Session: Alaska State Capitol, Rm.104 Juneau, AK 99801-1182 Office: (907) 465-2693



Interim: 145 Main St Loop Kenai, AK 99611 Office: (907) 283-2030

Representative Justin Ruffridge

District 7 - Kenai/Soldotna

HB 112 Sectional Analysis ver CS

"An Act relating to the Board of Pharmacy; relating to the practice of pharmacy; relating to pharmacies; relating to prescription drug manufacturers; relating to licensing and registration requirement for certain wholesale drug distributors; relating to prescriptions for epinephrine; relating to the administration of epinephrine; and providing for an effective date."

Section 1

Alters composition of the seven-member Board of Pharmacy by designating one member to be a licensed pharmacy technician, and one being an individual with no financial interest in the healthcare industry

Section 2

- (b)(10) Separates out the licensing/regulating entities relating to manufacturing and distributing of drugs and devices by use of the word "or"
- (b)(12) adds an epinephrine auto-injector training program
- (b)(14) Clarifies that only pharmacists who dispense federally scheduled controlled substances be required to register with the Prescription Drug Monitoring Program (PDMP)
- (b)(16) Adds pharmacies and manufacturers from out-of-state to the list of entities to be licensed and inspected
- (b)(17) Adds internet-based pharmacies to the list of entities to be licensed if they are servicing Alaskans
- (b)(18) adds language adopting regulations pertaining to retired pharmacist status

Section 3

This section deals with reciprocity and license transfer for pharmacists who are licensed in other jurisdictions and remove and renumbers subsections as a result of changes.

- (3) Removes character requirement "of good moral character"
- (4) Removes internship details this is a national standard among schools of pharmacy Renumbering of statute items in this section

Section 4

Language in this section has been added since version A.

(h) States the board may suspend, revoke, deny, or refuse to renew the license of a facility or pharmacy on the following reasons:

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- (1) Finding by the board of violations of a federal, state, or local law relating to various practices
- (2) A felony conviction under federal, state, or local law for certain individuals
- (3) The furnishing of false or fraudulent material in an application
- (4) Suspension or revocation by federal, state, or local government of a license current or previously held by the applicant
- (5) Obtaining renumeration by fraud, misrepresentation or deception
- (6) Dealing with drugs or devices that are known or should have been known to be stolen drugs or devices
- (7) Dispensing or distributing drugs or devices directly to patients by a wholesale drug distributor other than a pharmacy unless
- (A) the drug or device is a dialysate
- (i) necessary to perform home dialysis
- (ii) approved by the United States Food and Drug Administration as required by federal law
- (iii) delivered in its original, sealed, and labeled packaging
- (B) The wholesale drug distributor
- (i) delivers the dialysate drug or device directly to a patient or to the designee
- (ii) creates a verification system
- (iii) additional accuracy and delivery checks
- (C) allows a licensed pharmacist to serve as a consultant to the wholesale drug distributor
- (i) conduct an audit of 10 percent of drug and device orders every month
- (ii) perform assessments at least twice monthly to ensure quality of product storage, handling, and distribution

Numbering for remaining sections have been changed as a result of new section 4.

Section 5

(k) this adds out-of-state pharmacies and manufacturers to the list of entities that must be licensed and inspected

Section 6

Adds "distributing a prescription drug to a person, pharmacy, manufacturer" to those out-of-state entities that must be licensed and inspected, under the Drug Supply Chain and Security Act

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Section 7

adds "pharmacy and manufacturer" to list that may be inspected if located outside the state

Section 8

10) Removes the word "registration" since the bill mandates licensure of a facility

Section 9

(e) Allows a pharmacist to administer epinephrine to a person or prescribe epinephrine autoinjectors to someone who has completed the epinephrine auto-injector training program

Section 10

(a) Adds an additional salary range option for the executive administrator, if the executive administrator has a pharmacist license

Section 11

(a) adds the term "apothecary" to list of those that cannot be used in media or advertising unless the store employs a licensed pharmacist with regular hours

Section 12

(a)(23) adds pharmacist and pharmacy technician to list of professions where a background check is required under AS 08.80. Aligns with State of Alaska's nursing requirements and pharmacy requirements typical in other states. This adds a national level background check

Section 13

Allows anyone over 18 to purchase or be prescribed an epinephrine auto-injector, and to administer epinephrine in an emergency to another person if they have completed an epinephrine auto-injector training program approved by the board. (2)removes outdated language from this section regarding ampules

Section 14

(a) Allows the board, rather than the department, to adopt standards for the epinephrine autoinjector training program and deletes outdated language for (2) epinephrine ampules

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Section 15

(b) Allows the board, rather than the department, to approve an epinephrine auto-injector training program that meets the board's standards

Section 16

States that this chapter does not apply to someone currently authorized under another law to administer epinephrine, such as a nurse or doctor, or some other authorized professional. Deletes "or to a person who is prescribed epinephrine for personal use".

Section 17

Outlines that a person may not be sued who administers epinephrine to another in an emergency, and in good faith, if he or she has completed the epinephrine auto-injector training program approved by the board

Section 18

(3) defines the "board" as the Board of Pharmacy

Section 19

Repeals AS 08.80.110(2) Furnish the board with at least two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;

Repeals 08.80.158 *Registration* of pharmacies located outside the state since this bill would now *require* licensure

Repeals AS 17.22.020(c) which is the Department's epinephrine auto-injector training program

Repeals AS 17.22.090(1) that defines the department as the Dept of Health, since it will no longer be the approving entity of the epinephrine auto-injector training program

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Section 20

TRANSITION: EFFECT ON CURRENT REGISTERED PHARMACIES

A new section that would allow pharmacies previously registered to continue to ship, mail or deliver prescription drugs to its customers in Alaska until their registration expires under AS 08.80. At that time, they will then have to apply for licensure.

Section 21

TRANSITION: REGULATIONS. The uncodified law of the State of Alaska is amended by adding language that allows the Board of Pharmacy and DCCED to adopt regulations to carry out the changes laid out in this legislation, and when regulations take effect.

Section 22

Section 21 has an immediate effective date under AS 01.10.070(c)

Section 23

Section 4 of this Act takes effect May 7, 2023.

Section 24

Except as provided in secs 22 and 23 of this Act, This Act takes effect November 26, 2023.