As Introduced

132nd General Assembly
Regular Session
2017-2018

H. B. No. 642

Representative Gonzales
Cosponsor: Representative Brinkman

A BILL

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Revoke, suspend, restrict, limit, or refuse to grant or 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 moral turpitude, as defined in section 4776.10 of the Revised Code;

(b) Engaged in dishonesty or unprofessional conduct in the practice of pharmacy;

(c) Is addicted to or abusing alcohol or drugs or is impaired physically or mentally to such a degree as to render the pharmacist or pharmacy intern unfit to practice pharmacy;

(d) Has been convicted of a misdemeanor related to, or committed in, the practice of pharmacy;

(e) Violated, conspired to violate, attempted to violate, or aided and abetted the violation of any of the provisions of this chapter, sections 3715.52 to 3715.72 of the Revised Code, Chapter 2925. or 3719. of the Revised Code, or any rule adopted by the board under those provisions;

(f) Permitted someone other than a pharmacist or pharmacy intern to practice pharmacy;

(g) Knowingly lent the pharmacist's or pharmacy intern's name to an illegal practitioner of pharmacy or had a professional connection with an illegal practitioner of pharmacy;

(h) Divided or agreed to divide remuneration made in the practice of pharmacy with any other individual, including, but not limited to, any licensed health professional authorized to prescribe drugs or any owner, manager, or employee of a health care facility, residential care facility, or nursing home;

(i) Violated the terms of a consult agreement entered into pursuant to section 4729.39 of the Revised Code;

(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;

(k) Failed to comply with an order of the board or a settlement agreement;

(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.

(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.

(C) As used in this section:

"Unprofessional conduct in the practice of pharmacy" includes any of the following:

(1) Advertising or displaying signs that promote dangerous drugs to the public in a manner that is false or misleading;

(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;

(3) Knowingly dispensing medication pursuant to false or forged prescriptions;

(4) Knowingly failing to maintain complete and accurate

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

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

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

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

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

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

(D) The board may suspend a license 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.

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

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

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

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 not be subject to suspension by a court during pendency of any appeal filed under section 119.12 of the Revised Code.

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

(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 action or any sanction imposed by the board under this section: records of any conviction, guilty plea, judicial finding of guilt resulting from a plea of no contest, or a judicial finding of eligibility for a pretrial diversion program or intervention in lieu of conviction. The board shall not be required to seal, destroy, redact, or otherwise modify its records to reflect the court's sealing of conviction records.

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

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

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

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

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

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

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

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

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

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

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.