30-LS0191\J
Bruce
3/23/17

CS FOR SENATE BILL NO. 37(L&C)

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTIETH LEGISLATURE - FIRST SESSION

BY THE SENATE LABOR AND COMMERCE COMMITTEE

Offered:
Referred:

Sponsor(s): SENATOR GIESSEL BY REQUEST

A BILL

FOR AN ACT ENTITLED

"An Act relating to the Board of Pharmacy; relating to the licensing and inspection of certain facilities located outside the state; and relating to drug supply chain security."

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

*** Section 1.** AS 08.80.030(b) 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 restriction of licenses to engage in the practice of pharmacy;

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

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

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

(12) establish standards for the independent administration by a 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) license and inspect the facilities of wholesale drug distributors and outsourcing facilities located outside the state under AS 08.80.159.

*** Sec. 2.** 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. 3.** AS 08.80.157 is amended by adding a new subsection to read:

(k) This section applies to wholesale drug distributors and outsourcing facilities located outside the state under AS 08.80.159.

*** Sec. 4.** 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 or 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 (b) 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 or outsourcing facility for a license under this section, the board may

(1) require an inspection of a 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. 5.** AS 08.80.480 is amended by adding a new paragraph 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.