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Bruce
4/6/17

CS FOR HOUSE BILL NO. 9()
IN THE LEGISLATURE OF THE STATE OF ALASKA
THIRTIETH LEGISLATURE - FIRST SESSION

BY

Offered:
Referred:

Sponsor(s): REPRESENTATIVE SADDLER

A BILL
FOR AN ACT ENTITLED

1 **"An Act relating to the Board of Pharmacy; relating to the licensing of certain entities**
2 **and inspection of certain facilities located outside the state; relating to drug supply chain**
3 **security; creating a position of executive administrator for the Board of Pharmacy; and**
4 **providing for an effective date."**

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

6 *** Section 1.** AS 08.80.030(b) is amended to read:

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

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

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

13 (3) assist the department in inspections and investigations for
14 violations of this chapter, or of any other state or federal statute relating to the practice

1 of pharmacy;

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

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

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

9 (7) establish for pharmacists and pharmacies minimum specifications
10 for the physical facilities, technical equipment, personnel, and procedures for the
11 storage, compounding, and dispensing of drugs or related devices, and for the
12 monitoring of drug therapy;

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

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

18 (10) issue licenses to persons engaged in the manufacture and
19 distribution of drugs and related devices;

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

22 (12) establish standards for the independent administration by a
23 pharmacist of vaccines and related emergency medications under AS 08.80.168,
24 including the completion of an immunization training program approved by the board;

25 (13) establish standards for the independent dispensing by a
26 pharmacist of an opioid overdose drug under AS 17.20.085, including the completion
27 of an opioid overdose training program approved by the board;

28 **(14) establish the qualifications and duties of the executive**
29 **administrator and delegate authority to the executive administrator that is**
30 **necessary to conduct board business.**

31 * **Sec. 2.** AS 08.80.030(b), as amended by sec. 1 of this Act, is amended to read:

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

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

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

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

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

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

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

17 (7) establish for pharmacists and pharmacies minimum specifications
18 for the physical facilities, technical equipment, personnel, and procedures for the
19 storage, compounding, and dispensing of drugs or related devices, and for the
20 monitoring of drug therapy;

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

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

26 (10) issue licenses to persons engaged in the manufacture and
27 distribution of drugs and related devices;

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

30 (12) establish standards for the independent administration by a
31 pharmacist of vaccines and related emergency medications under AS 08.80.168,

including the completion of an immunization training program approved by the board;

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

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

(15) license and inspect the facilities of wholesale drug distributors, third-party logistics providers, and outsourcing facilities located outside the state under AS 08.80.159.

* **Sec. 3.** AS 08.80.030 is amended by adding a new subsection to read:

(c) The minimum specifications for facilities, equipment, personnel, and procedures for the compounding, storage, and dispensing of drugs established under (b)(7) of this section must be consistent with the requirements of 21 U.S.C. 201 - 208 (Drug Supply Chain Security Act).

* **Sec. 4.** AS 08.80.157 is amended by adding a new subsection to read:

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

* **Sec. 5.** AS 08.80 is amended by adding a new section to read:

Sec. 08.80.159. Licensing and inspection of facilities outside of state. (a)

Before shipping, mailing, or delivering prescription drugs to a licensee in the state or advertising in the state, a wholesale drug distributor, third-party logistics provider, or an outsourcing facility that is located outside the state shall

- (1) obtain a license under AS 08.80.157;
- (2) appoint an agent on whom process can be served in the state; and
- (3) authorize inspection of the facility by a designee of the board under

(c) of this section.

(b) In addition to the requirements of (a) of this section, an outsourcing facility shall

- (1) register as an outsourcing facility with the United States Food and Drug Administration; and

(2) comply with the requirements of 21 U.S.C. 503B (Drug Quality and Security Act of 2013).

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

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

(2) approve a designee to conduct the inspection.

(d) The board shall adopt regulations necessary to implement this section.

* **Sec. 6.** AS 08.80 is amended by adding a new section to article 2 to read:

Sec. 08.80.270. Executive administrator of the board. (a) The board shall employ an executive administrator to carry out the duties established under (b) of this section. The executive administrator is the principal executive officer of the board. The executive administrator is in the partially exempt service under AS 39.25.120 and is entitled to receive a monthly salary equal to a step in Range 23 on the salary schedule set out in AS 39.27.011(a).

(b) The executive administrator shall

(1) perform duties associated with the licensing and regulation of licensees under this chapter as prescribed by the board; and

(2) serve as a liaison to the legislative and executive branches of state government, the media, and other state pharmacy boards.

* **Sec. 7.** AS 08.80.480 is amended by adding new paragraphs to read:

(37) "outsourcing facility" means a facility at one geographic location or address that is engaged in the compounding of sterile drugs for a facility at another geographic location.

(38) "third-party logistics provider" means an entity that provides or coordinates warehousing or other logistics services for a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the product, and that does not take ownership of the product or have responsibility to direct the sale or disposition of the product.

* **Sec. 8.** AS 39.25.120(c)(7) is amended to read:

(7) the principal executive officer of the following boards, councils, or

commissions:

- (A) Alaska Public Broadcasting Commission;
- (B) Professional Teaching Practices Commission;
- (C) Parole Board;
- (D) Board of Nursing;
- (E) Real Estate Commission;
- (F) Alaska Royalty Oil and Gas Development Advisory Board;
- (G) Alaska State Council on the Arts;
- (H) Alaska Police Standards Council;
- (I) Alaska Commission on Aging;
- (J) Alaska Mental Health Board;
- (K) State Medical Board;
- (L) Governor's Council on Disabilities and Special Education;
- (M) Advisory Board on Alcoholism and Drug Abuse;
- (N) Statewide Suicide Prevention Council;
- (O) State Board of Registration for Architects, Engineers, and
Land Surveyors;
- (P) Alaska Health Care Commission;
- (Q) Board of Pharmacy;**

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

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

* **Sec. 10.** Sections 1, 6, 8, and 9 of this Act take effect immediately under AS 01.10.070(c).

* **Sec. 11.** Except as provided in sec. 10 of this Act, this Act takes effect July 1, 2018.