

## As Introduced

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H. B. No. 454

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

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### A B I L L

To amend section 3719.81 and to enact section 1  
3719.811 of the Revised Code regarding the 2  
distribution of sample drugs by and to charitable 3  
pharmacies. 4

#### BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

**Section 1.** That section 3719.81 be amended and section 5  
3719.811 of the Revised Code be enacted to read as follows: 6

**Sec. 3719.81.** (A) As used in this section, "sample drug" has 7  
the same meaning as in section 2925.01 of the Revised Code. 8

(B) A person may furnish another a sample ~~of any drug of 9~~  
~~abuse, or of any drug or pharmaceutical preparation that would be 10~~  
~~hazardous to health or safety if used without the supervision of a 11~~  
~~licensed health professional authorized to prescribe drugs, if all 12~~  
of the following apply: 13

(1) The sample drug is furnished free of charge by a 14  
manufacturer, manufacturer's representative, or wholesale dealer 15  
in pharmaceuticals to a licensed health professional authorized to 16  
prescribe drugs, or is furnished free of charge by such a 17  
professional to a patient for use as medication; 18

(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. 49

(4) Prohibit a 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. 50  
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(5) Prohibit a pharmacist acting on behalf of a charitable pharmacy from dispensing a sample drug to a person in accordance with section 3719.811 of the Revised Code. 55  
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~~(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. 58  
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**Sec. 3719.811.** (A) As used in this section: 61

(1) "Charitable pharmacy" means a pharmacy that meets all of the following requirements: 62  
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(a) Holds a terminal distributor of dangerous drugs license under section 4729.54 of the Revised Code. 64  
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(b) Is exempt from federal taxation pursuant to 26 U.S.C. 501(a) and (c)(3). 66  
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(c) Is not a hospital as defined in section 3727.01 of the Revised Code. 68  
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(2) "Prescription" has the same meaning as in section 4729.01 of the Revised Code. 70  
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(3) "Sample drug" means a dangerous drug, other than a controlled substance, that, at one time, had been placed in a container plainly marked as a sample by a manufacturer. 72  
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(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: 75  
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(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. 78  
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(2) Prior to its being furnished, the sample drug has been stored under the proper conditions to prevent its deterioration or contamination. 81  
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(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. 84  
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(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. 92  
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(5) The sample drug is furnished free of charge. 96

(C) A representative of a manufacturer of dangerous drugs may furnish a sample drug to a charitable pharmacy if all of the following apply: 97  
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(1) The state board of pharmacy has adopted rules under division (F) of this section to permit such a representative to furnish a sample drug to a charitable pharmacy. 100  
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(2) The representative complies with standards and procedures established in rules adopted under division (F) of this section. 103  
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(3) The requirements in divisions (B)(1) to (5) of this section are satisfied. 105  
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(D) A pharmacist acting on behalf of a charitable pharmacy 107

may dispense a sample drug to a person if all of the following 108  
apply: 109

(1) The person to whom the sample drug is dispensed is 110  
eligible for the sample drug under standards established by the 111  
body responsible for the charitable pharmacy's general management. 112

(2) The person to whom the sample is dispensed presents to 113  
the pharmacist a valid prescription for the sample drug. 114

(3) The sample drug is dispensed free of charge. 115

(4) The requirements in divisions (B)(1) to (4) of this 116  
section are satisfied. 117

(E) Divisions (B), (C), and (D) of this section do not do 118  
either of the following: 119

(1) Apply to or restrict the furnishing of any sample of a 120  
nonnarcotic substance if the substance may, under the "Federal 121  
Food, Drug, and Cosmetic Act" and under the law of this state, 122  
otherwise be lawfully sold over the counter without a 123  
prescription. 124

(2) Authorize a pharmacist acting on behalf of a charitable 125  
pharmacy to dispense a sample drug that the charitable pharmacy is 126  
unauthorized to possess, have custody or control of, or 127  
distribute. 128

(F) The state board of pharmacy shall, in accordance with 129  
Chapter 119. of the Revised Code, adopt rules as necessary to give 130  
effect to this section. The rules may permit representatives of 131  
manufacturers of dangerous drugs to furnish sample drugs to 132  
charitable pharmacies under this section. If they do so, the rules 133  
shall establish standards and procedures for the representatives 134  
to furnish the sample drugs. 135

**Section 2.** That existing section 3719.81 of the Revised Code 136  
is hereby repealed. 137