AMENDED IN SENATE JUNE 13, 2017

AMENDED IN ASSEMBLY MAY 26, 2017

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CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL No. 602

Introduced by Assembly Member Bonta

February 14, 2017

An act to amend Sections 4057, 4081, and 4301 of, and to add Sections ~~4025.2~~ *4025.2*, *4084.1*, and 4160.5 to, the Business and Professions Code, relating to pharmacy, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 602, as amended, Bonta. Pharmacy: nonprescription diabetes test devices.

The Pharmacy Law provides for the licensing and regulation of the practice of pharmacy by the California State Board of Pharmacy within the Department of Consumer Affairs. That law authorizes the board to take disciplinary action against any holder of a license who is guilty of unprofessional conduct, as described, or whose license has been issued by mistake. That law also requires the records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices to be open for inspection during business hours and preserved for at least 3 years, as specified. *That law authorizes a board inspector to embargo any dangerous drug or dangerous device that the board inspector finds or has probable cause to believe is adulterated, misbranded, or counterfeit.* Under that law, a person who

fails to maintain or produce those records and who violates any provision of that law, when no other penalty is provided, is guilty of a crime.

This bill would make it unprofessional conduct for a licensee to *acquire a nonprescription diabetes test device from a person that the licensee knew or should have known was not the nonprescription diabetes test device's manufacturer or manufacturer's authorized distributor or to* submit to specified persons a claim for reimbursement for a nonprescription diabetes test device when the licensee knew or should have known that the diabetes test device was not purchased directly from the manufacturer or from a manufacturer's authorized distributor. *The bill would authorize the board to embargo any nonprescription diabetes test device that a board inspector finds or has probable cause to believe was not purchased directly from the manufacturer or from a manufacturer's authorized distributor, as specified.* The bill would require pharmacies that dispense nonprescription diabetes *test* devices pursuant to prescriptions to retain records of acquisition and sale of those nonprescription diabetes *test* devices for at least 3 years and keep those records open to inspection during business hours, as described above. The bill would require a manufacturer of nonprescription diabetes test devices to make the names of its authorized distributors available on its Internet Web site, to provide those names to the board, and to, within 30 days of making changes, update its Internet Web site and inform the board of the ~~changes.~~ *changes, as specified.* The bill would require the board to post the names of authorized distributors on the board's Internet Web ~~site.~~ *site, as specified.* By expanding the scope of an existing crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: $^2/_3$. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4025.2 is added to the Business and Professions Code, to read:

4025.2. "Nonprescription diabetes test device" means a glucose meter or test strip for use in the treatment of prediabetic or diabetic individuals that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and the federal government.

SEC. 2. Section 4057 of the Business and Professions Code is amended to read:

4057. (a) Except as provided in Section 4006, subdivision (d) of Section 4081, Section 4240, ~~subdivision (t)~~ *subdivisions (t) and (u)* of Section 4301, and Section 4342, this chapter does not apply to the retail sale of nonprescription drugs that are not subject to Section 4022 and that are packaged or bottled in the manufacturer's or distributor's container and labeled in accordance with applicable federal and state drug labeling requirements.

(b) This chapter does not apply to specific dangerous drugs and dangerous devices listed in board regulations, where the sale or furnishing is made to any of the following:

(1) A physician, dentist, podiatrist, pharmacist, medical technician, medical technologist, optometrist, or chiropractor holding a currently valid and unrevoked license and acting within the scope of his or her profession.

(2) A clinic, hospital, institution, or establishment holding a currently valid and unrevoked license or permit under Division 2 (commencing with Section 1200) of the Health and Safety Code, or Chapter 2 (commencing with Section 3300) of Division 3 of, or Part 2 (commencing with Section 6250) of Division 6 of, the Welfare and Institutions Code.

(c) This chapter shall not apply to a home health agency licensed under Chapter 8 (commencing with Section 1725) of, or a hospice licensed under Chapter 8.5 (commencing with Section 1745) of, Division 2 of, the Health and Safety Code, when it purchases, stores, furnishes, or transports specific dangerous drugs and dangerous devices listed in board regulations in compliance with applicable law and regulations including:

(1) Dangerous devices described in subdivision (b) of Section 4022, as long as these dangerous devices are furnished only upon the prescription or order of a physician, dentist, or podiatrist.

(2) Hypodermic needles and syringes.

(3) Irrigation solutions of 50 cubic centimeters or greater.

(d) This chapter does not apply to the storage of devices in secure central or ward supply areas of a clinic, hospital, institution, or establishment holding a currently valid and unrevoked license or permit pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code, or pursuant to Chapter 2 (commencing with Section 3300) of Division 3 of, or Part 2 (commencing with Section 6250) of Division 6 of, the Welfare and Institutions Code.

(e) This chapter does not apply to the retail sale of vitamins, mineral products, or combinations thereof or to foods, supplements, or nutrients used to fortify the diet of humans or other animals or poultry and labeled as such that are not subject to Section 4022 and that are packaged or bottled in the manufacturer's or distributor's container and labeled in accordance with applicable federal and state labeling requirements.

(f) This chapter does not apply to the furnishing of dangerous drugs and dangerous devices to recognized schools of nursing. These dangerous drugs and dangerous devices shall not include controlled substances. The dangerous drugs and dangerous devices shall be used for training purposes only, and not for the cure, mitigation, or treatment of disease in humans. Recognized schools of nursing for purposes of this subdivision are those schools recognized as training facilities by the California Board of Registered Nursing.

SEC. 3. Section 4081 of the Business and Professions Code is amended to read:

4081. (a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a

currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge, responsible manager, or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge, responsible manager, or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) Pharmacies that dispense nonprescription diabetes test devices pursuant to prescriptions shall retain records of acquisition and sale of those nonprescription diabetes *test* devices for at least three years from the date of making. The records shall be at all times during business hours open to inspection by authorized officers of the law.

SEC. 4. Section 4084.1 is added to the Business and Professions Code, to read:

4084.1. The board may embargo any nonprescription diabetes test device that a board inspector finds or has probable cause to believe was not purchased either directly from the manufacturer or from the nonprescription diabetes test device manufacturer's authorized distributors as identified in Section 4160.5. For the purposes of this section, the board shall embargo these products following the same procedures and protections used for adulterated, misbranded, or counterfeit drugs or dangerous devices in Sections 4084, 4085, and 4086.

~~SEC. 4.~~

SEC. 5. Section 4160.5 is added to the Business and Professions Code, to read:

4160.5. ~~On and after January 1, 2018,~~ *Within 30 days of the effective date of the act adding this section,* a manufacturer of a nonprescription diabetes test device shall make the names of its

authorized distributors available on its Internet Web site and shall provide the board with the names of its authorized distributors. ~~The~~ *Within 30 days of receiving that information from a manufacturer of a nonprescription diabetes test device, the* board shall post the names of authorized distributors of nonprescription diabetes test devices on the board's Internet Web site. A manufacturer of a nonprescription diabetes test device shall, within 30 days of making changes to its authorized distributors, update its Internet Web site and inform the board of changes to its authorized distributors. *Within 30 days of receiving notice of any change from a manufacturer of a nonprescription diabetes test device, the board shall post the updated list of the manufacturer's authorized distributors on its Internet Web site.*

~~SEC. 5.~~

SEC. 6. Section 4301 of the Business and Professions Code is amended to read:

4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Procurement of a license by fraud or misrepresentation.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(*l*) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending

the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of

dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code. For purposes of this section, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

(t) The acquisition of a nonprescription diabetes test device from a person that the licensee knew or should have known was not the nonprescription diabetes test device's manufacturer or the manufacturer's authorized distributors as identified in Section 4160.5.

~~(t)~~

(u) The submission of a reimbursement claim for a nonprescription diabetes test device to a pharmaceutical benefit manager, health insurer, government agency, or other third-party payor when the licensee knew or reasonably should have known that the diabetes test device was not purchased either directly from the manufacturer or from the nonprescription diabetes test device manufacturer's authorized distributors as identified in Section ~~4106.5.~~ *4160.5.*

~~SEC. 6.~~

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

~~SEC. 7.~~

SEC. 8. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the California Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to immediately prevent the sale of nonprescription diabetes test devices that may have been tampered with or improperly stored, it is necessary that this act take effect immediately.

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