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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
10/21/2019 3:24 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Implements legislative changes for various rules by adoption, amend or repeal.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/26/2019 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 11/26/2019

TIME: 9:30 AM

OFFICER: Rachel Melvin

ADDRESS: Portland State Office

Building - Conf. Rm 1A

800 NE Oregon St.

Portland, OR 97232

NEED FOR THE RULE(S):

2019 HB 3030 & 2019 SB 688 adds military spouse/domestic partner temporary authorization for licensure. 2019 SB 855 encourages reducing licensure barriers for immigrants or refugees. ORS 689.689 sunsets age 18 contraceptive requirement. 2019 SB 910 amends/repeals rules to naloxone access in Oregon pharmacies.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

2019 HB 3030 & 2019 SB 688, 2019 SB 855, ORS 689.689 and 2019 SB 910.

FISCAL AND ECONOMIC IMPACT:

The military spouse/domestic partner temporary authorization will not generate an additional fiscal impact to the licensing fees required by individuals. Foreign Pharmacy Graduates will no longer have to mail their original certificate to the Board, this is a cost savings. There is no negative fiscal impact on outlets that offer contraceptive services. Pharmacies providing naloxone services shall provide written notice in a conspicuous manner that the drug and medical supplies are available; dispensing and prescribing costs associated with this drug could be impacted.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the

rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

There are less than 200 pharmacy outlets that report as a small business in Oregon. New naloxone requirements may result in additional costs to provide notice as required by 2019 SB 910.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were not involved in the development of these rules; revisions are legislatively required.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

Revisions are legislatively required.

RULES PROPOSED:

855-010-0130, 855-019-0150, 855-019-0420, 855-019-0450, 855-019-0455, 855-019-0460, 855-031-0010, 855-041-2300, 855-041-2340

ADOPT: 855-010-0130

RULE SUMMARY: New rules are proposed to Division 010 to address directives of 2019 HB 3030 and 2019 SB 688, to provide the spouse or domestic partner of a member of the U.S. Armed Forces stationed in Oregon a temporary authorization to practice their healthcare profession. The spouse or domestic partner must hold a current active license in good standing by another state with substantially similar requirements and must have demonstrated competency in the profession. To implement the bills, the proposed language allows issuance of a temporary authorization for a license. The law is effective January 1, 2020.

CHANGES TO RULE:

855-010-0130

Military Spouse or Domestic Partner

(1) "Military spouse or domestic partner" means a spouse or domestic partner of an active member of the Armed Forces of the United States who is the subject of a military transfer to Oregon. ¶

(2) To qualify for licensure under this rule, the military spouse or domestic partner must meet the following requirements: ¶

(a) Meet the qualifications for licensure as stated in OAR Division 855-019 or OAR 855-025.¶

(b) Be married to, or in a domestic partnership with, a member of the Armed Forces of the United States who is assigned to a duty station located in Oregon by official active duty military order;¶

(c) Applicant must complete an application for licensure, provide the Board with a valid email address, and complete and pass a national fingerprint-based criminal background check;¶

(d) Provide evidence of current licensure as a pharmacist or pharmacy technician issued by another state;¶

(e) Provide to the Board, in a manner determined by the Board, sufficient proof that the person is in good standing with the issuing out-of-state professional licensing board; and ¶

(f) Demonstrate competency as a pharmacist or pharmacy technician by having at least one year of active practice during the three years immediately preceding the application.¶

(3) A temporary authorization under this section is valid until the earliest of the following: ¶

(a) Two years after the date of issuance; ¶

(b) The date the spouse or domestic partner of the person to whom the authorization was issued completes their term of service in this state; or¶

(c) The date the person's authorization issued by the other state expires.¶

(4) A temporary authorization issued under this section is not renewable.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.265, 2019 OL Ch. 142, 2019 OL Ch. 626

AMEND: 855-019-0150

RULE SUMMARY: The requirement to provide the original FPGEC certificate is a potential barrier to licensure for foreign pharmacy graduates (who could be immigrants or refugees).

CHANGES TO RULE:

855-019-0150

Foreign Pharmacy Graduates ¶¶

(1) Foreign Pharmacy Graduates applying for licensure in Oregon must meet the following requirements:¶¶

(a) Provide a copy of a valid visa permitting full time employment;¶¶

(b) Provide a copy of the original certificate issued by the NABP Foreign Pharmacy Graduate Examination Committee (FPGEC); and¶¶

(c) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam with a score of not less than 75. A candidate who does not attain this score may retake the exam after a minimum of 91 days. This score shall only be valid for one year unless the Board grants an extension;¶¶

(d) After having completed the required number of intern hours, pass the MPJE with a score of not less than 75. A candidate who does not attain this score may retake the exam after a minimum of 30 days. The MPJE score shall only be valid for 6 months unless extended by the Board.¶¶

(2) An applicant must complete 1440 hours in pharmacy practice as an intern that must be certified to the Board by the preceptors.¶¶

(3) An applicant may not count internship hours or practice as a pharmacist completed outside the United States toward Oregon's internship requirement.¶¶

(4) An applicant may not count internship hours or practice as a pharmacist that is completed before passing the Foreign Pharmacy Graduate Equivalency Examination (FPGEE), and either the TOEFL with TSE, or TOEFL (IBT) exams toward Oregon's internship requirement.¶¶

(5) The Board may waive any requirement of this rule if a waiver will further public health or safety. A waiver granted under this section shall only be effective when it is issued in writing.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.255

REPEAL: 855-019-0420

RULE SUMMARY: Repeal due to ORS 689.689 sunset provision effective 1/1/2020 which restricted prescribing to a person younger than 18 years old.

CHANGES TO RULE:

~~855-019-0420~~

~~Contraceptive – Delivery of Care: Age Requirements ¶¶~~

~~A pharmacist may prescribe injectable hormonal contraceptives and self-administered hormonal contraceptives to a person who is:¶¶~~

~~(1) At least 18 years of age; or¶¶~~

~~(2) Under 18 years of age, only if the person has evidence of a previous prescription from a primary care practitioner or women's health care practitioner for a hormonal contraceptive patch or self-administered oral hormonal contraceptive.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.005, 689.683~~

REPEAL: 855-019-0450

RULE SUMMARY: Repeal; rule language condensed

CHANGES TO RULE:

~~855-019-0450~~

~~Purpose~~

~~The purpose of OAR 855-019-0450 through 855-019-0460 is to develop standard procedures for the prescribing and recordkeeping of naloxone by a pharmacist in Oregon.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.305, 689.681, 2016 OL Ch. 100~~

REPEAL: 855-019-0455

RULE SUMMARY: Repeal; rule language condensed

CHANGES TO RULE:

~~855-019-0455~~

~~Naloxone – Qualifications ¶~~

~~A pharmacist acting in good faith, exercising reasonable care and who is educated in opiate overdose and naloxone rescue can prescribe naloxone and the necessary medical supplies to administer the naloxone.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.305, 689.681, 2016 OL Ch. 100, 2017 OL Ch. 683~~

AMEND: 855-019-0460

RULE SUMMARY: Rule edits are proposed to Divisions 019 to address directives of 2019 SB 910, related to naloxone access in Oregon pharmacies. Statutory changes to Oregon's naloxone laws intend to reduce barriers and increase access to naloxone, the life-saving opiate reversal drug. Language in Division 019 is condensed and allows for a pharmacist to offer naloxone to a patient when filling an opioid prescription for greater than 50 morphine milligram equivalents (MME) per day dosage.

CHANGES TO RULE:

855-019-0460

Naloxone - Delivery of Care and Prescribing ¶¶

(1) A pharmacist, having determined that there is an identified medical need, can prescribe naloxone and the necessary medical supplies ~~for opiate overdose training.~~¶¶

~~(2) A pharmacist can prescribe naloxone and the necessary medical supplies to an individual or~~ to administer naloxone for opiate overdose: ¶¶

(a) When dispensing any opiate or opioid prescription in excess of 50 morphine milligram equivalents (MME);¶¶

(b) To an individual seeking naloxone;¶¶

(c) To an entity seeking naloxone.¶¶

~~(32)~~ The pharmacist shall determine that the individual (or the individual on behalf of an entity) seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.¶¶

~~(43)~~ The pharmacist may prescribe naloxone in any FDA approved dosage form and the necessary medical supplies needed to administer naloxone.¶¶

~~(54)~~ The pharmacist shall dispense the naloxone product in a properly labeled container.¶¶

~~(65)~~ Naloxone may not be prescribed without offering to provide oral counseling to the authorized recipient, which may include dose, effectiveness, adverse effects, storage conditions, and safety.¶¶

~~(76)~~ The pharmacist must document the encounter and the prescription, and maintain records for three years.¶¶

~~(87)~~ Any person, having once lawfully obtained naloxone may possess, distribute or administer it for the purpose of reversing opiate overdose.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.684, ORS 689.305, ORS 689.681, ORS 689.682, 2019 OL Ch. 470

AMEND: 855-031-0010

RULE SUMMARY: The requirement to provide the original FPGEC certificate is a potential barrier to licensure for foreign pharmacy graduates (who could be immigrants or refugees).

CHANGES TO RULE:

855-031-0010

Intern License Application ¶

(1) Applications for licensure as an intern may be obtained from the Board office or from the Board web-site at ~~www.pharmacy.state.or.us.~~ ¶

(a) Failure to completely, accurately and honestly answer all questions on the application form for licensure or renewal of licensure is grounds for discipline; ¶

(b) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application. ¶

(2) The Board may issue a license to a qualified intern after the receipt of: ¶

(a) A completed application; ¶

(b) Payment of the fee prescribed in OAR 855-110-0005; ¶

(c) A current, passport regulation size photograph (full front, head to shoulders); ¶

(d) ~~Any fingerprint card or other~~ Furnish documentation required by the Board to conduct a criminal to conduct a national fingerprint based background check; and ¶

(e) Confirmation from a school of pharmacy that the applicant is enrolled in a course of study, except for foreign pharmacy graduates who must: ¶

(A) Provide a copy of a valid visa permitting full-time employment; ¶

(B) Provide a copy of the original certificate issued by the Foreign Pharmacy Graduate Equivalency Examination Committee; and ¶

(C) Provide evidence that they have passed the Test of English as a Foreign Language (TOEFL) Internet-based Test (IBT) with a minimum score of 26 in Speaking, 21 in Reading, 18 in Listening and 24 in Writing, ~~however scores will be accepted until June 30, 2010 from candidates who have already passed or are scheduled to take the TOEFL and the Test of Spoken English (TSE).~~ ¶

(3) The Board may issue an intern license after processing the application, however unless the applicant is a foreign graduate or an applicant for licensure by reciprocity, it is not valid until the intern has started a course of study. ~~For licenses issued after May 1, 2010, t~~ The initial license is valid until the last day of November following the second anniversary of issue unless terminated automatically by any one of the following events. Renewed licenses are valid for two years unless terminated automatically by any one of the following events: ¶

(a) Licensure to practice pharmacy is granted in any state; or ¶

(b) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by reciprocity, fails to maintain enrollment or active registration in a pharmacy degree program for a period greater than one year; or ¶

(c) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by reciprocity, has been graduated from a school of pharmacy for 12 months; ¶

(d) The intern is dismissed, terminated or expelled by the school of pharmacy, or withdraws from the program. ¶

(4) An intern must surrender their license to the Board within 30 days of one of the above events. ¶

(5) Notwithstanding the requirements of section (3) above, upon written request the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing. ¶

[Publications: Publications referenced are available from the agency.]

Statutory/Other Authority: ORS 689.151, ORS 689.205

Statutes/Other Implemented: ORS 689.207, ORS 689.255, ~~2009 OL Ch. 536~~ ORS 689.455

REPEAL: 855-041-2300

RULE SUMMARY: Repeal; rule language condensed

CHANGES TO RULE:

~~855-041-2300~~

~~Purpose and Scope~~

~~The purpose of OAR 855-041-2300 through 855-041-2330 is to define the procedures for distributing emergency medication to certain authorized individuals for the use in emergency health circumstances. The authorized person is someone who has been trained under the guidelines set forth in 333-055-0110.~~

~~Statutory/Other Authority: ORS 689.205, 2013 OL Ch. 340~~

~~Statutes/Other Implemented: ORS 689.155, 2013 OL Ch. 34~~

AMEND: 855-041-2340

RULE SUMMARY: Rule edits are proposed to Division 041 to address directives of 2019 SB 910, related to naloxone access in Oregon pharmacies. Statutory changes to Oregon's naloxone laws intend to reduce barriers and increase access to naloxone, the life-saving opiate reversal drug. Language adds legislatively mandated requirement for written notice of naloxone availability.

CHANGES TO RULE:

855-041-2340

~~Naloxone – Pharmacist Prescribing of Naloxone ¶¶~~

~~The p~~Pharmacyies providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:¶¶

(1) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction; ~~and¶¶~~

(2) Documentation and recordkeeping; ~~and¶¶~~

(3) Provide written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.305, ORS 689.681, ~~2016 OL Ch. 100~~ORS 689.682, ~~2017 OL Ch. 683~~470