

SB

37

<TARGET><BILL>SB 37</BILL><SUBJECT>SB
37</SUBJECT><COMM>HRLS30</COMM></TARGET>

30-LS0191\T
Radford
4/15/18

HOUSE CS FOR CS FOR SENATE BILL NO. 37(RLS)
IN THE LEGISLATURE OF THE STATE OF ALASKA
THIRTIETH LEGISLATURE - SECOND SESSION

BY THE HOUSE RULES COMMITTEE

Offered:
Referred:

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;

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

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

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

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

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

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

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

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

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

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

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

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

30 (8) enforce the provisions of this chapter relating to the conduct or
31 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)**

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

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

7 (c) of this section.

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

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

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

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

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

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

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

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

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

27 (b) The executive administrator shall

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

30 (2) serve as a liaison to the legislative and executive branches of state
31 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. **The member serving**
19 **as chair also serves as executive director of the commission and, as executive**
20 **director, is responsible for and has authority over the internal administrative and**
21 **personnel 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:

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

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

6 **Sec. 16.43.060. Compensation.** Members of the commission are in the exempt
7 service and are entitled to a monthly salary. The member serving as chair is paid a
8 salary equal to a step in Range 27, and the other commissioner is paid a salary
9 equal to a step in Range 24, of the salary schedule in AS 39.27.011.

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

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

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

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

21 * **Sec. 15.** AS 39.25.120(c)(7) is amended to read:

22 (7) the principal executive officer of the following boards, councils, or
23 commissions:

- 24 (A) Alaska Public Broadcasting Commission;
25 (B) Professional Teaching Practices Commission;
26 (C) Parole Board;
27 (D) Board of Nursing;
28 (E) Real Estate Commission;
29 (F) Alaska Royalty Oil and Gas Development Advisory Board;
30 (G) Alaska State Council on the Arts;
31 (H) Alaska Police Standards Council;

- 1 (I) Alaska Commission on Aging;
- 2 (J) Alaska Mental Health Board;
- 3 (K) State Medical Board;
- 4 (L) Governor's Council on Disabilities and Special Education;
- 5 (M) Advisory Board on Alcoholism and Drug Abuse;
- 6 (N) Statewide Suicide Prevention Council;
- 7 (O) State Board of Registration for Architects, Engineers, and
- 8 Land Surveyors;
- 9 (P) Alaska Health Care Commission;
- 10 **(Q) Board of Pharmacy;**

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

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

16 * **Sec. 17.** The uncodified law of the State of Alaska is amended by adding a new section to
 17 read:

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

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

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

ALASKA STATE LEGISLATURE



HOUSE RULES COMMITTEE

State Capitol Room 216, Juneau, AK 99801 (907) 465-4998
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Explanation of Changes

HCS for CSSB 37(RLS) ver T. – PHARMACY BD & STAFF; DRUG DISTRIB/MANUFACT

Section 8 on Page 6, lines 10 through 21:

Sec 16.43.020 Alaska Commercial Fisheries Entry Commission.

Subsection (a) is amended to reduce the number of commissioners appointed to the Commercial Fisheries Entry Commission (CFEC) from three to two.

Subsection (b) is amended to specify that the chair of the commission shall serve as executive director and be responsible for and have authority over the internal administrative and personnel practices and procedures of the commission.

Section 9 on Page 6, lines 22 through 25:

AS 16.43.030.

Subsection (c) is amended to allow a single commissioner to exercise the powers and duties of the commission when there is a vacancy on the commission.

Section 10 on Page 6, lines 26 through 30:

AS 16.43.040 is amended to allow for a quorum of one commissioner if there is a vacancy on the commission.

Section 11 on Page 6, line 31 through Page 7, line 4:

AS 16.43.050 is amended with conforming language to clarify that the commission consists of two commissioners instead of three.

Section 12 on Page 7, lines 5 through 9:

AS 16.43.060 is amended so that the member serving as chair will be paid a step in Range 27; adjusts the salary range from 27 to 24 for the other commissioner.

Section 13 on Page 7, lines 10 through 14:

AS 16.43.110 is amended by adding a new subsection that specifies that in the event of a 1-1 tie in an adjudicatory hearing, the original decision of the hearing officer will become the final administrative decision of the commission subject to review by the Superior Court.

Section 14 on Page 7, lines 15 through 20:

AS 16.43.960(d) is amended to allow for show cause hearings to be conducted before one commissioner if there is a vacancy on the commission.

Section 16 on Page 8, lines 11 through 15:

Adds an applicability clause to uncodified law that establishes that the salary change outlined in Section 12 of the bill will apply to commissioners appointed after the bill's effective date.

LEGAL SERVICES

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MEMORANDUM

April 15, 2018

SUBJECT: HCS CSSB 37(RLS) and the single subject rule
(HCS CSSB 37(RLS); Work Order Nos. 30-LS0191\T;
30-GH1053\N)

TO: Representative Gabrielle LeDoux
Attn: Courtney Enright

FROM: Claire E. Radford
Legislative Counsel



You requested a CS that merges CSHB 231(RLS) into CSSB 37(FIN), which is attached, and an accompanying memorandum regarding the single subject rule.¹ CSHB 231(RLS) relates to the Board of Pharmacy, licensing and inspection of certain facilities located out-of-state, drug supply chain security, and creates an executive administrator position for the Board of Pharmacy. CSSB 37(FIN) reduces the membership of the Alaska Commercial Fisheries Entry Commission to two individuals, relates to the duties of the commissioner serving as chair of the commission; provides that a single commissioner may exercise all powers and duties of the commission if there is a vacancy on the commission, provides for commissioner compensation, and relates to tie votes of the commission.

As I previously advised in my phone conversation on April 14, 2018, with Greg Smith, these bills may generally fit under the broad subject of "boards or commissions." As I also advised at that time, I am unsure how broad courts will interpret single subjects to be if a challenge were raised. Since these bills do not only make changes to the Board of Pharmacy, and the Alaska Commercial Fisheries Entry Commission is not structured in the same manner, it is possible that a court may find that the bills are too disparate to fit a single subject. However, since both bills appear to fit the subject "boards or commissions," it is more likely that a court will find there is no single subject violation.

If I may be of further assistance, please advise.

CER:boo
18-308.boo

Attachment

¹ Article II, §13, Constitution of the State of Alaska.