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Bill Analysis

Legislative Service Commission

H.B. 454

125th General Assembly
(As Introduced)

Reps. White, Seitz, Clancy, McGregor, Raga, Schmidt, Setzer, Chandler, Kearns, Schaffer, Webster, Miller, Perry, Distel, Strahorn

BILL SUMMARY

- Requires that a 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 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 acting on behalf of 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 representative of a manufacturer to furnish to a charitable pharmacy, under certain conditions, a sample drug as long as the drug is not a controlled substance.

CONTENT AND OPERATION

Background

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

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,

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

There are exceptions to the prohibition. The prohibition does not apply to licensed health professionals authorized to prescribe drugs, pharmacists, owners of pharmacies, or manufacturers and wholesalers of controlled substances.⁶

Current exception to prohibition against furnishing a sample drug

(R.C. 3719.81)

Current law provides an additional exception to the prohibition against knowingly furnishing another with a sample drug. Manufacturers of controlled substances, manufacturer's representatives, and wholesale dealers in pharmaceuticals may furnish sample drugs to licensed health professionals authorized to prescribe drugs. Such a professional may furnish a sample drug to a patient for use as medication if the following conditions are met:

(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.

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, II, IV, or V. (R.C. 3719.01.)*

(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 the sample drug 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 establishes a new condition. The sample drug must be furnished free of charge.

Furnishing sample drugs to and by charitable pharmacies

(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 sample drugs that are not controlled substances. 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 acting on behalf of a charitable pharmacy may dispense a sample drug that is not a controlled substance to a person. Also, a representative of a manufacturer of dangerous 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.

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. This includes the bill's new condition that the sample drug be furnished free of charge.

The bill establishes additional conditions for representatives of a manufacturer of dangerous drugs and pharmacists acting on behalf of a charitable pharmacy. A manufacturer's representative must comply with standards and

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).*

procedures that the State Board of Pharmacy is to establish in rules if the Board adopts rules permitting such representatives 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 unauthorized 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.

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	04-06-04	p. 1755

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