SENATE FILE NO. SF0121

Wyoming Pharmacy Act-amendments.

Sponsored by: Senator(s) Baldwin and Dockstader and Representative(s) Barlow and Walters

A BILL

for

AN ACT relating to the Wyoming Pharmacy Act; modifying grounds for suspension and revocation of pharmacy licenses; modifying responsibilities of the secretary of the state board of pharmacy; modifying provisions related to examination and reexamination; modifying mailing requirements for license renewal notices and examination notices; removing authorization for the board to credit continuing education units to another year; modifying drug substitution procedures; authorizing pharmacists to dispense biosimilars as specified; modifying definitions; removing obsolete language; repealing provisions related to pharmacist pedigree documents; and providing for an effective date.

Be It Enacted by the Legislature of the State of Wyoming:

Section 1. W.S. 33-24-101(b)(iii), (iv)(F) and (G), 33-24-105, 33-24-113(a)(intro), (d)(intro), (v), (vii) and (viii), 33-24-116(a)(iv), 33-24-119, 33-24-120, 33-24-121(a), (c) and (d)(intro), 33-24-122(a)(viii), 33-24-133, 33-24-134(a)(i), 33-24-141, 33-24-149(a), (b), (d), (e) and by creating a new subsection (f), 33-24-152(a)(intro), (e)(v), (vii) and (viii), 33-24-153(b), (j) and (k)(i)(B) are amended to read:

33-24-101. Short title; definitions.

(b) As used in this act:

(iii) "Collaborative pharmaceutical care" means a pharmacist working in collaboration with ~~physicians and other medical providers~~ practitioners authorized to prescribe medications;

(iv) "Unprofessional conduct" means:

(F) Filling a prescription which is more than ~~two (2) years~~ one (1) year old;

(G) Filling a prescription without reasonable inquiry and confirmation of its validity if there are reasonable grounds to doubt the current existence of a doctor-patient relationship between the ~~prescriber~~ practitioner and the customer seeking to obtain the drug;

33-24-105. State board of pharmacy; oath or affirmation of members.

Each member of the board hereinafter appointed shall, before entering upon the duties of his office, take and subscribe an oath or affirmation that the member will support the constitution and the laws of the United States and the state of Wyoming, and that the member will faithfully perform the duties as a member of the state board of pharmacy. ~~examiners of the state.~~

33-24-113. Licensing of resident pharmacy; exceptions; display of license; suspension, revocation, letter of admonition, administrative penalty or refusal to renew; appeals.

(a) Any pharmacy located in this state which dispenses, mails or in any manner delivers controlled substances or ~~dangerous~~ prescription drugs or devices in this state pursuant to a prescription or provides pharmaceutical care in this state shall:

(d) The board may deny, suspend, revoke or refuse to renew a license issued under ~~the~~ this section, may issue a letter of admonition to a resident pharmacy licensee and may assess an administrative penalty, not to exceed two thousand dollars ($2,000.00) per violation, against a resident pharmacy licensee on any of the following grounds:

(v) Suspension or revocation of a pharmacy license or any other disciplinary action against the licensee in any other state;

(vii) Purchase or receipt of a ~~dangerous~~ prescription drug, controlled substance or medical device from a source other than a manufacturer, wholesaler or pharmacy licensed by the board;

(viii) Purchase or receipt of a ~~dangerous~~ prescription drug, controlled substance or medical device that is not approved by the federal food and drug administration;

33-24-116. Qualifications of applicants for licensure as a pharmacist by examination.

(a) Any person seeking licensure by examination to practice pharmacy in this state may make application in writing to the board. The applicant shall:

(iv) Have graduated and received ~~the first~~ professional ~~undergraduate~~ degree from a college or school of pharmacy that has been approved by the board or have graduated from a foreign college of pharmacy. Graduates from a foreign college of pharmacy shall have completed a transcript verification program, taken and passed a college of pharmacy equivalency exam and completed a communication ability test as provided in board regulations;

33-24-119. Reexamination fees; no refund of fees; notice of results of examination; application for reexamination.

(a) All reexamination fees shall be the same as the current fee for the initial examination to be paid to the ~~secretary of the~~ board. Before such examination is had, the fee must be paid, and in no case shall the examination or reexamination fee be refunded.

(b) The applicant shall be informed within a reasonable time if he passed or failed to pass the examination. ~~A notification as aforesaid shall be made by mail to the address furnished therefor by applicant in his application.~~

(c) An applicant who fails in his examination shall have the privilege, if he so desires, of applying to the board for a reexamination. ~~at the next scheduled examination meeting.~~ This application shall be made in writing and shall be accompanied with the proper fee.

33-24-120. Records as prima facie evidence.

The board shall keep a record in which shall be recorded the names and addresses and pertinent information of all applicants and such other matters as shall afford a full record of its activities; the records or transcripts therefrom, duly certified by the ~~secretary of the~~ board, shall be prima facie evidence before all the courts of this state of the entries therein contained.

33-24-121. Renewal license certificate; late fee; expiration upon failure to renew; reinstatement; continuing professional education requirement for renewal; reduction or exception determined by board.

(a) On or before December 31 of each year, any pharmacist licensed to practice pharmacy in this state shall transmit to the ~~secretary of the~~ board his signature, registration number and address together with proof of compliance with subsection (d) of this section, the annual fee determined by the board and the relevant information pertaining to criminal, substance abuse, professional liability and licensure history. Upon receipt and

compliance with all requirements, the ~~secretary~~ board shall issue a renewal license certificate.

(c) If the licensee fails to secure the renewal certificate before December 31, the license to practice expires ten (10) days after mailing of written notice to renew sent to the holder by certified mail~~, return receipt requested,~~ to the address last recorded for the licensee with the ~~secretary~~ board. An expired license may be restored by the board upon compliance with this section not later than March 31 following expiration of the license.

(d) The board may require that any person applying for renewal in accordance with subsection (a) of this section shall satisfactorily complete not less than six (6) nor more than fifteen (15) contact hours or not less than three-fifths (3/5) of one (1) continuing education unit nor more than one and one-half (1 1/2) continuing education units of approved continuing pharmaceutical education courses each year. For purposes of this subsection, one (1) continuing education unit is equivalent to ten (10) contact hours. No hours or units used for one (1) year shall apply to any other year. ~~The board may allow hours completed in~~

~~one (1) year to be credited to another year.~~ The board shall promulgate rules and regulations necessary to administer this subsection and may reduce or make exception to the requirements of this subsection for the initial year of application and for emergency or hardship cases. The board may require a person licensed as an inactive pharmacist, who seeks to be licensed as an active pharmacist, to:

33-24-122. Revocation or suspension of license and registration; letter of admonition; summary suspension; administrative penalties; probation; grounds.

(a) The license and registration of any pharmacist may be revoked or suspended by the board of pharmacy or the board may issue a letter of admonition, refuse to issue or renew any license or require successful completion of a rehabilitation program or issue a summary suspension for any of the following causes:

(viii) If the person's registration or license to practice has been refused, ~~or~~ lapsed for cause, ~~or~~ expired for cause, ~~or~~ revoked for cause, or suspended for

cause in this or any other jurisdiction or if the person has otherwise been disciplined in this or any other jurisdiction;

33-24-133. Association with boards of pharmacy of other jurisdictions.

In order to be informed and to determine the status of boards of pharmacy of other jurisdictions which desire to effect arrangements for reciprocal registration of pharmacists, and in order to also be advised regarding fitness of applicants, and of the progress and changes in pharmacy throughout the country, the board may annually select at least one (1) of its members to meet with like representatives from other jurisdictions, and may join in creating and maintaining an association for such mutual ends, and in its discretion the board may contribute such information as it possesses which is useful to such aims and objects. Additionally, the board may subscribe for and secure the services of associations engaged in the compilation of pharmaceutical information, knowledge and progress, specially adapted to secure excellence and efficiency in the work of the board.

33-24-134. Reciprocity.

(a) The board, in its sole discretion, may license as a pharmacist in this state without examination, any person who proposes to practice pharmacy in this state who is duly licensed by examination in some other state. An applicant for a license pursuant to this section shall:

(i) Submit ~~a written~~ an application in the form and containing information as prescribed by the board;

33-24-141. Use of letters "RPh" or word "pharmacist".

Whenever any person shall append the letters "~~R. Ph.~~ RPh" or word "pharmacist" or such similar designation to his name in any way, for advertising, or upon any card, stationery, door or sign, or occasion either of the same to be done, the same shall be prima facie evidence that such person is ~~engaged in the practice of pharmacy and~~ subject to the regulations and convictions and penalties of this act.

33-24-149. Drug substitution procedures.

(a) A pharmacist who receives a prescription for a brand name ~~dangerous~~ prescription drug may dispense any generically equivalent drug of the brand name ~~dangerous~~ prescription drug prescribed, unless the prescribing practitioner has clearly indicated substitution is not permitted.~~, if the drug to be dispensed has a lower, regular and customary retail price than the brand name dangerous drug prescribed, as provided in W.S. 33-24-148.~~

(b) If a physician prescribes a ~~dangerous~~ prescription drug by its generic name, the pharmacist ~~shall~~ may dispense the ~~lowest retail cost brand in stock which is~~ generically equivalent drug as defined in this act.

(d) The national drug code number or the name of the manufacturer or distributor of the generic drug dispensed shall be noted on the prescription ~~memorandum~~ record by the pharmacist.

(e) A prescription dispensed by a pharmacist shall bear upon the label the name of the medication in the

container except if the prescriber ~~writes~~ orders "do not label", or words of similar import, on the prescription ~~memorandum~~ or so designates in an oral or electronic transmission of the prescription.

(f) A pharmacist who receives a prescription for a biological product may dispense a biosimilar in accordance with the following:

(i) A pharmacist shall only dispense a biosimilar pursuant to this subsection that has been licensed by the federal food and drug administration as interchangeable with the prescribed product;

(ii) A pharmacist shall not dispense an interchangeable biosimilar pursuant to this subsection if:

(A) The prescriber indicates the substitute of the interchangeable biosimilar is not authorized by specifying on the prescription "brand medically necessary"; or

(B) The patient insists on the dispensing of the prescribed biological product.

(iii) In the case of an oral prescription, the prescriber's oral dispensing instructions regarding dispensing of an interchangeable biosimilar shall be followed;

(iv) When a pharmacist dispenses an interchangeable biosimilar in the place of a prescribed biological product, the pharmacist or his designee shall inform the patient prior to dispensing the interchangeable biosimilar;

(v) The pharmacist or his designee shall indicate, unless otherwise directed by the prescriber, on both the record of dispensing and the prescription label, the brand name or, in the case of an interchangeable biosimilar, the product name and the name of the manufacturer or distributor of the interchangeable biosimilar;

(vi) Whenever a pharmacist substitutes an interchangeable biosimilar pursuant to a prescription written for a brand name product, the pharmacist or his designee shall label the drug with the name of the interchangeable biosimilar followed by the words "Substituted for" and the name of the biological product for which the prescription was written;

(vii) Records of substitutions of interchangeable biosimilars shall be maintained by the pharmacist for a period of not less than two (2) years from the date of dispensing;

(viii) For purposes of this subsection:

(A) "Biological product" means a product that is derived from a living organism source such as humans, animals, microorganisms or yeast;

(B) "Biosimilar" means a biological product that is highly similar to a specific reference biological product notwithstanding minor differences in clinically inactive compounds, such that there are no clinically

meaningful differences between the reference biological product and the biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. section 262(k);

(C) "Interchangeable" means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. section 262(k)(4);

(D) "Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. section 262(a) against which a biological product is evaluated in an application submitted to the federal food and drug administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. section 262(k).

33-24-152. Nonresident pharmacy registration; requirements for registration; fees; renewal; denial, letter of admonition, administrative penalty, revocation or suspension; advertising.

(a) Any pharmacy located outside this state which ships, mails or delivers, in any manner, controlled

substances or ~~dangerous~~ prescription drugs or devices into this state pursuant to a prescription or provides pharmaceutical care to a resident of this state shall be considered a nonresident pharmacy, shall obtain a license from the board, and shall:

(e) The board may deny, suspend, revoke or refuse to renew a license issued under this section, may issue a letter of admonition to a nonresident pharmacy licensee and may assess an administrative penalty, not to exceed two thousand dollars ($2,000.00) per violation, against a nonresident pharmacy licensee on any of the following grounds:

(v) Suspension or revocation of a pharmacy license or any other disciplinary action against the licensee in any other state;

(vii) Purchase or receipt of a ~~dangerous~~ prescription drug, controlled substance or medical device from a source other than a manufacturer, wholesaler or pharmacy licensed by the regulatory authority in the state where the pharmacy is located;

(viii) Purchase or receipt of a ~~dangerous~~ prescription drug, controlled substance or medical device that is not approved by the federal food and drug administration;

33-24-153. Manufacturer or wholesaler registration; requirements for registration; bonds or other security; fees; renewal; denial, revocation or suspension; record keeping; summary orders; administrative penalties; definitions.

(b) Applications for a drug distributor's license under this section shall be made on a form furnished by the board. ~~By January 1, 2009, current license holders and~~ Applicants for licensure under this section shall provide the board with fingerprints, necessary fees and other information required to perform a criminal history record background check as provided for by W.S. 7-19-201 for the designated representative for each wholesale drug distributor site.

(j) The board shall require each person engaged in wholesale distribution of prescription drugs to establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of the drugs. ~~The records shall include pedigrees for all prescription drugs that are or ever have been distributed outside the normal distribution channel as established by board regulations.~~

(k) The board shall issue an order to cease distribution of a prescription drug if the board finds that there is probable cause that:

(i) A drug distributor has:

(B) ~~Falsified a pedigree or~~ Sold, distributed, transferred, manufactured, repackaged, handled or held a counterfeit prescription drug intended for human or animal use.

Section 2. W.S. 33-24-132 and 33-24-153(n)(iii) and (r)(ii) are repealed.

Section 3. This act is effective July 1, 2017.

(END)