

AN ACT

To amend section 3719.81 and to enact sections 3719.811, 3719.812, and 3719.813 of the Revised Code regarding the distribution of sample drugs by and to charitable pharmacies.

Be it enacted by the General Assembly of the State of Ohio:

SECTION 1. That section 3719.81 be amended and sections 3719.811, 3719.812, and 3719.813 of the Revised Code be enacted to read as follows:

Sec. 3719.81. (A) As used in this section, "sample drug" has the same meaning as in section 2925.01 of the Revised Code.

~~(B) A person may furnish another a sample of any drug of abuse, or of any drug 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, if all of the following apply:~~

(1) The sample drug is furnished free of charge by a manufacturer, manufacturer's representative, or wholesale dealer in pharmaceuticals to a licensed health professional authorized to prescribe drugs, or is furnished free of charge by such a professional to a patient for use as medication;

(2) 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;

(3) Prior to its being furnished, the sample drug ~~sample~~ has been stored under the proper conditions to prevent its deterioration or contamination;

(4) If the sample drug is of a type which deteriorates with time, the sample container is plainly marked with the date beyond which the sample drug ~~sample~~ is unsafe to use, and the date has not expired on the sample furnished. Compliance with the labeling requirements of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, shall be deemed compliance with this section.

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

~~(B)~~(C) Division ~~(A)~~(B) of this section does not do any of the following:

(1) Apply to or restrict the furnishing of any sample of a nonnarcotic substance if the substance may, under the "Federal Food, Drug, and Cosmetic Act" and under the laws of this state, otherwise be lawfully sold over the counter without a prescription;

(2) Authorize a licensed health professional authorized to prescribe drugs who is a clinical nurse specialist, certified nurse-midwife, certified nurse practitioner, or advanced practice nurse to furnish a sample ~~of a~~ drug that is not a drug the nurse is authorized to prescribe;

(3) Authorize an optometrist to furnish a sample ~~of a~~ drug that is not a drug the optometrist is authorized to prescribe.

(4) Prohibit a licensed health professional authorized to prescribe drugs, manufacturer of dangerous drugs, wholesale distributor of dangerous drugs, or representative of a manufacturer of dangerous drugs from furnishing a sample drug to a charitable pharmacy in accordance with section 3719.811 of the Revised Code.

(5) Prohibit a pharmacist working, whether or not for compensation, in a charitable pharmacy from dispensing a sample drug to a person in accordance with section 3719.811 of the Revised Code.

~~(C)~~(D) The state board of pharmacy shall, in accordance with Chapter 119. of the Revised Code, adopt rules as necessary to give effect to this section.

Sec. 3719.811. (A) As used in this section:

(1) "Charitable pharmacy" means a pharmacy that meets all of the following requirements:

(a) Holds a terminal distributor of dangerous drugs license under section 4729.54 of the Revised Code.

(b) Is exempt from federal taxation pursuant to 26 U.S.C. 501(a) and (c)(3).

(c) Is not a hospital as defined in section 3727.01 of the Revised Code.

(2) "Prescription" has the same meaning as in section 4729.01 of the Revised Code.

(3) "Sample drug" has the same meaning as in section 2925.01 of the Revised Code.

(B) A manufacturer of dangerous drugs or wholesale distributor of dangerous drugs may furnish a sample drug to a charitable pharmacy if all of the following apply:

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

(2) Prior to its being furnished, the sample drug has been 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 container in which the sample drug is stored is plainly marked with the date beyond which the sample drug is unsafe to use, and the date has not expired on the sample drug furnished. Compliance with the labeling requirements of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C. 301, as amended, constitutes compliance with division (B)(3) of this section.

(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, including a child, for whom it may present a health or safety hazard.

(5) The sample drug is furnished free of charge.

(6) The sample drug is not a controlled substance.

(C) A representative of a manufacturer of dangerous drugs or a licensed health professional authorized to prescribe drugs may furnish a sample drug to a charitable pharmacy if all of the following apply:

(1) The state board of pharmacy has adopted rules under division (F) of this section to permit such a representative or health professional to furnish a sample drug to a charitable pharmacy.

(2) The representative or health professional complies with standards and procedures established in rules adopted under division (F) of this section.

(3) The requirements in divisions (B)(1) to (6) of this section are satisfied.

(D) A pharmacist working, whether or not for compensation, in a charitable pharmacy may dispense a sample drug to a person if all of the following apply:

(1) The person to whom the sample drug is dispensed is eligible for the sample drug under standards established by the body responsible for the charitable pharmacy's general management.

(2) The person to whom the sample is dispensed presents to the pharmacist a valid prescription for the sample drug.

(3) The sample drug is dispensed free of charge.

(4) The requirements in divisions (B)(1) to (4) and (6) of this section are satisfied.

(E) Divisions (B), (C), and (D) of this section do not do either of the following:

(1) Apply to or restrict the furnishing of any sample of a nonnarcotic substance if the substance may, under the "Federal Food, Drug, and Cosmetic Act" and under the law of this state, otherwise be lawfully sold

over the counter without a prescription.

(2) Authorize a pharmacist working, whether or not for compensation, in a charitable pharmacy to dispense a sample drug that the charitable pharmacy is unauthorized to possess, have custody or control of, or distribute.

(F) The state board of pharmacy shall, in accordance with Chapter 119. of the Revised Code, adopt rules as necessary to give effect to this section. The rules may permit representatives of manufacturers of dangerous drugs or licensed health professionals authorized to prescribe drugs to furnish sample drugs to charitable pharmacies under this section. If they do so, the rules shall establish standards and procedures for the representatives or health professionals to furnish the sample drugs.

Sec. 3719.812. The state board of pharmacy; any person that donates a sample drug as permitted under section 3719.811 of the Revised Code; any charitable pharmacy or pharmacist working in a charitable pharmacy that accepts or dispenses sample drugs as permitted under section 3719.811 of the Revised Code; and any licensed health professional authorized to prescribe drugs who accepts delivery of a sample drug on behalf of a charitable pharmacy as permitted under section 3719.811 of the Revised Code shall not, in the absence of bad faith, be subject to any of the following for matters related to donating, accepting, or dispensing sample drugs under section 3719.811 of the Revised Code: criminal prosecution; liability in tort or other civil action for injury, death, or loss to person or property; or professional disciplinary action.

Sec. 3719.813. A drug manufacturer shall not, in the absence of bad faith, be 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 the drug manufacturer that is donated by any person as permitted under section 3719.811 of the Revised Code, including but not limited to liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug.

SECTION 2. That existing section 3719.81 of the Revised Code is hereby repealed.

Speaker _____ of the House of Representatives.

President _____ of the Senate.

Passed _____, 20____

Approved _____, 20____

Governor.

Am. Sub. H. B. No. 454

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The section numbering of law of a general and permanent nature is complete and in conformity with the Revised Code.

Director, Legislative Service Commission.

Filed in the office of the Secretary of State at Columbus, Ohio, on the
____ day of _____, A. D. 20____.

Secretary of State.

File No. _____ Effective Date _____