

**As Introduced**

**132nd General Assembly**

**Regular Session**

**2017-2018**

**H. B. No. 642**

**Representative Gonzales**

**Cosponsor: Representative Brinkman**

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**A BILL**

To amend sections 3715.63, 4729.16, and 4729.37 and 1  
to enact sections 3715.75 and 4729.371 of the 2  
Revised Code to classify as adulterated a 3  
nonprescription diabetes test device that was 4  
not purchased or acquired directly from the 5  
device's manufacturer or an authorized 6  
distributor, to establish recordkeeping and 7  
other requirements for pharmacists who dispense 8  
nonprescription diabetes test devices, and to 9  
declare an emergency. 10

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

**Section 1.** That sections 3715.63, 4729.16, and 4729.37 be 11  
amended and sections 3715.75 and 4729.371 of the Revised Code be 12  
enacted to read as follows: 13

**Sec. 3715.63.** (A) A drug or device is adulterated within 14  
the meaning of sections 3715.01 and 3715.52 to 3715.72 of the 15  
Revised Code, if any of the following apply: 16

(1) It consists, in whole or in part, of any filthy, 17  
putrid, or decomposed substance. 18

(2) It has been produced, processed, prepared, packed, or 19  
held under unsanitary conditions whereby it may have been 20  
contaminated with filth, or whereby it may have been rendered 21  
injurious to health. 22

(3) It is a drug and its container is composed, in whole 23  
or in part, of any poisonous or deleterious substance that may 24  
render the contents injurious to health. 25

(4) It is a drug and it bears or contains, for purposes of 26  
coloring only, a coal-tar color other than one from a batch 27  
certified under authority of the "Federal Food, Drug, and 28  
Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as 29  
amended. 30

(5) It purports to be or is represented as a drug the name 31  
of which is recognized in the United States pharmacopoeia and 32  
national formulary, or any supplement to them, and its strength 33  
differs from or its quality or purity falls below the standard 34  
set forth in those compendiums. A determination as to strength, 35  
quality, or purity shall be made in accordance with the tests or 36  
methods of assay set forth in the compendiums, or in the absence 37  
or inadequacy of such tests or methods of assay, those 38  
prescribed under the authority of the "Federal Food, Drug, and 39  
Cosmetic Act." A drug recognized in the compendiums is not 40  
adulterated under this division because it differs from the 41  
standard of strength, quality, or purity set forth for that drug 42  
in the compendiums, if the difference in strength, quality, or 43  
purity is plainly stated on its label. Whenever a drug is 44  
recognized in both the homoeopathic pharmacopoeia of the United 45  
States and in the United States pharmacopoeia and national 46  
formulary, including their supplements, it shall be subject to 47  
the requirements of the United States pharmacopoeia and national 48

formulary unless it is labeled and offered for sale as a 49  
homoeopathic drug, in which case it shall be subject to the 50  
provisions of the homoeopathic pharmacopoeia of the United 51  
States and not to those of the United States pharmacopoeia and 52  
national formulary. 53

(6) It is not subject to the provisions of division (A) (5) 54  
of this section, and its strength differs from or its purity or 55  
quality falls below that which it purports or is represented to 56  
possess. 57

(7) It is a drug and any substance has been: 58

(a) Mixed or packed with the drug so as to reduce the 59  
drug's quality or strength; 60

(b) Substituted wholly or in part for the drug. 61

(8) It is a nonprescription diabetes test device, as 62  
defined in section 3715.75 of the Revised Code, and the device 63  
is not purchased or acquired either directly from the device's 64  
manufacturer or one of the manufacturer's authorized 65  
distributors identified under section 3715.75 of the Revised 66  
Code. 67

(B) An expired drug is not adulterated within the meaning 68  
of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code 69  
if the drug is donated pursuant to sections 3715.88 to 3715.92 70  
of the Revised Code. 71

Sec. 3715.75. As used in this section, "nonprescription 72  
diabetes test device" means a glucose meter or test strip that 73  
is for use in the treatment of individuals with diabetes or 74  
prediabetes, that may be sold without a prescription, and that 75  
is labeled for consumer use. 76

Each manufacturer of nonprescription diabetes test devices 77  
shall publish on its internet web site the names of each of its 78  
authorized distributors of the devices and shall report those 79  
names to the state board of pharmacy. Not later than thirty days 80  
after receiving such a report from a manufacturer, the board 81  
shall publish on its internet web site the names of the 82  
manufacturer's authorized distributors. 83

Each manufacturer shall update the information on its 84  
internet web site any time it makes a change to its list of 85  
authorized distributors and report the change to the board. Both 86  
actions shall be taken not later than thirty days after the 87  
change is made. Not later than thirty days after receiving such 88  
a report from a manufacturer, the board shall publish on its 89  
internet web site an updated list of the manufacturer's 90  
authorized distributors. 91

**Sec. 4729.16.** (A) (1) The state board of pharmacy, after 92  
notice and hearing in accordance with Chapter 119. of the 93  
Revised Code, may impose any one or more of the following 94  
sanctions on a pharmacist or pharmacy intern if the board finds 95  
the individual engaged in any of the conduct set forth in 96  
division (A) (2) of this section: 97

(a) Revoke, suspend, restrict, limit, or refuse to grant 98  
or renew a license; 99

(b) Reprimand or place the license holder on probation; 100

(c) Impose a monetary penalty or forfeiture not to exceed 101  
in severity any fine designated under the Revised Code for a 102  
similar offense, or in the case of a violation of a section of 103  
the Revised Code that does not bear a penalty, a monetary 104  
penalty or forfeiture of not more than five hundred dollars. 105

(2) The board may impose the sanctions listed in division	106
(A) (1) of this section if the board finds a pharmacist or	107
pharmacy intern:	108
(a) Has been convicted of a felony, or a crime of moral	109
turpitude, as defined in section 4776.10 of the Revised Code;	110
(b) Engaged in dishonesty or unprofessional conduct in the	111
practice of pharmacy;	112
(c) Is addicted to or abusing alcohol or drugs or is	113
impaired physically or mentally to such a degree as to render	114
the pharmacist or pharmacy intern unfit to practice pharmacy;	115
(d) Has been convicted of a misdemeanor related to, or	116
committed in, the practice of pharmacy;	117
(e) Violated, conspired to violate, attempted to violate,	118
or aided and abetted the violation of any of the provisions of	119
this chapter, sections 3715.52 to 3715.72 of the Revised Code,	120
Chapter 2925. or 3719. of the Revised Code, or any rule adopted	121
by the board under those provisions;	122
(f) Permitted someone other than a pharmacist or pharmacy	123
intern to practice pharmacy;	124
(g) Knowingly lent the pharmacist's or pharmacy intern's	125
name to an illegal practitioner of pharmacy or had a	126
professional connection with an illegal practitioner of	127
pharmacy;	128
(h) Divided or agreed to divide remuneration made in the	129
practice of pharmacy with any other individual, including, but	130
not limited to, any licensed health professional authorized to	131
prescribe drugs or any owner, manager, or employee of a health	132
care facility, residential care facility, or nursing home;	133

(i) Violated the terms of a consult agreement entered into pursuant to section 4729.39 of the Revised Code;	134 135
(j) Committed fraud, misrepresentation, or deception in applying for or securing a license issued by the board under this chapter or under Chapter 3715. or 3719. of the Revised Code;	136 137 138 139
(k) Failed to comply with an order of the board or a settlement agreement;	140 141
(l) Engaged in any other conduct for which the board may impose discipline as set forth in rules adopted under section 4729.26 of the Revised Code.	142 143 144
(B) Any individual whose license is revoked, suspended, or refused, shall return the license to the offices of the state board of pharmacy within ten days after receipt of notice of such action.	145 146 147 148
(C) As used in this section:	149
"Unprofessional conduct in the practice of pharmacy" includes any of the following:	150 151
(1) Advertising or displaying signs that promote dangerous drugs to the public in a manner that is false or misleading;	152 153
(2) Except as provided in section 4729.281 or 4729.44 of the Revised Code, the dispensing or sale of any drug for which a prescription is required, without having received a prescription for the drug;	154 155 156 157
(3) Knowingly dispensing medication pursuant to false or forged prescriptions;	158 159
(4) Knowingly failing to maintain complete and accurate	160

records of all dangerous drugs received or dispensed in 161  
compliance with federal laws and regulations and state laws and 162  
rules; 163

(5) Obtaining any remuneration by fraud, 164  
misrepresentation, or deception; 165

(6) Failing to conform to prevailing standards of care of 166  
similar pharmacists or pharmacy interns under the same or 167  
similar circumstances, whether or not actual injury to a patient 168  
is established; 169

(7) Submitting a claim for payment for a nonprescription 170  
diabetes test device to a health insurer, government entity, 171  
pharmacy benefit manager as defined in section 3959.01 of the 172  
Revised Code, or any other third-party payer as defined in 173  
section 3901.38 of the Revised Code when the pharmacist or 174  
pharmacy intern knew or reasonably should have known that the 175  
dispensed device was adulterated as described in division (A) (8) 176  
of section 3715.63 of the Revised Code; 177

(8) Knowingly failing to maintain and retain records of 178  
the acquisition and sale of nonprescription diabetes test 179  
devices in accordance with section 4729.371 of the Revised Code; 180

(9) Engaging in any other conduct that the board specifies 181  
as unprofessional conduct in the practice of pharmacy in rules 182  
adopted under section 4729.26 of the Revised Code. 183

(D) The board may suspend a license under division (B) of 184  
section 3719.121 of the Revised Code by utilizing a telephone 185  
conference call to review the allegations and take a vote. 186

(E) For purposes of this division, an individual 187  
authorized to practice as a pharmacist or pharmacy intern 188  
accepts the privilege of practicing in this state subject to 189

supervision by the board. By filing an application for or 190  
holding a license to practice as a pharmacist or pharmacy 191  
intern, an individual gives consent to submit to a mental or 192  
physical examination when ordered to do so by the board in 193  
writing and waives all objections to the admissibility of 194  
testimony or examination reports that constitute privileged 195  
communications. 196

If the board has reasonable cause to believe that an 197  
individual who is a pharmacist or pharmacy intern is physically 198  
or mentally impaired, the board may require the individual to 199  
submit to a physical or mental examination, or both. The expense 200  
of the examination is the responsibility of the individual 201  
required to be examined. 202

Failure of an individual who is a pharmacist or pharmacy 203  
intern to submit to a physical or mental examination ordered by 204  
the board, unless the failure is due to circumstances beyond the 205  
individual's control, constitutes an admission of the 206  
allegations and a suspension order shall be entered without the 207  
taking of testimony or presentation of evidence. Any subsequent 208  
adjudication hearing under Chapter 119. of the Revised Code 209  
concerning failure to submit to an examination is limited to 210  
consideration of whether the failure was beyond the individual's 211  
control. 212

If, based on the results of an examination ordered under 213  
this division, the board determines that the individual's 214  
ability to practice is impaired, the board shall suspend the 215  
individual's license or deny the individual's application and 216  
shall require the individual, as a condition for an initial, 217  
continued, reinstated, or renewed license to practice, to submit 218  
to a physical or mental examination and treatment. 219



An order of suspension issued under this division shall 220  
not be subject to suspension by a court during pendency of any 221  
appeal filed under section 119.12 of the Revised Code. 222

(F) If the board is required under Chapter 119. of the 223  
Revised Code to give notice of an opportunity for a hearing and 224  
the applicant or licensee does not make a timely request for a 225  
hearing in accordance with section 119.07 of the Revised Code, 226  
the board is not required to hold a hearing, but may adopt a 227  
final order that contains the board's findings. In the final 228  
order, the board may impose any of the sanctions listed in 229  
division (A) of this section. 230

(G) Notwithstanding the provision of division (C) (2) of 231  
section 2953.32 of the Revised Code specifying that if records 232  
pertaining to a criminal case are sealed under that section the 233  
proceedings in the case must be deemed not to have occurred, 234  
sealing of the following records on which the board has based an 235  
action under this section shall have no effect on the board's 236  
action or any sanction imposed by the board under this section: 237  
records of any conviction, guilty plea, judicial finding of 238  
guilt resulting from a plea of no contest, or a judicial finding 239  
of eligibility for a pretrial diversion program or intervention 240  
in lieu of conviction. The board shall not be required to seal, 241  
destroy, redact, or otherwise modify its records to reflect the 242  
court's sealing of conviction records. 243

(H) No pharmacist or pharmacy intern shall knowingly 244  
engage in any conduct described in divisions (A) (2) (b) or (A) (2) 245  
(e) to (l) of this section. 246

**Sec. 4729.37.** A copy of an original prescription may only 247  
be filled in accordance with the rules and regulations adopted 248  
by the state board of pharmacy. 249

Prescriptions received electronically or by word of mouth, 250  
telephone, telegraph, or other means of communication shall be 251  
recorded in writing by the pharmacist and the record so made by 252  
the pharmacist shall constitute the original prescription to be 253  
filled by the pharmacist. ~~All~~ 254

All prescriptions shall be preserved on file at the 255  
pharmacy for a period of three years, subject to inspection by 256  
the proper officers of the law. 257

Sec. 4729.371. As used in this section, "nonprescription 258  
diabetes test device" has the same meaning as in section 3715.75 259  
of the Revised Code. 260

In the case of a pharmacist who dispenses nonprescription 261  
diabetes test devices pursuant to prescriptions, the pharmacist 262  
shall maintain complete and accurate records of the pharmacist's 263  
acquisition of the devices and of the sale of the devices. The 264  
records are in addition to the records of the prescriptions for 265  
the devices that are preserved in accordance with section 266  
4729.37 of the Revised Code. 267

Each record of the acquisition or sale of nonprescription 268  
diabetes test devices shall be retained for at least three years 269  
from the date of the acquisition or sale. 270

All records maintained and retained under this section 271  
shall be made available during business hours for inspection by 272  
the proper officers of the law. 273

**Section 2.** That existing sections 3715.63, 4729.16, and 274  
4729.37 of the Revised Code are hereby repealed. 275

**Section 3.** As used in this section, "nonprescription 276  
diabetes test device" has the same meaning as in section 3715.75 277  
of the Revised Code. 278

In the case of a manufacturer of nonprescription diabetes test devices in operation on the effective date of this act, the manufacturer shall comply not later than thirty days after the effective date of this act with the requirements of section 3715.75 of the Revised Code to publish on its Internet web site the names of each of its authorized distributors of the devices and to report those names to the State Board of Pharmacy.

**Section 4.** This act is hereby declared to be an emergency measure necessary for the immediate preservation of the public peace, health, and safety. The reason for such necessity is to prevent the purchase or acquisition of nonprescription diabetes test devices that may have been tampered with or improperly stored and, if used, could jeopardize the health of individuals who rely on the devices for accurate blood-glucose level monitoring.