### As Passed by the Senate

**132nd General Assembly** 

Regular Session 2017-2018

Sub. H. B. No. 101

**Representative Merrin** 

Cosponsors: Representatives Becker, Thompson, Seitz, Stein, West, Roegner, Sheehy, Sprague, Hood, Smith, R., Anielski, Antani, Antonio, Arndt, Boyd, Brenner, Brinkman, Butler, Carfagna, Celebrezze, Clyde, Conditt, Craig, Cupp, Dever, DeVitis, Duffey, Edwards, Galonski, Gavarone, Ginter, Goodman, Greenspan, Hagan, Hambley, Hill, Holmes, Hughes, Johnson, Keller, Kick, Koehler, Landis, Leland, Lepore-Hagan, Lipps, Manning, McColley, O'Brien, Patterson, Patton, Pelanda, Perales, Ramos, Reineke, Retherford, Rogers, Ryan, Schaffer, Slaby, Smith, K., Strahorn, Sweeney, Wiggam, Young

Senators Beagle, Bacon, Brown, Coley, Hackett, Hoagland, Hottinger, Jordan, Kunze, LaRose, Obhof, Peterson, Uecker, Wilson, Yuko

# A BILL

То	amend sections 3728.03, 4729.16, 4729.23,	1
	4729.28, 4729.41, 4729.43, 4729.45, 4729.553,	2
	4729.99, and 4731.96 and to enact sections	3
	3707.60, 4729.382, 4729.47, and 4731.961 of the	4
	Revised Code to establish provisions to be known	5
	as the "Epinephrine Accessibility Act" and to	6
	make other changes to the laws governing the	7
	State Board of Pharmacy.	8

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

Section 1. That sections 3728.03, 4729.16, 4729.23,	9
4729.28, 4729.41, 4729.43, 4729.45, 4729.553, 4729.99, and	10
4731.96 be amended and sections 3707.60, 4729.382, 4729.47, and	11
4731.961 of the Revised Code be enacted to read as follows:	12

	1.0
Sec. 3707.60. (A) As used in this section, "board of	13
health" means a board of health of a city or general health	14
district or the authority having the duties of a board of health	15
under section 3709.05 of the Revised Code.	16
(B) A board of health that has, through a physician	17
serving as the board's health commissioner or medical director,	18
established a protocol that meets the requirements specified by	19
the state board of pharmacy in rules adopted under section	20
4729.47 of the Revised Code may authorize pharmacists and	21
pharmacy interns practicing pharmacy in a county that includes	22
all or part of the health district represented by the board to	23
use the protocol for the purpose of dispensing epinephrine under	24
section 4729.47 of the Revised Code.	25
Sec. 3728.03. (A) A qualified entity may acquire and	26
maintain a supply of epinephrine autoinjectors <del>that, in</del>	27
accordance with section 4723.483, 4730.433, or 4731.96 of the	28
Revised Code, pursuant to either of the following:	29
(1) The autoinjectors are personally furnished by a	30
prescriber $_{\scriptscriptstyle L}$ or obtained pursuant to a prescription issued by a	31
prescriber, in accordance with section 4723.483, 4730.433, or	32
4731.96 of the Revised Code.	33
(2) The autoinjectors are dispensed by a pharmacist or	34
pharmacy intern in accordance with a protocol as authorized	35
under section 4729.47 of the Revised Code.	36
<u>ander section 4723.47 of the Revised Code</u> .	50
(B) Epinephrine autoinjectors acquired pursuant to this	37
section shall be stored in a location readily accessible in an	38
emergency and maintained in accordance with the manufacturer's	39
instructions and any additional requirements that may be	40
established by the department of health under section 3728.11 of	41

the Revised Code.

(C) A qualified entity that acquires epinephrine 43 autoinjectors pursuant to this section shall designate one or 44 more individuals who are employees or agents of the entity and 45 have successfully completed anaphylaxis training in accordance 46 with section 3728.04 of the Revised Code to be responsible for 47 oversight of the epinephrine autoinjectors, including storage, 48 maintenance, and control. The qualified entity may authorize 49 those individuals and other individuals who have successfully 50 completed the anaphylaxis training to administer epinephrine. 51

Sec. 4729.16. (A) (1) The state board of pharmacy, after 52 notice and hearing in accordance with Chapter 119. of the 53 Revised Code, may impose any one or more of the following 54 sanctions on a pharmacist or pharmacy intern if the board finds 55 the individual engaged in any of the conduct set forth in 56 division (A) (2) of this section: 57

(a) Revoke, suspend, restrict, limit, or refuse to grantor renew a license;

(b) Reprimand or place the license holder on probation;

(c) Impose a monetary penalty or forfeiture not to exceed
in severity any fine designated under the Revised Code for a
similar offense, or in the case of a violation of a section of
the Revised Code that does not bear a penalty, a monetary
penalty or forfeiture of not more than five hundred dollars.

(2) The board may impose the sanctions listed in division(A) (1) of this section if the board finds a pharmacist or pharmacy intern:

(a) Has been convicted of a felony, or a crime of moral69turpitude, as defined in section 4776.10 of the Revised Code;70

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practice of pharmacy;	72
(c) Is addicted to or abusing alcohol or drugs or is	73
impaired physically or mentally to such a degree as to render	74
the pharmacist or pharmacy intern unfit to practice pharmacy;	75
(d) Has been convicted of a misdemeanor related to, or	76
committed in, the practice of pharmacy;	77
(e) Violated, conspired to violate, attempted to violate,	78
or aided and abetted the violation of any of the provisions of	79
this chapter, sections 3715.52 to 3715.72 of the Revised Code,	80
Chapter 2925. or 3719. of the Revised Code, or any rule adopted	81
by the board under those provisions;	82
(f) Permitted someone other than a pharmacist or pharmacy	83
intern to practice pharmacy;	84
(g) Knowingly lent the pharmacist's or pharmacy intern's	85
name to an illegal practitioner of pharmacy or had a	86
professional connection with an illegal practitioner of	87
pharmacy;	88
(h) Divided or agreed to divide remuneration made in the	89
practice of pharmacy with any other individual, including, but	90
not limited to, any licensed health professional authorized to	91
prescribe drugs or any owner, manager, or employee of a health	92
care facility, residential care facility, or nursing home;	93
(i) Violated the terms of a consult agreement entered into	94
pursuant to section 4729.39 of the Revised Code;	95
(j) Committed fraud, misrepresentation, or deception in	96
applying for or securing a license issued by the board under	97

this chapter or under Chapter 3715. or 3719. of the Revised

(b) Engaged in dishonesty or unprofessional conduct in the

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Code;	99
(k) Failed to comply with an order of the board or a	100
settlement agreement;	101
(1) Engaged in any other conduct for which the board may	102
impose discipline as set forth in rules adopted under section	103
4729.26 of the Revised Code.	104
(B) Any individual whose license is revoked, suspended, or	105
refused, shall return the license to the offices of the state	106
board of pharmacy within ten days after receipt of notice of	107
such action.	
(C) As used in this section:	109
"Unprofessional conduct in the practice of pharmacy"	110
includes any of the following:	111
(1) Advertising or displaying signs that promote dangerous	112
drugs to the public in a manner that is false or misleading;	113
(2) Except as provided in section 4729.281-or_, 4729.44,	114
or 4729.47 of the Revised Code, the dispensing or sale of any	115
drug for which a prescription is required, without having	116
received a prescription for the drug;	117
(3) Knowingly dispensing medication pursuant to false or	118
forged prescriptions;	119
(4) Knowingly failing to maintain complete and accurate	120
records of all dangerous drugs received or dispensed in	121
compliance with federal laws and regulations and state laws and	122
rules;	123
(5) Obtaining any remuneration by fraud,	124
misrepresentation, or deception;	125

(6) Failing to conform to prevailing standards of care of 126 similar pharmacists or pharmacy interns under the same or 127 similar circumstances, whether or not actual injury to a patient 128 is established; 129

(7) Engaging in any other conduct that the board specifies 130 as unprofessional conduct in the practice of pharmacy in rules 131 adopted under section 4729.26 of the Revised Code. 132

(D) The board may suspend a license under division (B) of 133 section 3719.121 of the Revised Code by utilizing a telephone 134 conference call to review the allegations and take a vote. 135

(E) For purposes of this division, an individual 136 authorized to practice as a pharmacist or pharmacy intern 137 accepts the privilege of practicing in this state subject to 138 supervision by the board. By filing an application for or 139 holding a license to practice as a pharmacist or pharmacy 140 intern, an individual gives consent to submit to a mental or 141 physical examination when ordered to do so by the board in 142 writing and waives all objections to the admissibility of 143 testimony or examination reports that constitute privileged 144 communications. 145

If the board has reasonable cause to believe that an 146 individual who is a pharmacist or pharmacy intern is physically 147 or mentally impaired, the board may require the individual to 148 submit to a physical or mental examination, or both. The expense 149 of the examination is the responsibility of the individual 150 required to be examined. 151

Failure of an individual who is a pharmacist or pharmacy 152 intern to submit to a physical or mental examination ordered by 153 the board, unless the failure is due to circumstances beyond the 154

individual's control, constitutes an admission of the 155
allegations and a suspension order shall be entered without the 156
taking of testimony or presentation of evidence. Any subsequent 157
adjudication hearing under Chapter 119. of the Revised Code 158
concerning failure to submit to an examination is limited to 159
consideration of whether the failure was beyond the individual's 160
control. 161

If, based on the results of an examination ordered under 162 this division, the board determines that the individual's 163 ability to practice is impaired, the board shall suspend the 164 individual's license or deny the individual's application and 165 shall require the individual, as a condition for an initial, 166 continued, reinstated, or renewed license to practice, to submit 167 to a physical or mental examination and treatment. 168

An order of suspension issued under this division shall169not be subject to suspension by a court during pendency of any170appeal filed under section 119.12 of the Revised Code.171

(F) If the board is required under Chapter 119. of the 172 Revised Code to give notice of an opportunity for a hearing and 173 the applicant or licensee does not make a timely request for a 174 hearing in accordance with section 119.07 of the Revised Code, 175 the board is not required to hold a hearing, but may adopt a 176 final order that contains the board's findings. In the final 177 order, the board may impose any of the sanctions listed in 178 division (A) of this section. 179

(G) Notwithstanding the provision of division (C) (2) of
section 2953.32 of the Revised Code specifying that if records
pertaining to a criminal case are sealed under that section the
proceedings in the case must be deemed not to have occurred,
sealing of the following records on which the board has based an

action under this section shall have no effect on the board's 185 action or any sanction imposed by the board under this section: 186 records of any conviction, guilty plea, judicial finding of 187 quilt resulting from a plea of no contest, or a judicial finding 188 of eligibility for a pretrial diversion program or intervention 189 in lieu of conviction. The board shall not be required to seal, 190 destroy, redact, or otherwise modify its records to reflect the 191 court's sealing of conviction records. 192

(H) No pharmacist or pharmacy intern shall knowingly
engage in any conduct described in divisions (A) (2) (b) or (A) (2)
(e) to (1) of this section.

Sec. 4729.23. (A) Except as provided in division (B) of 196 this section, information received by the state board of 197 pharmacy pursuant to an investigation is confidential, is not a 198 public record, and is not subject to discovery in any civil 199 action. Any record that identifies a patient, confidential 200 informant, or individual who files a complaint with the board or 201 may reasonably lead to the identification of the patient, 202 203 informant, or complainant is not a public record for purposes of section 149.43 of the Revised Code and is not subject to-204 inspection or copying under section 1347.08 of the Revised Code. 205

(B) The board shall conduct all investigations or 206 inspections and proceedings in a manner that protects the 207 confidentiality of patients, confidential informants, and 208 individuals who file complaints with the board. The board shall 209 not make public the names or any other identifying information 210 of patients, confidential informants, or complainants unless 211 proper consent is given or, in the case of a patient, a waiver 212 of the patient privilege exists under division (B) of section 213 2317.02 of the Revised Code. The consent or waiver is not 214 required if the board possesses reliable and substantial 215 evidence that no bona fide physician-patient relationship 216 exists. 217

On request, the board may share any information it 218 receives pursuant to an investigation or inspection, including 219 patient records and patient record information, with law 220 enforcement agencies, other licensing boards, and other state or 221 federal governmental agencies that are prosecuting, 222 223 adjudicating, or investigating alleged violations of statutes or administrative rules. An agency or board that receives the 224 225 information shall comply with the same requirements regarding confidentiality as those with which the state board of pharmacy 226 must comply, notwithstanding any conflicting provision of the 227 Revised Code or agency procedure that applies when the agency is 228 dealing with other information in its possession. 229

Any information the board receives from a state or federal 230 agency is subject to the same confidentiality requirements as 231 the agency from which it was received and shall not be released 232 by the board without prior authorization from that agency. 233

The board may, for good cause shown, disclose or authorize 234 disclosure of information gathered pursuant to an investigation. 235

(C) Any board activity that involves continued monitoring 236 of an individual for treatment or recovery purposes as part of 237 or following any disciplinary action taken under section-238 4729.16, 4729.56, or 4729.57 of the Revised Code this chapter 239 shall be conducted in a manner that maintains an individual's 240 confidentiality with respect to the individual's treatment or 241 recovery program. Information received or maintained by the 242 board with respect to the board's monitoring activities is not 243 subject to discovery in any civil action, is not a public 244 record, and is confidential, except that the board may disclose 245 information to law enforcement officers and government entities 246 for purposes of an investigation of a license or certificate 247 holder. 248

Sec. 4729.28. No (A) As used in this section, "dispense" has the meaning specified by the state board of pharmacy in rules adopted under section 4729.26 of the Revised Code.

(B) (1) Except as provided in division (B) (2) of this 252 section, no person who is not a pharmacist or a pharmacy intern 253 under the personal supervision of a pharmacist shall compound, 254 dispense, or sell dangerous drugs or otherwise engage in the 255 practice of pharmacy. 256

(2) Except as provided in sections 3701.048, 4729.44, and2574729.47 of the Revised Code or rules adopted by the board under258section 4729.26 of the Revised Code, no person who is not a259pharmacist shall dispense dangerous drugs.260

Sec. 4729.382. (A) As used in this section, "epinephrine261autoinjector" means a device used to administer epinephrine only262in a manufactured dosage form.263

(B) Subject to division (C) of this section, a pharmacist264dispensing an epinephrine autoinjector pursuant to a265prescription that identifies a specific type of epinephrine266autoinjector may substitute the prescribed autoinjector with267another epinephrine autoinjector, but only if the form of268epinephrine contained in the autoinjector to be dispensed by269substitution meets either of the following conditions:270

(1) It is identical to the form of epinephrine in the type271of autoinjector that was prescribed.272

(2) It is a pharmaceutical equivalent of the form of 273

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epinephrine in the type of autoinjector that was prescribed in	274
that it contains identical amounts of the identical active	275
ingredients, but not necessarily the same inactive ingredients;	276
it has been approved by the United States food and drug	277
administration; and it has not been excluded from recognition as	278
a pharmaceutical equivalent form of epinephrine by rules adopted	279
under division (H) of this section.	280
(C) All of the following conditions apply with respect to	281
a pharmacist's authority to dispense an epinephrine autoinjector	282
by substitution:	283
(1) The pharmacist shall not make the substitution if the	284
person receiving the autoinjector pursuant to the prescription	285
instructs otherwise.	286
(2) The pharmacist shall not make the substitution if	287
either of the following applies to the prescription:	288
(a) In the case of a written or electronic prescription,	289
including a computer-generated prescription, the prescriber	290
handwrites or actively causes to display on the prescription	291
"dispense as written," "D.A.W.," "do not substitute," "medically	292
necessary as prescribed," or any other statement or numerical	293
code that indicates the prescriber's intent to prevent	294
substitution. Such a designation shall not be preprinted or	295
stamped on the prescription, but a reminder to the prescriber of	296
the designation procedure may be preprinted or displayed on the	297
prescription form or electronic system the prescriber uses to	298
issue the prescription.	299
(b) In the case of an oral prescription, the prescriber	300
specifies that the epinephrine autoinjector as prescribed is	301
medically necessary or otherwise indicates the prescriber's	302

intent to prevent substitution.

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<u>intent to prevent substitution.</u>	303
(3) The pharmacist shall not make the substitution unless	304
its price to the patient is less than or equal to the price of	305
the prescribed epinephrine autoinjector, except that a	306
pharmacist may substitute an epinephrine autoinjector with a	307
price to the patient that is greater than the prescribed	308
autoinjector if the patient specifically requests the more	309
expensive autoinjector.	310
(4) The pharmacist, or a pharmacy intern or agent of the	311
pharmacist, shall make a reasonable attempt to inform the	312
patient or the patient's representative if a type of epinephrine	313
autoinjector is available at a lower or equal cost.	314
(5) The pharmacist, or a pharmacy intern or agent of the	315
pharmacist, shall inform the patient or the patient's	316
representative of the person's right to refuse substitution of	317
the prescribed epinephrine autoinjector.	318
(D)(1) Unless the prescriber instructs otherwise, the	319
label for every epinephrine autoinjector dispensed shall include	320
the epinephrine autoinjector's name, if any, and the distributor	321
of the autoinjector. Abbreviations may be used as necessary.	322
(2) When dispensing at retail an epinephrine autoinjector	323
by substitution, the pharmacist shall indicate on the	324
autoinjector's label or container that a substitution was made.	325
(3) The labeling requirements established by divisions (D)	326
(1) and (2) of this section are in addition to all other	327
labeling requirements as required in rules adopted by the state	328
board of pharmacy.	329
(E) When a pharmacist dispenses an epinephrine	330
autoinjector by substitution, the pharmacist or a pharmacy	331

intern shall provide to the person receiving the device	332
instruction on the proper method of administering epinephrine	333
with the device, except that the instruction does not have to be	334
provided if the person is receiving the same device that was	335
dispensed when the person last received the device by having a	336
prescription filled or refilled.	337
(F) A pharmacist who dispenses an epinephrine autoinjector	338
pursuant to this section assumes no greater liability for	339
dispensing the autoinjector by substitution than would be	340
incurred for dispensing the autoinjector identified on the	341
prescription.	342
(G) The failure of a prescriber to restrict a prescription	343
by indicating an intent to prevent substitution pursuant to this	344
section shall not constitute evidence of the prescriber's	345
negligence unless the prescriber had reasonable cause to believe	346
that the health condition of the patient for whom the	347
epinephrine autoinjector was intended warranted the prescription	348
of a specific type of epinephrine autoinjector and no other. No	349
prescriber shall be liable for civil damages or in any criminal	350
prosecution arising from a pharmacist dispensing an epinephrine	351
autoinjector by substitution, unless the type of autoinjector	352
prescribed would have reasonably caused the same loss, damage,	353
injury, or death.	354
(H) The state board of pharmacy may adopt rules in	355
accordance with Chapter 119. of the Revised Code to implement	356
this section. The rules may specify forms of epinephrine that	357
are not to be recognized as pharmaceutical equivalents of other	358
forms of epinephrine for purposes of this section.	359
(I) No pharmacist shall knowingly engage in conduct that	360
is prohibited by division (C) or (D) of this section.	361

Sec. 4729.41. (A)(1) A pharmacist licensed under this	362
chapter who meets the requirements of division (B) of this	363
section, and a pharmacy intern licensed under this chapter who	364
meets the requirements of division (B) of this section and is	365
working under the direct supervision of a pharmacist who meets	366
the requirements of that division, may do any of the following:	367
(a) Administer immunizations for influenza to individuals	368
who are seven years of age or older;	369
(b) Only pursuant to a prescription, administer to	370
individuals who are seven years of age or older but not more	371
than thirteen years of age any of the immunizations included in	372
division (A)(2) of this section;	373
(c) Administer to individuals who are thirteen years of	374
age or older any of the immunizations included in division (A)	375
(2) of this section.	376
(2) A pharmacist or pharmacy intern may administer in	377
accordance with divisions (A)(1)(b) and (c) of this section	378
either of the following:	379
(a) Any immunization that on <del>the effective date of this</del>	380
amendment March 19, 2015, is included in either of the following	381
immunization schedules recommended by the advisory committee on	382
immunization practices of the centers for disease control and	383
prevention in the United States department of health and human	384
services:	385
(i) The recommended immunization schedule for persons aged	386
zero through eighteen years;	387
(ii) The recommended adult immunization schedule.	388
(b) Any other immunization specified in rules adopted	389

under division (E)(1)(d) of this section.	390
(3) As part of engaging in the administration of	391
immunizations or supervising a pharmacy intern's administration	392
of immunizations, a pharmacist may administer epinephrine or	393
diphenhydramine, or both, to individuals in emergency situations	394
resulting from adverse reactions to the immunizations	395
administered by the pharmacist or pharmacy intern.	396
(B) For a pharmacist or pharmacy intern to be authorized	397
to engage in the administration of immunizations pursuant to	398
division (A) of this section, the pharmacist or pharmacy intern	399
shall do all of the following:	400
(1) Successfully complete a course in the administration	401
of immunizations that has been approved by the state board of	402
pharmacy as meeting the standards established for such courses	403
by the centers for disease control and prevention;	404
(2) Receive and maintain certification to perform basic	405
life-support procedures by successfully completing a basic life-	406
support training course <u>that is c</u> ertified by the American red	407
cross or American heart association or approved by the state	408
board of pharmacy;	409
(3) Practice in accordance with a definitive set of	410
treatment guidelines specified in a protocol established by a	411
physician and approved by the state board of pharmacy.	412
(C) The protocol required by division (B)(3) of this	413
section shall include provisions for implementation of the	414
following requirements:	415

(1) The pharmacist or pharmacy intern who administers an
immunization shall observe the individual who receives the
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immunization to determine whether the individual has an adverse
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reaction to the immunization. The length of time and location of 419 the observation shall comply with the standards specified in 420 rules adopted by the state board of pharmacy under division (E) 421 of this section for the approval of protocols. The protocol 422 shall specify procedures to be followed by a pharmacist when 423 administering epinephrine, diphenhydramine, or both, to an 424 425 individual who has an adverse reaction to an immunization 426 administered by the pharmacist or a pharmacy intern.

(2) For each immunization administered to an individual by 427 a pharmacist or pharmacy intern, other than an immunization for 428 influenza administered to an individual eighteen years of age or 429 older, the pharmacist or pharmacy intern shall notify the 430 individual's family physician or, if the individual has no 431 family physician, the board of health of the health district in 432 which the individual resides or the authority having the duties 433 of a board of health for that district under section 3709.05 of 434 the Revised Code. The notice shall be given not later than 435 thirty days after the immunization is administered. 436

(3) For each immunization administered by a pharmacist or
(3) For each immunization administered by a pharmacist or
(3) pharmacy intern to an individual younger than eighteen years of
(3) age pursuant to division (A) (1) of this section, the pharmacist
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(D)(1) No pharmacist shall do either of the following: 444

(a) Engage in the administration of immunizations unlessthe requirements of division (B) of this section have been met;446

(b) Delegate to any person the pharmacist's authority to 447

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engage in or supervise the administration of immunizations.	448
(2) No pharmacy intern shall engage in the administration	449
of immunizations unless the requirements of division (B) of this	450
section have been met.	451
(E)(1) The state board of pharmacy shall adopt rules to	452
implement this section. The rules shall be adopted in accordance	453
with Chapter 119. of the Revised Code and shall include the	454
following:	455
(a) Provisions for approval of courses in administration	456
of immunizations;	457
(b) Provisions for approval of protocols to be followed by	458
pharmacists and pharmacy interns in engaging in the	459
administration of immunizations, including protocols that	460
contain provisions specifying the locations at which a	461
pharmacist or pharmacy intern may engage in the administration	462
of immunizations;	463
(c) Procedures to be followed by pharmacists and pharmacy	464
interns in obtaining from the individual's parent or legal	465
guardian permission to administer immunizations to an individual	466
younger than eighteen years of age pursuant to division (A)(1)	467
of this section;	468
(d) Provisions specifying any immunizations that may be	469
administered under division (A)(2)(b) of this section.	470
(2) Prior to adopting rules regarding approval of	471
protocols to be followed by pharmacists and pharmacy interns in	472
engaging in the administration of immunizations, the state board	473
of pharmacy shall consult with the state medical board and the	474
board of nursing.	475

(3) Prior to adopting rules specifying any immunizations	476
that may be administered under division (A)(2)(b) of this	477
section, the state board of pharmacy shall consult with the	478
state medical board.	479
(F) In addition to the rules it adopts under division (E)	480
of this section, the board may adopt rules that change the	481
immunizations authorized by division (A)(2)(a) of this section	482
to reflect changes in the recommendations of the advisory	483
committee on immunization practices. The rules shall be adopted	484
in accordance with Chapter 119 <u>.</u> of the Revised Code.	485
Sec. 4729.43. (A) As used in this section:	486
(1) "Home health agency" has the same meaning as in	487
section 3701.881 of the Revised Code.	488
(2) "Hospice care program" and "hospice patient" have the	489
same meanings as in section 3712.01 of the Revised Code.	490
(B) With regard to a dangerous drug that is indicated for	491
the treatment of cancer or a cancer-related illness, must be	492
administered intravenously or by subcutaneous injection, and	493
cannot reasonably be self-administered by the patient to whom	494
the drug is prescribed or by an individual assisting the patient	495
with the self-administration, a pharmacist or pharmacy intern-	496
shall not dispense the drug by delivering the drug directly to	497
any of the following or causing the drug to be delivered	498
directly to any of the following:	499
(1) The patient;	500
(2) The patient's representative, which may include the	501
patient's guardian or a family member or friend of the patient;	502
(3) The patient's private residence unless any of the	503

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following is the case:

(a) The patient's private residence is a nursing home, 505
residential care facility, rehabilitation facility, or similar 506
institutional facility or heath care facility. 507

(b) If the patient is an adult and a hospice patient or 508 client of a home health agency, the patient, the licensed health 509 professional authorized to prescribe drugs who prescribed the 510 drug to the patient, or an employee or agent of the prescriber 511 has notified the pharmacist or pharmacy intern that the patient 512 is a hospice patient or client of a home health agency and an 513 employee or agent of the hospice care program or home health 514 agency will be administering the drug to the patient. 515

(c) If the patient is a minor and a hospice patient or 516 client of a home health agency, either of the following has 517 notified the pharmacist or pharmacy intern that the patient is a 518 client of a home health agency and an employee or agent of the 519 hospice care program or home health agency will be administering 520 the drug to the patient: 521

(i) The licensed health professional authorized to 522
prescribe drugs who prescribed the drug to the patient or an 523
employee or agent of the prescriber; 524

(ii) The parent, guardian, or other person who has care or
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charge of the patient and is authorized to consent to medical
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treatment on behalf of the patient.
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Sec. 4729.45. (A) As used in this section, "physician"528means an individual authorized under Chapter 4731. of the529Revised Code to practice medicine and surgery or osteopathic530medicine and surgery.531

(B)(1) Subject to division (C) of this section, a 532

pharmacist licensed under this chapter may administer by 533 injection any of the following drugs as long as the drug that is 534 to be administered has been prescribed by a physician and the 535 individual to whom the drug was prescribed has an ongoing 536 physician-patient relationship with the physician: 537 (a) An opioid antagonist used for treatment of drug 538 addiction and administered in a long-acting or extended-release 539 form; 540 (b) An antipsychotic drug administered in a long-acting or 541 extended-release form; 542 543 (c) Hydroxyprogesterone caproate; (d) Medroxyprogesterone acetate; 544 (e) Cobalamin. 545 (2) As part of engaging in the administration of drugs by 546 injection pursuant to this section, a pharmacist may administer 547 epinephrine or diphenhydramine, or both, to an individual in an 548 emergency situation resulting from an adverse reaction to a drug 549 administered by the pharmacist. 550 (C) To be authorized to administer drugs pursuant to this 551 section, a pharmacist must do all of the following: 552 (1) Successfully complete a course in the administration 553 of drugs that satisfies the requirements established by the 554 state board of pharmacy in rules adopted under division (H)(1) 555 (a) of this section; 556 (2) Receive and maintain certification to perform basic 557 life-support procedures by successfully completing a basic life-558 support training course that is certified by the American red 559

support training course <u>that is</u> certified by the American red 559 cross or American heart association<u>or approved by the state</u> 560 board of pharmacy; 561 (3) Practice in accordance with a protocol that meets the 562 requirements of division (F) of this section. 563 (D) Each time a pharmacist administers a drug pursuant to 564 this section, the pharmacist shall do all of the following: 565 (1) Obtain permission in accordance with the procedures 566 specified in rules adopted under division (H) of this section 567 and comply with the following requirements: 568 (a) Except as provided in division (D)(1)(c) of this 569 section, for each drug administered by a pharmacist to an 570 individual who is eighteen years of age or older, the pharmacist 571 shall obtain permission from the individual. 572 (b) For each drug administered by a pharmacist to an 573 individual who is under eighteen years of age, the pharmacist 574 shall obtain permission from the individual's parent or other 575 person having care or charge of the individual. 576 (c) For each drug administered by a pharmacist to an 577 individual who lacks the capacity to make informed health care 578 decisions, the pharmacist shall obtain permission from the 579 person authorized to make such decisions on the individual's 580 behalf. 581 (2) In the case of an opioid antagonist described in 582 division (B) of this section, obtain in accordance with division 583 (E) of this section test results indicating that it is 584 appropriate to administer the drug to the individual if either 585 of the following is to be administered: 586

(a) The initial dose of the drug; 587

(b) Any subsequent dose, if the administration occurs more 588

than thirty days after the previous dose of the drug was	589
administered.	590
(3) Observe the individual to whom the drug is	591
administered to determine whether the individual has an adverse	592
reaction to the drug;	593
(4) Notify the physician who prescribed the drug that the	594
drug has been administered to the individual.	595
(E) A pharmacist may obtain the test results described in	596
division (D)(2) of this section in either of the following ways:	597
(1) From the physician;	598
(2) By ordering blood and urine tests for the individual	599
to whom the opioid antagonist is to be administered.	600
If a pharmacist orders blood and urine tests, the	601
pharmacist shall evaluate the results of the tests to determine	602
whether they indicate that it is appropriate to administer the	603
opioid antagonist. A pharmacist's authority to evaluate test	604
results under this division does not authorize the pharmacist to	605
make a diagnosis.	606
(F) All of the following apply with respect to the	607
protocol required by division (C)(3) of this section:	608
(1) The protocol must be established by a physician who	609
has a scope of practice that includes treatment of the condition	610
for which the individual has been prescribed the drug to be	611
administered.	612
(2) The protocol must satisfy the requirements established	613
in rules adopted under division (H)(1)(b) of this section.	614
(3) The protocol must do all of the following:	615

(b) Specify the locations at which a pharmacist may engage 617 in the administration of drugs pursuant to this section; 618 (c) Include provisions for implementing the requirements 619 of division (D) of this section, including for purposes of 620 division (D)(3) of this section provisions specifying the length 621 of time and location at which a pharmacist must observe an 622 623 individual who receives a drug to determine whether the individual has an adverse reaction to the drug; 624 (d) Specify procedures to be followed by a pharmacist when 625 administering epinephrine, diphenhydramine, or both, to an 626 individual who has an adverse reaction to a drug administered by 627 the pharmacist. 628 (G) A pharmacist shall not do either of the following: 629 (1) Engage in the administration of drugs pursuant to this 630 section unless the requirements of division (C) of this section 631 have been met; 6.32

(a) Specify a definitive set of treatment guidelines;

(2) Delegate to any person the pharmacist's authority to633engage in the administration of drugs pursuant to this section.634

(H) (1) The state board of pharmacy shall adopt rules to
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implement this section. The rules shall be adopted in accordance
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with Chapter 119. of the Revised Code and include all of the
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following:
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(a) Requirements for courses in administration of drugs; 639

(b) Requirements f	for protocols to be followed by	640
pharmacists in administ	ering drugs pursuant to this section;	641

(c) Procedures to be followed by a pharmacist in obtaining 642

permission to administer a drug to an individual. 643 (2) The board shall consult with the state medical board 644 before adopting rules regarding requirements for protocols under 645 this section. 646 Sec. 4729.47. (A) As used in this section: 647 (1) "Board of health" means a board of health of a city or 648 general health district or an authority having the duties of a 649 board of health under section 3709.05 of the Revised Code. 650 (2) "Physician" means an individual authorized under 651 Chapter 4731. of the Revised Code to practice medicine and 652 surgery, osteopathic medicine and surgery, or podiatric medicine 653 and surgery. 654 (B) If use of a protocol that has been developed pursuant 655 to rules adopted under division (G) of this section has been 656 authorized under section 3707.60 or 4731.961 of the Revised 657 Code, a pharmacist or pharmacy intern may dispense epinephrine 658 without a prescription in accordance with that protocol to 659 either of the following individuals so long as the individual is 660 661 at least eighteen years of age: (1) An individual who there is reason to believe is 662 experiencing or at risk of experiencing anaphylaxis if the 663 pharmacy affiliated with the pharmacist or intern has a record 664 of previously dispensing epinephrine to the individual in 665 accordance with a prescription issued by a licensed health 666 professional authorized to prescribe drugs; 667 (2) An individual acting on behalf of a qualified entity, 668 as defined in section 3728.01 of the Revised Code. 669

(C)(1) A pharmacist or pharmacy intern who dispenses 670

epinephrine under this section shall instruct the individual to	671
whom epinephrine is dispensed to summon emergency services as	672
soon as practicable either before or after administering	673
epinephrine.	674
(2) A pharmacist or pharmacy intern who dispenses	675
epinephrine to an individual identified in division (B)(1)(a) of	676
this section shall provide notice of the dispensing to the	677
individual's primary care provider, if known, or to the	678
prescriber who issued the individual the initial prescription	679
for epinephrine.	680
(D) A pharmacist may document the dispensing of	681
epinephrine by the pharmacist or a pharmacy intern supervised by	682
the pharmacist on a prescription form. The form may be assigned	683
a number for record-keeping purposes.	684
(E) This section does not affect the authority of a	685
pharmacist or pharmacy intern to fill or refill a prescription	686
for epinephrine.	687
	<u> </u>
(F) A board of health that in good faith authorizes a	688
pharmacist or pharmacy intern to dispense epinephrine without a	689
prescription in accordance with a protocol developed pursuant to	690
rules adopted under division (G) of this section is not liable	691
for or subject to any of the following for any action or	692
omission of the individual to whom the epinephrine is dispensed:	693
damages in any civil action, prosecution in any criminal	694
proceeding, or professional disciplinary action.	695
A physician who in good faith authorizes a pharmacist or	696
pharmacy intern to dispense epinephrine without a prescription	697
in accordance with a protocol developed pursuant to rules	698
adopted under division (G) of this section is not liable for or	699

subject to any of the following for any action or omission of	700
the individual to whom the epinephrine is dispensed: damages in	701
any civil action, prosecution in any criminal proceeding, or	702
professional disciplinary action.	703
A pharmacist or pharmacy intern authorized under this	704
section to dispense epinephrine without a prescription who does	705
so in good faith is not liable for or subject to any of the	706
following for any action or omission of the individual to whom	707
the epinephrine is dispensed: damages in any civil action,	708
prosecution in any criminal proceeding, or professional	709
disciplinary action.	710
(G) Not later than ninety days after the effective date of	711
this section, the state board of pharmacy shall, after	712
consulting with the state medical board, adopt rules to	713
implement this section. The rules shall specify minimum	714
requirements for protocols established by physicians under which	715
pharmacists or pharmacy interns may dispense epinephrine without	716
a prescription.	717
All rules adopted under this section shall be adopted in	718
accordance with Chapter 119. of the Revised Code.	719
Sec. 4729.553. (A) As used in this section:	720
(1) "Controlled substance" has the same meaning as in	721
section 3719.01 of the Revised Code.	722
(2) "Hospital" means a hospital registered with the	723
department of health under section 3701.07 of the Revised Code.	724
(3) "Office-based opioid treatment" means the treatment of	725
opioid dependence or addiction using a controlled substance.	726
(B)(1) Except as provided in division (B)(2) of this	727

section, no person shall knowingly operate a facility, clinic, or other location where a prescriber provides office-based 729 opioid treatment to more than thirty patients or that meets any 730 other identifying criteria established in rules adopted under 731 division (G) of this section without holding a category III 732 terminal distributor of dangerous drugs license with an office-733 based opioid treatment classification. 734 (2) Division (B)(1) of this section does not apply to any 735 of the following: 736 737 (a) A hospital; (b) A facility for the treatment of opioid dependence or 738 addiction that is operated by a hospital; 739 (c) A physician practice owned or controlled, in whole or 740 in part, by a hospital or by an entity that owns or controls, in 741 whole or in part, one or more hospitals; 742 (d) A facility that conducts only clinical research and 743 uses controlled substances in studies approved by a hospital-744 based institutional review board or an institutional review 745 board that is accredited by the association for the 746 accreditation of human research protection programs, inc.; 747 748 (e) A facility that holds a category III terminal distributor of dangerous drugs license in accordance with 749 section 4729.54 of the Revised Code for the purpose of treating 750 drug dependence or addiction as part of an opioid treatment 751 program and is the subject of a current, valid certification 752 from the substance abuse and mental health services 753 administration of the United States department of health and 754

(f) A program or facility that is licensed or certified 756

human services pursuant to 42 C.F.R. 8.11;

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holds a license or certification issued by the department of	757
mental health and addiction services under Chapter 5119. of the	758
Revised Code if the license or certification is approved by the	759
state board of pharmacy;	760
(g) A federally qualified health center or federally	761
qualified health center look-alike, as defined in section	762
3701.047 of the Revised Code;	763
(h) A state or local correctional facility, as defined in	764
section 5163.45 of the Revised Code;	765
(i) Any other facility specified in rules adopted under	766
this section.	767
(C) To be eligible to receive a license as a category III	768
terminal distributor of dangerous drugs with an office-based	769
opioid treatment classification, an applicant shall submit	770
evidence satisfactory to the state board of pharmacy that the	771
applicant's office-based opioid treatment will be operated in	772
accordance with the requirements specified in division (D) of	773
this section and that the applicant meets any other applicable	774
requirements of this chapter.	775
If the board determines that an applicant meets all of the	776
requirements, the board shall issue to the applicant a license	777
as a category III terminal distributor of dangerous drugs with	778
an office-based opioid treatment classification.	779
(D) The holder of a category III terminal distributor	780
license with an office-based opioid treatment classification	781
shall do all of the following:	782
(1) Be in control of a facility that is owned and operated	783
solely by one or more physicians authorized under Chapter 4731.	784
of the Revised Code to practice medicine and surgery or	785

osteopathic medicine and surgery, unless the state board of pharmacy has exempted the holder from waives this requirement 787 for the holder; 788 (2) Comply with the requirements for conducting office-789 based opioid treatment, as established by the state medical 790 board in rules adopted under section 4731.056 of the Revised 791 Code; 792 (3) Require any person with ownership of the facility to 793 submit to a criminal records check in accordance with section 794 4776.02 of the Revised Code and send the results of the criminal 795 records check directly to the state board of pharmacy for review 796 and decision under section 4729.071 of the Revised Code; 797 (4) Require all employees of each person employed by or 798 seeking employment with the facility to submit to a criminal 799 records check in accordance with section 4776.02 of the Revised 800 801 Code and ensure ; (5) Ensure that no a person is not employed who has 802 previously been by the facility if the person, within the ten 803 years immediately preceding the date the person applied for 804 805 <u>employment</u>, was convicted of  $\tau$  or pleaded guilty to  $\tau$  either of the following, unless the state board of pharmacy permits the 806 person to be employed by waiving this requirement for the 807 808 facility: (a) A theft offense, described in division (K) (3) of 809 section 2913.01 of the Revised Code, that would constitute a 810 felony under the laws of this state, any other state, or the 811 United States; 812

(b) A felony drug offense, as defined in section 2925.01 813 of the Revised Code. 814

(5)(6)Maintain a list of each person with ownership of815the facility and notify the state board of pharmacy of any816change to that list.817

(E) No person subject to licensure as a category III
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terminal distributor of dangerous drugs with an office-based
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opioid treatment classification shall knowingly fail to remain
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in compliance with the requirements of division (D) of this
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section and any other applicable requirements of this chapter.

(F) The state board of pharmacy may impose a fine of not
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more than five thousand dollars on a person who violates
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division (B) or (E) of this section. A separate fine may be
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imposed for each day the violation continues. In imposing the
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fine, the board's actions shall be taken in accordance with
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Chapter 119. of the Revised Code.

(G) The state board of pharmacy shall adopt rules as it
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considers necessary to implement and administer this section.
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The rules shall be adopted in accordance with Chapter 119. of
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the Revised Code.
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Sec. 4729.99. (A) Whoever violates division (H) of section8334729.16, division (G) of section 4729.38, division (I) of834section 4729.382, section 4729.57, or division (F) of section8354729.96 of the Revised Code is guilty of a minor misdemeanor,836unless a different penalty is otherwise specified in the Revised837Code. Each day's violation constitutes a separate offense.838

(B) Whoever violates section 4729.27, 4729.28, or 4729.36
(B) Whoever violates section 4729.27, 4729.28, or 4729.36
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misdemeanor of the second degree.

(C) Whoever violates	section 4729.32, 4729.33	or 4729.34 845
of the Revised Code is gu	ilty of a misdemeanor.	846

(D) Whoever violates division (A), (B), (C), (D), (F), or
(G) of section 4729.51 of the Revised Code is guilty of a
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misdemeanor of the first degree.
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(E) (1) Whoever violates section 4729.37, division (E) (1) 850 (b) of section 4729.51, division (J) of section 4729.54, 851 division (B) or (D) of section 4729.553, or section 4729.61 of 852 the Revised Code is quilty of a felony of the fifth degree. If 853 the offender previously has been convicted of or pleaded quilty 854 to a violation of this chapter or a violation of Chapter 2925. 855 or 3719. of the Revised Code, that person is guilty of a felony 856 of the fourth degree. 857

(2) If an offender is convicted of or pleads guilty to a 858 violation of section 4729.37, division (E) of section 4729.51, 859 division (J) of section 4729.54, or section 4729.61 of the 860 Revised Code, if the violation involves the sale, offer to sell, 861 or possession of a schedule I or II controlled substance, with 862 863 the exception of marihuana, and if the court imposing sentence upon the offender finds that the offender as a result of the 864 violation is a major drug offender, as defined in section 865 2929.01 of the Revised Code, and is guilty of a specification of 866 the type described in division (A) of section 2941.1410 of the 867 Revised Code, the court, in lieu of the prison term authorized 868 or required by division (E)(1) of this section and sections 869 2929.13 and 2929.14 of the Revised Code and in addition to any 870 other sanction imposed for the offense under sections 2929.11 to 871 2929.18 of the Revised Code, shall impose upon the offender, in 872 accordance with division (B)(3) of section 2929.14 of the 873

Deviced Code, the mendetenu prises term enceified in that	874
Revised Code, the mandatory prison term specified in that	-
division.	875
(3) Notwithstanding any contrary provision of section	876
3719.21 of the Revised Code, the clerk of court shall pay any	877
fine imposed for a violation of section 4729.37, division (E) of	878
section 4729.51, division (J) of section 4729.54, or section	879
4729.61 of the Revised Code pursuant to division (A) of section	880
2929.18 of the Revised Code in accordance with and subject to	881
the requirements of division (F) of section 2925.03 of the	882
Revised Code. The agency that receives the fine shall use the	883
fine as specified in division (F) of section 2925.03 of the	884
Revised Code.	885
(F) Whoever violates section 4729.531 of the Revised Code	886
or any rule adopted thereunder or section 4729.532 of the	887
Revised Code is guilty of a misdemeanor of the first degree.	888
Revised code is guilty of a misdemeanor of the first degree.	000
(G) Whoever violates division (E)(1)(a) of section 4729.51	889
of the Revised Code is guilty of a felony of the fourth degree.	890
If the offender has previously been convicted of or pleaded	891
guilty to a violation of this chapter, or of a violation of	892
Chapter 2925. or 3719. of the Revised Code, that person is	893
guilty of a felony of the third degree.	894
(H) Whoever violates division (E)(1)(c) of section 4729.51	895
of the Revised Code is quilty of a misdemeanor of the first	896
degree. If the offender has previously been convicted of or	897
pleaded guilty to a violation of this chapter, or of a violation	898
of Chapter 2925. or 3719. of the Revised Code, that person is	899
guilty of a felony of the fifth degree.	900
j	200

(I) (1) Whoever violates division (A) of section 4729.95 of901the Revised Code is guilty of unauthorized pharmacy-related drug902

conduct. Except as otherwise provided in this section,	903
unauthorized pharmacy-related drug conduct is a misdemeanor of	904
the second degree. If the offender previously has been convicted	905
of or pleaded guilty to a violation of division (A), (B), or (C)	906
of that section, unauthorized pharmacy-related drug conduct is a	907
misdemeanor of the first degree on a second offense and a felony	908
of the fifth degree on a third or subsequent offense.	909

(2) Whoever violates division (B) or (C) of section 910 4729.95 of the Revised Code is guilty of permitting unauthorized 911 912 pharmacy-related drug conduct. Except as otherwise provided in this section, permitting unauthorized pharmacy-related drug 913 conduct is a misdemeanor of the second degree. If the offender 914 previously has been convicted of or pleaded quilty to a 915 violation of division (A), (B), or (C) of that section, 916 permitting unauthorized pharmacy-related drug conduct is a 917 misdemeanor of the first degree on a second offense and a felony 918 of the fifth degree on a third or subsequent offense. 919

(3) Notwithstanding any contrary provision of section 920 3719.21 of the Revised Code or any other provision of law that 921 governs the distribution of fines, the clerk of the court shall 922 pay any fine imposed pursuant to division (I)(1) or (2) of this 923 section to the state board of pharmacy if the board has adopted 924 a written internal control policy under division (F)(2) of 925 section 2925.03 of the Revised Code that addresses fine moneys 926 that it receives under Chapter 2925. of the Revised Code and if 927 the policy also addresses fine moneys paid under this division. 928 The state board of pharmacy shall use the fines so paid in 929 accordance with the written internal control policy to subsidize 930 the board's law enforcement efforts that pertain to drug 931 offenses. 932

(J) (1) Whoever violates division (A) (1) of section 4729.86
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of the Revised Code is guilty of a misdemeanor of the third
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degree. If the offender has previously been convicted of or
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pleaded guilty to a violation of division (A) (1), (2), or (3) of
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section 4729.86 of the Revised Code, that person is guilty of a
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misdemeanor of the first degree.
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(2) Whoever violates division (A)(2) of section 4729.86 of the Revised Code is guilty of a misdemeanor of the first degree. If the offender has previously been convicted of or pleaded guilty to a violation of division (A)(1), (2), or (3) of section 4729.86 of the Revised Code, that person is guilty of a felony of the fifth degree.

(3) Whoever violates division (A) (3) of section 4729.86 of the Revised Code is guilty of a felony of the fifth degree. If the offender has previously been convicted of or pleaded guilty to a violation of division (A) (1), (2), or (3) of section 4729.86 of the Revised Code, that person is guilty of a felony of the fourth degree.

(K) A person who violates division (C) of section 4729.552
951 of the Revised Code is guilty of a misdemeanor of the first
952 degree. If the person previously has been convicted of or
953 pleaded guilty to a violation of division (C) of section
954 4729.552 of the Revised Code, that person is guilty of a felony
955 of the fifth degree.
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Sec. 4731.96. (A) As used in this section and section 957 4731.961 of the Revised Code, "physician" means an individual 958 authorized under this chapter to practice medicine and surgery, 959 osteopathic medicine and surgery, or podiatric medicine and 960 surgery. 961

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(B) (1) Subject to division (B) (2) of this section, and
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notwithstanding any provision of this chapter or rule adopted by
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the state medical board, a physician may do either of the
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following without having examined an individual to whom
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epinephrine may be administered:
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(a) Personally furnish a supply of epinephrine
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 autoinjectors for use in accordance with sections 3313.7110,
 3313.7111, 3314.143, 3326.28, 3328.29, 3728.03 to 3728.05, and
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 5101.76 of the Revised Code;
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(b) Issue a prescription for epinephrine autoinjectors for
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 use in accordance with sections 3313.7110, 3313.7111, 3314.143,
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 3326.28, 3328.29, 3728.03 to 3728.05, and 5101.76 of the Revised
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 Code.
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(2) An epinephrine autoinjector personally furnished or
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prescribed under division (B) (1) of this section must be
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furnished or prescribed in such a manner that it may be
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administered only in a manufactured dosage form.
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(C) A physician who acts in good faith in accordance with
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this section is not liable for or subject to any of the
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following for any action or omission of an entity to which an
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epinephrine autoinjector is furnished or a prescription is
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issued: damages in any civil action, prosecution in any criminal
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proceeding, or professional disciplinary action.

Sec. 4731.961. A physician who has established a protocol985that meets the requirements specified by the state board of986pharmacy in rules adopted under section 4729.47 of the Revised987Code may authorize one or more pharmacists and any of the988pharmacy interns supervised by the pharmacist or pharmacists to989use the protocol for the purpose of dispensing epinephrine under990

section 4729.47 of the Revised Code. 991 Section 2. That existing sections 3728.03, 4729.16, 992 4729.23, 4729.28, 4729.41, 4729.43, 4729.45, 4729.553, 4729.99, 993 and 4731.96 of the Revised Code are hereby repealed. 994 Section 3. The provisions of this act that amend and enact 995 sections 3707.60, 3728.03, 4729.16, 4729.382, 4729.47, 4729.99, 996 4731.96, and 4731.961 of the Revised Code shall be known as the 997 "Epinephrine Accessibility Act." 998