State of Arizona
Senate
Fifty-fourth Legislature
First Regular Session
2019

CHAPTER 320

SENATE BILL 1536

AN ACT

AMENDING SECTIONS 32-1904 AND 36-2604, ARIZONA REVISED STATUTES; RELATING TO THE ARIZONA STATE BOARD OF PHARMACY.

(TEXT OF BILL BEGINS ON NEXT PAGE)

Be it enacted by the Legislature of the State of Arizona:

Section 1. Section 32-1904, Arizona Revised Statutes, as amended by Senate Bill 1103, section 1, fifty-fourth legislature, first regular session, as transmitted to the governor, is amended to read:

32-1904. Powers and duties of board; immunity

A. The board shall:

1. Make bylaws and adopt rules that are necessary to protect the public and that pertain to the practice of pharmacy, the manufacturing, wholesaling or supplying of drugs, devices, poisons or hazardous substances, the use of pharmacy technicians and support personnel and the lawful performance of its duties.

2. Fix standards and requirements to register and reregister pharmacies, except as otherwise specified.

3. Investigate compliance as to the quality, label and labeling of all drugs, devices, poisons or hazardous substances and take action necessary to prevent the sale of these if they do not conform to the standards prescribed in this chapter, the official compendium or the federal act.

4. Enforce its rules. In so doing, the board or its agents have free access, during the hours reported with the board or the posted hours at the facility, to any pharmacy, manufacturer, wholesaler, third-party logistics provider, nonprescription drug permittee or other establishment in which drugs, devices, poisons or hazardous substances are manufactured, processed, packed or held, or to enter any vehicle being used to transport or hold such drugs, devices, poisons or hazardous substances for the purpose of:

(a) Inspecting the establishment or vehicle to determine whether any provisions of this chapter or the federal act are being violated.

(b) Securing samples or specimens of any drug, device, poison or hazardous substance after paying or offering to pay for the sample.

(c) Detaining or embargoing a drug, device, poison or hazardous substance in accordance with section 32-1994.

5. Examine and license as pharmacists and pharmacy interns all qualified applicants as provided by this chapter.

6. Require each applicant for an initial license to apply for a fingerprint clearance card pursuant to section 41-1758.03. If an applicant is issued a valid fingerprint clearance card, the applicant shall submit the valid fingerprint clearance card to the board with the completed application. If an applicant applies for a fingerprint clearance card and is denied, the applicant may request that the board consider the application for licensure notwithstanding the absence of a valid fingerprint clearance card. The board, in its discretion, may approve an application for licensure despite the denial of a valid fingerprint clearance card if the board determines that the applicant's

criminal history information on which the denial was based does not alone disqualify the applicant from licensure.

7. Issue duplicates of lost or destroyed permits on the payment of a fee as prescribed by the board.

8. Adopt rules to rehabilitate pharmacists and pharmacy interns as provided by this chapter.

9. At least once every three months, notify pharmacies regulated pursuant to this chapter of any modifications on prescription writing privileges of podiatrists, dentists, doctors of medicine, registered nurse practitioners, osteopathic physicians, veterinarians, physician assistants, optometrists and homeopathic physicians of which it receives notification from the state board of podiatry examiners, state board of dental examiners, Arizona medical board, Arizona state board of nursing, Arizona board of osteopathic examiners in medicine and surgery, Arizona state veterinary medical examining board, Arizona regulatory board of physician assistants, state board of optometry or board of homeopathic and integrated medicine examiners.

10. Charge a permittee a fee, as determined by the board, for an inspection if the permittee requests the inspection.

11. Issue only one active or open license per individual.

12. Allow a licensee to regress to a lower level license on written explanation and review by the board for discussion, determination and possible action.

B. The board may:

1. Employ chemists, compliance officers, clerical help and other employees subject to title 41, chapter 4, article 4 and provide laboratory facilities for the proper conduct of its business.

2. Provide, by educating and informing the licensees and the public, assistance in curtailing abuse in the use of drugs, devices, poisons and hazardous substances.

3. Approve or reject the manner of storage and security of drugs, devices, poisons and hazardous substances.

4. Accept monies and services to assist in enforcing this chapter from other than licensees:

(a) For performing inspections and other board functions.

(b) For the cost of copies of the pharmacy and controlled substances laws, the annual report of the board and other information from the board.

5. Adopt rules for professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession of pharmacy.

6. Grant permission to deviate from a state requirement for experimentation and technological advances.

7. Adopt rules for the training and practice of pharmacy interns, pharmacy technicians and support personnel.

8. Investigate alleged violations of this chapter, conduct hearings in respect to violations, subpoena witnesses and take such action as it deems necessary to revoke or suspend a license or a permit, place a licensee or permittee on probation or warn a licensee or permittee under this chapter or to bring notice of violations to the county attorney of the county in which a violation took place or to the attorney general.

9. By rule, approve colleges or schools of pharmacy.

10. By rule, approve programs of practical experience, clinical programs, internship training programs, programs of remedial academic work and preliminary equivalency examinations as provided by this chapter.

11. Assist in the continuing education of pharmacists and pharmacy interns.

12. Issue inactive status licenses as provided by this chapter.

13. Accept monies and services from the federal government or others for educational, research or other purposes pertaining to the enforcement of this chapter.

14. By rule, except from the application of all or any part of this chapter any material, compound, mixture or preparation containing any stimulant or depressant substance included in section 13-3401, paragraph 6, subdivision (c) or (d) from the definition of dangerous drug if the material, compound, mixture or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, provided that such admixtures are included in such combinations, quantity, proportion or concentration as to vitiate the potential for abuse of the substances that do have a stimulant or depressant effect on the central nervous system.

15. Adopt rules for the revocation, suspension or reinstatement of licenses or permits or the probation of licensees or permittees as provided by this chapter.

16. Issue a certificate of free sale to any person that is licensed by the board as a manufacturer for the purpose of manufacturing or distributing food supplements or dietary supplements as defined in rule by the board and that wants to sell food supplements or dietary supplements domestically or internationally. The application shall contain all of the following:

(a) The applicant's name, address, e-mail address, telephone and fax number.

(b) The product's full, common or usual name.

(c) A copy of the label for each product listed. If the product is to be exported in bulk and a label is not available, the applicant shall include a certificate of composition.

(d) The country of export, if applicable.

(e) The number of certificates of free sale requested.

17. Establish an inspection process to issue certificates of free sale or good manufacturing practice certifications. The board shall establish in rule:

(a) A fee to issue certificates of free sale.

(b) A fee to issue good manufacturing practice certifications.

(c) An annual inspection fee.

18. Delegate to the executive director the authority to:

(a) Void a license or permit application and deem all fees forfeited by the applicant if the applicant provided inaccurate information on the application. ~~Except for inaccurate information provided regarding education or criminal history,~~ The applicant shall have the opportunity to correct the inaccurate information within thirty days after the initial application was ~~voided. If the applicant provides inaccurate information regarding education or criminal history and the application is voided, the applicant may submit a new application with all associated fees~~ REVIEWED BY BOARD STAFF AND THE APPLICANT WAS INFORMED OF THE INACCURACY.

(b) If the president or vice president of the board concurs after reviewing the case, enter into an interim consent agreement with a licensee or permittee if there is evidence that a restriction against the license or permit is needed to mitigate danger to the public health and safety. The board ~~shall~~ MAY subsequently formally adopt the interim consent agreement with any modifications the board deems necessary ~~for the agreement to be fully enforceable~~.

(c) Take no action or dismiss a complaint that has insufficient evidence that a violation of statute or rule GOVERNING THE PRACTICE OF PHARMACY occurred.

(d) Request an applicant or licensee to provide court documents and police reports if the applicant or licensee has been charged with or convicted of a criminal offense. The executive director may do either of the following if the applicant or licensee fails to provide the requested documents to the board within ~~fourteen~~ THIRTY business days after the request:

(i) Close the application, deem the application fee forfeited and not consider a new application complete unless the requested documents are submitted with the application.

~~(ii) Suspend the licensee and open a complaint for unprofessional conduct.~~

(ii) NOTIFY THE LICENSEE OF AN OPPORTUNITY FOR A HEARING IN ACCORDANCE WITH SECTION 41-1061 TO CONSIDER SUSPENSION OF THE LICENSEE.

(e) PURSUANT TO SECTION 36-2604, SUBSECTION B, REVIEW PRESCRIPTION INFORMATION COLLECTED PURSUANT TO TITLE 36, CHAPTER 28, ARTICLE 1.

C. At each regularly scheduled board meeting the executive director shall provide to the board a list of the executive director's actions

taken pursuant to subsection B, paragraph 18, subdivisions (a), (c) and (d) of this section since the last board meeting.

D. THE BOARD SHALL DEVELOP SUBSTANTIVE POLICY STATEMENTS PURSUANT TO SECTION 41-1091 FOR EACH SPECIFIC LICENSING AND REGULATORY AUTHORITY THE BOARD DELEGATES TO THE EXECUTIVE DIRECTOR.

~~D.~~ E. The executive director and other personnel or agents of the board are not subject to civil liability for any act done or proceeding undertaken or performed in good faith and in furtherance of the purposes of this chapter.

Sec. 2. Section 36-2604, Arizona Revised Statutes, is amended to read:

36-2604. Use and release of confidential information; definitions

A. Except as otherwise provided in this section, prescription information submitted to the board pursuant to this article is confidential and is not subject to public inspection. The board shall establish procedures to ensure the privacy and confidentiality of patients and that patient information that is collected, recorded and transmitted pursuant to this article is not disclosed except as prescribed in this section.

B. The board or its designee shall review the prescription information collected pursuant to this article. If the board or its designee has reason to believe an act of unprofessional or illegal conduct has occurred, the board or its designee shall notify the appropriate professional licensing board or law enforcement or criminal justice agency and provide the prescription information required for an investigation. THE BOARD MAY DELEGATE THE DUTIES PRESCRIBED IN THIS SUBSECTION TO THE EXECUTIVE DIRECTOR PURSUANT TO SECTION 32-1904.

C. The board may release data collected by the program to the following:

1. A person who is authorized to prescribe or dispense a controlled substance, or a delegate who is authorized by the prescriber or dispenser, to assist that person to provide medical or pharmaceutical care to a patient or to evaluate a patient.

2. An individual who requests the individual's own prescription monitoring information pursuant to section 12-2293.

3. A medical practitioner regulatory board established pursuant to title 32, chapter 7, 11, 13, 14, 15, 16, 17, 18, 25 or 29.

4. A local, state or federal law enforcement or criminal justice agency. Except as required pursuant to subsection B of this section, the board shall provide this information only if the requesting agency states in writing that the information is necessary for an open investigation or complaint.

5. The Arizona health care cost containment system administration AND CONTRACTORS regarding persons who are receiving services pursuant to

~~chapter~~ CHAPTERS 29 AND 34 of this title. Except as required pursuant to subsection B of this section, the board shall provide this information only if the administration OR A CONTRACTOR states in writing that the information is necessary for an open investigation or complaint, for performing a drug utilization review for controlled substances to help combat opioid overuse or abuse or for ensuring the continuity of care.

6. A person who is serving a lawful order of a court of competent jurisdiction.

7. A person who is authorized to prescribe or dispense a controlled substance and who performs an evaluation on an individual pursuant to section 23-1026.

8. A county medical examiner or alternate medical examiner who is directing an investigation into the circumstances surrounding a death as described in section 11-593 or a delegate who is authorized by the county medical examiner or alternate medical examiner.

9. The department of health services regarding persons who are receiving or prescribing controlled substances in order to implement a public health response to address opioid overuse or abuse, including a review pursuant to section 36-198. Except as required pursuant to subsection B of this section, the board shall provide this information only if the department states in writing that the information is necessary to implement a public health response to help combat opioid overuse or abuse.

D. The board may provide data to public or private entities for statistical, research or educational purposes after removing information that could be used to identify individual patients or persons who received prescriptions from dispensers.

E. A PERSON WHO IS AUTHORIZED TO PRESCRIBE OR DISPENSE A CONTROLLED SUBSTANCE OR THE CHIEF MEDICAL OFFICER OF THE ADMINISTRATION OR A CONTRACTOR SHALL DEACTIVATE A DELEGATE WITHIN FIVE BUSINESS DAYS AFTER AN EMPLOYMENT STATUS CHANGE, THE REQUEST OF THE DELEGATE OR THE INAPPROPRIATE USE OF THE CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM'S CENTRAL DATABASE TRACKING SYSTEM.

~~E.~~ F. For the purposes of this section: ~~,~~

1. "ADMINISTRATION" AND "CONTRACTOR" HAVE THE SAME MEANINGS PRESCRIBED IN SECTION 36-2901.

2. "Delegate" means any of the following:

~~1.~~ (a) A licensed health care professional who is employed in the office of or in a hospital with the prescriber or dispenser.

~~2.~~ (b) An unlicensed medical records technician, medical assistant or office manager who is employed in the office of or in a hospital with the prescriber or dispenser and who has received training regarding both the health insurance portability and accountability act privacy standards~~,~~ (45 Code of Federal Regulations part 164, subpart E~~,~~) and security standards~~,~~ (45 Code of Federal Regulations part 164, subpart C).

~~3.~~ (c) A forensic pathologist, medical death investigator or other qualified person who is assigned duties in connection with a death investigation pursuant to section 11-594.

~~4.~~ (d) A licensed pharmacy technician trainee, pharmacy technician or pharmacy intern who works in a facility with the dispenser.

(e) ANY EMPLOYEE OF THE ADMINISTRATION OR A CONTRACTOR WHO IS AUTHORIZED BY THE ADMINISTRATION'S OR CONTRACTOR'S CHIEF MEDICAL OFFICER.

Sec. 3. Controlled substances prescription monitoring program; report; delayed repeal

A. On or before October 1, 2019, the Arizona state board of pharmacy shall convene a committee to analyze and develop appropriate use and accessibility parameters by licensed health care professionals and other delegates referenced in section 36-2604, Arizona Revised Statutes, as amended by this act, for patient information contained in the controlled substances prescription monitoring program.

B. The committee shall be composed of representatives of the department of health services, the Arizona health care cost containment system administration, contractors of the administration, hospitals, prescribers and dispensers.

C. On or before January 1, 2020, the department of health services and the Arizona health care cost containment system administration shall jointly develop and submit to the president of the senate, the speaker of the house of representatives and the governor a report based on the committee's recommendations, including the appropriate use of and accessibility by health care professionals and delegates to the controlled substances prescription monitoring program. The department and the administration shall provide a copy of this report to the secretary of state.

D. This section is repealed from and after June 30, 2020.

Sec. 4. Controlled substances prescription monitoring program; unlicensed delegates; delayed repeal

A. A delegate of the Arizona health care cost containment system administration or a contractor of the administration is not required to hold or obtain a license or certification issued by a health profession regulatory board as a condition of being assigned and provided delegate access to the controlled substances prescription monitoring program pursuant to section 36-2604, Arizona Revised Statutes, as amended by this act, by the Arizona state board of pharmacy.

B. This section is repealed from and after September 30, 2020.

Sec. 5. Conditional enactment

Section 32-1904, Arizona Revised Statutes, as amended by this act, does not become effective unless Senate Bill 1103, section 1, fifty-fourth legislature, first regular session, relating to the Arizona state board of pharmacy, becomes law.

APPROVED BY THE GOVERNOR JUNE 7, 2019.

FILED IN THE OFFICE OF THE SECRETARY OF STATE JUNE 7, 2019.