# As Passed by the House

**134th General Assembly** 

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Sub. H. B. No. 558

**Representatives Roemer, Jordan** 

Cosponsors: Representatives Brinkman, Click, Gross, Hall, Lanese, Richardson, Seitz, Wiggam, Bird, Ginter, West, Abrams, Boyd, Carruthers, Creech, Crossman, Cutrona, Davis, Denson, Fraizer, Galonski, Ghanbari, Grendell, Hicks-Hudson, Holmes, John, Jones, Kick, Lampton, Leland, Lepore-Hagan, Lightbody, Lipps, Liston, Manning, McClain, Miller, A., Miller, J., O'Brien, Oelslager, Patton, Plummer, Ray, Riedel, Russo, Smith, K., Smith, M., Stein, Stephens, Stewart, Sweeney, Upchurch, White, Wilkin, Young, T., Speaker Cupp

# A BILL

То	amend sections 3715.87, 3715.871, 3715.872,	1
	3715.873, and 4729.54 of the Revised Code to	2
	modify the laws governing the drug repository	3
	program for donated prescription drugs and to	4
	make temporary changes regarding certificates of	5
	need.	6

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

Section 1. That sections 3715.87, 3715.871, 3715.872,	7
3715.873, and 4729.54 of the Revised Code be amended to read as	8
follows:	9
Sec. 3715.87. (A) As used in this section and in sections	10
3715.871, 3715.872, and 3715.873 of the Revised Code:	11
	1.0
(1) "Controlled substance" has the same meaning as in	12
section 3719.01 of the Revised Code.	13

(2) "Charitable pharmacy" has the same meaning as in	14
section 3719.811 of the Revised Code.	15
(3) "Health care facility" has the same meaning as in	16
section 1337.11 of the Revised Code.	17
(3) (4) "Hospital" has the same meaning as in section	18
3727.01 of the Revised Code.	19
(4) (5) "Nonprofit clinic" means a charitable nonprofit	20
corporation organized and operated pursuant to Chapter 1702. of	21
the Revised Code, or any charitable organization not organized	22
and not operated for profit, that provides health care services	23
to indigent and uninsured persons, as defined in section	24
2305.234 of the Revised Code, or to underinsured persons, as	25
defined in rules adopted under section 3715.873 of the Revised	26
Code. "Nonprofit clinic" does not include a hospital-as defined	27
in section 3727.01 of the Revised Code, a facility licensed	28
under Chapter 3721. of the Revised Code, or a facility that is	29
operated for profit.	30
(5) (6) "Prescription drug" means any drug to which the	31
following applies:	32
(a) Under the "Food, Drug, and Cosmetic Act," 52 Stat.	33
1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required	34
to bear a label containing the legend, "Caution: Federal law	35
prohibits dispensing without prescription" or "Caution: Federal	36
law restricts this drug to use by or on the order of a licensed	37
veterinarian" or any similar restrictive statement, or the drug	38
may be dispensed only upon a prescription.	39
(b) Under Chapter 3715. or 3719. of the Revised Code, the	40
drug may be dispensed only upon a prescription.	41
(B) The state board of pharmacy shall establish a drug	42

repository program to accept and dispense prescription drugs	43
donated or given for the purpose of being dispensed distributed	44
to individuals who are residents of this state and meet	45
eligibility standards established in rules adopted <del>by the board</del>	46
under section 3715.873 of the Revised Code. Except	47
(C) as provided in division (C) of this section, all All	48
of the following conditions shall apply to the <u>drugs that are</u>	40
accepted and distributed under the program:	50
(1) Only-Except as provided in division (D) of this	51
section:	52
(a) Only drugs in their original sealed and tamper-evident	53
unit dose packaging may be accepted and dispensed; distributed.	54
(2) (b) The packaging must be unopened, except that drugs	55
packaged in single unit doses may be accepted and <del>dispensed</del>	56
distributed when the outside packaging is opened if the single	57
unit dose packaging is undisturbed <del>;</del> .	58
<del>(3) <u>(</u>2) A</del> drug shall not be accepted or <del>dispensed</del>	59
<u>distributed if there either of the following is the case:</u>	60
<u>(a) There</u> is reason to believe that <del>it the drug</del> is	61
adulterated, as described in section 3715.63 of the Revised	62
Code.	63
	00
(b) The drug, as determined in accordance with rules	64
adopted under section 3715.873 of the Revised Code, is a drug	65
for which the United States food and drug administration	66
requires, as a risk evaluation and mitigation strategy, that the	67
patient be registered with the drug's manufacturer.	68
(C) (D) Drugs that are not in their original sealed and	69
tamper-evident unit dose packaging may be accepted and	70

<u>distributed under the program, subject to rules adopted under</u>	71
section 3715.873 of the Revised Code, if the drugs are included	
in either of the following categories and are not controlled	
substances:	74
(1) Orally administered cancer drugs that are not	75
controlled substances and that do not require refrigeration,	76
freezing, or storage at a special temperature may be accepted	77
and dispensed even if not in original sealed and tamper evident	78
unit dose packaging, subject to rules adopted by the board	79
pursuant to section 3715.873 of the Revised Code;	80
(2) Drugs that are accepted and distributed under the	81
program by a charitable pharmacy, hospital, or nonprofit clinic,	82
including any such drugs that are orally administered cancer	83
drugs or that may require storage at a special temperature.	84
<del>(D) <u>(E)</u> Subject to the limitations specified in divisions</del>	85
(D) (E) Subject to the limitations specified in divisions (B) <del>and (C) <u>to</u> (D) of this section, unused drugs <del>dispensed for</del></del>	85 86
(B) and (C) to (D) of this section, unused drugs dispensed for	86
(B) and (C) to (D) of this section, unused drugs dispensed for purposes of for which the cost was covered by the medicaid	86 87
(B) and (C) to (D) of this section, unused drugs dispensed for purposes of for which the cost was covered by the medicaid program may be accepted and dispensed distributed under the drug	86 87 88
(B) and (C) to (D) of this section, unused drugs dispensed for purposes of for which the cost was covered by the medicaid program may be accepted and dispensed distributed under the drug repository program.	86 87 88 89
<ul> <li>(B) and (C) to (D) of this section, unused drugs dispensed for purposes of for which the cost was covered by the medicaid program may be accepted and dispensed distributed under the drug repository program.</li> <li>Sec. 3715.871. (A) Any person, including a pharmacy, drug</li> </ul>	86 87 88 89 90
(B) and (C) to (D) of this section, unused drugs dispensed for purposes of for which the cost was covered by the medicaid program may be accepted and dispensed distributed under the drug repository program. Sec. 3715.871. (A) Any person, including a pharmacy, drug manufacturer, or health care facility, or any other person or	86 87 88 89 90 91
(B) and (C) to (D) of this section, unused drugs dispensed for purposes of for which the cost was covered by the medicaid program may be accepted and dispensed distributed under the drug repository program. 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	86 87 88 89 90 91 92
(B) and (C) to (D) of this section, unused drugs dispensed for purposes of for which the cost was covered by the medicaid program may be accepted and dispensed distributed under the drug repository program. 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	86 87 88 89 90 91 92 93
(B) and (C) to (D) of this section, unused drugs dispensed for- purposes of for which the cost was covered by the medicaid program may be accepted and dispensed distributed under the drug repository program. 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	86 87 88 90 91 92 93 94
(B) and (C) to (D) of this section, unused drugs dispensed for purposes of for which the cost was covered by the medicaid program may be accepted and dispensed distributed under the drug repository program. 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,	86 87 88 90 91 92 93 94 95

and if it meets eligibility criteria for participation in the

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program, as established in rules adopted by the state board of	100
pharmacy-under section 3715.873 of the Revised Code.	101
Participation in the program by pharmacies, hospitals, and	102
nonprofit clinics is voluntary. Nothing in this or any other	103
section of the Revised Code requires a pharmacy, hospital, or	104
nonprofit clinic to participate in the program.	105
<del>(B) <u>(C)</u> A pharmacy, hospital, or nonprofit clinic <del>eligible</del></del>	106
to participate participating in the program shall dispense	107
<u>distribute the drugs donated or given under this section it</u>	108
accepts under the program to individuals who are residents of	109
this state and meet the eligibility standards established in	110
rules adopted <del>by the board </del> under section 3715.873 of the Revised	111
Code <del>or by using either of the following methods of</del>	112
distribution:	113
(1) Distributing the drugs to eligible individuals at the	114
pharmacy, hospital, or nonprofit clinic;	115
(2) Distributing the drugs to other government entities	116
and nonprofit private entities, which then shall distribute the	117
drugs to be dispensed to eligible individuals who meet the	118
eligibility standards. A	119
<u>Regardless of which method of distribution is used, a drug</u>	120
may be <del>dispensed <u>distributed</u> to an eligible individual only by</del>	121
being dispensed by a pharmacist pursuant to a prescription	122
issued by a licensed health professional authorized to prescribe	123
drugs <del>, as defined in section 4729.01 of the Revised Code_or by_</del>	124
being personally furnished by such a prescriber. $A$	125
(D) A pharmacy, hospital, or nonprofit clinic that accepts	126
donated or given drugs participating in the program shall comply	127

donated or given drugs participating in the program shall comply127with all applicable federal laws and laws of this state dealing128

with storage and distribution of dangerous drugs and shall, in 129 accordance with rules adopted pursuant to under section 3715.873 130 of the Revised Code, inspect all drugs prior to dispensing 131 distributing them to determine that they are not or appear not 132 to be adulterated. The-133 (E) A pharmacy, hospital, or nonprofit clinic 134 participating in the program may charge individuals receiving 135 donated or given drugs a <u>nominal</u> handling fee established in 136 accordance with rules adopted by the board under section 137 3715.873 of the Revised Code. <del>Drugs <u>Except for occasional sales</u></del> 138 at wholesale by charitable pharmacies, hospitals, and nonprofit 139 clinics, as authorized in rules adopted under section 3715.873 140 of the Revised Code, drugs that are donated or given to the 141 repository program may not be resold. 142 Sec. 3715.872. (A) As used in this section, "health care 143 professional" means any of the following who provide medical, 144 dental, or other health-related diagnosis, care, or treatment: 145 (1) Individuals authorized under Chapter 4731. of the 146 Revised Code to practice medicine and surgery, osteopathic 147 medicine and surgery, or podiatric medicine and surgery; 148 (2) Registered nurses and licensed practical nurses 149 licensed under Chapter 4723. of the Revised Code; 150 (3) Physician assistants authorized to practice-licensed 151 under Chapter 4730. of the Revised Code; 152(4) Dentists and dental hygienists licensed under Chapter 153 4715. of the Revised Code; 154 (5) Optometrists licensed under Chapter 4725. of the 155 Revised Code; 156

(6) Pharmacists licensed under Chapter 4729. of the 157Revised Code. 158

(B) For matters related to donating, giving, accepting, or
 dispensing drugs activities conducted under the drug repository
 program, all of the following apply:

(1) Any person, including a <u>A</u> pharmacy, drug manufacturer,
or-health care facility, or any other person or government
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entity that donates or gives drugs to the drug repository
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program, and any person or government entity that facilitates
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the donation or gift, shall not be subject to liability in tort
or other civil action for injury, death, or loss to person or
property.

(2) A pharmacy, hospital, or nonprofit clinic that accepts or <u>dispenses\_distributes</u> drugs under the program 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 pharmacy, hospital, or nonprofit clinic constitutes willful and wanton misconduct.

(3) A health care professional who accepts-or, dispenses, 175 or personally furnishes drugs under the program on behalf of a 176 pharmacy, hospital, or nonprofit clinic participating in the 177 program, and the pharmacy, hospital, or nonprofit clinic that 178 employs or otherwise uses the services of the health care 179 professional, shall not be subject to liability in tort or other 180 civil action for injury, death, or loss to person or property, 181 unless an action or omission of the health care professional, 182 pharmacy, hospital, or nonprofit clinic constitutes willful and 183 wanton misconduct. 184

(4) The state board of pharmacy and the director of health 185

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shall not be subject to liability in tort or other civil action186for injury, death, or loss to person or property, unless an187action or omission of the board or director constitutes willful188and wanton misconduct.189

(C) (5) In addition to the civil immunity granted under 190 division (B)(1) of this section, any person, including a 191 pharmacy, drug manufacturer, or health care facility, and any or 192 other person or government entity that donates or gives drugs to 193 the program, and any person or government entity that 194 facilitates the donation or gift, shall not be subject to 195 criminal prosecution for the donation, giving, acceptance, or 196 dispensing of drugs matters related to activities that it 197 conducts or another party conducts under the program, unless an 198 action or omission of the person or government entity party that 199 donates, gives, or facilitates the donation or gift of the drugs 200 does not comply with the provisions of this chapter or the rules 201 adopted under it. 202

(D) In the case of a drug manufacturer, the immunities 203 from civil liability and criminal prosecution granted to another 204 <u>party</u> under divisions (B)(1) and  $\frac{(C)}{(5)}$  of this section apply 205 with respect to extend to the manufacturer when any drug 206 207 manufactured by the drug manufacturer that it manufactures is donated or given by any person or government entity the subject 208 of an activity conducted under the program, including. This 209 extension of immunities includes, but is not limited to, 210 immunity from liability or prosecution for failure to transfer 211 or communicate product or consumer information or the expiration 212 date of the a drug that is donated or given. 213

Sec. 3715.873. In consultation with the director of214health, the The state board of pharmacy shall adopt rules215

governing the drug repository program that establish all of the following:

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

(B) Standards and procedures for accepting, safely 222storing, and dispensing distributing drugs donated or given; 223

224 (C) With respect to drugs that are donated or given, other than orally administered cancer drugs described in division (C) 225 of section 3715.87 of the Revised Code that are not in original 226 sealed and tamper-evident unit dose packaging, standards 227 <u>Standards</u> and procedures for inspecting the drugs <u>described in</u> 228 division (C)(1) of section 3715.87 of the Revised Code to 229 determine that the original unit dose packaging is sealed and 230 tamper-evident and that the drugs are unadulterated, safe, and 231 suitable for <u>dispensing</u> <u>distribution</u>; 232

(D) With respect to orally administered cancer drugs
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described in division (C) (D) of section 3715.87 of the Revised
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Code that are not in original sealed and tamper-evident unit
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dose packaging, standards and procedures to determine based on a
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basic visual inspection that the drugs appear to be
unadulterated, safe, and suitable for dispensing distribution;
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(E) Eligibility standards based on economic need for239individuals to receive drugs <u>under the program</u>;240

(F) A means, such as an identification card, by which an
individual who is eligible to receive drugs under the program
may demonstrate eligibility to the <u>a</u> pharmacy, hospital, or
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nonprofit clinic dispensing the drugs participating in the
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## program;

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(G) A form that an individual receiving a drug under the	246
program must sign before receiving the drug to confirm that the	247
individual understands the immunity provisions of the program;	248
(H) A form that each individual who is donating or giving	249
drugs to the program, or who represents the person or government	250
entity that is donating or giving drugs to the program, must	251
sign stating that the individual or the person or government	252
entity being represented is the owner of the drugs and intends	253
to voluntarily donate or give them to the program;	254
(I) A formula to determine the amount of a <u>nominal</u>	255
handling fee that pharmacies, hospitals, and nonprofit clinics	256
participating in the program may charge to drug recipients to	257
cover restocking and dispensing distribution costs;	258
(I) In addition, for drugs donated or given to the program-	259
by individuals:	260
(1) (J) A list of drugs, arranged either by category or by	261
individual drug, that the program will accept from individuals.	262
The list shall include orally administered cancer drugs that are	263
described in division (C) of section 3715.87 of the Revised	264
<del>Code.</del>	265
(2) A list of drugs, arranged either by category or by-	266
individual drug, that the program will not accept from	267
individuals. The list shall not include orally administered	268
cancer drugs that are described in division (C) of section	269
3715.87 of the Revised Code. The list must include or drug	270
types, if applicable, that are ineligible to be donated or given	271
types, if applicable, that are ineligible to be donated or given under the program, including those described in division (C)(2)	271 272

to why the <del>drug is <u>listed</u> drugs or drug types are </del> ineligible to	274
be donated or given <del>.</del>	275
(3) A form each donor must sign stating that the donor is	276
the owner of the drugs and intends to voluntarily donate them to	277
the program.	278
(J) In addition, for drugs donated to the program by-	279
health care facilities:	280
(1) A list of drugs, arranged either by category or by	281
individual drug, that the program will accept from health care	282
facilities. The list shall include orally administered cancer	283
drugs that are described in division (C) of section 3715.87 of	284
the Revised Code.	285
(2) A list of drugs, arranged either by category or by	286
individual drug, that the program will not accept from health-	287
care facilities. The list shall not include orally administered	288
cancer drugs that are described in division (C) of section-	289
3715.87 of the Revised Code. The list must include a statement	290
as to why the drug is ineligible to be donated or given.;	291
(K) The standards by which a charitable pharmacy,	292
hospital, or nonprofit clinic participating in the program may	293
make occasional sales at wholesale, pursuant to section 4729.51	294
of the Revised Code, of drugs that have been donated or given to	295
the program;	296
(L) Any other standards and procedures the board considers	297
appropriate.	298
The rules shall be adopted in accordance with Chapter 119.	299
of the Revised Code.	300
Sec. 4729.54. (A) As used in this section:	301

(1) "Category II" means any dangerous drug that is not 302 included in category III. 303 (2) "Category III" means any controlled substance that is 304 contained in schedule I, II, III, IV, or V. 305 (3) "Emergency medical service organization" has the same 306 meaning as in section 4765.01 of the Revised Code. 307 (4) "Emergency medical service organization satellite" 308 means a location where dangerous drugs are stored that is 309 separate from, but associated with, the headquarters of an 310 emergency medical service organization. "Emergency medical 311 service organization satellite" does not include the units under 312 the control of the emergency medical service organization. 313 (5) "Person" includes an emergency medical service 314 organization or an emergency medical service organization 315 satellite. 316 (6) "Schedule I," "schedule II," "schedule III," "schedule 317 IV, " and "schedule V" have the same meanings as in section 318 3719.01 of the Revised Code. 319 (B)(1) A person seeking to be licensed as a terminal 320 distributor of dangerous drugs shall file with the executive 321 director of the state board of pharmacy a verified application. 322 After it is filed, the application may not be withdrawn without 323 approval of the board. 324 (2) An application shall contain all the following that 325 apply in the applicant's case: 326 (a) Information that the board requires relative to the 327 qualifications of a terminal distributor of dangerous drugs set 328 forth in section 4729.55 of the Revised Code; 329

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(b) A statement as to whether the person is seeking to be
licensed as a category II, category III, limited category II, or
limited category III terminal distributor of dangerous drugs;
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(c) If the person is seeking to be licensed as a limited 333 category II or limited category III terminal distributor of 334 dangerous drugs, a list of the dangerous drugs that the person 335 is seeking to possess, have custody or control of, and 336 distribute, which list shall also specify the purpose for which 337 those drugs will be used and their source; 338

(d) If the person is an emergency medical service 339
organization, the information that is specified in divisions (C) 340
(1) and (2) of this section, and if the person is an emergency 341
medical service organization satellite, the information required 342
under division (D) of this section; 343

(e) Except with respect to the units under the control of an emergency medical service organization, the identity of the one establishment or place at which the person intends to engage in the sale or other distribution of dangerous drugs at retail, and maintain possession, custody, or control of dangerous drugs for purposes other than the person's own use or consumption;

(f) If the application pertains to a pain management 350 clinic, information that demonstrates, to the satisfaction of 351 the board, compliance with division (A) of section 4729.552 of 352 the Revised Code; 353

(g) If the application pertains to a facility, clinic, or
other location described in division (B) of section 4729.553 of
the Revised Code that must hold a category III terminal
distributor of dangerous drugs license with an office-based
opioid treatment classification, information that demonstrates,

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of that section.

(C) (1) Each emergency medical service organization that 361 applies for a terminal distributor of dangerous drugs license 362 shall submit with its application all of the following: 363 (a) A copy of its standing orders or protocol, which 364 365 orders or protocol shall be signed by a physician; (b) A list of the dangerous drugs that the units under its 366 control may carry, expressed in standard dose units, which shall 367 be signed by a physician; 368 (c) A list of the personnel employed or used by the 369 organization to provide emergency medical services in accordance 370 with Chapter 4765. of the Revised Code. 371 In accordance with Chapter 119. of the Revised Code, the 372 board shall adopt rules specifying when an emergency medical 373

to the satisfaction of the board, compliance with division (C)

service organization that is licensed as a terminal distributor374must notify the board of any changes in its documentation375submitted pursuant to division (C) (1) of this section.376

(2) An emergency medical service organization seeking to
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 be licensed as a terminal distributor of dangerous drugs shall
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 list in its application for licensure the following additional
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 information:

(a) The units under its control that the organization
determines will possess dangerous drugs for the purpose of
administering emergency medical services in accordance with
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Chapter 4765. of the Revised Code;
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(b) With respect to each such unit, whether the dangerous 385 drugs that the organization determines the unit will possess are 386

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in category II or III.

(3) An emergency medical service organization that is
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licensed as a terminal distributor of dangerous drugs shall file
a new application for such licensure if there is any change in
the number or location of any of its units or if there is any
change in the category of the dangerous drugs that any unit will
gossess.

(4) A unit listed in an application for licensure pursuant 394 395 to division (C)(2) of this section may obtain the dangerous drugs it is authorized to possess from its emergency medical 396 service organization or, on a replacement basis, from a hospital 397 pharmacy. If units will obtain dangerous drugs from a hospital 398 pharmacy, the organization shall file, and maintain in current 399 form, the following items with the pharmacist who is responsible 400 for the hospital's terminal distributor of dangerous drugs 401 license: 402

(a) A copy of its standing orders or protocol;

(b) A list of the personnel employed or used by the
organization to provide emergency medical services in accordance
with Chapter 4765. of the Revised Code, who are authorized to
possess the drugs, which list also shall indicate the personnel
who are authorized to administer the drugs.

(D) Each emergency medical service organization satellite
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that applies for a terminal distributor of dangerous drugs
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license shall submit with its application all of the information
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that the board requires to be submitted with the application, as
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specified in rules the board shall adopt in accordance with
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Chapter 119. of the Revised Code.

(E) There shall be four categories of terminal distributor 415

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of dangerous drugs licenses. The categories are as follows: 416 (1) Category II license. A person who obtains this license 417

may possess, have custody or control of, and distribute only the 418 dangerous drugs described in category II. 419

(2) Limited category II license. A person who obtains this
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license may possess, have custody or control of, and distribute
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only the dangerous drugs described in category II that were
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listed in the application for licensure.

(3) Category III license, which may include a pain
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management clinic classification issued under section 4729.552
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of the Revised Code. A person who obtains this license may
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possess, have custody or control of, and distribute the
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dangerous drugs described in category II and category III. If
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the license includes a pain management clinic classification,
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the person may operate a pain management clinic.

(4) Limited category III license. A person who obtains
this license may possess, have custody or control of, and
distribute only the dangerous drugs described in category II or
category III that were listed in the application for licensure.
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(F) Except for an application made by a county dog warden 435 or on behalf of an animal shelter, if an applicant for a limited 436 category II license or limited category III license intends to 437 administer dangerous drugs to a person or animal, the applicant 438 shall submit, with the application, a copy of its protocol or 439 standing orders. The protocol or orders shall be signed by a 440 licensed health professional authorized to prescribe drugs, 441 specify the dangerous drugs to be administered, and list 442 personnel who are authorized to administer the dangerous drugs 443 in accordance with federal law or the law of this state. 444

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An application made by a county dog warden or on behalf of 445 an animal shelter shall include a list of the dangerous drugs to 446 be administered to animals and the personnel who are authorized 447 to administer the drugs to animals in accordance with section 448 4729.532 of the Revised Code. 449

In accordance with Chapter 119. of the Revised Code, the 450 board shall adopt rules specifying when a licensee must notify 451 the board of any changes in its documentation submitted pursuant 452 to this division. 453

(G) (1) Each Except as provided in division (G) (3) of this
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section, each applicant for licensure as a terminal distributor
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of dangerous drugs shall submit, with the application, a license
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fee. The amount assessed shall not be returned to the applicant
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if the applicant fails to qualify for the license.

(2) The following fees apply under division (G)(1) of this section:

(a) Except as provided in division (G)(2)(b) of this461462

(i) Three hundred twenty dollars for a category II or463limited category II license;464

(ii) Four hundred forty dollars for a category III
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license, including a license with a pain management clinic
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classification issued under section 4729.552 of the Revised
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Code, or a limited category III license.
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(b) One hundred twenty dollars for all of the following:

(i) A person who is required to hold a license as a
terminal distributor of dangerous drugs pursuant to division (D)
of section 4729.541 of the Revised Code;
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(ii) A professional association, corporation, partnership,	473
or limited liability company organized for the purpose of	474
practicing veterinary medicine that is not included in division	475
(G)(2)(b)(i) of this section;	476
(iii) An emergency medical service organization satellite.	477
(3) No fee applies for a license issued to a charitable	478
pharmacy, as defined in section 3719.811 of the Revised Code, if	479
the charitable pharmacy is participating in the drug repository	480
program established under section 3715.87 of the Revised Code.	481
(H)(1) The board shall issue a terminal distributor of	482
dangerous drugs license to each person who submits an	483
application for such licensure in accordance with this section,	484
pays the required license fee, is determined by the board to	485
meet the requirements set forth in section 4729.55 of the	486
Revised Code, and satisfies any other applicable requirements of	487
this section.	488
(2) Except for the license of a county dog warden, the	489
license shall describe the one establishment or place at which	490
the licensee may engage in the sale or other distribution of	491
dangerous drugs at retail and maintain possession, custody, or	492
control of dangerous drugs for purposes other than the	493

licensee's own use or consumption. The one establishment or 494 place shall be that which is identified in the application for 495 licensure. 496

No such license shall authorize or permit the terminal497distributor of dangerous drugs named in it to engage in the sale498or other distribution of dangerous drugs at retail or to499maintain possession, custody, or control of dangerous drugs for500any purpose other than the distributor's own use or consumption,501

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at any establishment or place other than that described in the502license, except that an agent or employee of an animal shelter503or county dog warden may possess and use dangerous drugs in the504course of business as provided in section 4729.532 of the505Revised Code.506

(3) The license of an emergency medical service
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organization shall cover the organization's headquarters and, in
addition, shall cover and describe all the units of the
organization listed in its application for licensure.
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(I) (1) All licenses issued or renewed pursuant to this 511 section shall be effective for a period specified by the board 512 in rules adopted under section 4729.26 of the Revised Code. The 513 effective period for an initial or renewed license shall not 514 exceed twenty-four months unless the board extends the period in 515 rules to adjust license renewal schedules. A license shall be 516 renewed by the board according to the provisions of this 517 section, the standard renewal procedure of Chapter 4745. of the 518 Revised Code, and rules adopted by the board under section 519 4729.26 of the Revised Code. A person seeking to renew a license 520 shall submit an application for renewal and pay the required fee 521 on or before the date specified in the rules adopted by the 522 board. The fee required for the renewal of a license shall be 523 the same as the license fee paid that applies under division (G) 524 (G)(2) of this section. 525

(2) (a) Subject to division (I) (2) (b) of this section, a
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license that has not been renewed by the date specified in rules
adopted by the board may be reinstated only upon payment of the
required renewal fee and a penalty fee of one hundred ten
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dollars.

(b) If an application for renewal has not been submitted

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by the sixty-first day after the renewal date specified in rules 532 adopted by the board, the license is considered void and cannot 533 be renewed, but the license holder may reapply for licensure. 534

(3) A terminal distributor of dangerous drugs that fails
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to renew licensure in accordance with this section and rules
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adopted by the board is prohibited from engaging in the retail
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sale, possession, or distribution of dangerous drugs until a
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valid license is issued by the board.
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(J) (1) No emergency medical service organization that is
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licensed as a terminal distributor of dangerous drugs shall fail
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to comply with division (C) (1), (3), or (4) of this section.
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(2) No licensed terminal distributor of dangerous drugs shall possess, have custody or control of, or distribute dangerous drugs that the terminal distributor is not entitled to possess, have custody or control of, or distribute by virtue of its category of licensure.

(3) No licensee that is required by division (F) of this
section to notify the board of changes in its protocol or
standing orders, or in personnel, shall fail to comply with that
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division.

(K) The board may enter into agreements with other states, 552 federal agencies, and other entities to exchange information 553 concerning licensing and inspection of terminal distributors of 554 dangerous drugs located within or outside this state and to 555 investigate alleged violations of the laws and rules governing 556 distribution of drugs by terminal distributors. Any information 557 received pursuant to such an agreement is subject to the same 558 confidentiality requirements applicable to the agency or entity 559 from which it was received and shall not be released without 560

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prior authorization from that agency or entity. 561

 Section 2. That existing sections 3715.87, 3715.871,
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 3715.872, 3715.873, and 4729.54 of the Revised Code are hereby
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 repealed.
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Section 3. Notwithstanding division (A) of section 565 3702.523 and divisions (A) and (B) of section 3702.524 of the 566 Revised Code, or any other conflicting provision in sections 567 3702.51 to 3702.62 of the Revised Code, all of the following 568 apply in the case of a certificate of need granted during the 569 period beginning March 9, 2020, and ending June 18, 2021: 570

(A) The Director of Health shall grant the holder of a certificate of need a twenty-four-month extension to obligate capital expenditures and commence construction for a proposed project. The extension shall be effective during the twenty-four-month period immediately following the expiration date of the twenty-four-month period that otherwise would apply, as described in division (A) of section 3702.524 of the Revised Code. The Director shall notify the holder of the certificate of need of the date on which the twenty-four-month extension expires.

(B) (1) Subject to division (B) (2) of this section, the
transfer of a certificate of need, or the transfer of the
controlling interest in an entity that holds a certificate of
need, prior to completion of the reviewable activity for which
the certificate of need was granted, does not void the
certificate of need.

(2) In the event of a transfer as described in division 587
(B) (1) of this section, upon receipt of written notice from the 588
transferee that provides sufficient evidence to enable the 589

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Director to determine that recognizing the new owner and	590
operator will not cause any of the circumstances specified in	591
division (B) of section 3702.59 of the Revised Code to occur,	592
the Director shall recognize the transfer of ownership of the	593
entity granted the certificate of need to the new owner.	594