

SBILDS

HOUSE COMMITTEE REPORT

(11)

Date Referred: April 24, 1992

FURTHER REFERRALS:

Date of Committee Action: 5/9/92

The FINANCE Committee considered:

CSSB 125(HES)

CS FOR SENATE BILL NO. 125 (HES)

REGISTRATION OF OUT OF STATE PHARMACIES

"An Act relating to pharmacies located outside of the state."

RECOMMENDATIONS: [] the same title
 be replaced with _____ [] a new title

[] have attached amendments(s)

[] do pass

[] do not pass

[] no recommendations

[] individual recommendations

[] additional referral to the _____ Committee

ADOPTS: _____ letter of Intent

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

APPROVES PREVIOUS: (Dept/Date) _____

[] fiscal impact _____

[] fiscal note(s) DCED 3/27/92

[] zero fiscal note _____

[] zero fiscal note(s) _____

SIGNING <u>DO</u> PASS	DP	OTHER RECOMMENDATIONS	DNP	NR	AM
<i>Mike Navarre</i> NAVARRE	✓				
<i>Mark Boyer</i> BOYER	X				
<i>Kopmen</i> KOPMEN	✓				
<i>Tay Brown</i> BROWN	✓				
<i>Phillips</i> PHILLIPS	✓				
<i>Lansu</i> LANSU	X				
<i>Burns</i> BURNS	X				

Mike Navarre NAVARRE

 CO-CHAIRMAN'S SIGNATURE

1992 LEGISLATIVE SESSION

Revision Date: 03/24/92 Department Affected: Commerce & Economic Development
 Title: An Act relating to pharmacies located outside BRU: Occupational Licensing
of the state. Component: Administration
 Sponsor: Senator Menard
 Requestor: Senate HES COMPONENT SERIAL NO.

0	3	5	6
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Expenditures/Revenues: (Thousands of Dollars)

OPERATING	FY 93	FY 94	FY 95	FY 96	FY 97	FY 98
PERSONAL SERVICES	0.0	0.0	0.0	0.0	0.0	0.0
TRAVEL	0.0	0.0	0.0	0.0	0.0	0.0
CONTRACTUAL	3.0	3.0	3.0	3.0	3.0	3.0
SUPPLIES	0.0	0.0	0.0	0.0	0.0	0.0
EQUIPMENT	0.0	0.0	0.0	0.0	0.0	0.0
LAND & STRUCTURES	0.0	0.0	0.0	0.0	0.0	0.0
GRANTS, CLAIMS	0.0	0.0	0.0	0.0	0.0	0.0
MISCELLANEOUS	0.0	0.0	0.0	0.0	0.0	0.0
TOTAL OPERATING	3.0	3.0	3.0	3.0	3.0	3.0

CAPITAL	0.0	0.0	0.0	0.0	0.0	0.0
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REVENUE	3.0	3.0	3.0	3.0	3.0	3.0
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FUNDING: (Thousands of Dollars)

GENERAL FUND	0.0	0.0	0.0	0.0	0.0	0.0
FEDERAL FUNDS	0.0	0.0	0.0	0.0	0.0	0.0
OTHER - GF/PR	3.0	3.0	3.0	3.0	3.0	3.0
TOTAL	3.0	3.0	3.0	3.0	3.0	3.0

POSITIONS:

FULL-TIME	0.0	0.0	0.0	0.0	0.0	0.0
PART-TIME	0.0	0.0	0.0	0.0	0.0	0.0
TEMPORARY	0.0	0.0	0.0	0.0	0.0	0.0

Estimate of current year impact: None

ANALYSIS: (Attach a separate page if necessary)

The bill establishes a registration requirement for out-of-state pharmacies who regularly deliver drugs to consumers in Alaska. There have been many inquiries made to the Board of Pharmacy about licensing requirements for out-of-state pharmacies; however, there is no way to estimate the numbers that may apply. (Continued on attached page)

Prepared By: Jennifer Strickler Phone: 465-2144
 Division: Occupational Licensing Date: 03/24/92
 Approved by Commissioner: Gleam A. Olds
 Agency: Commerce & Economic Development Date: 3.24.92

Distribution (by preparer): Legislative Finance, Legislative Sponsor, Requestor, OMB, & Impacted Agency(ies).

Continuation of Fiscal Note Analysis - CSHB 125(HES)

The contractual services cost of \$3.0 will provide funding for public notices of the new requirement, printing of applications, postage, communication expenses, and other contractual needs.

Information received by the division indicate that some States which currently regulate out-of-state pharmacies experience that most applicants come from the nearest surrounding states. Although we have no way of knowing the numbers of applicants that may seek registration under this bill, the division anticipates on establishing a registration fee that will cover program costs.

CS FOR SENATE BILL NO. 125 (HES)
IN THE LEGISLATURE OF THE STATE OF ALASKA
SEVENTEENTH LEGISLATURE - FIRST SESSION

BY THE SENATE HEALTH, EDUCATION AND SOCIAL SERVICES COMMITTEE

Offered: 3/27/91
Referred: Labor and Commerce

Sponsor(s): SENATOR MENARD

A BILL

FOR AN ACT ENTITLED

1 "An Act relating to pharmacies located outside of the state."

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

3 * Section 1. AS 08.80 is amended by adding a new section to read:

4 Sec. 08.80.158. REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF STATE.

5 (a) A pharmacy located outside of the state that regularly ships, mails, or delivers prescription
6 drugs to consumers in the state shall register with the board.

7 (b) A pharmacy registering with the board under (a) of this section shall furnish to the
8 board annually

9 (1) the location, names, and titles of all principal corporate officers and of all
10 pharmacists who are dispensing prescription drugs to residents of the state;

11 (2) a copy of a current valid license, permit, or registration to conduct operations
12 in the jurisdiction in which it is located, and a copy of the most recent report resulting from an
13 inspection of the pharmacy by the regulatory or licensing agency of the jurisdiction in which the
14 pharmacy is located;

1 (3) a sworn statement indicating that the pharmacy complies with all lawful
2 directions and requests for information from the regulatory or licensing authority of the
3 jurisdiction in which the pharmacy is licensed; and

4 (4) proof satisfactory to the board that the pharmacy maintains its records of
5 prescription drugs dispensed to persons in the state so that the records are readily retrievable from
6 the records of other prescription drugs dispensed by the pharmacy.

7 (c) A pharmacy subject to this section shall, during its regular hours of operation, provide
8 a toll-free telephone service to facilitate communication between persons in the state and a
9 pharmacist at the pharmacy who has access to records concerning the dispensing of prescription
10 drugs to persons in the state. The toll-free number and the hours that the service is available
11 shall be disclosed on a label affixed to each container of drugs dispensed to persons in the state.
12 The telephone service shall be available at least 40 hours a week and at least six days a week.

13 (d) The board may, after a hearing, deny, revoke, or suspend the registration of a
14 pharmacy located outside of the state and subject to this section if the pharmacy fails to comply
15 with the requirements of this section, AS 17.20.080 - 17.20.135, or AS 17.30.020 - 17.30.080,
16 or if the license, permit, or registration of the pharmacy is denied, revoked, or suspended by the
17 licensing or regulatory agency of the jurisdiction in which the pharmacy is located.

18 (e) A pharmacy located outside of the state that is subject to this section but is not regis-
19 tered with the board under this section may not ship, mail, or deliver prescription drugs into the
20 state and may not advertise its services in the state.

21 (f) A pharmacy subject to this section shall appoint a registered agent in the state who
22 is empowered to accept, on behalf of the pharmacy, process, notice, and demand required or
23 permitted by law to be served upon the pharmacy. If the pharmacy fails to appoint an agent
24 under this subsection, if the registered agent cannot with reasonable diligence be found at the
25 registered office, or if the registration of the pharmacy is suspended or revoked, the commissioner
26 of commerce and economic development is an agent upon whom process, notice, or demand may
27 be served. Service is made upon the commissioner in the same manner as provided for
28 corporations under AS 10.06.175(b), except that for the purposes of AS 10.06.175(b)(2)(A), the
29 address shall be the last registered address of the pharmacy as shown by the records of the board.

30 (g) The board shall by regulation define "regularly" for this section.

31 * Sec. 2. AS 08.80.160 is amended by adding a new paragraph to read:

1 (14) registration of a pharmacy located outside of the state.

2 * Sec. 3. AS 08.80.480 is amended by adding new paragraphs to read:

3 (19) "pharmacy located outside of the state" means a pharmacy that prepares or
4 mixes prescription drugs outside of the state, regardless of the location at which those drugs may
5 be shipped, mailed, or delivered to the consumer;

6 (20) "prescription drug" means a drug that requires a physician's prescription
7 before it may be dispensed.

DIVISION OF LEGAL SERVICES
LEGISLATIVE AFFAIRS AGENCY
STATE OF ALASKA

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240 Main Street, Suite 500
Juneau, Alaska 99801-2101

MEMORANDUM

March 2, 1992

SUBJECT: State's potential for liability under CSSB 125(HES)

TO: Senator Drue Pearce
Attn: Bill

FROM: Theresa L. Bannister *TB*
Legislative Counsel

You have asked for a brief memo addressing whether the state is exposing itself to liability by enacting a bill requiring the registration of out-of-state pharmacies. It is my understanding from your questions that you mean liability for personal injury, not liability for contractual obligations.

Initially, please be aware that this memo addresses only the state's potential liability under the bill. Determination of actual liability depends on the specific facts of each case. The state's potential for liability for personal injury is generally governed by AS 09.50.250. In that statute, the state indicates to what extent and in what cases it waives its sovereign immunity from liability.

Generally, a claim could not be maintained against the state for injuries suffered by a person if the claim was based on the state's failure to exercise or perform a discretionary function or duty under the registration procedures enacted by the bill. Discretionary acts are those acts that rise to the level of planning or policy formulation. They would include such acts as management decisions on how to implement the new registration requirements.

On the other hand, under AS 09.50.250 the state would have a potential for liability if state employees did not use due care when carrying out the registration provisions. This type of liability only arises when there is negligence in the performance of activities that are merely operational in nature, thereby implementing policy decisions, and are not discretionary acts discussed in the preceding paragraph. Just because a person is injured by a pharmacy registered under bill (e.g. pharmacy sends the wrong prescription) does not mean the state is potentially liable for the injury. The state

Senator Drue Pearce
March 2, 1992
Page 2

must be negligent in these operational activities before the potential for liability arises.^{1/}

If I may be of further assistance, please advise.

TLB:pl
92-148.plm

^{1/}And, of course, other requirements for liability must be present, such as a connection between the state negligence and the injury.



Alaska State Legislature

Senator Curt Menard



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E

SPONSOR STATEMENT

SB 125 "An Act relating to pharmacies located outside of the state"

There is a growing number of mail order pharmacies doing business in the state who are not accountable to their Alaskan customers. SB 125 addresses this consumer protection problem and provides reassurance to Alaskans who rely on those services.

SB 125 requires any pharmacy located outside of the state that ships, mails, or delivers prescription drugs into Alaska on a routine basis to register with the Alaska State Board of Pharmacy.

In order to register the pharmacy must provide specific documents that indicate compliance with licensing requirements in their home jurisdiction. The bill sets reasonable standards of disclosure to the Alaska Board of Pharmacy.

The most important requirement of this bill is the provision for out of state pharmacies to provide a toll free telephone service at least 40 hours a week and at least six days a week. When questions or problems resulting from prescription medication arise, it is imperative that the customer or medical responder be able to contact the dispensing pharmacist.

This legislation provides important measures to protect the health, safety and welfare of Alaskan consumers. Your support is greatly appreciated.

When an individual has questions about medication they receive from a mail order drug house the first place they go to is their local neighborhood pharmacist who can not provide adequate answers because they didn't fill the prescription. This bill has been introduced to eliminate that problem. It will not hinder the ability Alaskans now have to freely choose to do business through the mails with a reputable mail order pharmacist.

The bill requires out-of-state pharmacies to register with the state of Alaska. In order to do so they would have to provide:

- . Proof of a current valid license in the jurisdiction in which it is located and a sworn statement indicating compliance with the regulating authority of that jurisdiction. The majority of other states regulate pharmaceutical practices considerably more closely than Alaska and all of them regulate at least as closely as Alaska.

- . Proof that records of prescription drugs dispensed to Alaska residents are readily retrievable.

The most important provision, though, is the requirement for a toll-free telephone service. This will provide at least a minimum amount of customer service.

Most of the customers using out-of-state pharmacies are on maintenance medication. The form that the medication comes in may change with each purchase, the customer must be able to contact the dispensing pharmacist to verify that this is the same, and correct, medication.

Or maybe a prescription comes in the mail with "take as directed" on the label. Alaskan consumers need to be able to check the specifics of that instruction with the dispensing pharmacist.

If a problem arises, the doctor that attends to the patient must have immediate access to that vital information.

The bill has the support of the Dept. of Commerce and Economic Development, individual pharmacists and the Alaska Association of Pharmacists. It has a zero fiscal note and although the amount is not estimated--would generate revenue through an established registration fee.

This legislation was originally introduced late in the Sixteenth Legislature. The bill reference at that time was HB 508, the information in your packets that refers to HB 508 applies now to SB 125, the bill before you.

SB 125: An Act relating to pharmacies located outside of the state.

SB 125 establishes requirements for pharmacies located outside of Alaska to register with the Alaska Board of Pharmacy, if the pharmacy ships, mails, or delivers prescription drugs into the state.

The out-of-state pharmacy will be required to meet certain criteria established in the bill, including 1) registration of the names and locations of pharmacists who dispense prescription drugs to Alaska residents, 2) proof of maintenance of a current license and active pharmacy inspection in the jurisdiction in which the pharmacy is located, 3) compliance with all laws of the licensing authority within the jurisdiction where the pharmacy is located, and 4) proof that the pharmacy may readily retrieve the records of drugs prescribed to Alaska residents.

Currently, Alaska is not able to monitor or identify the out-of-state pharmacies who distribute prescription drugs to residents within the state. SB 125 will allow the Alaska Board of Pharmacy to require registration of outside pharmacies, thus providing some level of oversight -- albeit minimal -- of their activities in Alaska. The current lack of any review of outside pharmacies that mail, ship or deliver prescription drugs in Alaska raises consumer protection concerns.

Pharmacies located in Alaska are regulated by law to protect the health, safety and welfare of Alaskan consumers. Pharmacies located outside the state who service Alaska residents with prescription drugs should be subject to some degree of regulatory oversight. For this reason, the department supports SB 125.



Glenn A. Olds, Commissioner
Department of Commerce and
Economic Development

Date: 3/20/01

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JUNIOR VOICE
APRIL 1990

HEALTH & MEDICINE

Seniors: More drug use, more adverse reactions

by Jeffrey R. Richardson

Older adults use 25 percent of prescription drugs, more than people in younger age brackets. This makes them, as a group, proportionately more susceptible to adverse drug reactions, according to Cameale Johnson, clinical pharmacist at Humana Hospital-Alaska.

"Older adults are more frequently hospitalized due to adverse drug reactions," Johnson said. And medication misuse accounts for two-thirds of adverse drug reactions in the senior population, she said.

Drug side-effects that may be mild to nonexistent in younger people "may be significant in older adults," Johnson noted.

The phrase "adverse drug reaction" refers to any effect occurring from the use of a drug that is undesirable, including the failure to absorb the drug properly so it can address the targeted problem. A side-effect is a form of adverse reaction which can usually be anticipated because of the constituents of drugs and their known impact on the human organism.

Johnson said there are a number of reasons why people handle drugs differently as they age:

- To be effective, all drugs must be absorbed. Often changes in the gastro-intestinal system prevent

drugs from being readily absorbed.

- Drug effectiveness is dependent on good circulation. Throughout the aging process there are changes in the circulatory system which affect the ability of drugs to go to get where they are needed.

- Body composition, that is, the amount of fat or lean muscle tissue in a person, is a factor in the way the body handles drugs, since many drugs are taken up and stored in fat tissue.

"Probably the most significant one is the way we metabolize and excrete the drug," Johnson said. "The activity of the liver declines with age. Also, the kidneys don't always work quite as well. If they don't eliminate them, they're going to be subject to the toxic effect."

Johnson acknowledged it's easy to get prescription drugs confused, especially if a person is being treated for more than one condition. This raises the problem of adverse drug reactions resulting from drug interactions.

A number of steps can be taken to prevent harmful drug interactions. The most important is to utilize the services of one pharmacist who is familiar with your medical history and all of the drugs being utilized. In this way,

'Medication misuse accounts for two-thirds of adverse drug reactions in the senior population.'

- Cameale Johnson

interactions can be spotted that might be missed because doctors, or other pharmacists, don't know all the drugs a person is taking.

Johnson cautioned against storing prescription drugs in the bathroom, where they can rapidly deteriorate.

"It's the worst place you can store medications. It's a damp, humid environment," Johnson said. She suggested a hall closet, out of the reach of children.

Johnson also urges people to pay attention to the age of medications.

"I think it's important when you're no longer taking a medication to discard it."

Generally, drugs should not be kept longer than one year from the date the prescription was filled.

Johnson also warns people who tend to lose track of their dosages:

"In general, you should not double up on medications if you think you've skipped a dose."

Johnson concluded. *This information is presented by Senior Health Exchange, co-sponsored by Humana Seniors Association and Older Persons Action Group, Inc.*

PLEASE MICROFILM TOP PAGE ONLY

**DOCUMENTS WHICH HAVE NOT BEEN FILMED BUT ARE
AVAILABLE IN THE ORIGINAL FILE INCLUDE:**

CORRESPONDENCE IN SUPPORT OF SB 125 FROM:

- 1. ALASKA BOARD OF PHARMACY/DC&E, 4/06/92**
- 2. THE PHARMACY SERVICE OF THE AMERICAN
ASSOCIATION OF RETIRED PERSONS, 3/25/91**
- 3. ALASKA PHARMACEUTICAL ASSOCIATION, 2/25/91**
- 4. DOA, DIVISION OF RETIREMENT & BENEFITS, 3/19/90**