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CS FOR HOUSE BILL NO. 112(L&C) am

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-THIRD LEGISLATURE - FIRST SESSION

BY THE HOUSE LABOR AND COMMERCE COMMITTEE

Amended: 5/16/23

Offered: 4/19/23

Sponsor(s): REPRESENTATIVES RUFFRIDGE, Mears, Fields, Wright, Josephson

SENATORS Merrick, Gray-Jackson, Dunbar, Claman, Stedman, Stevens

A BILL

FOR AN ACT ENTITLED

1 **"An Act relating to the Board of Pharmacy; relating to the practice of pharmacy;**
2 **relating to pharmacies; relating to prescription drug manufacturers; relating to**
3 **licensing and registration requirements for certain wholesale drug distributors; relating**
4 **to prescriptions for epinephrine; relating to the administration of epinephrine; and**
5 **providing for an effective date."**

6 **BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:**

7 *** Section 1.** AS 08.80.010(a) is amended to read:

8 (a) There is created the Board of Pharmacy, composed of seven members, five
9 of whom shall be pharmacists licensed in the state who have been actively engaged in
10 the practice of pharmacy in the state for a period of three years immediately preceding
11 their appointment. **One shall be a pharmacy technician licensed in the state for a**
12 **period of two years immediately preceding appointment. One** [TWO] shall be **a**
13 **person** [PERSONS] with no direct financial interest in the health care industry.

1 Whenever possible, the board shall include at least one member from each judicial
2 district.

3 * **Sec. 2.** AS 08.80.030(b) is amended to read:

4 (b) In order to fulfill its responsibilities, the board has the powers necessary
5 for implementation and enforcement of this chapter, including the power to

6 (1) elect a president and secretary from its membership and adopt rules
7 for the conduct of its business;

8 (2) license by examination or by license transfer the applicants who are
9 qualified to engage in the practice of pharmacy;

10 (3) assist the department in inspections and investigations for
11 violations of this chapter, or of any other state or federal statute relating to the practice
12 of pharmacy;

13 (4) adopt regulations to carry out the purposes of this chapter;

14 (5) establish and enforce compliance with professional standards and
15 rules of conduct for pharmacists engaged in the practice of pharmacy;

16 (6) determine standards for recognition and approval of degree
17 programs of schools and colleges of pharmacy whose graduates shall be eligible for
18 licensure in this state, including the specification and enforcement of requirements for
19 practical training, including internships;

20 (7) establish for pharmacists and pharmacies minimum specifications
21 for the physical facilities, technical equipment, personnel, and procedures for the
22 storage, compounding, and dispensing of drugs or related devices, and for the
23 monitoring of drug therapy, including independent monitoring of drug therapy;

24 (8) enforce the provisions of this chapter relating to the conduct or
25 competence of pharmacists practicing in the state, and the suspension, revocation, or
26 restriction of licenses to engage in the practice of pharmacy;

27 (9) license and regulate the training, qualifications, and employment of
28 pharmacy interns and pharmacy technicians;

29 (10) **license and regulate the qualifications of entities and**
30 **individuals** [ISSUE LICENSES TO PERSONS] engaged in the manufacture **or**
31 [AND] distribution of drugs and related devices;

1 (11) establish and maintain a controlled substance prescription
2 database as provided in AS 17.30.200;

3 (12) establish standards for the independent prescribing and
4 administration of vaccines and related emergency medications under AS 08.80.168,
5 including the completion of an immunization training program approved by the board
6 **and an epinephrine auto-injector training program under AS 17.22.020(b);**

7 (13) establish standards for the independent prescribing and dispensing
8 by a pharmacist of an opioid overdose drug under AS 17.20.085, including the
9 completion of an opioid overdose training program approved by the board;

10 (14) require that a licensed pharmacist **who dispenses a schedule II,**
11 **III, or IV controlled substance under federal law to a person in the state** register
12 with the controlled substance prescription database under AS 17.30.200(n);

13 (15) establish the qualifications and duties of the executive
14 administrator and delegate authority to the executive administrator that is necessary to
15 conduct board business;

16 (16) license and inspect the facilities of **pharmacies, manufacturers,**
17 wholesale drug distributors, third-party logistics providers, and outsourcing facilities
18 located outside the state under AS 08.80.159;

19 **(17) license Internet-based pharmacies providing services to**
20 **residents in the state;**

21 **(18) adopt regulations pertaining to retired pharmacist status.**

22 * **Sec. 3.** AS 08.80.145 is amended to read:

23 **Sec. 08.80.145. Reciprocity; license transfer.** If another jurisdiction allows
24 licensure in that jurisdiction of a pharmacist licensed in this state under conditions
25 similar to those in this section, the board may license as a pharmacist in this state a
26 person licensed as a pharmacist in the other jurisdiction if the person

27 (1) submits a written application to the board on a form required by the
28 board;

29 (2) is at least 18 years of age;

30 (3) [IS OF GOOD MORAL CHARACTER;

31 (4)] possesses at the time of the request for licensure as a pharmacist in

1 this state the qualifications necessary to be eligible for licensure in this state;

2 (4) [(5)] has engaged in the practice of pharmacy for at least one year
3 [OR HAS MET THE INTERNSHIP REQUIREMENTS OF THIS STATE WITHIN
4 THE ONE-YEAR PERIOD] immediately before applying for a license under this
5 section;

6 (5) [(6)] presents proof satisfactory to the board that the person is
7 currently licensed as a pharmacist in the other jurisdiction and does not currently have
8 a pharmacist license suspended, revoked, or otherwise restricted except for failure to
9 apply for renewal or failure to obtain the required continuing education credits;

10 (6) [(7)] has passed an examination approved by the board that tests
11 the person's knowledge of Alaska laws relating to pharmacies and pharmacists and the
12 regulations adopted under those laws; and

13 (7) [(8)] pays all required fees.

14 * **Sec. 4.** AS 08.80.157(h) is amended to read:

15 (h) The board may suspend, revoke, deny, or refuse to renew the license of a
16 facility or pharmacy on the following grounds:

17 (1) the finding by the board of violations of a federal, state, or local
18 law relating to the practice of pharmacy, drug samples, wholesale or retail drug or
19 device distribution, or distribution of controlled substances;

20 (2) a felony conviction under federal, state, or local law of an owner of
21 the facility or pharmacy or of an employee of the facility or pharmacy;

22 (3) the furnishing of false or fraudulent material in an application made
23 in connection with drug or device manufacturing or distribution;

24 (4) suspension or revocation by federal, state, or local government of a
25 license currently or previously held by the applicant for the manufacture or
26 distribution of drugs or devices, including controlled substances;

27 (5) obtaining remuneration by fraud, misrepresentation, or deception;

28 (6) dealing with drugs or devices that are known or should have been
29 known to be stolen drugs or devices;

30 (7) dispensing or distributing drugs or devices directly to patients by a
31 wholesale drug distributor other than a pharmacy **unless**

1 **(A) the drug or device is a dialysate, drug composed solely**
 2 **of fluids, electrolytes, and sugars, or device that is**

3 **(i) necessary to perform home dialysis;**

4 **(ii) approved by the United States Food and Drug**
 5 **Administration, as required by federal law; and**

6 **(iii) delivered in its original, sealed, and labeled**
 7 **packaging only upon the receipt of a physician's order; and**

8 **(B) the wholesale drug distributor**

9 **(i) delivers the dialysate drug or device directly to a**
 10 **patient with end-stage renal disease, or to the patient's designee,**
 11 **for the patient's self-administration of dialysis therapy;**

12 **(ii) uses a bar code scanning and verification system**
 13 **confirming that the dialysate drug or device selected to fill the**
 14 **patient-specific order matches the information on the patient-**
 15 **specific label; and**

16 **(iii) has additional secondary accuracy and delivery**
 17 **checks in place; and**

18 **(C) a licensed pharmacist serves as a consultant to the**
 19 **wholesale drug distributor to**

20 **(i) conduct a retrospective audit of 10 percent of the**
 21 **dialysate drug and device orders provided directly to patients**
 22 **processed by the wholesale drug distributor every month; and**

23 **(ii) perform assessments at least twice monthly to**
 24 **ensure quality of product storage, handling, and distribution by the**
 25 **wholesale drug distributor, and to ensure product expiration dates**
 26 **are later than three months after the date of assessment;**

27 (8) violation of this chapter or a regulation adopted under this chapter.

28 * **Sec. 5.** AS 08.80.157(k) is amended to read:

29 (k) This section applies to **pharmacies, manufacturers,** wholesale drug
 30 distributors, third-party logistics providers, and outsourcing facilities located outside
 31 the state under AS 08.80.159.

1 * **Sec. 6.** AS 08.80.159(a) is amended to read:

2 (a) Before shipping, mailing, **distributing**, or delivering **a** prescription **drug**
 3 [DRUGS] to a **person** [LICENSEE] in the state or advertising in the state, a
 4 **pharmacy, manufacturer**, wholesale drug distributor, third-party logistics provider,
 5 or an outsourcing facility that is located outside the state shall

6 (1) obtain a license under AS 08.80.157;

7 (2) appoint an agent on whom process can be served in the state; and

8 (3) authorize inspection of the facility by a designee of the board under

9 (c) of this section.

10 * **Sec. 7.** AS 08.80.159(c) is amended to read:

11 (c) Upon application by a **pharmacy, manufacturer**, wholesale drug
 12 distributor, third-party logistics provider, or an outsourcing facility for a license under
 13 this section, the board may

14 (1) require an inspection of the applicant's facility located outside the
 15 state; and

16 (2) approve a designee to conduct the inspection.

17 * **Sec. 8.** AS 08.80.160 is amended to read:

18 **Sec. 08.80.160. Fees.** The Department of Commerce, Community, and
 19 Economic Development shall set fees under AS 08.01.065 for the following:

20 (1) examination;

21 (2) reexamination;

22 (3) investigation for licensing by license transfer;

23 (4) pharmacist license;

24 (5) temporary license;

25 (6) pharmacy technician license;

26 (7) pharmacy intern license;

27 (8) emergency permit;

28 (9) license amendment or replacement;

29 (10) [REGISTRATION OR] licensure of a facility classified under
 30 AS 08.80.157(b).

31 * **Sec. 9.** AS 08.80.168 is amended by adding a new subsection to read:

1 (e) A pharmacist may independently administer epinephrine to a patient or
 2 prescribe epinephrine auto-injectors to a person who has completed a training program
 3 approved by the board under AS 17.22.020(b).

4 * **Sec. 10.** AS 08.80.270(a) is amended to read:

5 (a) The board shall employ an executive administrator to carry out the duties
 6 established under (b) of this section. The executive administrator is the principal
 7 executive officer of the board. The executive administrator is in the partially exempt
 8 service under AS 39.25.120 and is entitled to receive a monthly salary equal to a step
 9 in range 23 on the salary schedule set out in AS 39.27.011(a). **If the executive**
 10 **administrator has a pharmacist license, the executive administrator is entitled to**
 11 **a monthly salary based on the salary classification for pharmacists.**

12 * **Sec. 11.** AS 08.80.420(a) is amended to read:

13 (a) A person may not use or exhibit the title "pharmacist," "assistant
 14 pharmacist," or "druggist," or the descriptive term "pharmacy," "drug store," "drug
 15 sundries," "**apothecary,**" or other similar title or term containing the word "drug," in
 16 any business premises [,] or in an advertisement through the media of press [,] or
 17 publication, or by radio or television, unless the business has a licensed pharmacist in
 18 regular and continuous employment.

19 * **Sec. 12.** AS 12.62.400(a) is amended to read:

20 (a) To obtain a national criminal history record check for determining a
 21 person's qualifications for a license, permit, registration, employment, or position, a
 22 person shall submit the person's fingerprints to the department with the fee established
 23 by AS 12.62.160. The department may submit the fingerprints to the Federal Bureau
 24 of Investigation to obtain a national criminal history record check of the person for the
 25 purpose of evaluating a person's qualifications for

26 (1) a license or conditional contractor's permit to manufacture, sell,
 27 offer for sale, possess for sale or barter, traffic in, or barter an alcoholic beverage
 28 under AS 04.11;

29 (2) licensure as a mortgage lender, a mortgage broker, or a mortgage
 30 loan originator under AS 06.60;

31 (3) admission to the Alaska Bar Association under AS 08.08;

- 1 (4) licensure as a collection agency operator under AS 08.24;
- 2 (5) a certificate of fitness to handle explosives under AS 08.52;
- 3 (6) licensure as a massage therapist under AS 08.61;
- 4 (7) licensure to practice nursing or certification as a nurse aide under
- 5 AS 08.68;
- 6 (8) certification as a real estate appraiser under AS 08.87;
- 7 (9) a position involving supervisory or disciplinary power over a minor
- 8 or dependent adult for which criminal justice information may be released under
- 9 AS 12.62.160(b)(9);
- 10 (10) a teacher certificate under AS 14.20;
- 11 (11) a registration or license to operate a marijuana establishment
- 12 under AS 17.38;
- 13 (12) admittance to a police training program under AS 18.65.230 or for
- 14 certification as a police officer under AS 18.65.240 if that person's prospective
- 15 employer does not have access to a criminal justice information system;
- 16 (13) licensure as a security guard under AS 18.65.400 - 18.65.490;
- 17 (14) a concealed handgun permit under AS 18.65.700 - 18.65.790;
- 18 (15) licensure as an insurance producer, managing general agent,
- 19 reinsurance intermediary broker, reinsurance intermediary manager, surplus lines
- 20 broker, or independent adjuster under AS 21.27;
- 21 (16) serving and executing process issued by a court by a person
- 22 designated under AS 22.20.130;
- 23 (17) a school bus driver license under AS 28.15.046;
- 24 (18) licensure as an operator or an instructor for a commercial driver
- 25 training school under AS 28.17;
- 26 (19) registration as a broker-dealer, agent, investment adviser
- 27 representative, or investment adviser under AS 45.56.300 - 45.56.350;
- 28 (20) licensure, license renewal, certification, certification renewal, or
- 29 payment from the Department of Health of an individual and an entity subject to the
- 30 requirements for a criminal history check under AS 47.05.310, including
- 31 (A) a public home care provider described in AS 47.05.017;

1 (B) a provider of home and community-based waiver services
2 financed under AS 47.07.030(c);

3 (C) a case manager to coordinate community mental health
4 services under AS 47.30.530;

5 (D) an entity listed in AS 47.32.010(b) and (c), including an
6 owner, officer, director, member, partner, employee, volunteer, or contractor of
7 an entity; or

8 (E) an individual or entity not described in (A) - (D) of this
9 paragraph that is required by statute or regulation to be licensed or certified by
10 the Department of Health or that is eligible to receive payments, in whole or in
11 part, from the Department of Health to provide for the health, safety, and
12 welfare of persons who are served by the programs administered by the
13 Department of Health;

14 (21) employment as a village public safety officer under AS 18.65.672
15 or certification as a village public safety officer under AS 18.65.682;

16 (22) licensure, license renewal, certification, or certification renewal
17 by the Department of Family and Community Services of an individual or entity, or
18 payment from the Department of Family and Community Services to an individual or
19 entity, subject to the requirements for a criminal history check under AS 47.05.310 for
20 a foster home, child placement agency, and runaway shelter listed in AS 47.32.010(c),
21 including an owner, officer, director, member, partner, employee, volunteer, or
22 contractor of an entity;

23 **(23) licensure as a pharmacist or pharmacy technician under**
24 **AS 08.80.**

25 * **Sec. 13.** AS 17.22.010 is amended to read:

26 **Sec. 17.22.010. Prescription, purchase, and administration of epinephrine**
27 **by a trained individual.** An individual who is 18 years of age or older may obtain a
28 prescription for, purchase, and, in an emergency situation, administer epinephrine **to**
29 **another person** using

30 [(1)] an auto-injector, if the individual has successfully completed a
31 training program approved by the **board** [DEPARTMENT] under as 17.22.020(b) [;

1 OR

2 (2) AN AMPULE, IF THE INDIVIDUAL HAS SUCCESSFULLY
3 COMPLETED A TRAINING PROGRAM APPROVED BY THE DEPARTMENT
4 UNDER AS 17.22.020(c)].

5 * **Sec. 14.** AS 17.22.020(a) is amended to read:

6 (a) The **board** [DEPARTMENT] shall adopt standards for the approval of **a**
7 training **program** [PROGRAMS] for the use of

8 [(1)] epinephrine auto-injectors [; AND

9 (2) EPINEPHRINE AMPULES].

10 * **Sec. 15.** AS 17.22.020(b) is amended to read:

11 (b) The **board** [DEPARTMENT] shall approve an auto-injector training
12 program that meets standards adopted under **(a)** [(a)(1)] of this section. The standards
13 must require an epinephrine auto-injector program to provide training in

14 (1) techniques on how to recognize symptoms of severe asthmatic or
15 allergic reactions, including anaphylaxis;

16 (2) standards and procedures for the storage of epinephrine auto-
17 injectors and administration of epinephrine using auto-injectors; and

18 (3) emergency follow-up procedures.

19 * **Sec. 16.** AS 17.22.030 is amended to read:

20 **Sec. 17.22.030. Applicability.** This chapter does not apply to a person who is
21 authorized under another law to administer epinephrine [OR TO A PERSON WHO IS
22 PRESCRIBED EPINEPHRINE FOR PERSONAL USE].

23 * **Sec. 17.** AS 17.22.040 is amended to read:

24 **Sec. 17.22.040. Liability of certified individual.** A claim for relief may not be
25 brought against an individual who has successfully completed **an auto-injector** [A]
26 training program approved by the **board** [DEPARTMENT] under AS 17.22.020 for an
27 act or omission relating to the administration of epinephrine to another individual in an
28 emergency situation if the individual who completed the training program acted in
29 good faith under the authority granted by this chapter.

30 * **Sec. 18.** AS 17.22.090 is amended by adding a new paragraph to read:

31 (3) "board" means the Board of Pharmacy.

1 * **Sec. 19.** AS 08.80.110(2), 08.80.158; AS 17.22.020(c), and 17.22.090(1) are repealed.

2 * **Sec. 20.** The uncodified law of the State of Alaska is amended by adding a new section to
3 read:

4 TRANSITION: EFFECT ON CURRENT REGISTERED PHARMACIES. On and
5 after the effective date of sec. 19 of this Act, a pharmacy registered under AS 08.80.158 on
6 the effective date of sec. 19 of this Act may continue to ship, mail, or deliver prescription
7 drugs to consumers in the state under the registration until the registration expires normally
8 under AS 08.80.

9 * **Sec. 21.** The uncodified law of the State of Alaska is amended by adding a new section to
10 read:

11 TRANSITION: REGULATIONS. The Board of Pharmacy and the Department of
12 Commerce, Community, and Economic Development may adopt regulations necessary to
13 implement the changes made by this Act. The regulations take effect under AS 44.62
14 (Administrative Procedure Act), but not before the effective date of the relevant provision of
15 this Act implemented by the regulation.

16 * **Sec. 22.** Sections 4 and 21 of this Act take effect immediately under AS 01.10.070(c).

17 * **Sec. 23.** Except as provided in sec. 22 of this Act, this Act takes effect November 26,
18 2023.