

**As Introduced**

**134th General Assembly**

**Regular Session**

**2021-2022**

**H. B. No. 558**

**Representatives Roemer, Jordan**

**Cosponsors: Representatives Brinkman, Click, Gross, Hall, Lanese, Richardson,  
Seitz, Wiggam**

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**A BILL**

To amend sections 3715.87, 3715.871, 3715.872, and 1  
3715.873 of the Revised Code to modify the laws 2  
governing the drug repository program for 3  
donated prescription drugs. 4

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

**Section 1.** That sections 3715.87, 3715.871, 3715.872, and 5  
3715.873 of the Revised Code be amended to read as follows: 6

**Sec. 3715.87.** (A) As used in this section and in sections 7  
3715.871, 3715.872, and 3715.873 of the Revised Code: 8

(1) "Controlled substance" has the same meaning as in 9  
section 3719.01 of the Revised Code. 10

(2) "Charitable pharmacy" has the same meaning as in 11  
section 3719.811 of the Revised Code. 12

(3) "Health care facility" has the same meaning as in 13  
section 1337.11 of the Revised Code. 14

~~(3)~~ (4) "Hospital" has the same meaning as in section 15  
3727.01 of the Revised Code. 16

~~(4)~~ (5) "Nonprofit clinic" means a charitable nonprofit corporation organized and operated pursuant to Chapter 1702. of the Revised Code, or any charitable organization not organized and not operated for profit, that provides health care services to indigent and uninsured persons, as defined in section 2305.234 of the Revised Code, or to underinsured persons, as defined in rules adopted under section 3715.873 of the Revised Code. "Nonprofit clinic" does not include a hospital ~~as defined in section 3727.01 of the Revised Code,~~ a facility licensed under Chapter 3721. of the Revised Code, or a facility that is operated for profit.

~~(5)~~ (6) "Prescription drug" means any drug to which the following applies:

(a) Under the "Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required 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 the drug may be dispensed only upon a prescription.

(b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription.

(B) The state board of pharmacy shall establish a drug repository program to accept ~~and dispense~~ prescription drugs donated or given for the purpose of being ~~dispensed~~ distributed to individuals who are residents of this state and meet eligibility standards established in rules adopted ~~by the board~~ under section 3715.873 of the Revised Code. ~~Except~~

(C) Except as provided in division ~~(C)~~ (D) of this

section, all of the following conditions shall apply to the 46  
drugs that are accepted and distributed under the program: 47

(1) Only drugs in their original sealed and tamper-evident 48  
unit dose packaging may be accepted and ~~dispensed~~ distributed; 49

(2) The packaging must be unopened, except that drugs 50  
packaged in single unit doses may be accepted and ~~dispensed~~ 51  
distributed when the outside packaging is opened if the single 52  
unit dose packaging is undisturbed; 53

(3) A drug shall not be accepted or ~~dispensed~~ distributed 54  
if there is reason to believe that it is adulterated, as 55  
described in section 3715.63 of the Revised Code. 56

~~(C)~~ (D) Drugs that are not in their original sealed and 57  
tamper-evident packaging may be accepted and distributed under 58  
the program, subject to rules adopted under section 3715.873 of 59  
the Revised Code, if the drugs are included in either of the 60  
following categories and are not controlled substances: 61

(1) Orally administered cancer drugs that are not 62  
controlled substances and that do not require refrigeration, 63  
freezing, or storage at a special temperature may be accepted 64  
and dispensed even if not in original sealed and tamper-evident 65  
unit dose packaging, subject to rules adopted by the board 66  
pursuant to section 3715.873 of the Revised Code; 67

(2) Drugs that are accepted and distributed under the 68  
program by a charitable pharmacy or nonprofit clinic, including 69  
any such drugs that are orally administered cancer drugs or that 70  
may require storage at a special temperature. 71

~~(D)~~ (E) Subject to the limitations specified in divisions 72  
(B) and (C) to (D) of this section, unused drugs dispensed for 73  
purposes of for which the cost was covered by the medicaid 74

program may be accepted and ~~dispensed~~distributed under the drug repository program. 75  
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**Sec. 3715.871.** (A) Any ~~person, including a~~ pharmacy, drug manufacturer, ~~or~~ health care facility, or ~~any other person or~~ government entity may donate or give prescription drugs to the drug repository program. Any person or government entity may facilitate the donation or gift of drugs to the program. ~~The drugs must~~ Drugs may be donated or given only at a pharmacy, hospital, or nonprofit clinic participating in the program. 77  
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~~(B) Any pharmacy, hospital, or nonprofit clinic that elects may elect to participate in the drug repository program and if it meets eligibility criteria for participation in the program, as established in rules adopted by the state board of pharmacy under section 3715.873 of the Revised Code.~~ 84  
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Participation in the program by pharmacies, hospitals, and nonprofit clinics is voluntary. Nothing in this or any other section of the Revised Code requires a pharmacy, hospital, or nonprofit clinic to participate in the program. 89  
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~~(B)~~ (C) A pharmacy, hospital, or nonprofit clinic eligible to participate participating in the program shall dispense distribute the drugs donated or given under this section it accepts under the program to individuals who are residents of this state and meet the eligibility standards established in rules adopted by the board under section 3715.873 of the Revised Code or by using either of the following methods of distribution: 93  
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(1) Distributing the drugs to eligible individuals at the pharmacy, hospital, or nonprofit clinic; 101  
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(2) Distributing the drugs to other government entities 103

and nonprofit private entities, which then shall distribute the 104  
drugs to be dispensed to eligible individuals who meet the 105  
eligibility standards. A- 106

Regardless of which method of distribution is used, a drug 107  
may be dispensed distributed to an eligible individual only by 108  
being dispensed by a pharmacist pursuant to a prescription 109  
issued by a licensed health professional authorized to prescribe 110  
drugs, as defined in section 4729.01 of the Revised Code or by 111  
being personally furnished by such a prescriber. A- 112

(D) A pharmacy, hospital, or nonprofit clinic that accepts- 113  
donated or given drugs participating in the program shall comply 114  
with all applicable federal laws and laws of this state dealing 115  
with storage and distribution of dangerous drugs and shall, in 116  
accordance with rules adopted pursuant to under section 3715.873 117  
of the Revised Code, inspect all drugs prior to dispensing- 118  
distributing them to determine that they are not or appear not 119  
to be adulterated. The- 120

(E) A pharmacy, hospital, or nonprofit clinic 121  
participating in the program may charge individuals receiving 122  
donated or given drugs a handling fee established in accordance 123  
with rules adopted by the board under section 3715.873 of the 124  
Revised Code. Drugs-Except for occasional sales by charitable 125  
pharmacies and nonprofit clinics, as authorized in rules adopted 126  
under section 3715.873 of the Revised Code, drugs that are 127  
donated or given to the repository program may not be resold. 128

**Sec. 3715.872.** (A) As used in this section, "health care 129  
professional" means any of the following who provide medical, 130  
dental, or other health-related diagnosis, care, or treatment: 131

(1) Individuals authorized under Chapter 4731. of the 132

Revised Code to practice medicine and surgery, osteopathic	133
medicine and surgery, or podiatric medicine and surgery;	134
(2) Registered nurses and licensed practical nurses	135
licensed under Chapter 4723. of the Revised Code;	136
(3) Physician assistants <del>authorized to practice</del> <u>licensed</u>	137
under Chapter 4730. of the Revised Code;	138
(4) Dentists and dental hygienists licensed under Chapter	139
4715. of the Revised Code;	140
(5) Optometrists licensed under Chapter 4725. of the	141
Revised Code;	142
(6) Pharmacists licensed under Chapter 4729. of the	143
Revised Code.	144
(B) For matters related to <del>donating, giving, accepting, or</del>	145
<del>dispensing drugs</del> <u>activities conducted</u> under the drug repository	146
program, all of the following apply:	147
(1) <del>Any person, including a</del> <u>A pharmacy, drug manufacturer,</u>	148
<del>or health care facility, or any other person or</del> government	149
entity that donates or gives drugs to the <del>drug repository</del>	150
<u>program, and any person or government entity that facilitates</u>	151
<u>the donation or gift,</u> shall not be subject to liability in tort	152
or other civil action for injury, death, or loss to person or	153
property.	154
(2) A pharmacy, hospital, or nonprofit clinic that accepts	155
or <del>dispenses</del> <u>distributes</u> drugs under the program shall not be	156
subject to liability in tort or other civil action for injury,	157
death, or loss to person or property, unless an action or	158
omission of the pharmacy, hospital, or nonprofit clinic	159
constitutes willful and wanton misconduct.	160

(3) A health care professional who accepts~~or,~~ dispenses, ~~or personally furnishes~~ drugs under the program on behalf of a pharmacy, hospital, or nonprofit clinic participating in the program, and the pharmacy, hospital, or nonprofit clinic that employs or otherwise uses the services of the health care professional, shall not be subject to liability in tort or other civil action for injury, death, or loss to person or property, unless an action or omission of the health care professional, pharmacy, hospital, or nonprofit clinic constitutes willful and wanton misconduct.

(4) The state board of pharmacy ~~and the director of health~~ shall not be subject to liability in tort or other civil action for injury, death, or loss to person or property, unless an action or omission of the board ~~or director~~ constitutes willful and wanton misconduct.

~~(C)~~ (5) In addition to the civil immunity granted under division (B)(1) of this section, ~~any person, including a pharmacy, drug manufacturer, or health care facility, and any or other person or government entity that donates or gives drugs to the program, and any person or government entity that facilitates the donation or gift,~~ shall not be subject to criminal prosecution for ~~the donation, giving, acceptance, or dispensing of drugs matters related to activities that it conducts or another party conducts~~ under the program, unless an action or omission of the ~~person or government entity party that donates, gives, or facilitates the donation or gift of the drugs~~ does not comply with the provisions of this chapter or the rules adopted under it.

~~(D)~~ (6) In the case of a drug manufacturer, the immunities from civil liability and criminal prosecution granted to another

~~party~~ under divisions (B) (1) and ~~(C) (5)~~ of this section ~~apply~~ 191  
~~with respect to extend to the manufacturer when any drug~~ 192  
~~manufactured by the drug manufacturer that it manufactures is~~ 193  
~~donated or given by any person or government entity the subject~~ 194  
~~of an activity conducted under the program, including. This~~ 195  
~~extension of immunities includes, but is not limited to,~~ 196  
~~immunity from liability or prosecution for failure to transfer~~ 197  
or communicate product or consumer information or the expiration 198  
date of ~~the a~~ drug that is donated or given. 199

**Sec. 3715.873.** ~~In consultation with the director of~~ 200  
~~health, the~~ The state board of pharmacy shall adopt rules 201  
governing the drug repository program that establish all of the 202  
following: 203

(A) Eligibility criteria for pharmacies, hospitals, and 204  
nonprofit clinics to ~~receive and dispense drugs donated or given~~ 205  
~~under participate in the program, including, in the case of~~ 206  
nonprofit clinics, a definition of "underinsured person"; 207

(B) Standards and procedures for accepting, safely 208  
storing, and ~~dispensing distributing~~ drugs donated or given; 209

(C) ~~With respect to drugs that are donated or given, other~~ 210  
~~than orally administered cancer drugs described in division (C)~~ 211  
~~of section 3715.87 of the Revised Code that are not in original~~ 212  
~~sealed and tamper-evident unit dose packaging, standards~~ 213  
Standards and procedures for inspecting the drugs described in 214  
division (C) of section 3715.87 of the Revised Code to determine 215  
that the original unit dose packaging is sealed and tamper- 216  
evident and that the drugs are unadulterated, safe, and suitable 217  
for ~~dispensing~~ distribution; 218

(D) With respect to ~~orally administered cancer drugs~~ 219



described in division ~~(C)~~ (D) of section 3715.87 of the Revised 220  
Code ~~that are not in original sealed and tamper-evident unit-~~ 221  
~~dose packaging,~~ standards and procedures to determine based on a 222  
basic visual inspection that the drugs appear to be 223  
unadulterated, safe, and suitable for ~~dispensing~~ distribution; 224

(E) Eligibility standards based on economic need for 225  
individuals to receive drugs under the program; 226

(F) A means, such as an identification card, by which an 227  
individual who is eligible to receive drugs under the program 228  
may demonstrate eligibility to ~~the a~~ pharmacy, hospital, or 229  
nonprofit clinic ~~dispensing the drugs~~ participating in the 230  
program; 231

(G) A form that an individual receiving a drug under the 232  
program must sign before receiving the drug to confirm that the 233  
individual understands the immunity provisions of the program; 234

(H) A form that each individual who is donating or giving 235  
drugs to the program, or who represents the person or government 236  
entity that is donating or giving drugs to the program, must 237  
sign stating that the individual or the person or government 238  
entity being represented is the owner of the drugs and intends 239  
to voluntarily donate or give them to the program; 240

(I) A formula to determine the amount of a handling fee 241  
that pharmacies, hospitals, and nonprofit clinics participating 242  
in the program may charge to drug recipients to cover restocking 243  
and ~~dispensing~~ distribution costs; 244

~~(I) In addition, for drugs donated or given to the program~~ 245  
~~by individuals:~~ 246

~~(1) (J) A list of drugs, arranged either by category or by~~ 247  
~~individual drug, that the program will accept from individuals.~~ 248

~~The list shall include orally administered cancer drugs that are described in division (C) of section 3715.87 of the Revised Code.~~ 249  
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~~(2) A list of drugs, arranged either by category or by individual drug, that the program will not accept from individuals. The list shall not include orally administered cancer drugs that are described in division (C) of section 3715.87 of the Revised Code. The list must include or drug types, if applicable, that are ineligible to be donated or given under the program, including a statement as to why the drug or drug type is ineligible to be donated or given.~~ 252  
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~~(3) A form each donor must sign stating that the donor is the owner of the drugs and intends to voluntarily donate them to the program.~~ 260  
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~~(J) In addition, for drugs donated to the program by health care facilities:~~ 263  
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~~(1) A list of drugs, arranged either by category or by individual drug, that the program will accept from health care facilities. The list shall include orally administered cancer drugs that are described in division (C) of section 3715.87 of the Revised Code.~~ 265  
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~~(2) A list of drugs, arranged either by category or by individual drug, that the program will not accept from health care facilities. The list shall not include orally administered cancer drugs that are described in division (C) of section 3715.87 of the Revised Code. The list must include a statement as to why the drug is ineligible to be donated or given.;~~ 270  
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~~(K) The standards by which a charitable pharmacy or nonprofit clinic participating in the program may make~~ 276  
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<u>occasional sales at wholesale, pursuant to section 4729.51 of</u>	278
<u>the Revised Code, of drugs that have been donated or given to</u>	279
<u>the program;</u>	280
(L) Any other standards and procedures the board considers	281
appropriate.	282
The rules shall be adopted in accordance with Chapter 119.	283
of the Revised Code.	284
<b>Section 2.</b> That existing sections 3715.87, 3715.871,	285
3715.872, and 3715.873 of the Revised Code are hereby repealed.	286