

As Passed by the Senate

**126th General Assembly
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Sub. S. B. No. 18

Senators Wachtmann, Austria, Spada, Dann

—

A BILL

To amend section 4729.01 of the Revised Code 1
regarding the compounding of drugs by pharmacists. 2

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

Section 1. That section 4729.01 of the Revised Code be 3
amended to read as follows: 4

Sec. 4729.01. As used in this chapter: 5

(A) "Pharmacy," except when used in a context that refers to 6
the practice of pharmacy, means any area, room, rooms, place of 7
business, department, or portion of any of the foregoing where the 8
practice of pharmacy is conducted. 9

(B) "Practice of pharmacy" means providing pharmacist care 10
requiring specialized knowledge, judgment, and skill derived from 11
the principles of biological, chemical, behavioral, social, 12
pharmaceutical, and clinical sciences. As used in this division, 13
"pharmacist care" includes the following: 14

(1) Interpreting prescriptions; 15

(2) ~~Compounding or dispensing~~ Dispensing drugs and ~~dispensing~~ 16
drug therapy related devices; 17

(3) Compounding drugs; 18

(4) Counseling individuals with regard to their drug therapy, 19

recommending drug therapy related devices, and assisting in the 20
selection of drugs and appliances for treatment of common diseases 21
and injuries and providing instruction in the proper use of the 22
drugs and appliances; 23

~~(4)~~(5) Performing drug regimen reviews with individuals by 24
discussing all of the drugs that the individual is taking and 25
explaining the interactions of the drugs; 26

~~(5)~~(6) Performing drug utilization reviews with licensed 27
health professionals authorized to prescribe drugs when the 28
pharmacist determines that an individual with a prescription has a 29
drug regimen that warrants additional discussion with the 30
prescriber; 31

~~(6)~~(7) Advising an individual and the health care 32
professionals treating an individual with regard to the 33
individual's drug therapy; 34

~~(7)~~(8) Acting pursuant to a consult agreement with a 35
physician authorized under Chapter 4731. of the Revised Code to 36
practice medicine and surgery or osteopathic medicine and surgery, 37
if an agreement has been established with the physician; 38

~~(8)~~(9) Administering the adult immunizations specified in 39
section 4729.41 of the Revised Code, if the pharmacist has met the 40
requirements of that section. 41

(C) "Compounding" means the preparation, mixing, assembling, 42
packaging, and labeling of one or more drugs in any of the 43
following circumstances: 44

(1) Pursuant to a prescription issued by a licensed health 45
professional authorized to prescribe drugs; 46

(2) Pursuant to the modification of a prescription made in 47
accordance with a consult agreement; 48

(3) As an incident to research, teaching activities, or 49

chemical analysis;	50
(4) In anticipation of prescription drug orders <u>for drugs</u>	51
<u>pursuant to prescriptions</u> , based on routine, regularly observed	52
dispensing patterns;	53
(5) <u>Pursuant to a request made by a licensed health</u>	54
<u>professional authorized to prescribe drugs for a drug that is to</u>	55
<u>be used by the professional for the purpose of direct</u>	56
<u>administration to patients in the course of the professional's</u>	57
<u>practice, if all of the following apply:</u>	58
(a) <u>The drug is not commercially available.</u>	59
(b) <u>A limited quantity of the drug is compounded and provided</u>	60
<u>to the professional.</u>	61
(c) <u>The drug is compounded and provided to the professional</u>	62
<u>as an occasional exception to the normal practice of dispensing</u>	63
<u>drugs pursuant to patient-specific prescriptions.</u>	64
(D) "Consult agreement" means an agreement to manage an	65
individual's drug therapy that has been entered into by a	66
pharmacist and a physician authorized under Chapter 4731. of the	67
Revised Code to practice medicine and surgery or osteopathic	68
medicine and surgery.	69
(E) "Drug" means:	70
(1) Any article recognized in the United States pharmacopoeia	71
and national formulary, or any supplement to them, intended for	72
use in the diagnosis, cure, mitigation, treatment, or prevention	73
of disease in humans or animals;	74
(2) Any other article intended for use in the diagnosis,	75
cure, mitigation, treatment, or prevention of disease in humans or	76
animals;	77
(3) Any article, other than food, intended to affect the	78
structure or any function of the body of humans or animals;	79

(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:

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

(b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription.

(2) Any drug that contains a schedule V controlled substance and that is exempt from Chapter 3719. of the Revised Code or to which that chapter does not apply;

(3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body.

(G) "Federal drug abuse control laws" has the same meaning as in section 3719.01 of the Revised Code.

(H) "Prescription" means a written, electronic, or oral order for drugs or combinations or mixtures of drugs to be used by a particular individual or for treating a particular animal, issued by a licensed health professional authorized to prescribe drugs.

(I) "Licensed health professional authorized to prescribe drugs" or "prescriber" means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related

devices in the course of the individual's professional practice,	110
including only the following:	111
(1) A dentist licensed under Chapter 4715. of the Revised Code;	112 113
(2) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a certificate to prescribe issued under section 4723.48 of the Revised Code;	114 115 116
(3) An optometrist licensed under Chapter 4725. of the Revised Code to practice optometry under a therapeutic pharmaceutical agents certificate;	117 118 119
(4) A physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatry;	120 121 122
(5) A veterinarian licensed under Chapter 4741. of the Revised Code.	123 124
(J) "Sale" and "sell" include delivery, transfer, barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as principal proprietor, agent, or employee.	125 126 127 128
(K) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.	129 130 131
(L) "Retail sale" and "sale at retail" mean any sale other than a wholesale sale or sale at wholesale.	132 133
(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 or establish responsibility.	134 135 136 137 138
(N) "Price information" means the price charged for a	139

prescription for a particular drug product and, in an easily	140
understandable manner, all of the following:	141
(1) The proprietary name of the drug product;	142
(2) The established (generic) name of the drug product;	143
(3) The strength of the drug product if the product contains	144
a single active ingredient or if the drug product contains more	145
than one active ingredient and a relevant strength can be	146
associated with the product without indicating each active	147
ingredient. The established name and quantity of each active	148
ingredient are required if such a relevant strength cannot be so	149
associated with a drug product containing more than one	150
ingredient.	151
(4) The dosage form;	152
(5) The price charged for a specific quantity of the drug	153
product. The stated price shall include all charges to the	154
consumer, including, but not limited to, the cost of the drug	155
product, professional fees, handling fees, if any, and a statement	156
identifying professional services routinely furnished by the	157
pharmacy. Any mailing fees and delivery fees may be stated	158
separately without repetition. The information shall not be false	159
or misleading.	160
(O) "Wholesale distributor of dangerous drugs" means a person	161
engaged in the sale of dangerous drugs at wholesale and includes	162
any agent or employee of such a person authorized by the person to	163
engage in the sale of dangerous drugs at wholesale.	164
(P) "Manufacturer of dangerous drugs" means a person, other	165
than a pharmacist, who manufactures dangerous drugs and who is	166
engaged in the sale of those dangerous drugs within this state.	167
(Q) "Terminal distributor of dangerous drugs" means a person	168
who is engaged in the sale of dangerous drugs at retail, or any	169

person, other than a wholesale distributor or a pharmacist, who 170
has possession, custody, or control of dangerous drugs for any 171
purpose other than for that person's own use and consumption, and 172
includes pharmacies, hospitals, nursing homes, and laboratories 173
and all other persons who procure dangerous drugs for sale or 174
other distribution by or under the supervision of a pharmacist or 175
licensed health professional authorized to prescribe drugs. 176

(R) "Promote to the public" means disseminating a 177
representation to the public in any manner or by any means, other 178
than by labeling, for the purpose of inducing, or that is likely 179
to induce, directly or indirectly, the purchase of a dangerous 180
drug at retail. 181

(S) "Person" includes any individual, partnership, 182
association, limited liability company, or corporation, the state, 183
any political subdivision of the state, and any district, 184
department, or agency of the state or its political subdivisions. 185

(T) "Finished dosage form" has the same meaning as in section 186
3715.01 of the Revised Code. 187

(U) "Generically equivalent drug" has the same meaning as in 188
section 3715.01 of the Revised Code. 189

(V) "Animal shelter" means a facility operated by a humane 190
society or any society organized under Chapter 1717. of the 191
Revised Code or a dog pound operated pursuant to Chapter 955. of 192
the Revised Code. 193

(W) "Food" has the same meaning as in section 3715.01 of the 194
Revised Code. 195

Section 2. That existing section 4729.01 of the Revised Code 196
is hereby repealed. 197