As Reported by the House Health Committee

134th General Assembly

Regular Session 2021-2022

Sub. H. B. No. 558

Representatives Roemer, Jordan

Cosponsors: Representatives Brinkman, Click, Gross, Hall, Lanese, Richardson, Seitz, Wiggam, Bird, Ginter, West

A BILL

Τc	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 3715.871, 3715.872, and 3715.873 of the Revised Code:	10 11
5715.871, 5715.872, and 5715.875 of the Revised Code.	
(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.

(3) (4)"Hospital" has the same meaning as in section183727.01 of the Revised Code.19

(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 <u>Code</u>. "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
34
to bear a label containing the legend, "Caution: Federal law
prohibits dispensing without prescription" or "Caution: Federal
1aw 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
44
to individuals who are residents of this state and meet
45

17

20

21

22

23

24

25

26

27

28

29

30

31

32

40

eligibility standards established in rules adopted by the board	46
under section 3715.873 of the Revised Code. Except	
(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>	49
accepted and distributed under the program:	50
(1) Only <u>Except</u> 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 dispensed -	56
distributed when the outside packaging is opened if the single	57
unit dose packaging is undisturbed ;	58
(3) (2) A drug shall not be accepted or dispensed	59
<u>distributed</u> if there either of the following is the case:	60
<u>(a) There</u> is reason to believe that it the drug is	61
adulterated, as described in section 3715.63 of the Revised	62
Code <u>.</u>	63
(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
distributed under the program, subject to rules adopted under	71
section 3715.873 of the Revised Code, if the drugs are included	72
in either of the following categories and are not controlled	73

Page 3

substances:

(1) Orally administered cancer drugs that are not controlled substances and that do not require refrigeration, freezing, or storage at a special temperature may be accepted and dispensed even if not in original sealed and tamper evidentunit dose packaging, subject to rules adopted by the board pursuant to section 3715.873 of the Revised Code; (2) Drugs that are accepted and distributed under the program by a charitable pharmacy, hospital, or nonprofit clinic, including any such drugs that are orally administered cancer drugs or that may require storage at a special temperature. (D)-(E) Subject to the limitations specified in divisions (B) and (C) to (D) of this section, unused drugs dispensed forpurposes 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
90
manufacturer, or health care facility, or any other person or
91
government entity may donate or give prescription drugs to the
92
drug repository program. Any person or government entity may
93
facilitate the donation or gift of drugs to the program. The
94
drugs must Drugs may be donated or given only at a pharmacy,
95
hospital, or nonprofit clinic participating in the program.

(B) Any pharmacy, hospital, or nonprofit clinic that97elects may elect to participate in the drug repository program98and if it meets eligibility criteria for participation in the99program, as established in rules adopted by the state board of100pharmacy under section 3715.873 of the Revised Code.101Participation in the program by pharmacies, hospitals, and102

Page 4

74

75

76

77

78

79

80

81

82

83

84

85

86

87

88

nonprofit clinics is voluntary. Nothing in this or any other103section of the Revised Code requires a pharmacy, hospital, or104nonprofit clinic to participate in the program.105(B) (C) A pharmacy, hospital, or nonprofit clinic eligible106to participate participating in the program shall dispense107distribute the drugs donated or given under this section it108accepts under the program to individuals who are residents of109

this state and meet the eligibility standards established in110rules adopted by the board under section 3715.873 of the Revised111Code or by using either of the following methods of112distribution:113

(1) Distributing the drugs to eligible individuals at the114pharmacy, hospital, or nonprofit clinic;115

(2) Distributing the drugs to other government entities and nonprofit private entities, which then shall distribute the drugs to be dispensed to eligible individuals who meet the eligibility standards. A-

Regardless of which method of distribution is used, a drug120may be dispensed distributed to an eligible individual only by121being dispensed by a pharmacist pursuant to a prescription122issued by a licensed health professional authorized to prescribe123drugs, as defined in section 4729.01 of the Revised Code or by124being personally furnished by such a prescriber.A125

(D) A pharmacy, hospital, or nonprofit clinic that accepts 126 donated or given drugs participating in the program shall comply 127 with all applicable federal laws and laws of this state dealing 128 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

Page 5

116

117

118

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 h</u> andling fee established in	136
accordance with rules adopted by the board under section	137
3715.873 of the Revised Code. Drugs <u>Except</u> for occasional sales	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	
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	157
Revised Code.	158
(B) For matters related to donating, giving, accepting, or	159

Page 6

dispensing drugs activities conducted under the drug repository 160 program, all of the following apply: 161 (1) Any person, including a A pharmacy, drug manufacturer, 162 or health care facility, or any other person or government 163 entity that donates or gives drugs to the drug repository-164 program, and any person or government entity that facilitates 165 the donation or gift, shall not be subject to liability in tort 166 or other civil action for injury, death, or loss to person or 167 property. 168 (2) A pharmacy, hospital, or nonprofit clinic that accepts 169 or dispenses distributes drugs under the program shall not be 170 subject to liability in tort or other civil action for injury, 171 death, or loss to person or property, unless an action or 172 omission of the pharmacy, hospital, or nonprofit clinic 173 constitutes willful and wanton misconduct. 174 (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
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
188
and wanton misconduct.

(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) (6) In the case of a drug manufacturer, the immunities 203 from civil liability and criminal prosecution granted to another 204 party under divisions (B)(1) and $\frac{(C)}{(S)}$ (5) of this section apply-205 with respect to extend to the manufacturer when any drug 206 manufactured by the drug manufacturer that it manufactures is 207 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 rules215governing the drug repository program that establish all of the216following:217

(A) Eligibility criteria for pharmacies, hospitals, and 218nonprofit clinics to receive and dispense drugs donated or given 219

under participate in the program, including, in the case of	220
nonprofit clinics, a definition of "underinsured person";	221
(B) Standards and procedures for accepting, safely	222
storing, and dispensing distributing drugs donated or given;	223
(C) With respect to drugs that are donated or given, other-	224
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
Standards and procedures for inspecting the drugs described in	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-dispensing distribution;	232
(D) With respect to orally administered cancer drugs	233
described in division (C) <u>(</u>D) of section 3715.87 of the Revised	234
Code that are not in original sealed and tamper evident unit	235
dose packaging, standards and procedures to determine based on a	236
basic visual inspection that the drugs appear to be	237
unadulterated, safe, and suitable for <u>dispensing distribution</u> ;	238
(E) Eligibility standards based on economic need for	239
individuals to receive drugs <u>under the program</u> ;	240
(F) A means, such as an identification card, by which an	241
individual who is eligible to receive drugs under the program	242
may demonstrate eligibility to the <u>a</u>pharmacy, hospital, or	243
nonprofit clinic-dispensing the drugs participating in the	244
program;	245
(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) <u>A form that each individual who is donating or giving</u>
249
<u>drugs to the program, or who represents the person or government</u>
250
<u>entity that is donating or giving drugs to the program, must</u>
251
<u>sign stating that the individual or the person or government</u>
252
<u>entity being represented is the owner of the drugs and intends</u>
253
<u>to voluntarily donate or give them to the program;</u>

(I) A formula to determine the amount of a <u>nominal</u> 255 handling fee that pharmacies, hospitals, and nonprofit clinics 256 <u>participating in the program</u> may charge to drug recipients to 257 cover restocking and <u>dispensing_distribution_costs</u>; 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 by261individual drug, that the program will accept from individuals.262The list shall include orally administered cancer drugs that are263described in division (C) of section 3715.87 of the Revised264Code.265

(2) A list of drugs, arranged either by category or by 266 individual drug, that the program will not accept from 2.67 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 under the program, including those described in division (C)(2) 272 (b) of section 3715.87 of the Revised Code, and a statement as 273 to why the drug is listed drugs or drug types are ineligible to 274 be donated or given-275

(3) A form each donor must sign stating that the donor is276the owner of the drugs and intends to voluntarily donate them to277

278 the program. (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. 285 286 (2) A list of drugs, arranged either by category or by 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 295 296 the program; (L) Any other standards and procedures the board considers 297 298 appropriate. 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 is304contained 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 325 326 apply in the applicant's case: (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 (b) A statement as to whether the person is seeking to be 330 licensed as a category II, category III, limited category II, or 331 limited category III terminal distributor of dangerous drugs; 332

(c) If the person is seeking to be licensed as a limited 333

category II or limited category III terminal distributor of334dangerous drugs, a list of the dangerous drugs that the person335is seeking to possess, have custody or control of, and336distribute, which list shall also specify the purpose for which337those 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;
344

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

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

(C) (1) Each emergency medical service organization that361applies for a terminal distributor of dangerous drugs license362

354

355

356

357

358

359

shall submit with its application all of the following:
(a) A copy of its standing orders or protocol, which
orders or protocol shall be signed by a physician;
(b) A list of the dangerous drugs that the units under its
(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;
(c) A list of the personnel employed or used by the

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 service organization that is licensed as a terminal distributor 374 must notify the board of any changes in its documentation 375 submitted pursuant to division (C)(1) of this section. 376

(2) An emergency medical service organization seeking to
 377
 be licensed as a terminal distributor of dangerous drugs shall
 378
 list in its application for licensure the following additional
 379
 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
Chapter 4765. of the Revised Code;

(b) With respect to each such unit, whether the dangerousdrugs that the organization determines the unit will possess arein category II or III.387

(3) An emergency medical service organization that is
388
licensed as a terminal distributor of dangerous drugs shall file
a new application for such licensure if there is any change in
390

the number or location of any of its units or if there is any 391 change in the category of the dangerous drugs that any unit will 392 possess. 393

(4) A unit listed in an application for licensure pursuant 394 to division (C)(2) of this section may obtain the dangerous 395 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 399 400 form, the following items with the pharmacist who is responsible 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
404
organization to provide emergency medical services in accordance
405
with Chapter 4765. of the Revised Code, who are authorized to
406
possess the drugs, which list also shall indicate the personnel
407
who are authorized to administer the drugs.
408

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

(E) There shall be four categories of terminal distributordangerous drugs licenses. The categories are as follows:416

(1) Category II license. A person who obtains this license
may possess, have custody or control of, and distribute only the
dangerous drugs described in category II.

(2) Limited category II license. A person who obtains this
420
license may possess, have custody or control of, and distribute
421
only the dangerous drugs described in category II that were
422
listed in the application for licensure.

(3) Category III license, which may include a pain
424
management clinic classification issued under section 4729.552
425
of the Revised Code. A person who obtains this license may
426
possess, have custody or control of, and distribute the
427
dangerous drugs described in category II and category III. If
428
the license includes a pain management clinic classification,
429
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.
431

(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

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	
to this division.	
(G)(1) Each Except as provided in division (G)(3) of this	454
section, each applicant for licensure as a terminal distributor	455
of dangerous drugs shall submit, with the application, a license	456
fee. The amount assessed shall not be returned to the applicant	457
if the applicant fails to qualify for the license.	458
(2) The following fees apply under division (G)(1) of this	459
section:	460
(2) Recent of provided in distinition $(2)(2)(b)$ of this	1 (1
(a) Except as provided in division (G)(2)(b) of this	461
section:	462
(i) Three hundred twenty dollars for a category II or	463
limited category II license;	464
(ii) Four hundred forty dollars for a category III	465
license, including a license with a pain management clinic	466
classification issued under section 4729.552 of the Revised	467
Code, or a limited category III license.	468
(b) One hundred twenty dollars for all of the following:	469
(i) A person who is required to hold a license as a	470
terminal distributor of dangerous drugs pursuant to division (D)	471
of section 4729.541 of the Revised Code;	472
(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	
program established under section 3715.87 of the Revised Code.	
(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.	
(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	
licensure.	
No such license shall authorize or permit the terminal	497

No such license shall authorize or permit the terminal 497 distributor of dangerous drugs named in it to engage in the sale 498 or other distribution of dangerous drugs at retail or to 499 maintain possession, custody, or control of dangerous drugs for 500 any purpose other than the distributor's own use or consumption, 501 at any establishment or place other than that described in the 502 license, except that an agent or employee of an animal shelter 503 or county dog warden may possess and use dangerous drugs in the 504 course of business as provided in section 4729.532 of the 505 Revised Code. 506

(3) The license of an emergency medical service

Page 18

organization shall cover the organization's headquarters and, in 508 addition, shall cover and describe all the units of the 509 organization listed in its application for licensure. 510

(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 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 dollars.

(b) If an application for renewal has not been submitted by the sixty-first day after the renewal date specified in rules adopted by the board, the license is considered void and cannot be renewed, but the license holder may reapply for licensure.

(3) A terminal distributor of dangerous drugs that fails
535
to renew licensure in accordance with this section and rules
536
adopted by the board is prohibited from engaging in the retail
537

526

527

528

529

530

531

532

533

sale, possession, or distribution of dangerous drugs until a 538 valid license is issued by the board. 539 (J) (1) No emergency medical service organization that is 540 licensed as a terminal distributor of dangerous drugs shall fail 541 to comply with division (C)(1), (3), or (4) of this section. 542 (2) No licensed terminal distributor of dangerous drugs 543 shall possess, have custody or control of, or distribute 544 dangerous drugs that the terminal distributor is not entitled to 545 possess, have custody or control of, or distribute by virtue of 546 its category of licensure. 547 548 (3) No licensee that is required by division (F) of this section to notify the board of changes in its protocol or 549 standing orders, or in personnel, shall fail to comply with that 550 division. 551 (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 information557received pursuant to such an agreement is subject to the same558confidentiality requirements applicable to the agency or entity559from which it was received and shall not be released without560prior authorization from that agency or entity.561

 Section 2. That existing sections 3715.87, 3715.871,
 562

 3715.872, 3715.873, and 4729.54 of the Revised Code are hereby
 563

 repealed.
 564

Section 3. Notwithstanding division (A) of section5653702.523 and divisions (A) and (B) of section 3702.524 of the566

Revised Code, or any other conflicting provision in sections5673702.51 to 3702.62 of the Revised Code, all of the following568apply in the case of a certificate of need granted during the569period beginning March 9, 2020, and ending June 18, 2021:570

(A) The Director of Health shall grant the holder of a 571 certificate of need a twenty-four-month extension to obligate 572 capital expenditures and commence construction for a proposed 573 project. The extension shall be effective during the twenty-574 four-month period immediately following the expiration date of 575 the twenty-four-month period that otherwise would apply, as 576 described in division (A) of section 3702.524 of the Revised 577 Code. The Director shall notify the holder of the certificate of 578 579 need of the date on which the twenty-four-month extension expires. 580

(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 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

581

582

583

584

585