## As Reported by the House Health Committee

## **132nd General Assembly**

# Regular Session 2017-2018

Am. H. B. No. 101

# Representative Merrin

Cosponsors: Representatives Becker, Thompson, Seitz, Stein, West, Roegner, Sheehy, Sprague, Hood, Smith, R.

### A BILL

То	amend sections 3728.03, 4729.16, 4729.99, and	1
	4731.96 and to enact sections 3707.60, 4729.382,	2
	4729.46, and 4731.961 of the Revised Code to	3
	authorize an epinephrine autoinjector	4
	substitution when a prescription is filled or	5
	refilled, to authorize epinephrine to be	6
	dispensed without a prescription under a	7
	physician-established protocol, and to declare	8
	the act the "Epinephrine Accessibility Act."	9

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

Section 1. That sections 3728.03, 4729.16, 4729.99, and	10
4731.96 be amended and sections 3707.60, 4729.382, 4729.46, and	11
4731.961 of the Revised Code be enacted to read as follows:	12
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
4729.46 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 4729.46 of the Revised Code.	25
Sec. 3728.03. (A) A qualified entity may acquire and	26
maintain a supply of epinephrine autoinjectors that, in	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
$\operatorname{prescriber}_{\boldsymbol{L}}$ 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 4729.46 of the Revised Code.	36
(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.	42
(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 grant	58
or renew a license;	59
(b) Reprimand or place the license holder on probation;	60
(c) Impose a monetary penalty or forfeiture not to exceed	61
in severity any fine designated under the Revised Code for a	62
similar offense, or in the case of a violation of a section of	63
the Revised Code that does not bear a penalty, a monetary	64
penalty or forfeiture of not more than five hundred dollars.	65
(2) The board may impose the sanctions listed in division	66
(A)(1) of this section if the board finds a pharmacist or	67
pharmacy intern:	68
(a) Has been convicted of a felony, or a crime of moral	69
turpitude, as defined in section 4776.10 of the Revised Code;	70
(b) Engaged in dishonesty or unprofessional conduct in the	71
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

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- (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 or identification card
  under division (B) of section 3719.121 of the Revised Code by
  utilizing a telephone conference call to review the allegations
  and take a vote.

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- (E) For purposes of this division, an individual 137 authorized to practice as a pharmacist or pharmacy intern 138 accepts the privilege of practicing in this state subject to 139 supervision by the board. By filing an application for or 140 holding a license to practice as a pharmacist or pharmacy 141 intern, an individual gives consent to submit to a mental or 142 physical examination when ordered to do so by the board in 143 writing and waives all objections to the admissibility of 144 testimony or examination reports that constitute privileged 145 communications. 146

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

Failure of an individual who is a pharmacist or pharmacy

intern to submit to a physical or mental examination ordered by

the board, unless the failure is due to circumstances beyond the

individual's control, constitutes an admission of the

allegations and a suspension order shall be entered without the

taking of testimony or presentation of evidence. Any subsequent

adjudication hearing under Chapter 119. of the Revised Code

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concerning failure to submit to an examination is limited to	160
consideration of whether the failure was beyond the individual's	161
control.	162

If, based on the results of an examination ordered under

this division, the board determines that the individual's

ability to practice is impaired, the board shall suspend the

individual's license or deny the individual's application and

shall require the individual, as a condition for an initial,

continued, reinstated, or renewed license to practice, to submit

to a physical or mental examination and treatment.

An order of suspension issued under this division shall 170 not be subject to suspension by a court during pendency of any 171 appeal filed under section 119.12 of the Revised Code. 172

- (F) If the board is required under Chapter 119. of the 173 Revised Code to give notice of an opportunity for a hearing and 174 the applicant or licensee does not make a timely request for a 175 hearing in accordance with section 119.07 of the Revised Code, 176 the board is not required to hold a hearing, but may adopt a 177 final order that contains the board's findings. In the final 178 order, the board may impose any of the sanctions listed in 179 division (A) of this section. 180
- (G) Notwithstanding the provision of division (C)(2) of 181 section 2953.32 of the Revised Code specifying that if records 182 pertaining to a criminal case are sealed under that section the 183 proceedings in the case must be deemed not to have occurred, 184 sealing of the following records on which the board has based an 185 action under this section shall have no effect on the board's 186 action or any sanction imposed by the board under this section: 187 records of any conviction, guilty plea, judicial finding of 188 quilt resulting from a plea of no contest, or a judicial finding 189

(C) All of the following conditions apply with respect to

a pharmacist's authority to dispense an epinephrine autoinjector

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by substitution:	219
(1) The pharmacist shall not make the substitution if the	220
person receiving the autoinjector pursuant to the prescription	221
instructs otherwise.	222
(2) The pharmacist shall not make the substitution if	223
either of the following applies to the prescription:	224
(a) In the case of a written or electronic prescription,	225
including a computer-generated prescription, the prescriber	226
handwrites or actively causes to display on the prescription	227
"dispense as written," "D.A.W.," "do not substitute," "medically	228
necessary as prescribed," or any other statement or numerical	229
code that indicates the prescriber's intent to prevent	230
substitution. Such a designation shall not be preprinted or	231
stamped on the prescription, but a reminder to the prescriber of	232
the designation procedure may be preprinted or displayed on the	233
prescription form or electronic system the prescriber uses to	234
issue the prescription.	235
(b) In the case of an oral prescription, the prescriber	236
specifies that the epinephrine autoinjector as prescribed is	237
medically necessary or otherwise indicates the prescriber's	238
intent to prevent substitution.	239
(3) The pharmacist shall not make the substitution unless	240
its price to the patient is less than or equal to the price of	241
the prescribed epinephrine autoinjector, except that a	242
pharmacist may substitute an epinephrine autoinjector with a	243
price to the patient that is greater than the prescribed	244
autoinjector if the patient specifically requests the more	245
<pre>expensive autoinjector.</pre>	246
(1) The pharmacist or a pharmacy interp or agent of the	247

pharmacist, shall inform the patient or the patient's	248
representative if a type of epinephrine autoinjector is	249
available at a lower or equal cost, and of the person's right to	250
refuse substitution of the prescribed epinephrine autoinjector.	251
(D) (1) Unless the prescriber instructs otherwise, the	252
label for every epinephrine autoinjector dispensed shall include	253
the epinephrine autoinjector's name, if any, and the distributor	254
of the autoinjector. Abbreviations may be used as necessary.	255
(2) When dispensing at retail an epinephrine autoinjector	256
by substitution, the pharmacist shall indicate on the	257
autoinjector's label or container that a substitution was made.	258
(3) The labeling requirements established by divisions (D)	259
(1) and (2) of this section are in addition to all other	260
labeling requirements as required in rules adopted by the state	261
board of pharmacy.	262
(E) When a pharmacist dispenses an epinephrine	263
autoinjector by substitution, the pharmacist or a pharmacy	264
intern shall provide to the person receiving the device	265
instruction on the proper method of administering epinephrine	266
with the device, except that the instruction does not have to be	267
provided if the person is receiving the same device that was	268
dispensed when the person last received the device by having a	269
prescription filled or refilled.	270
(F) A pharmacist who dispenses an epinephrine autoinjector	271
pursuant to this section assumes no greater liability for	272
dispensing the autoinjector by substitution than would be	273
incurred for dispensing the autoinjector identified on the	274
prescription.	275
(G) The failure of a prescriber to restrict a prescription_	276

by indicating an intent to prevent substitution pursuant to this	277
section shall not constitute evidence of the prescriber's	278
negligence unless the prescriber had reasonable cause to believe	279
that the health condition of the patient for whom the	280
epinephrine autoinjector was intended warranted the prescription	281
of a specific type of epinephrine autoinjector and no other. No	282
prescriber shall be liable for civil damages or in any criminal	283
prosecution arising from a pharmacist dispensing an epinephrine	284
autoinjector by substitution, unless the type of autoinjector	285
prescribed would have reasonably caused the same loss, damage,	286
injury, or death.	287
(H) The state board of pharmacy may adopt rules in	288
accordance with Chapter 119. of the Revised Code to implement	289
this section. The rules may specify forms of epinephrine that	290
are not to be recognized as pharmaceutical equivalents of other	291
forms of epinephrine for purposes of this section.	292
(I) No pharmacist shall knowingly engage in conduct that	293
is prohibited by division (C) or (D) of this section.	294
Sec. 4729.46. (A) As used in this section:	295
(1) "Board of health" means a board of health of a city or	296
general health district or an authority having the duties of a	297
board of health under section 3709.05 of the Revised Code.	298
(2) "Physician" means an individual authorized under	299
Chapter 4731. of the Revised Code to practice medicine and	300
surgery, osteopathic medicine and surgery, or podiatric medicine	301
and surgery.	302
(B) If use of a protocol that has been developed pursuant	303
to rules adopted under division (G) of this section has been	304
authorized under section 3707.60 or 4731.961 of the Revised	305

Code, a pharmacist or pharmacy intern may dispense epinephrine	306
without a prescription in accordance with that protocol to	307
either of the following individuals so long as the individual is	308
at least eighteen years of age:	309
(1) An individual who there is reason to believe is	310
experiencing or at risk of experiencing anaphylaxis if the	311
pharmacy affiliated with the pharmacist or intern has a record	312
of previously dispensing epinephrine to the individual in	313
accordance with a prescription issued by a licensed health	314
<pre>professional authorized to prescribe drugs;</pre>	315
(2) An individual acting on behalf of a qualified entity,	316
as defined in section 3728.01 of the Revised Code.	317
(C) (1) A pharmacist or pharmacy intern who dispenses	318
epinephrine under this section shall instruct the individual to	319
whom epinephrine is dispensed to summon emergency services as	320
soon as practicable either before or after administering	321
epinephrine.	322
(2) A pharmacist or pharmacy intern who dispenses	323
epinephrine to an individual identified in division (B)(1)(a) of	324
this section shall provide notice of the dispensing to the	325
individual's primary care provider, if known, or to the	326
prescriber who issued the individual the initial prescription	327
for epinephrine.	328
(D) A pharmacist may document the dispensing of	329
epinephrine by the pharmacist or a pharmacy intern supervised by	330
the pharmacist on a prescription form. The form may be assigned	331
a number for record-keeping purposes.	332
(E) This section does not affect the authority of a	333
pharmacist or pharmacy intern to fill or refill a prescription	334

for epinephrine.	335
(F) A board of health that in good faith authorizes a	336
pharmacist or pharmacy intern to dispense epinephrine without a	337
prescription in accordance with a protocol developed pursuant to	338
rules adopted under division (G) of this section is not liable	339
for or subject to any of the following for any action or	340
omission of the individual to whom the epinephrine is dispensed:	341
damages in any civil action, prosecution in any criminal	342
proceeding, or professional disciplinary action.	343
A physician who in good faith authorizes a pharmacist or	344
pharmacy intern to dispense epinephrine without a prescription	345
in accordance with a protocol developed pursuant to rules	346
adopted under division (G) of this section is not liable for or	347
subject to any of the following for any action or omission of	348
the individual to whom the epinephrine is dispensed: damages in	349
any civil action, prosecution in any criminal proceeding, or	350
professional disciplinary action.	351
A pharmacist or pharmacy intern authorized under this	352
section to dispense epinephrine without a prescription who does	353
so in good faith is not liable for or subject to any of the	354
following for any action or omission of the individual to whom	355
the epinephrine is dispensed: damages in any civil action,	356
prosecution in any criminal proceeding, or professional	357
disciplinary action.	358
(G) Not later than ninety days after the effective date of	359
this section, the state board of pharmacy shall, after	360
consulting with the state medical board, adopt rules to	361
implement this section. The rules shall specify minimum	362
requirements for protocols established by physicians under which	363
pharmacists or pharmacy interns may dispense epinephrine without	364

a prescription.	365
All rules adopted under this section shall be adopted in	366
accordance with Chapter 119. of the Revised Code.	367
Sec. 4729.99. (A) Whoever violates division (H) of section	368
4729.16, division (G) of section 4729.38, <u>division (I) of</u>	369
section 4729.382, section 4729.57, or division (F) of section	370
4729.96 of the Revised Code is guilty of a minor misdemeanor,	371
unless a different penalty is otherwise specified in the Revised	372
Code. Each day's violation constitutes a separate offense.	373
(B) Whoever violates section 4729.27, 4729.28, or 4729.36	374
of the Revised Code is guilty of a misdemeanor of the third	375
degree. Each day's violation constitutes a separate offense. If	376
the offender previously has been convicted of or pleaded guilty	377
to a violation of this chapter, that person is guilty of a	378
misdemeanor of the second degree.	379
(C) Whoever violates section 4729.32, 4729.33, or 4729.34	380
of the Revised Code is guilty of a misdemeanor.	381
(D) Whoever violates division (A), (B), (C), (D), (F), or	382
(G) of section 4729.51 of the Revised Code is guilty of a	383
misdemeanor of the first degree.	384
(E)(1) Whoever violates section 4729.37, division (E)(1)	385
(b) of section 4729.51, division (J) of section 4729.54,	386
division (B) or (D) of section 4729.553, or section 4729.61 of	387
the Revised Code is guilty of a felony of the fifth degree. If	388
the offender previously has been convicted of or pleaded guilty	389
to a violation of this chapter or a violation of Chapter 2925.	390
or 3719. of the Revised Code, that person is guilty of a felony	391
of the fourth degree.	392
(2) If an offender is convicted of or pleads guilty to a	393

violation of section 4729.37, division (E) of section 4729.51,	394
division (J) of section 4729.54, or section 4729.61 of the	395
Revised Code, if the violation involves the sale, offer to sell,	396
or possession of a schedule I or II controlled substance, with	397
the exception of marihuana, and if the court imposing sentence	398
upon the offender finds that the offender as a result of the	399
violation is a major drug offender, as defined in section	400
2929.01 of the Revised Code, and is guilty of a specification of	401
the type described in section 2941.1410 of the Revised Code, the	402
court, in lieu of the prison term authorized or required by	403
division (E)(1) of this section and sections 2929.13 and 2929.14	404
of the Revised Code and in addition to any other sanction	405
imposed for the offense under sections 2929.11 to 2929.18 of the	406
Revised Code, shall impose upon the offender, in accordance with	407
division (B)(3) of section 2929.14 of the Revised Code, the	408
mandatory prison term specified in that division.	409

- (3) Notwithstanding any contrary provision of section 410 3719.21 of the Revised Code, the clerk of court shall pay any 411 fine imposed for a violation of section 4729.37, division (E) of 412 section 4729.51, division (J) of section 4729.54, or section 413 4729.61 of the Revised Code pursuant to division (A) of section 414 2929.18 of the Revised Code in accordance with and subject to 415 the requirements of division (F) of section 2925.03 of the 416 Revised Code. The agency that receives the fine shall use the 417 fine as specified in division (F) of section 2925.03 of the 418 Revised Code. 419
- (F) Whoever violates section 4729.531 of the Revised Code
  or any rule adopted thereunder or section 4729.532 of the
  Revised Code is guilty of a misdemeanor of the first degree.
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  - (G) Whoever violates division (E)(1)(a) of section 4729.51 423

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of the Revised Code is guilty of a felony of the fourth degree.	424
If the offender has previously been convicted of or pleaded	425
guilty to a violation of this chapter, or of a violation of	426
Chapter 2925. or 3719. of the Revised Code, that person is	427
guilty of a felony of the third degree.	428

- (H) Whoever violates division (E)(1)(c) of section 4729.51 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 this chapter, or of a violation of Chapter 2925. or 3719. of the Revised Code, that person is guilty of a felony of the fifth degree.
- (I)(1) Whoever violates division (A) of section 4729.95 of 435 the Revised Code is quilty of unauthorized pharmacy-related drug 436 conduct. Except as otherwise provided in this section, 437 unauthorized pharmacy-related drug conduct is a misdemeanor of 438 the second degree. If the offender previously has been convicted 439 of or pleaded quilty to a violation of division (A), (B), or (C) 440 of that section, unauthorized pharmacy-related drug conduct is a 441 misdemeanor of the first degree on a second offense and a felony 442 of the fifth degree on a third or subsequent offense. 443
- (2) Whoever violates division (B) or (C) of section 444 4729.95 of the Revised Code is quilty of permitting unauthorized 445 pharmacy-related drug conduct. Except as otherwise provided in 446 this section, permitting unauthorized pharmacy-related drug 447 conduct is a misdemeanor of the second degree. If the offender 448 previously has been convicted of or pleaded quilty to a 449 violation of division (A), (B), or (C) of that section, 450 permitting unauthorized pharmacy-related drug conduct is a 451 misdemeanor of the first degree on a second offense and a felony 452 of the fifth degree on a third or subsequent offense. 453

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- (3) Notwithstanding any contrary provision of section 454 3719.21 of the Revised Code or any other provision of law that 455 governs the distribution of fines, the clerk of the court shall 456 pay any fine imposed pursuant to division (I)(1) or (2) of this 457 section to the state board of pharmacy if the board has adopted 458 a written internal control policy under division (F)(2) of 459 section 2925.03 of the Revised Code that addresses fine moneys 460 that it receives under Chapter 2925. of the Revised Code and if 461 the policy also addresses fine moneys paid under this division. 462 The state board of pharmacy shall use the fines so paid in 463 accordance with the written internal control policy to subsidize 464 the board's law enforcement efforts that pertain to drug 465 offenses. 466
- (J) (1) Whoever violates division (A) (1) of section 4729.86 of the Revised Code is guilty of a misdemeanor of the third 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 misdemeanor of the first degree.
- (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 479 the Revised Code is guilty of a felony of the fifth degree. If 480 the offender has previously been convicted of or pleaded guilty 481 to a violation of division (A)(1), (2), or (3) of section 482 4729.86 of the Revised Code, that person is guilty of a felony 483

of the fourth degree.	484
(K) A person who violates division (C) of section 4729.552	485
of the Revised Code is guilty of a misdemeanor of the first	486
degree. If the person previously has been convicted of or	487
pleaded guilty to a violation of division (C) of section	488
4729.552 of the Revised Code, that person is guilty of a felony	489
of the fifth degree.	490
Sec. 4731.96. (A) As used in this section and section	491
4731.961 of the Revised Code, "physician" means an individual	492
authorized under this chapter to practice medicine and surgery,	493
osteopathic medicine and surgery, or podiatric medicine and	494
surgery.	495
(B)(1) Subject to division (B)(2) of this section, and	496
notwithstanding any provision of this chapter or rule adopted by	497
the state medical board, a physician may do either of the	498
following without having examined an individual to whom	499
epinephrine may be administered:	500
(a) Personally furnish a supply of epinephrine	501
autoinjectors for use in accordance with sections 3313.7110,	502
3313.7111, 3314.143, 3326.28, 3328.29, 3728.03 to 3728.05, and	503
5101.76 of the Revised Code;	504
(b) Issue a prescription for epinephrine autoinjectors for	505
use in accordance with sections 3313.7110, 3313.7111, 3314.143,	506
3326.28, 3328.29, 3728.03 to 3728.05, and 5101.76 of the Revised	507
Code.	508
(2) An epinephrine autoinjector personally furnished or	509
prescribed under division (B)(1) of this section must be	510
furnished or prescribed in such a manner that it may be	511
administered only in a manufactured dosage form.	512

(C) A physician who acts in good faith in accordance with	513
this section is not liable for or subject to any of the	514
following for any action or omission of an entity to which an	515
epinephrine autoinjector is furnished or a prescription is	516
issued: damages in any civil action, prosecution in any criminal	517
proceeding, or professional disciplinary action.	518
Sec. 4731.961. A physician who has established a protocol	519
that meets the requirements specified by the state board of	520
pharmacy in rules adopted under section 4729.46 of the Revised	521
Code may authorize one or more pharmacists and any of the	522
pharmacy interns supervised by the pharmacist or pharmacists to	523
use the protocol for the purpose of dispensing epinephrine under	524
section 4729.46 of the Revised Code.	525
Section 2. That existing sections 3728.03, 4729.16,	526
4729.99, and 4731.96 of the Revised Code are hereby repealed.	527
Section 3. This act shall be known as the "Epinephrine	528
Accessibility Act."	529
Section 4. Section 4729.99 of the Revised Code is	530
presented in this act as a composite of the section as amended	531
by both Sub. H.B. 505 and Sub. S.B. 319 of the 131st General	532
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Assembly. The General Assembly, applying the principle stated in	533
Assembly. The General Assembly, applying the principle stated in division (B) of section 1.52 of the Revised Code that amendments	
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division (B) of section 1.52 of the Revised Code that amendments	533 534
division (B) of section 1.52 of the Revised Code that amendments are to be harmonized if reasonably capable of simultaneous	<ul><li>533</li><li>534</li><li>535</li></ul>