

SB

158

FISCAL NOTE

3

STATE OF ALASKA
1996 LEGISLATIVE SESSION

Bill Number: CSSB 158(L&C)
(S) Publish Date: 2-21-96

Revision Date: February 20, 1996 Department: Commerce and Economic Development
 Title: An Act relating to pharmacists and pharmacies. BRU: Occupational Licensing
 Component: Operations
 Sponsor: Senator Miller
 Requestor: Senate Rules COMPONENT SERIAL NO. 1844

Expenditures/Revenues (Thousands of Dollars)

OPERATING EXPENDITURES	FY 97	FY 98	FY 99	FY 00	FY 01	FY 02
PERSONAL SERVICES						
TRAVEL						
CONTRACTUAL						
SUPPLIES						
EQUIPMENT						
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING	0.0	0.0	0.0	0.0	0.0	0.0

CAPITAL EXPENDITURES						
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CHANGE IN REVENUES						
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FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts						
1003 GF Match						
1004 General Fund						
1005 GF/Program Receipts						
1006 GF/MHTIA						
Other 1091 Designated PR						
TOTAL	0.0	0.0	0.0	0.0	0.0	0.0

Estimate of any current year (FY 96) cost: \$ 0.0

POSITIONS

FULL-TIME						
PART-TIME						
TEMPORARY						

ANALYSIS: (Attach a separate page if necessary)
 CSSB 158(L&C) is a rewrite of the pharmacy statutes based on the Model State Pharmacy Act of the National Association of Boards of Pharmacy (NABP). There are significant changes in the bill however, new funds are not required to implement the changes.

Prepared by: Jennifer Strickler, Administrative Officer
 Division: Occupational Licensing Phone: 465-2144
 Approved by Commissioner: William L. Hensley
 Agency: Commerce and Economic Development Date: February 20, 1996
 Date: 2-20-96

(7)

HOUSE COMMITTEE REPORT

Date Referred to Committee: February 22, 1996

FURTHER REFERRALS:

Date of Committee Action: 4/11/96

The HEALTH, EDUCATION AND SOCIAL SERVICES Committee considered:

CSSB 158(L&C) am

CS FOR SENATE BILL NO. 158(L&C) am

PHARMACISTS AND PHARMACIES

"An Act relating to pharmacists and pharmacies."

recommends it be replaced with the following committee substitute HCS CS SB 158(HES) [X] the same title [] a new title

[] additional referral to _____ Committee [] attached amendment(s)

ADOPTS: _____ Letter of Intent

ATTACHES NEW FISCAL NOTE(S): (Dept) _____

APPROVES PREVIOUS: (Dept/Date) _____

[] fiscal note(s) _____

[] fiscal note(s) _____

[] zero fiscal note(s) _____

[X] zero fiscal note(s) CED 2-20-96

SIGNING WITH RECOMMENDATIONS	DP	DNP	NR	AM
<i>[Signature]</i>			✓	✓
<i>[Signature]</i>			✓	
<i>[Signature]</i>	✓	✓		
<i>[Signature]</i>	✓			
<i>[Signature]</i>				

CHAIR'S SIGNATURE *Car Bunde*

9-LS0525R ✓
Lauterbach
4/9/96

HOUSE CS FOR CS FOR SENATE BILL NO. 158()
IN THE LEGISLATURE OF THE STATE OF ALASKA
NINETEENTH LEGISLATURE - SECOND SESSION

BY

Offered:
Referred:

Sponsor(s): SENATOR MILLER

A BILL

FOR AN ACT ENTITLED

1 "An Act relating to pharmacists and pharmacies."

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

3 * Section 1. AS 08.02.010(a) is amended to read:

4 (a) An acupuncturist licensed under AS 08.06, an audiologist licensed under
5 AS 08.11, a person licensed in the state as a chiropractor under AS 08.20, a dentist
6 under AS 08.36, a marital and family therapist licensed under AS 08.63, a medical
7 practitioner or osteopath under AS 08.64, a direct-entry midwife certified under
8 AS 08.65, a registered nurse under AS 08.68, an optometrist under AS 08.72, a
9 licensed [REGISTERED] pharmacist under AS 08.80, a physical therapist or
10 occupational therapist licensed under AS 08.84, a psychologist under AS 08.86, or a
11 clinical social worker licensed under AS 08.95, shall use as professional identification
12 appropriate letters or a title after that person's name which represents that person's
13 specific field of practice. The letters or title shall appear on all signs, stationery, or
14 other advertising in which the person offers or displays personal professional services
15 to the public. In addition, a person engaged in the practice of medicine or osteopathy

1 as defined in AS 08.64.380, or a person engaged in any manner in the healing arts who
2 diagnoses, treats, tests, or counsels other persons in relation to human health or disease
3 and uses the letters "M.D." or the title "doctor" or "physician" or another title that
4 tends to show that the person is willing or qualified to diagnose, treat, test, or counsel
5 another person, shall clarify the letters or title by adding the appropriate specialist
6 designation, if any, such as "dermatologist", "radiologist", "audiologist", "naturopath",
7 or the like.

8 * Sec. 2. AS 08.80 is amended by adding new sections to read:

9 Sec. 08.80.003. PRACTICE OF PHARMACY AS A PROFESSION. The
10 practice of pharmacy is declared to be a professional practice affecting the public
11 health, safety, and welfare and is subject to regulation and control in the public
12 interest. It is further declared to be a matter of public interest that only qualified
13 persons be permitted to engage in the practice of pharmacy, and to ensure the quality
14 of drugs and related devices distributed in the state.

15 Sec. 08.80.005. STATEMENT OF PURPOSE. It is the purpose of this chapter
16 to promote, preserve, and protect the public health, safety, and welfare by and through
17 the effective control and regulation of the practice of pharmacy.

18 * Sec. 3. AS 08.80.010 is amended by adding a new subsection to read:

19 (b) An officer elected by the board serves a term of one year and may not
20 serve more than four consecutive full terms in a specific office.

21 * Sec. 4. AS 08.80.030 is repealed and reenacted to read:

22 Sec. 08.80.030. POWERS AND DUTIES OF THE BOARD. (a) The board
23 is responsible for the control and regulation of the practice of pharmacy.

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

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

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

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

1 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 * Sec. 5. AS 08.80.060 is amended to read:

21 Sec. 08.80.060. MEETINGS OF THE BOARD. The board shall meet at least
22 three times [ONCE] each year at the call of the president for the transaction of
23 business properly before it. The president shall also call the board into session when
24 requested in writing by at least two members. Meetings may be held telephonically
25 [THE SECRETARY SHALL GIVE AT LEAST 30 DAYS' WRITTEN NOTICE TO
26 ALL MEMBERS BEFORE A MEETING].

27 * Sec. 6. AS 08.80.070 is amended to read:

28 Sec. 08.80.070. QUORUM. Four members constitute a quorum for the
29 transaction of business. However, when the board meets for the purpose of examining
30 applications for licensure [REGISTRATION], three members of the board constitute
31 a quorum.

1 * Sec. 7. AS 08.80.110 is repealed and reenacted to read:

2 Sec. 08.80.110. QUALIFICATIONS FOR LICENSURE BY EXAMINATION.

3 An applicant for licensure as a pharmacist shall

4 (1) be fluent in the reading, writing, and speaking of the English
5 language;

6 (2) furnish the board with at least two affidavits from reputable citizens
7 that the applicant has known for at least one year attesting to the applicant's good
8 moral character;

9 (3) be a graduate of a college in a degree program approved by the
10 board;

11 (4) pass an examination or examinations given by the board or
12 acceptable to the board under the score transfer process administered by the National
13 Association of Boards of Pharmacy;

14 (5) have completed internship training or another program that has been
15 approved by the board or demonstrated to the board's satisfaction that the applicant
16 has experience in the practice of pharmacy that meets or exceeds the minimum
17 internship requirements of the board.

18 * Sec. 8. AS 08.80.116 is repealed and reenacted to read:

19 Sec. 08.80.116. INTERNSHIP AND OTHER TRAINING PROGRAMS. (a)

20 An applicant for licensure by examination shall obtain practical experience in the
21 practice of pharmacy concurrent with or after college attendance, or both, under terms
22 and conditions the board shall determine.

23 (b) The board shall establish licensure requirements for interns and standards
24 for internship or other training programs that are necessary to qualify an applicant for
25 the licensure examination and shall also determine the qualifications of preceptors used
26 in practical experience programs.

27 * Sec. 9. AS 08.80.120 is repealed and reenacted to read:

28 Sec. 08.80.120. GRADING AND CONTENT OF EXAMINATION. The

29 examination or examinations shall be prepared to measure the competence of the
30 applicant to engage in the practice of pharmacy. The board may employ, cooperate,
31 and contract with an organization or consultant in the preparation and grading of an

1 examination, but shall retain sole discretion and responsibility for determining which
2 applicants have successfully passed the examinations.

3 * Sec. 10. AS 08.80 is amended by adding new sections to read:

4 Sec. 08.80.145. RECIPROCITY; LICENSE TRANSFER. If another
5 jurisdiction allows licensure in that jurisdiction of a pharmacist licensed in this state
6 under conditions similar to those in this section, the board may license as a pharmacist
7 in this state a person licensed as a pharmacist in the other jurisdiction if the person

8 (1) submits a written application to the board on a form required by the
9 board;

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

11 (3) is of good moral character;

12 (4) possesses at the time of the request for licensure as a pharmacist
13 in this state the qualifications necessary to be eligible for licensure in this state;

14 (5) has engaged in the practice of pharmacy for at least one year or has
15 met the internship requirements of this state within the one-year period immediately
16 before applying for a license under this section;

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

21 (7) has passed an examination approved by the board that tests the
22 person's knowledge of Alaska laws relating to pharmacies and pharmacists and the
23 regulations adopted under those laws; and

24 (8) pays all required fees.

25 Sec. 08.80.147. RENEWAL OF LICENSURE. If a pharmacist fails to apply
26 for renewal of a license within five years from the expiration of the license, the person
27 must pass an examination for license renewal, except that a person who has continually
28 practiced pharmacy in another state under a license issued by the authority of that state
29 may renew an expired license in this state upon fulfillment of the requirements that
30 may be established by the board.

31 * Sec. 11. AS 08.80.150 is repealed and reenacted to read:

1 Sec. 08.80.150. TEMPORARY LICENSE. The board shall adopt regulations
2 regarding the issuance of a temporary license to practice pharmacy.

3 * Sec. 12. AS 08.80.155 is repealed and reenacted to read:

4 Sec. 08.80.155. EMERGENCY PERMIT. The board shall adopt regulations
5 regarding the issuance of an emergency permit to practice pharmacy.

6 * Sec. 13. AS 08.80.157 is repealed and reenacted to read:

7 Sec. 08.80.157. LICENSING OF FACILITIES. (a) A facility engaged in the
8 practice of pharmacy or in the manufacture, production, or wholesale distribution of
9 drugs or devices, and a pharmacy where drugs or devices are dispensed, shall be
10 licensed by the board, and shall renew the license at intervals determined by the board.
11 If operations are conducted at more than one location, each location shall be licensed
12 by the board.

13 (b) The board may by regulation determine the licensure classifications of
14 facilities and establish minimum standards for the facilities.

15 (c) The board shall establish by regulation the criteria that a facility must meet
16 to qualify for licensure in each classification. The board may issue licenses with
17 varying restrictions to facilities when the board considers it necessary to protect the
18 public interest.

19 (d) The board may deny or refuse to renew a license if it determines that the
20 granting or renewing of the license would not be in the public interest.

21 (e) Licenses issued by the board are not transferable or assignable.

22 (f) The board shall specify by regulation minimum standards for
23 responsibility of a facility or pharmacy that has employees or personnel engaged in the
24 practice of pharmacy or engaged in the manufacture, wholesale distribution,
25 production, or use of drugs or devices in the conduct of its business.

26 (g) A licensed facility shall report to the board

27 (1) permanent closing;

28 (2) change of ownership, management, location, or pharmacist-in-charge
29 of a pharmacy;

30 (3) theft or loss of drugs or devices as defined by regulations of the
31 board;

1 (4) conviction of an employee of violation of a state or federal drug
2 law;

3 (5) disasters, accidents, theft, destruction, or loss relating to records
4 required to be maintained by state or federal law;

5 (6) occurrences of significant adverse drug reactions as defined by
6 regulations of the board;

7 (7) other matters and occurrences the board may require by regulation.

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

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

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

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

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

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

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

23 (7) dispensing or distributing drugs or devices directly to patients by
24 a wholesale drug distributor other than a pharmacy;

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

26 (i) The board's regulations under (b) - (d) and (f) of this section may not
27 establish more stringent licensing requirements for the facilities governed by
28 AS 08.80.390 than are set out in AS 08.80.390.

29 (j) This section does not apply to the offices of physicians, osteopaths,
30 podiatrists, physician assistants, advanced nurse practitioners, dentists, veterinarians,
31 dispensing opticians, or optometrists.

1 * Sec. 14. AS 08.80.160 is amended to read:

2 Sec. 08.80.160. FEES. The Department of Commerce and Economic
3 Development shall set fees under AS 08.01.065 for the following:

- 4 (1) examination;
- 5 (2) reexamination;
- 6 (3) investigation for licensing by license transfer [CREDENTIALS];
- 7 (4) pharmacist license;
- 8 (5) temporary license;
- 9 (6) pharmacy technician [WHOLESALE DRUG DEALER] license;
- 10 (7) [RETAIL PHARMACY LICENSE];
- 11 (8)] pharmacy intern license [REGISTRATION];
- 12 (8) [(9)] emergency permit;
- 13 (9) [(10)] HOSPITAL PHARMACY LICENSE (INPATIENT AND
- 14 OUTPATIENT);
- 15 (11) HOSPITAL DRUG ROOM LICENSE (INPATIENT);
- 16 (12) NURSING HOME AND RELATED FACILITIES LICENSE FOR
- 17 INPATIENT DISPENSING;
- 18 (13)] license amendment or replacement;
- 19 (10) [(14)] registration or licensure of a facility classified under
- 20 AS 08.80.157(b) [PHARMACY LOCATED OUTSIDE OF THE STATE].

21 * Sec. 15. AS 08.80 is amended by adding a new section to read:

22 Sec. 08.80.165. CONTINUING EDUCATION REQUIREMENTS. The board
23 shall establish requirements for continuing education in pharmacy that must be satisfied
24 before a license issued under this chapter may be renewed.

25 * Sec. 16. AS 08.80.261 is amended to read:

26 Sec. 08.80.261. GROUNDS FOR IMPOSITION OF DISCIPLINARY
27 SANCTIONS. The board may, after a hearing, impose a disciplinary sanction
28 authorized under AS 08.01.075 on a person licensed under this chapter when the
29 board finds that the licensee

- 30 (1) secured a license through deceit, fraud, or intentional
31 misrepresentation;

1 (2) engaged in deceit, fraud, or intentional misrepresentation in the
2 course of providing professional services or engaging in professional activities;

3 (3) advertised professional services in a false or misleading manner;

4 (4) has been convicted of a felony or has been convicted of another
5 [OTHER] crime that affects the licensee's ability to continue to practice competently
6 and safely;

7 (5) intentionally or negligently engaged in or permitted the performance
8 of patient care by persons under the licensee's supervision that does not conform to
9 minimum professional standards regardless of whether actual injury to the patient
10 occurred;

11 (6) failed to comply with this chapter, with a regulation adopted under
12 this chapter, or with an order of the board;

13 (7) is incapable of engaging in the practice of pharmacy with
14 reasonable skill, competence, and safety for the public because of [CONTINUED
15 TO PRACTICE AFTER BECOMING UNFIT DUE TO]

16 (A) professional incompetence;

17 (B) failure to keep informed of or use current professional
18 theories or practices;

19 (C) addiction or severe dependency on alcohol or a drug that
20 impairs the licensee's ability to practice safely;

21 (D) physical or mental disability; or

22 (E) other factors determined by the board;

23 (8) engaged in [LEWD OR IMMORAL] conduct involving moral
24 turpitude or gross immorality [IN CONNECTION WITH THE DELIVERY OF
25 PROFESSIONAL SERVICE TO PATIENTS];

26 (9) made a controlled substance available to a person except upon
27 prescription issued by a person licensed to prescribe controlled substances;

28 (10) was convicted of selling federal legend drugs without the
29 prescription of a person licensed to prescribe federal legend drugs;

30 (11) violated state or federal laws or regulations pertaining to [THE
31 PROVISION OF ADEQUATE SECURITY FOR DANGEROUS] drugs or

1 pharmacies:

2 (12) failed to report relevant information to the board about a
3 pharmacist or pharmacy intern that the licensee knew or suspected was incapable
4 of engaging in the practice of pharmacy with reasonable skill, competence, and
5 safety to the public;

6 (13) aided another person to engage in the practice of pharmacy
7 or to use the title of "pharmacist" or "pharmacy intern" without a license; or

8 (14) engaged in unprofessional conduct, as defined in regulations
9 of the board.

10 * Sec. 17. AS 08.80.261 is amended by adding a new subsection to read:

11 (b) The board may place under seal all drugs that are owned by or in the
12 possession, custody, or control of a licensee at the time a license is suspended or
13 revoked or at the time the board refuses to renew a license. Except for perishable
14 items, the drugs may not be disposed of until the licensee has exhausted administrative
15 and judicial remedies relating to the licensing action. Perishable items may be sold
16 upon order of the court with the proceeds to be deposited with the court. The board
17 shall notify the Department of Health and Social Services about drugs placed under
18 seal under this subsection.

19 * Sec. 18. AS 08.80.295 is repealed and reenacted to read:

20 Sec. 08.80.295. SUBSTITUTION OF EQUIVALENT DRUG PRODUCTS.

21 (a) Unless the prescription indicates that it is to be dispensed only as written, the
22 pharmacist may, with the consent of the patient, substitute an equivalent drug product.

23 (b) A pharmacist who substitutes an equivalent drug product in compliance
24 with this section and applicable regulations incurs no greater liability in filling the
25 prescription than would be incurred in filling the prescription by dispensing the
26 prescribed name brand product.

27 * Sec. 19. AS 08.80 is amended by adding a new section to read:

28 Sec. 08.80.315. CONFIDENTIALITY OF RECORDS. Information maintained
29 by a pharmacist in the patient's records or that is communicated to the patient as part
30 of patient counseling is confidential and may be released only to

31 (1) the patient or as the patient directs;

1 (2) a practitioner or pharmacist when, in the pharmacist's professional
2 judgment, release is necessary to protect the patient's health and well-being; and

3 (3) other persons or governmental agencies authorized by law to receive
4 confidential information.

5 * Sec. 20. AS 08.80.330(a) is amended to read:

6 (a) Each pharmacy shall have a pharmacist-in-charge. Whenever an
7 applicable law or regulation requires or prohibits action by a pharmacy,
8 responsibility shall be that of the owner and the pharmacist-in-charge, whether
9 the owner is a sole proprietor, partnership, association, corporation, or otherwise
10 [IF THE OWNER OF A PHARMACY IS NOT A LICENSED PHARMACIST, THE
11 OWNER SHALL PLACE A LICENSED PHARMACIST, DESIGNATED THE
12 MANAGER, IN FULL CHARGE AND CONTROL OF THE PHARMACY]. The
13 pharmacist-in-charge [MANAGER] shall ensure compliance with all laws and
14 regulations governing the operation of the pharmacy. A licensed pharmacist appointed
15 as pharmacist-in-charge [MANAGER] of a pharmacy shall immediately advise the
16 board of that appointment.

17 * Sec. 21. AS 08.80.400 is amended to read:

18 Sec. 08.80.400. OTHER LICENSEES [PRACTICE OF MEDICINE] NOT
19 AFFECTED. This chapter does not affect the practice of medicine by a licensed
20 medical doctor, and does not limit a licensed medical doctor, osteopath, podiatrist,
21 physician assistant, advanced nurse practitioner, dentist, veterinarian, dispensing
22 optician, or optometrist in supplying a patient with any medicinal preparation or
23 article within the scope of the person's license [THAT THE LICENSED MEDICAL
24 DOCTOR CONSIDERS PROPER].

25 * Sec. 22. AS 08.80.410 is amended to read:

26 Sec. 08.80.410. USE OF TERM "PHARMACIST" PROHIBITED. A person
27 may not assume or use the title "pharmacist," or any variation of the title, or hold out
28 to be a pharmacist, without being licensed [REGISTERED].

29 * Sec. 23. AS 08.80.430 is amended to read:

30 Sec. 08.80.430 USE OF PHARMACY SYMBOLS PROHIBITED. A person
31 may not display in a place of business the characteristic pharmacy symbol of "Rx" in

1 any form [BOTTLES, OR GLOBES, WHICH ARE COLORED OR CONTAIN
2 COLORED LIQUIDS] 'unless the business has a pharmacist licensed [AND
3 REGISTERED] under this chapter [ON DUTY UNDER AS 08.80.320].

4 * Sec. 24. AS 08.80.480(4) is amended to read:

5 (4) "drug" means an article recognized as a drug in an official
6 compendium, or supplement to an official compendium [IN THE OFFICIAL
7 UNITED STATES PHARMACOPOEIA, OFFICIAL HOMEOPATHIC
8 PHARMACOPOEIA OF THE UNITED STATES, OR OFFICIAL NATIONAL
9 FORMULARY]; an article intended for use in the diagnosis, cure, mitigation,
10 treatment, or prevention of disease in man or animal; an article other than food,
11 intended to affect the structure or function of the body of man or animal; and an article
12 intended for use as a component of an article specified in this paragraph but does not
13 include devices or their components, parts, or accessories;

14 * Sec. 25. AS 08.80.480(11) is repealed and reenacted to read:

15 (11) "pharmacy" means a place in this state where drugs are dispensed
16 and pharmaceutical care is provided and a place outside of this state that is subject to
17 licensure or registration under AS 08.80.157(b);

18 * Sec. 26. AS 08.80.480(14) is repealed and reenacted to read:

19 (14) "prescription drug" means a drug that, under federal law, before
20 being dispensed or delivered, is required to be labeled with either of the following
21 statements: (A) "Caution: Federal law prohibits dispensing without prescription"; (B)
22 "Caution: Federal law restricts this drug to use by, or on the order of, a licensed
23 veterinarian"; or a drug that is required by an applicable federal or state law or
24 regulation to be dispensed only under a prescription drug order or is restricted to use
25 by practitioners only;

26 * Sec. 27. AS 08.80.480 is amended by adding new paragraphs to read:

27 (21) "administer" means the direct application of a drug to the body of
28 a patient or research subject by injection, inhalation, ingestion, or other means;

29 (22) "compounding" means the preparation, mixing, assembling,
30 packaging, or labeling of a drug or device (A) as the result of a practitioner's
31 prescription drug order or initiative based on the relationship of the practitioner,

1 patient, and pharmacist in the course of professional practice or (B) for the purpose of,
2 or as an incident to, research, teaching, or chemical analysis and not for sale or
3 dispensing; "compounding" also includes the preparation of drugs or devices in
4 anticipation of prescription drug orders based on routine, regularly observed
5 prescribing patterns;

6 (23) "deliver" or "delivery" means the actual, constructive, or attempted
7 transfer of a drug or device from one person to another, whether or not for
8 consideration;

9 (24) "device" means an instrument, apparatus, implement, machine,
10 contrivance, implant, or other similar or related article, including a component part or
11 accessory, that is required under federal law to bear the label "Caution: Federal or state
12 law requires dispensing by or on the order of a physician";

13 (25) "dispense" or "dispensing" means the preparation and delivery of
14 a drug or device to a patient or patient's agent under a lawful order of a practitioner
15 in a suitable container appropriately labeled for subsequent administration to, or use
16 by, a patient;

17 (26) "distribute" means the delivery of a drug or device other than by
18 administering or dispensing;

19 (27) "drug regimen review" includes evaluation of the prescription drug
20 order and patient record for

21 (A) known allergies;

22 (B) rational therapy-contraindications;

23 (C) reasonable dose and route of administration;

24 (D) reasonable directions for use;

25 (E) duplication of therapy;

26 (F) drug-drug, drug-food, and drug-disease interactions;

27 (G) adverse drug reactions; and

28 (H) proper utilization, including over- or under-utilization, and
29 optimum therapeutic outcomes;

30 (28) "equivalent drug product" means a drug product that has the same
31 established name, active ingredients, strength or concentration, dosage form, and route

1 of administration and that is formulated to contain the same amount of active
2 ingredients in the same dosage form and to meet the same compendia or other
3 applicable standards for strength, quality, purity, and identity, but that may differ in
4 characteristics such as shape, scoring configuration, packaging, excipients including
5 colors, flavors, preservatives, and expiration time;

6 (29) "intern" means an individual who is

7 (A) currently licensed by this state to engage in the practice of
8 pharmacy while under the personal supervision of a pharmacist and is
9 satisfactorily progressing toward meeting the requirements for licensure as a
10 pharmacist; or

11 (B) a graduate from a college of pharmacy who is currently
12 licensed by the board for the purpose of obtaining practical experience as a
13 requirement for licensure as a pharmacist;

14 (30) "labeling" means the process of preparing and affixing a label to
15 a drug container, exclusive, however, of the labeling by a manufacturer, packer, or
16 distributor of a nonprescription drug or commercially packed legend drug or device;

17 (31) "legend drug" means a prescription drug;

18 (32) "manufacturing" means the production, preparation, propagation,
19 conversion, or processing of a drug or device, either directly or indirectly, by
20 extraction from a substance of natural origin or independently by means of chemical
21 or biological synthesis, and includes packaging or repackaging of a substance or
22 labeling or relabeling of its container, and the promotion and marketing of drugs or
23 devices; "manufacturing" also includes the preparation and promotion of commercially
24 available products from bulk compounds for resale by pharmacies, practitioners, or
25 other persons;

26 (33) "patient counseling" means the communication by the pharmacist
27 of information, as defined in the regulations of the board, to the patient or care giver
28 in order to improve therapy by ensuring proper use of drugs and devices;

29 (34) "person" has the meaning given in AS 01.10.060 and also includes
30 a governmental agency;

31 (35) "pharmaceutical care" is the provision of drug therapy and other

1 pharmaceutical patient care services intended to achieve outcomes related to the cure
2 or prevention of a disease, elimination or reduction of a patient's symptoms, or
3 arresting or slowing of a disease process as defined in regulations of the board;

4 (36) "pharmacist" means an individual currently licensed by this state
5 to engage in the practice of pharmacy;

6 (37) "pharmacist-in-charge" means a pharmacist who accepts
7 responsibility for operation of a pharmacy in a manner that complies with laws and
8 regulations applicable to the practice of pharmacy and the distribution of drugs and
9 who is personally in charge of the pharmacy and the pharmacy's personnel;

10 (38) "pharmacy technician" means a supportive staff member who
11 works under the immediate supervision of a pharmacist;

12 (39) "practice of pharmacy" means the interpretation, evaluation, and
13 dispensing of prescription drug orders in the patient's best interest; participation in
14 drug and device selection, drug administration, drug regimen reviews, and drug or
15 drug-related research; provision of patient counseling and the provision of those acts
16 or services necessary to provide pharmaceutical care; and the responsibility for:
17 compounding and labeling of drugs and devices except labeling by a manufacturer,
18 repackager, or distributor of nonprescription drugs and commercially packaged legend
19 drugs and devices; proper and safe storage of drugs and devices; and maintenance of
20 proper records for them;

21 (40) "practitioner" means an individual currently licensed, registered,
22 or otherwise authorized by the jurisdiction in which the individual practices to
23 prescribe and administer drugs in the course of professional practice;

24 (41) "preceptor" means an individual who is currently licensed by the
25 board, meets the qualifications as a preceptor under the regulations of the board, and
26 participates in the instructional training of pharmacy interns;

27 (42) "prescription drug order" means a lawful order of a practitioner
28 for a drug or device for a specific patient;

29 (43) "prospective drug use review" means a review of the patient's drug
30 therapy and prescription drug order, as defined in the regulations of the board, before
31 dispensing the drug as part of a drug regimen review;

1 (44) "significant adverse drug reaction" means a drug-related incident
2 that may result in serious harm, injury, or death to the patient;

3 (45) "substitution" means to dispense without the prescriber's expressed
4 authorization, an equivalent drug product in place of the prescribed drug;

5 (46) "wholesale drug distributor" means anyone engaged in wholesale
6 distribution of drugs, including but not limited to manufacturers; repackagers; own-
7 label distributors; private label distributors; jobbers; brokers; warehouses, including
8 manufacturers' and distributors' warehouses; chain drug warehouses; wholesale drug
9 warehouses; independent wholesale drug traders; and retail pharmacies that conduct
10 wholesale distributions.

11 * Sec. 28. AS 08.80.040, 08.80.130, 08.80.140, 08.80.220, 08.80.230, 08.80.240, 08.80.270,
12 08.80.280, 08.80.290, 08.80.300, 08.80.310, 08.80.320, 08.80.340, 08.80.350, 08.80.360,
13 08.80.365, 08.80.370, 08.80.440, 08.80.480(2), 08.80.480(5), 08.80.480(6), 08.80.480(7),
14 08.80.480(13), 08.80.480(16), 08.80.480(17), 08.80.480(18), and 08.80.480(20) are repealed.

The Committee Substitute you have before you today contains changes suggested by the Division of Occupational Licensing. We support these changes:

Under Section 10, page 5, line 18, deletes "has never had" and inserts "does not currently have..."

This change relieves the concern of violating the Americans With Disabilities Act. For example, if a pharmacist's license were revoked in another state due to alcohol addiction and that person completed a mandated treatment program, they still would be prohibited from obtaining an Alaska license. This change alleviates that concern.

Under Section 10, line 22. New subsection "(8) passes the Alaska Jurisprudence examination."

This would require an applicant to pass an examination regarding state statutes and regulations.

Under Section 13, page 7, lines 10 and 11. Adds "owner(s)" after "facility" and "pharmacy."

Wanted to have the owners or individuals directly responsible and to prevent a person with a prior felony record from being able to own and operate a facility.

Under Section 13, page 7, line 28. Adds "osteopaths and podiatrists" to the list of exempted licenses.

Under Section 14, page 8. Delete (6), (7), (10), (11) and (12).

Re-number and add a new (10) pharmacy facilities classified in accordance with AS 08.80.157(b).

Add new (11) pharmacy technician.

This change allows the Board of Pharmacy to develop categories of facilities in regulation. The "technician" part is necessary to give the

Board of Pharmacy authority to set a license fee for technicians...if so desired.

Under Section 21, page 11, line 16. Adds "osteopaths and podiatrists" to the list of "OTHER LICENSEES" not affected by this bill.

Under Section 25, page 12, lines 10 and 11. After "... outside of this state" deletes "...where drugs are dispensed and pharmaceutical care is provided to residents of this state."

Replaces with "which may be required to be registered under AS 08.80.157(b).

Current wording is somewhat unclear by allowing the Board to extend its authority out of state.

Under Section 28. Delete AS 08.80.475.

This was a oversight and not meant to give the Board of Pharmacy authority over federal facilities.

Under Section 28. Add AS 08.80.140.

This section has been reworked under Section 14 of the Committee substitute and is redundant.

Alaska State Legislature

SENATOR

MIKE MILLER

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Senate

While in Juneau

State Capitol

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99801-1182

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Senate District O

SPONSOR STATEMENT

SB 158

"An Act Relating to Pharmacists and Pharmacies"

The passage of this legislation is necessary to keep the practice of pharmacy in Alaska in step with national standards and to afford the public the safety and protection it deserves.

Current statutes are antiquated and obsolete. For example, investigative personnel within the Division of Occupational Licensing have continually experienced difficulty in investigating and processing complaints against licensed personnel and facilities because of vague, inadequate or non-existent language regarding unprofessional conduct and disciplinary sanctions. Many of the statutes are dated from the 1970's and do not reflect the current practice of pharmacy or changing nature of the profession.

Using the Model State Pharmacy Act of the National Association of Boards of Pharmacy as a template, this legislation reflects over four years of work by the pharmacy community and is supported by the Alaska Pharmaceutical Association and the Alaska Board of Pharmacy.

SPONSOR STATEMENT

CSSB 158 (L & C)

Section 1: Amends AS 08.02.010(a) to change verbage from registered to licensed for consistency with balance of statutes. A license is a permission to act granted by competent authority as opposed to register which indicates to enroll or record.

Section 2: Amends AS 08.80 by adding new sections AS 08.80.003 "Practice of Pharmacy as a Profession" and AS 08.80.005 "Statement of Purpose." Pharmacy is a learned profession affecting public health and welfare and should be declared as such. The statement of purpose is designed to define the general scope of the Pharmacy Act. It provides for the control and regulation of the practice of pharmacy and the licenser of facilities engaged in the distribution of drugs and related devices. Because "distribution" is defined as delivery of a drug or device other than by administration or dispensing, practitioner's offices and medical clinics would not be subject to licenser by the Board of Pharmacy.

Section 3: Amends AS 08.80.010 by adding a new subsection (b) which establishes term limits for officers elected by the Board.

Section 4: Repeals AS 08.80.030 and reenacted to empower the Board to make such regulations as are necessary to fully administer and implement this Act. This section clarifies the responsibilities of the Board in order to protect the public health and welfare including licenser and renewal of licenses of personnel and facilities, regulation of pharmacists, interns, and technicians, the establishment of rules of conduct, professional standards and standards for education and training. Redundant language in the existing section is repealed.

Section 5: Amends AS 08.80.060 to specify at least three meetings annually, which is current practice.

Section 6: Amends AS 08.80.070 technical change by replacing "registration" with "licenser."

Section 7: Repeals and reenacts AS 08.80.110 by changing verbage from registration to licenser. Recognized that applicants for licenser must pass multiple examinations and recognizes the score transfer process administered by the National Association of Boards of Pharmacy. Removes specifics from the internship training clause, allowing that to be modified by regulation as needed. Allows a mechanism for graduates of foreign colleges of pharmacy to receive licenser upon meeting strict requirements of the National Association of Boards of Pharmacy.

Section 8: Repeals and reenacts AS 08.80.116 by providing broad authority to establish internship and training requirements. Specific requirements are repealed which will be addressed in regulation.

Section 9: Repeals and reenacts AS 08.80.120 states the examination or examinations shall be prepared to measure the competence of the applicant to engage in the practice of pharmacy. They board may employ, cooperate, and contract with an organization or consultant in the preparation and grading of an examination. The board shall retain sole discretion and responsibility for determining which applicants have successfully passed the examination.

Section 10: Amends AS 08.80 by adding two new sections AS 08.80.145, which provides and clarifies guidelines for reciprocity of license from another state, and AS 08.80.147 which provides guidelines for renewal of licenses which have been lapsed for five years or more.

Section 11: Repeals and reenacts AS 08.80.150 which grants the Board the authority to issue temporary licenses. Repeals specific language which can be modified as needed by regulation.

Section 12: Repeals and reenacts AS 08.80.155 which grants the Board the authority to issue emergency permits. Repeals specific language which can be modified as needed by regulation.

Section 13: Repeals and reenacts AS 08.80.157 which grants and clarifies the authority of the Board to license and renew licenses of facilities involved in the practice of pharmacy or the manufacture of drugs. Allows the Board to determine classifications and criteria for licenser. Specifies that each location must be licensed and that a license is not transferable or assignable. Provides reporting requirements for licensed facilities and grounds for denying a license or taking disciplinary action against a license.

Section 14: Amends AS 08.80.165 by changing the fees terminology.

Section 15: Amends AS 08.80 by adding a new section AS 08.80.165 granting the Board authority to establish continuing education requirements for pharmacists.

Section 16: Amends AS 08.80.261 by changing grounds for disciplinary action to insure protection of the public, while allowing the Board to adapt them to changing conditions as necessary. Board regulations will make the grounds for disciplinary action specific, understandable and reasonable.

Section 17: Adds a new section AS 08.80.261(b) which gives the Board the ability to seal drugs during certain licensing actions to prevent the unlawful distribution of prescription drugs in the absence of a licensed pharmacist or valid pharmacy license.

Section 18: Repeals and reenacts AS 08.80.295 which continues authority for substitution of equivalent drug products (as defined in AS 08.80.480) while allowing the Board to address specific requirements in regulation.

Section 19: Adds a new section AS 08.80.315 which clarifies the confidentiality of certain records and information.

Section 20: Amends AS 08.80.330 to standardize terminology to Pharmacist in Charge instead of manager. Also allows for owners who are pharmacists but not actively practicing to appoint a Pharmacist in Charge.

Section 21: Amends AS 08.80.400 to specify that this chapter does not affect the practice of medicine by a licensed medical doctor, and does not limit a licensed medical doctor, physician assistant, advanced nurse practitioner, dentist, dispensing optician, or optometrist in supplying a patient with any medicinal preparation or article within the scope of the person's license.

Section 22: Amends AS 08.80.410 by changing the word "registered" to "licensed."

Section 23: Amends AS 08.80.430 prohibits the use of the symbol "Rx" unless the business has a pharmacist licensed under this chapter.

Sections

24-27: Repeals and reenacts AS 08.80.480(11), 08.80.480(14) and amends AS 08.80.480. These are updated definitions for terms used in this bill. The definition of the "Practice of Pharmacy" is one of the most important clauses in the Act because it is expressed in broad terms to provide latitude to the Board of Pharmacy in the adoption of implementing regulations.

Section 28: Repeals numerous sections that are better addressed through regulation by the Board of Pharmacy.

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Regional Offices
5530 E. Northern Lights Blvd. #1A
Anchorage, Alaska
99504
(907) 333-2037



May 1, 1995

Senator Mike Miller
Labor and Commerce
Juneau, Alaska

Dear Senator Miller,

I urge you to support passage of SB158. As you have heard from previous testimony much work has gone into the preparation of these statute changes and additions over the past four years.

With the bill now introduced, please move it along to a speedy passage in the Senate and on to the House for their consideration.

As Pharmacy District Manager for Payless Drug Stores I support this bill in its entirety.

Thanks for your support.

Sincerely,

Stan Thompson, R.Ph.
Pharmacy District Manager
PayLess Drug Stores

"Because Alaska deserves more from a drug store."

JOY HOLLOMAN DONELSON
908 R STREET
ANCHORAGE, ALASKA 99501
PH 907 2775018 FAX 907 272-5175

APRIL 28, 1995

DEAR SENATOR,

I WRITE YOU TO URGE YOU TO SUPPORT SENATE BILL 158 WHICH IS
A REWRITE OF THE STATE PHARMACY STATUTES.
I HAVE PRACTICE PHARMACY IN ALASKA FOR 34 YEARS AND HAVE
SERVED ON THE STATE BOARD OF PHARMACY AND I ASSURE YOU
THAT OUR LAWS ARE WOEFULLY OUT OF DATE, MANY DATING BACK
TO THE FIFTIES. THESE CHANGES ARE NEEDED TO REFLECT THE
WAY THE PROFESSION IS PRACTICED TODAY AND TO PROTECT THE
CITIZENS OF THE STATE.
I APPRECIATE YOUR CONSIDERATION.

SINCERELY,



JOY H. DONELSON R.PH F.A.C.A.



ALASKA PHARMACEUTICAL ASSOCIATION

Box 10-1185 Anchorage, Alaska 99510

TO: ALASKAN STATE SENATORS

FROM: ALASKA PHARMACEUTICAL ASSOCIATION

SUBJECT: SB 158 PHARMACY

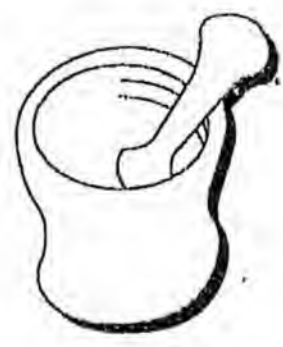
We urge you to support Senate Bill 158 which is a rewrite of the Alaskan pharmacy statutes. This bill has been introduced by Senator Miller and is being reviewed by the Labor and Commerce committee right now. This bill has been endorsed by the Alaska Pharmaceutical Association which represents all the pharmacists in this state and by the Alaska Board of Pharmacy. The Division of Occupational Licensing has requested a rewrite of our statutes because they have experienced difficulty investigating and processing complaints against pharmacists and pharmacies due to vague or non-existent language in the current pharmacy statutes. The Board of Pharmacy has been recommending specific statute revisions since 1984. Many of our current statutes were written in the 1930's -1950's and do not reflect the practice of pharmacy today.

SB 158 was written using the Model State Pharmacy Act provided by the National Association of Boards of Pharmacy. This bill will enable us to regulate our own profession better and discipline pharmacists or pharmacies that endanger the public health. SB 158 is needed to hold Alaskan pharmacists and pharmacies to standards of practice that apply in other states in this country. Please support this bill and give the Board of Pharmacy the necessary authority to discipline pharmacists and pharmacies when they threaten the public health.

Sincerely,

Abbie Thielen

Abbie Thielen
Legislative Chair
Alaska Pharmaceutical Association



Margaret D. Soden, RPh
PO Box 61328
Fairbanks, AK 99706-1328

April 17, 1995

Senator Mike Miller
Senate District Q
State Capitol, Room 125
Juneau, AK 99801-1182

RE: SB 158 "An Act relating to pharmacists and pharmacies"

Dear Senator Miller:

I am writing to urge you to support SB 158, "An Act relating to pharmacists and pharmacies." This bill will revise and update the antiquated, obsolete and inadequate statutes that currently govern the practice of pharmacy in Alaska. Many of our current statutes were enacted in a piecemeal fashion in the 1950's and 1960's and no longer reflect the current practice of pharmacy nor the changing nature of our profession. This has resulted in much overlap, ambiguity, vagueness, and omission, and there is often a conflict with federal law or other state statutes that also govern parts of our daily practice. Because of vague, inadequate, or non-existent language regarding unprofessional conduct and disciplinary sanctions, the Alaska Board of Pharmacy's investigators in the Division of Occupational Licensing have difficulty investigating and processing complaints against licensed personnel and facilities.

When I served on the Alaska Board of Pharmacy from 1981-1989, we made numerous unsuccessful attempts to revise our statutes in response to Legislative Audit Committee recommendations. Realizing the need to have the statutes governing our profession move into the 1990's and beyond, a task force from the Alaska Board of Pharmacy and the Alaska Pharmaceutical Association was formed with this goal in mind. The task force has been working for the last four years to draft these proposed statutory changes using the Model State Pharmacy Act of the National Association of Boards of Pharmacy as a guide. The membership of both groups have approved the changes proposed by the task force.

As a pharmacist, I work every day to care for the medication needs of my patients. I have worked in my chosen profession for 30 years and hope to work for 30 more. Because it is dynamic and ever changing, the laws that govern pharmacy practice need to be written to allow for change while still protecting the public's health. I believe this revision of the pharmacy statutes will accomplish this and urge you to support SB 158 in its entirety.

Sincerely yours,

Margaret D. Soden RPh
Margaret D. Soden, RPh

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