled substances, manufacturer's representatives, and wholesale dealers in pharmaceuticals, these persons or entities may furnish sample drugs to licensed health professionals authorized to prescribe drugs. Such a health professional may furnish a sample drug to a patient for use as medication if the following conditions are met:

¹ R.C. 2925.36.

² A drug is (1) any article recognized in the United States pharmacopoeia and national formulary, or any supplement to them, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals, (2) any other article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals, (3) any article, other than food, intended to affect the structure or any function of the body of humans or animals, and (4) certain articles intended for use as a component in the compounding of one or more drugs, excluding devices or their components, parts, or accessories. (R.C. 4729.01.)

³ The following are licensed health professionals authorized to prescribe drugs: dentists, optometrists holding a therapeutic pharmaceutical agents certificate, physicians, podiatrists, veterinarians, and clinical nurse specialists, certified nurse-midwives, and certified nurse practitioners who hold a certificate to prescribe. (R.C. 4729.01.)

⁴ A drug of abuse is any controlled substance, harmful intoxicant, or dangerous drug. (R.C. 3719.011.)

⁵ R.C. 2925.01.

⁶ A controlled substance is a drug, compound, mixture, preparation, or substance included in schedule I, II, III, IV, or V. (R.C. 3719.01.)

(1) The sample drug is in the original container in which it was placed by the manufacturer and the container is plainly marked as a sample.

(2) Prior to its being furnished, the sample drug was stored under the proper conditions to prevent its deterioration or contamination.

(3) If the sample drug is of a type that deteriorates with time, the sample container is plainly marked with the date beyond which the sample drug is unsafe to use and the date has not passed.⁷

(4) The sample drug is distributed, stored, or discarded in such a way that it may not be acquired or used by any unauthorized person or by any person for whom it may present a health or safety hazard.

The bill

The bill establishes a new condition under which a health professional authorized to prescribe drugs may furnish a sample drug: the sample drug must be furnished free of charge.

Furnishing sample drugs to and by charitable pharmacies specifically

(R.C. 3719.811)

The bill creates a new exception to the prohibition against knowingly furnishing another with a sample drug but applies the exception only to charitable pharmacies. Under the bill, if certain conditions are met, a manufacturer of dangerous drugs or wholesale distributor of dangerous drugs may furnish a sample drug that is *not* a controlled substance to a charitable pharmacy, and a pharmacist working, whether or not for compensation, in a charitable pharmacy may dispense to a person a sample drug that is not a controlled substance. Also, a representative of a manufacturer of dangerous drugs or a licensed health professional authorized to prescribe drugs is permitted to furnish a sample drug that is not a controlled substance to a charitable pharmacy if the State Board of Pharmacy adopts rules permitting such action. The bill defines "charitable pharmacy" as a licensed terminal distributor of dangerous drugs that is exempt from federal income taxation as a 501(c)(3) organization⁸ and is not a hospital.

⁷ *Compliance with the labeling requirements of the Federal Food, Drug, and Cosmetic Act is deemed compliance with this condition.*

⁸ *A 501(c)(3) organization is an organization exempt from taxation under sections 501(a) and (c)(3) of the Internal Revenue Code (26 U.S.C. 501).*

The conditions that must be met for a sample drug to be furnished to or by a charitable pharmacy are the same as the conditions that must be met under current law for a sample drug to be furnished by a manufacturer of controlled substances, manufacturer's representative, wholesale dealer in pharmaceuticals, or licensed health professional authorized to prescribe drugs with two exceptions: the sample drug must be furnished free of charge and must not be a controlled substance.

The bill establishes additional conditions for representatives of a manufacturer of dangerous drugs, licensed health professionals authorized to prescribe drugs, and pharmacists working, whether or not for compensation, in a charitable pharmacy. A manufacturer's representative must comply with standards and procedures that the State Board of Pharmacy is to establish in rules if the Board adopts rules permitting such representatives and health professionals to furnish sample drugs to charitable pharmacies. A pharmacist is permitted to dispense a sample drug on behalf of a charitable pharmacy only to a person who presents to the pharmacist a valid prescription for the sample drug and is eligible for the sample drug under standards established by the body responsible for the charitable pharmacy's general management.

The bill provides that the authorization to furnish sample drugs to and by charitable pharmacies does not do either of the following:

(1) Apply to or restrict the furnishing of any sample of a non-narcotic substance if the substance may be lawfully sold over the counter without a prescription under the Federal Food, Drug, and Cosmetic Act and Ohio law;

(2) Authorize a pharmacist acting on behalf of a charitable pharmacy to dispense a sample drug that the charitable pharmacy is not authorized to possess, have custody or control of, or distribute.

The State Board of Pharmacy is required to adopt rules as necessary to give effect to the bill's provisions regarding furnishing sample drugs to and by charitable pharmacies. The rules must be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119.), which requires public hearings.

Immunity from liability

The Pharmacy Board, donees, pharmacists, and charitable pharmacies

(R.C. 3719.812)

The bill provides that the following persons and entities are not subject to criminal prosecution; liability in tort or other civil action for injury, death, or loss to person or property; or professional disciplinary action if the person or entity, in the absence of bad faith, donates, accepts, or dispenses sample drugs:

- The State Board of Pharmacy;
- Any person who donates sample drugs as permitted by the bill;
- Any charitable pharmacy or pharmacist working in a charitable pharmacy that accepts or dispenses sample drugs as permitted by the bill;
- Any licensed health professional authorized to prescribe drugs who accepts delivery of a sample drug on behalf of a charitable pharmacy as permitted by the bill.

Drug manufacturers

(R.C. 3719.813)

The bill provides that a drug manufacturer is not, in the absence of bad faith, subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a drug manufactured by a drug manufacturer that is donated by any person as permitted by the bill. This immunity from liability includes, but is not limited to, liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug.

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	04-06-04	p. 1755
Reported, H. Health	05-12-04	p. 1899

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