

HOUSE CS FOR CS FOR SENATE BILL NO. 37(RLS) am H

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTIETH LEGISLATURE - SECOND SESSION

BY THE HOUSE RULES COMMITTEE

Amended: 4/23/18

Offered: 4/17/18

Sponsor(s): SENATOR GIESSEL BY REQUEST

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;**
4 **reducing the membership of the Alaska Commercial Fisheries Entry Commission to two**
5 **individuals; relating to the duties of the commissioner serving as chair of the**
6 **commission; providing that a single commissioner may exercise all powers and duties of**
7 **the commission if there is a vacancy on the commission; providing for commissioner**
8 **compensation; relating to tie votes of the commission; and providing for an effective**
9 **date."**

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

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

12 (b) In order to fulfill its responsibilities, the board has the powers necessary

1 for implementation and enforcement of this chapter, including the power to

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

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

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

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

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

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

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

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

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

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

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

29 (12) establish standards for the independent administration by a
30 pharmacist of vaccines and related emergency medications under AS 08.80.168,
31 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) require that a licensed pharmacist register with the controlled substance prescription database under AS 17.30.200(o);

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

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

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

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

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

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

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

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

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

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

(8) enforce the provisions of this chapter relating to the conduct or competence of pharmacists practicing in the state, and the suspension, revocation, or

1 restriction of licenses to engage in the practice of pharmacy;

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

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

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

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

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

14 (14) require that a licensed pharmacist register with the controlled
15 substance prescription database under AS 17.30.200(o);

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

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

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

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

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

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

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

31 **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.

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

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

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

10 * **Sec. 8.** AS 16.43.020 is amended to read:

11 **Sec. 16.43.020. Alaska Commercial Fisheries Entry Commission.** (a) There
12 is established the Alaska Commercial Fisheries Entry Commission as a regulatory and
13 quasi-judicial agency of the state. The commission consists of two [THREE] members
14 appointed by the governor and confirmed by the legislature in joint session.

15 (b) The governor shall designate one member of the commission as chair
16 [CHAIRMAN] of the commission. The designated member serves [DESIGNATED
17 SHALL SERVE] as chair [CHAIRMAN] for a term of two years [,] and may be
18 designated chair [CHAIRMAN] for successive two-year terms. When there is a
19 vacancy in the executive director position, the member serving as chair is
20 responsible for and has authority over the internal administrative and personnel
21 practices and procedures of the commission.

22 * **Sec. 9.** AS 16.43.030(c) is amended to read:

23 (c) If there is a [A] vacancy on the commission, [DOES NOT IMPAIR THE
24 AUTHORITY OF] a single commissioner may [QUORUM OF COMMISSIONERS
25 TO] exercise all the powers and perform all the duties of the commission.

26 * **Sec. 10.** AS 16.43.040 is amended to read:

27 **Sec. 16.43.040. Quorum.** Unless there is a vacancy on the commission, two
28 [TWO] members of the commission constitute a quorum for the transaction of
29 business, for the performance of a duty, or for the exercise of a power of the
30 commission.

31 * **Sec. 11.** AS 16.43.050 is amended to read:

Sec. 16.43.050. Qualifications. The commission shall consist of two [THREE] members with a broad range of professional experience, neither [NONE] of whom has a vested economic interest in an interim-use permit, entry permit, commercial fishing vessel or gear, or in any fishery resource processing or marketing business.

* **Sec. 12.** AS 16.43.060 is amended to read:

Sec. 16.43.060. Compensation. Members of the commission are in the exempt service and are entitled to a monthly salary equal to a step in Range 25 [27] of the salary schedule in AS 39.27.011.

* **Sec. 13.** AS 16.43.110 is amended by adding a new subsection to read:

(f) In case of a tie vote between commissioners in an adjudicatory proceeding, the decision of the hearing officer is the final administrative decision of the commission subject to review by a superior court under AS 44.62 (Administrative Procedure Act).

* **Sec. 14.** AS 16.43.960(d) is amended to read:

(d) Except when there is a vacancy as provided in AS 16.43.030(c), the [THE] show cause hearing shall be conducted before a quorum of commissioners and shall be presided over by a hearing officer appointed by the commission who shall rule on the presentation of evidence and other procedural matters. Hearings shall be conducted in accordance with regulations adopted under AS 16.43.110(b).

* **Sec. 15.** 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. 16.** The uncoded law of the State of Alaska is amended by adding a new section to read:

APPLICABILITY. AS 16.43.060, as amended by sec. 12 of this Act, applies to the compensation of commissioners of the Alaska Commercial Fisheries Entry Commission appointed after the effective date of this Act.

* **Sec. 17.** The uncoded 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. 18.** Sections 1, 6, and 8 - 17 of this Act take effect immediately under AS 01.10.070(c).

* **Sec. 19.** Except as provided in sec. 18 of this Act, this Act takes effect July 1, 2019.