As Introduced

131st General Assembly Regular Session 2015-2016

H. B. No. 421

Representative LaTourette

Cosponsors: Representatives Sprague, Koehler, Hambley, Sheehy

A BILL

To amend section 4729.01 and to enact sections	1
4729.45, 4730.412, and 4731.057 of the Revised	2
Code to authorize a pharmacist to administer by	3
injection certain prescribed drugs.	4

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

Section 1. That section 4729.01 be amended and sections	5
4729.45, 4730.412, and 4731.057 of the Revised Code be enacted	6
to read as follows:	7
Sec. 4729.01. As used in this chapter:	8
(A) "Pharmacy," except when used in a context that refers	9
to the practice of pharmacy, means any area, room, rooms, place	10
of business, department, or portion of any of the foregoing	11
where the practice of pharmacy is conducted.	12
(B) "Practice of pharmacy" means providing pharmacist care	13
requiring specialized knowledge, judgment, and skill derived	14
from the principles of biological, chemical, behavioral, social,	15
pharmaceutical, and clinical sciences. As used in this division,	16
"pharmacist care" includes the following:	17

(1) Interpreting prescriptions;

(3) Compounding drugs;

(2) Dispensing drugs and drug therapy related devices;

(4) Counseling individuals with regard to their drug 21 therapy, recommending drug therapy related devices, and 22 assisting in the selection of drugs and appliances for treatment 23 of common diseases and injuries and providing instruction in the 24 proper use of the drugs and appliances; 25

(5) Performing drug regimen reviews with individuals by 26 27 discussing all of the drugs that the individual is taking and explaining the interactions of the drugs; 28

(6) Performing drug utilization reviews with licensed health professionals authorized to prescribe drugs when the pharmacist determines that an individual with a prescription has a drug regimen that warrants additional discussion with the prescriber;

(7) Advising an individual and the health care professionals treating an individual with regard to the individual's drug therapy;

(8) Acting pursuant to a consult agreement with a 37 physician authorized under Chapter 4731. of the Revised Code to 38 practice medicine and surgery or osteopathic medicine and 39 surgery, if an agreement has been established with the 40 physician; 41

(9) Engaging in the administration of immunizations to the extent authorized by section 4729.41 of the Revised Code;

(10) Engaging in the administration of drugs to the extent 44 authorized by section 4729.45 of the Revised Code. 45

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(C) "Compounding" means the preparation, mixing, 46 assembling, packaging, and labeling of one or more drugs in any 47 of the following circumstances: 48 (1) Pursuant to a prescription issued by a licensed health 49 professional authorized to prescribe drugs; 50 (2) Pursuant to the modification of a prescription made in 51 accordance with a consult agreement; 52 (3) As an incident to research, teaching activities, or 53 chemical analysis; 54 (4) In anticipation of orders for drugs pursuant to 55 prescriptions, based on routine, regularly observed dispensing 56 patterns; 57 (5) Pursuant to a request made by a licensed health 58 professional authorized to prescribe drugs for a drug that is to 59 be used by the professional for the purpose of direct 60 administration to patients in the course of the professional's 61 practice, if all of the following apply: 62 (a) At the time the request is made, the drug is not 63 commercially available regardless of the reason that the drug is 64 not available, including the absence of a manufacturer for the 65 drug or the lack of a readily available supply of the drug from 66 a manufacturer. 67 (b) A limited quantity of the drug is compounded and 68 provided to the professional. 69 70 (c) The drug is compounded and provided to the professional as an occasional exception to the normal practice 71 of dispensing drugs pursuant to patient-specific prescriptions. 72 (D) "Consult agreement" means an agreement to manage an 73

74 individual's drug therapy that has been entered into by a pharmacist and a physician authorized under Chapter 4731. of the 75 Revised Code to practice medicine and surgery or osteopathic 76 medicine and surgery. 77 (E) "Drug" means: 78 (1) Any article recognized in the United States 79 pharmacopoeia and national formulary, or any supplement to them, 80 intended for use in the diagnosis, cure, mitigation, treatment, 81 or prevention of disease in humans or animals; 82 (2) Any other article intended for use in the diagnosis, 83 cure, mitigation, treatment, or prevention of disease in humans 84

or animals; (3) Any article, other than food, intended to affect the

structure or any function of the body of humans or animals;

(4) Any article intended for use as a component of any
article specified in division (E)(1), (2), or (3) of this
section; but does not include devices or their components,
parts, or accessories.

(F) "Dangerous drug" means any of the following:

(1) Any drug to which either of the following applies: 93

(a) Under the "Federal Food, Drug, and Cosmetic Act," 52
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Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is
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required to bear a label containing the legend "Caution: Federal
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law prohibits dispensing without prescription" or "Caution:
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Federal law restricts this drug to use by or on the order of a
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licensed veterinarian" or any similar restrictive statement, or
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the drug may be dispensed only upon a prescription;

(b) Under Chapter 3715. or 3719. of the Revised Code, the 101

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drug may be dispensed only upon a prescription. 102 (2) Any drug that contains a schedule V controlled 103 substance and that is exempt from Chapter 3719. of the Revised 104 Code or to which that chapter does not apply; 105 (3) Any drug intended for administration by injection into 106 the human body other than through a natural orifice of the human 107 108 body. (G) "Federal drug abuse control laws" has the same meaning 109 as in section 3719.01 of the Revised Code. 110 (H) "Prescription" means both of the following: 111 (1) A written, electronic, or oral order for drugs or 112 combinations or mixtures of drugs to be used by a particular 113 individual or for treating a particular animal, issued by a 114 licensed health professional authorized to prescribe drugs; 115 (2) For purposes of section sections 2925.61, 4723.488, 116 4729.44, 4730.431, and 4731.94 of the Revised Code, a written, 117 electronic, or oral order for naloxone issued to and in the name 118 of a family member, friend, or other individual in a position to 119 assist an individual who there is reason to believe is at risk 120 of experiencing an opioid-related overdose. 121 (I) "Licensed health professional authorized to prescribe 122 drugs" or "prescriber" means an individual who is authorized by 123 law to prescribe drugs or dangerous drugs or drug therapy 124 related devices in the course of the individual's professional 125 practice, including only the following: 126 (1) A dentist licensed under Chapter 4715. of the Revised 127 Code; 128 (2) A clinical nurse specialist, certified nurse-midwife, 129

or certified nurse practitioner who holds a certificate to 130 prescribe issued under section 4723.48 of the Revised Code; 131 (3) An optometrist licensed under Chapter 4725. of the 132 Revised Code to practice optometry under a therapeutic 133 pharmaceutical agents certificate; 134 (4) A physician authorized under Chapter 4731. of the 135 Revised Code to practice medicine and surgery, osteopathic 136 medicine and surgery, or podiatric medicine and surgery; 137 (5) A physician assistant who holds a license to practice 138 as a physician assistant issued under Chapter 4730. of the 139 Revised Code, holds a valid prescriber number issued by the 140 state medical board, and has been granted physician-delegated 141 prescriptive authority; 142 (6) A veterinarian licensed under Chapter 4741. of the 143 Revised Code. 144 (J) "Sale" and "sell" include delivery, transfer, barter, 145 exchange, or gift, or offer therefor, and each such transaction 146 made by any person, whether as principal proprietor, agent, or 147 employee. 148 (K) "Wholesale sale" and "sale at wholesale" mean any sale 149 in which the purpose of the purchaser is to resell the article 150

In which the purpose of the purchaser is to resell the article150purchased or received by the purchaser.151

(L) "Retail sale" and "sale at retail" mean any sale otherthan a wholesale sale or sale at wholesale.153

(M) "Retail seller" means any person that sells any
dangerous drug to consumers without assuming control over and
responsibility for its administration. Mere advice or
instructions regarding administration do not constitute control
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or establish responsibility.

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158 (N) "Price information" means the price charged for a 159 prescription for a particular drug product and, in an easily 160 understandable manner, all of the following: 161 162 (1) The proprietary name of the drug product; (2) The established (generic) name of the drug product; 163 (3) The strength of the drug product if the product 164 contains a single active ingredient or if the drug product 165 contains more than one active ingredient and a relevant strength 166 can be associated with the product without indicating each 167 active ingredient. The established name and quantity of each 168 active ingredient are required if such a relevant strength 169

cannot be so associated with a drug product containing more than 170 one ingredient. 171

(4) The dosage form;

(5) The price charged for a specific quantity of the drug 173 product. The stated price shall include all charges to the 174 consumer, including, but not limited to, the cost of the drug 175 product, professional fees, handling fees, if any, and a 176 statement identifying professional services routinely furnished 177 by the pharmacy. Any mailing fees and delivery fees may be 178 stated separately without repetition. The information shall not 179 be false or misleading. 180

(O) "Wholesale distributor of dangerous drugs" means a 181 person engaged in the sale of dangerous drugs at wholesale and 182 includes any agent or employee of such a person authorized by 183 the person to engage in the sale of dangerous drugs at 184 wholesale. 185 (P) "Manufacturer of dangerous drugs" means a person,
other than a pharmacist, who manufactures dangerous drugs and
who is engaged in the sale of those dangerous drugs within this
state.

(Q) "Terminal distributor of dangerous drugs" means a 190 person who is engaged in the sale of dangerous drugs at retail, 191 or any person, other than a wholesale distributor or a 192 pharmacist, who has possession, custody, or control of dangerous 193 drugs for any purpose other than for that person's own use and 194 195 consumption, and includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous 196 drugs for sale or other distribution by or under the supervision 197 of a pharmacist or licensed health professional authorized to 198 prescribe drugs. 199

(R) "Promote to the public" means disseminating a 200
representation to the public in any manner or by any means, 201
other than by labeling, for the purpose of inducing, or that is 202
likely to induce, directly or indirectly, the purchase of a 203
dangerous drug at retail. 204

(S) "Person" includes any individual, partnership,
association, limited liability company, or corporation, the
state, any political subdivision of the state, and any district,
department, or agency of the state or its political
subdivisions.

(T) "Finished dosage form" has the same meaning as insection 3715.01 of the Revised Code.211

(U) "Generically equivalent drug" has the same meaning as212in section 3715.01 of the Revised Code.213

(V) "Animal shelter" means a facility operated by a humane 214

society or any society organized under Chapter 1717. of the 215 Revised Code or a dog pound operated pursuant to Chapter 955. of 216 the Revised Code. 217 (W) "Food" has the same meaning as in section 3715.01 of 218 the Revised Code. 219 (X) "Pain management clinic" has the same meaning as in 220 section 4731.054 of the Revised Code. 221 222 Sec. 4729.45. (A) (1) A pharmacist licensed under this chapter who meets the requirements of division (B) of this 223 section may administer by injection any of the following drugs 224 as long as the drug that is to be administered has been 225 prescribed by a health professional with authority to prescribe 226 227 the drug: (a) An opioid antagonist used for treatment of drug 228 addiction and administered in a long-acting or extended-release 229 230 form; (b) An antipsychotic drug administered in a long-acting or 2.31 extended-release form; 232 233 (c) Hydroxyprogesterone caproate; 234 (d) Medroxyprogesterone acetate. (2) As part of engaging in the administration of drugs by 235 injection pursuant to this section, a pharmacist may administer 236 epinephrine or diphenhydramine, or both, to an individual in an 237 emergency situation resulting from an adverse reaction to a drug 238 administered by the pharmacist. 239 (B) To be authorized to administer drugs pursuant to this 240 section, a pharmacist must do all of the following: 241

(1) Successfully complete a course in the administration	242
of drugs that has been approved by the state board of pharmacy;	243
(2) Receive and maintain certification to perform basic	244
life-support procedures by successfully completing a basic life-	245
support training course certified by the American red cross or	246
American heart association;	247
(3) Practice in accordance with a protocol that meets the	248
requirements of division (D) of this section.	249
(C) Each time a pharmacist administers a drug pursuant to	250
this section, the pharmacist shall do all of the following:	251
(1) Observe the individual who receives the drug to	252
determine whether the individual has an adverse reaction to the	253
<u>drug;</u>	254
(2) Notify the health professional who prescribed the	255
<u>drug;</u>	256
(3) Obtain permission in accordance with the procedures	257
specified in rules adopted under division (F) of this section	258
and the following requirements:	259
(a) Except as provided in division (C)(3)(c) of this	260
section, for each drug administered by a pharmacist to an	261
individual who is eighteen years of age or older, the pharmacist	262
shall obtain permission from the individual.	263
(b) For each drug administered by a pharmacist to an	264
individual who is under eighteen years of age, the pharmacist	265
shall obtain permission from the individual's parent or other	266
person having care or charge of the individual.	267
(c) For each drug administered by a pharmacist to an	268
individual who lacks the capacity to make informed health care	269

decisions, the pharmacist shall obtain permission from the 270 person authorized to make such decisions on the individual's 271 behalf. 272 (D) All of the following apply with respect to the 273 protocol required by division (B)(3) of this section: 274 (1) The protocol must be established by a physician 275 authorized under Chapter 4731. of the Revised Code to practice 276 medicine and surgery or osteopathic medicine and surgery and 277 must be approved by the state board of pharmacy before it is 278 implemented. 279 (2) The board shall review each protocol it receives from 280 an individual seeking approval of the protocol. If the board 281 determines that the protocol meets the requirements of division 282 (D) (3) of this section and all other requirements for approval 283 established in rules adopted under this section, the board shall 284 approve the protocol. 285 (3) The protocol must do all of the following: 286 (a) Specify a definitive set of treatment quidelines; 287 (b) Specify the locations at which a pharmacist may engage 288 289 in the administration of drugs pursuant to this section; (c) Include provisions for implementing the requirements 290 of division (C) of this section, including provisions specifying 291 the length of time and location at which a pharmacist must 292 observe an individual who receives a drug to determine whether 293 the individual has an adverse reaction to the drug; 294 (d) Specify procedures to be followed by a pharmacist when 295 administering epinephrine, diphenhydramine, or both, to an_ 296 297 individual who has an adverse reaction to a drug administered by

the pharmacist.	298
(E) A pharmacist shall not do either of the following:	299
(1) Engage in the administration of drugs pursuant to this	300
section unless the requirements of division (B) of this section	301
have been met;	302
(2) Delegate to any person the pharmacist's authority to	303
engage in the administration of drugs pursuant to this section.	304
(F)(1) The state board of pharmacy shall adopt rules to	305
implement this section. The rules shall be adopted in accordance	306
with Chapter 119. of the Revised Code and include all of the	307
following:	308
(a) Provisions for approval of courses in administration	309
<u>of drugs;</u>	310
(b) Provisions for approval of protocols to be followed by	311
pharmacists in administering drugs pursuant to this section;	312
(c) Procedures to be followed by a pharmacist in obtaining	313
<u>permission to administer a drug to an individual.</u>	314
(2) The provisions for approval of protocols shall	315
establish standards regarding the length of time and location at	316
which a pharmacist must observe an individual to whom a drug is	317
administered to determine whether the individual has an adverse	318
reaction.	319
(3) The board shall consult with the state medical board	320
and the board of nursing before adopting rules regarding	321
approval of protocols under this section.	322
Sec. 4730.412. The state medical board, in consultation	323
with the state board of pharmacy, shall adopt rules in	324

accordance with Chapter 119. of the Revised Code that establish	325
standards and procedures to be followed by a physician assistant	326
when prescribing a drug that may be administered by a pharmacist	327
pursuant to section 4729.45 of the Revised Code. The state	328
medical board may determine whether the rules apply in	329
situations in which the physician assistant reasonably believes	330
that the drug will be administered by an individual other than a	331
pharmacist.	332
Sec. 4731.057. As used in this section, "physician" means	333
an individual authorized under this chapter to practice medicine	334
and surgery or osteopathic medicine and surgery.	335
The state medical board, in consultation with the state	336
board of pharmacy, shall adopt rules in accordance with Chapter	337
119. of the Revised Code that establish standards and procedures	338
to be followed by physicians when prescribing a drug that may be	339
administered by a pharmacist pursuant to section 4729.45 of the	340
Revised Code. The state medical board may determine whether the	341
rules apply in situations in which the physician reasonably	342
believes that the drug will be administered by an individual	343
other than a pharmacist.	344
Section 2. That existing section 4729.01 of the Revised	345
Code is hereby repealed.	346
Section 3. Section 4729.01 of the Revised Code is	347
presented in this act as a composite of the section as amended	348
by both Am. Sub. H.B. 4 and Sub. S.B. 110 of the 131st General	349
Assembly. The General Assembly, applying the principle stated in	350
division (B) of section 1.52 of the Revised Code that amendments	351
are to be harmonized if reasonably capable of simultaneous	352
operation, finds that the composite is the resulting version of	353
the section in effect prior to the effective date of the section	354

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as presented in this act.

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