SB

125

FISCAL NOTE

STATE OF ALASKA
1991 LEGISLATIVE SESSION

BILL NO. SB 125

Revision Date:

Department Affected: Commerce & Economic Dev.

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

BRU: Occupational Licensing

Component: Administration

Sponsor: Senator Menard

Requestor: Senate HES

COMPONENT SERIAL NO. 0 3 5 6

Expenditures/Revenues: (Thousands of Dollars)

OPERATING	FY 92	FY 93	FY 94	FY 95	FY 96	FY 97
PERSONAL SERVICES						
TRAVEL						
CONTRACTUAL						
SUPPLIES						
EQUIPMENT						
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING	0	0	0	0	0	0
CAPITAL						
REVENUE	0	0	0	0	0	0

FUNDING: (Thousands of Dollars)

GENERAL FUND						
FEDERAL FUNDS						
OTHER						
TOTAL	0	0	0	0	0	0

POSITIONS:

FULL-TIME	0	0	0	0	0	0
PART-TIME	0	0	0	0	0	0
TEMPORARY	0	0	0	0	0	0

Estimate of current year impact: None

ANALYSIS: (Attach a separate page if necessary.)

SB 125 creates another pharmacy licensing category by registering outside pharmacies that ship, mail or deliver prescription drugs into Alaska. New funds are not required to implement the bill. **Revenues: A registration fee will be charged however, at this time we are unable to estimate the number of outside pharmacies affected by the bill.

Prepared By: Jennifer Strickler, Administrative Officer Phone: 465-2144

Division: Occupational Licensing Date: March 18, 1991

Approved by Commissioner: Glenn A. Olds Asst. Comm.

Agency: Commerce and Economic Development Date: 3-20-91

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

Alaska State Legislature

Senator Curt Menard

While in Session:
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Juneau, Alaska
99811
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Senate District 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.

WE SUPPORT
MADE IN ALASKA

DIVISION OF LEGAL SERVICES

LEGISLATIVE AFFAIRS AGENCY
STATE OF ALASKA

(907) 465-3867 or 465-2450
FAX (907) 465-2029
Mail Stop 3101

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 TLB
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

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.

DIVISION OF LEGAL SERVICES

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

MEMORANDUM November 18, 1991

SUBJECT: Regulation of pharmacies and drugs (CSSB 125 (HES))

TO: Senator Curt Menard

FROM: Theresa L. Bannister
Legislative Counsel

You have requested an opinion regarding two questions that the Senate Labor and Commerce Committee raised while discussing CSSB 125 (HES). This memo addresses those questions.

1. Additional requirements for out-of-state pharmacies.

You have asked whether the commerce clause prevents Alaska from imposing requirements on out-of-state pharmacies that are in addition to those of the home jurisdiction of the pharmacy, such as maintaining an 800 telephone number. This memo assumes that the requirement would apply only to out-of-state pharmacies that do business to some degree in the state, such as mail order pharmacies, which brings them within the jurisdiction of the state. The state may impose the requirements if they satisfy the federal commerce clause criteria and equal protection criteria.

A. Commerce Clause--where requirement not imposed on in-state pharmacies. If the requirements are to be imposed only on out-of-state pharmacies, the requirements would discriminate against the out-of-state pharmacies. In such a situation, the commerce clause[1/] requires the state to demonstrate that the requirement serves a legitimate local purpose and that this purpose could not be served as well by available nondiscriminatory means. See Maine v. Taylor, 91 L.Ed.2d 110, 121 (1986), citing Hughes v. Oklahoma, 60 L.Ed.2d 250. The standards for such justification are high. See New Energy Co. v. Limbach, 100 L.Ed.2d 302, 312 (1988). The requirements will not be upheld "unless the discrimination is demonstrably justified by a valid factor unrelated to economic protectionism." New Energy, supra at 308.

[1/]The commerce clause is found at art. I, sec. 8, cl. 3 of the United States Constitution and reads in pertinent part as follows: "Congress shall have power . . . to regulate commerce with foreign nations, and among the several states....").

You give as an example requiring the out-of-state pharmacy to maintain an 800 phone number. I presume that the purpose of the 800 number is to make it easier and less costly for consumers who purchase drug products from a pharmacy that is located out of the state to place orders, check on orders, and to deal with problems that may arise with the order or the drug product. This requirement would arguably help maintain the health of the drug product consumer by facilitating the use of necessary drug products. This appears to be a legitimate purpose. However, there is no reason why in-state pharmacies should not be required to maintain an 800 number as well. Due to the great distances between communities in the state, some state residents may have to order from a distance within the state, particularly those residents living in outlying bush areas. The state's purpose for imposing the telephone requirement would be served better if the requirement were imposed on all pharmacies, not just out-of-state pharmacies. Therefore, imposing this requirement only on out-of-state pharmacies may violate the commerce clause, unless there is another significant justification for imposing it only on out-of-state pharmacies.

B. Commerce clause--where requirement imposed on all pharmacies. If the requirement is imposed on all pharmacies, whether they are in-state or out-of-state, the requirement does affect interstate commerce, but the criteria to satisfy the commerce clause are more relaxed.

Where a statute regulates evenhandedly to promote a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on the commerce is clearly excessive in relation to the putative local benefits. See Pike v. Bruce Church, 25 L.Ed.2d 174, 178 (1970), citing Huron Cement Co. v. Detroit, 4 L.Ed.2d 852, 856 (1960). With regard to the 800 number, as discussed above, having an 800 number would promote public health by facilitating the use of necessary drug products, so the statute would promote a legitimate local public interest.

The effect of the 800-number requirement on interstate commerce appears to be an incidental effect on interstate commerce, since it does not apply just to or otherwise discriminate against interstate commerce.[2/] It does not appear to be for the purpose of economic protectionism. The burden of the requirement on interstate commerce would, therefore, need to be balanced against the anticipated local benefits. For example, with regard to the 800 number, a court would examine the need for and purpose of easy telephone access. Then it would examine the

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[2/]It is not clear just what the court means by the term "incidental". However, it appears to mean a requirement that does not affirmatively discriminate against interstate commerce. See Maine v. Taylor, 91 L.Ed.2d 110, 120 (1986). The term "incidental" appears to be a modern replacement for the terms "direct" and "indirect". Notwithstanding the Pike court's reference to "incidental", the term does not appear to be significant to the current standard for commerce clause review. See L. Tribe, American Constitutional Law 408 (2d ed. 1988).

administrative and monetary costs for an out-of-state pharmacy to maintain the number, as well as the disruption the requirement would cause for a pharmacy to design its system to handle the requirement of one state. The monetary and administrative costs of maintaining an 800 number do not seem to be particularly burdensome for a pharmacy. When balanced against the benefits to consumer health, the costs do not seem excessive. Therefore, imposing the 800 number requirement on all pharmacies does not seem to violate the commerce clause. The success of other requirements depends on the circumstances of the particular requirement imposed.

C. Equal Protection. Although you have raised only the commerce clause issue, if the requirements are imposed only on out-of-state pharmacies, the issue arises whether the classification and discrimination between in-state pharmacies and out-of-state pharmacies would violate the equal protection provision of the Alaska State Constitution (art. I, sec. 1). Assuming that the state equal protection clause is not violated by the requirements, it is unlikely that the requirements would violate the more lenient federal equal protection clause.

Art. I, sec. 23 of the state constitution allows the state to prefer its residents over nonresidents. Although the term "resident" that is used in sec. 23 usually carries the connotation of a natural person, not a legally constructed entity, the use of the term in the section is susceptible to the argument that sec. 23 also covers resident corporations, partnerships, and other non-natural business entities. If the term "residents" is interpreted to include corporations, partnerships, and other non-natural business entities, then there would be no violation of the state's equal protection clause. If the term "residents" is interpreted to apply only to natural persons, then the proposed requirements would satisfy the state's equal protection criteria for natural persons, but may not for non-natural persons.

The printed legislative history of the provision and the summary of the measure in the 1988 Election Pamphlet do not provide much assistance on the interpretation. (If you would like me to review the committee and floor tapes on this matter, please advise.) The statement by Representative Donley in the election pamphlet in support of the measure indirectly lends support to the provision applying to more than natural persons. In it he mentions the bidders' preference, which is found at AS 36.30.170(b) and which naturally involves corporations and other artificial entities, as an example of an important state preference that would survive better under the federal equal protection provision (which would be a result of the new measure). At this point, the result of an interpretation by the Supreme Court is a toss-up and not really predictable.

If artificial persons are not covered by art. I, sec. 23, in order for a state requirement that discriminates between resident pharmacies and non-resident pharmacies to be valid under the equal protection clause, the classification between in-state and out-of-

state must be reasonable, not arbitrary, and must bear a fair and substantial relation to a legitimate governmental objective; depending on the importance of the interest involved, a greater or lesser burden will be placed on the state to show this fair and substantial relationship. Wilson v. Municipality of Anchorage, 669 P.2d 569 (Alaska 1983). For example, the 800 number, as indicated above, appears to bear a fair and substantial relation to a legitimate governmental objective. However, as also indicated above, the classification may be considered arbitrary because it would be as helpful to have the number for some in-state pharmacies as for out-of-state pharmacies. Therefore, the 800-number requirement may not satisfy the state's equal protection clause in this situation. Other requirements would have to be examined individually for compliance with the equal protection clause.

2. Country-of-origin labelling for drugs. You have asked whether the state could require drugs to be labelled with the country of origin. I understand this requirement to mean the country where the drug was manufactured. It is my understanding that the committee's concern is that the quality of drugs from some countries may be low and the consumer should be told the country of origin.

A. Necessity for state requirement. Drug products that are imported into the United States generally must be labelled with the country of origin, and this requirement extends to the consumer container. See 19 CFR 134. Once in the United States, federal law does not require that the country of origin appear on the label. Federal law allows the package to display the name and place of business of the manufacturer, packer, or distributor. 21 U.S.C.S. 352. Since the manufacturer, packer, and distributor of the drug product may not be located in the same country, and since the distributor or packer may be located in the United States, a label that gives the address of the distributor or the packer may not disclose that the product was manufactured in a foreign country.

A foreign country may registered its drug product with the United States under 21 U.S.C. 360, which involves Department of Agriculture inspection of the drug for compliance with the standards for new drugs under 21 U.S.C. 355. In order to register the drug the establishment must provide the department with considerable information to assist the department to determine whether the establishment's drugs meet U.S. standards. 21 U.S.C.S. 360(i). Unless the product is so registered, when the product arrives in the United States, U.S. Customs is required to deliver samples of the product to the Department of Agriculture. 21 U.S.C. 381. The Department then inspects the samples to determine if they are adulterated, misbranded, or violate the U.S. standards for new drugs under 21 U.S.C. 355. Once a foreign the drug product has been admitted into the U.S., the product is subject to the same requirements as all other drug products in the U.S. It is my understanding from talking with the Director for the Compliance Section of the FDA's office in Seattle that the United States inspects foreign establishments regularly to determine if they are meeting the U.S. standards for drug products.

A. Federal preemption. If the state chooses to require drug products to be labelled with the country of origin of the manufacturer, it is necessary to determine whether the FDCA has preempted state action in this area. Under the supremacy clause (art. VI, cl.2, of the federal constitution) a federal law can override state laws that interfere with or are contrary to federal law. Gibbons v. Ogden, 6 L.Ed.23 (1824). Predictions regarding preemption issues are difficult to make since the U.S. Supreme Court has not enunciated a clear preemption standard,[3/] and each case tends to be determined on an ad hoc basis.

In this situation, drug products in interstate commerce are heavily regulated by the federal government, particularly by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 - 392) ("FDCA").The FDCA regulates the interstate commerce activity of drug products, including the labelling of the products. As indicated above, the FDCA requires a drug to be labelled with the name and place of business of the manufacturer, packer, or distributor. See 21 U.S.C. 352(b). The FDCA does not require the drug to be labelled with the address of the manufacturer. The state labelling requirement would, therefore, be more restrictive than that of the FDCA.

The FDCA does not expressly prohibit states from imposing their own labelling requirements on drug products. In this situation, labelling with the country of origin of the manufacturer would satisfy both the FDCA and the state requirement, so it would be possible for a person to comply with both the federal and the state requirements. Although it could be argued that labelling uniformity in the country is a goal of the FDCA, the inclusion of the manufacturer's address is consistent with the FDCA requirement. The comprehensive nature of federal regulation of this area suggests that congress intended state law to be preempted. On the other hand, health and welfare are traditional areas of state regulation, so federal interest is not dominant in this area. Further, the state requirement does not stand as an obstacle to the goal of the FDCA, since both are attempting to protect the health of drug product consumers by proper labelling.

There is a presumption that state or local regulation of matters related to health and welfare is not invalidated under the supremacy clause. See Hillsborough County, Fla. v. Automated Medical Laboratories, Inc., 85 L.Ed.2d 714, 722 (1985). The historic police powers of the states are not preempted unless that was the clear and manifest purpose of Congress. Id. at 722-723 (quoting Jones v. Rath Packing Co., 51 L.Ed.2d 604, 614, reh'd denied, 53 L.Ed.2d 240 (1977)). There also appears to be an overriding reluctance to infer preemption in ambiguous cases. L. Tribe, American Constitutional Law 479 (2d ed. 1988).

[3/] See Rothschild, "A Proposed 'Tonic' with Florida Lime to Celebrate our New Federalism: How to Deal with the 'Headache' of Preemption", 38 U. of Miami L. Rev. 829, 833 (1983).

In light of the absence of express preemption, the lack of a conflict between the two statutes, the presumption for state health and welfare measures, and the reluctance to preempt state laws, it is my opinion that the labelling requirement would not be preempted by federal law.

B. Commerce clause. Since the labelling requirement would be imposed on all drug products (not just those in interstate commerce), the more relaxed commerce clause criteria used in 1.B. of this memo would be applied. Where a statute regulates evenhandedly to promote a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on the commerce is clearly excessive in relation to the putative local benefits. See Pike v. Bruce Church, 25 L.Ed.2d 174, 178 (1970), citing Huron Cement Co. v. Detroit, 4 L.Ed.2d 852, 856 (1960).

In this situation, the purpose of the labelling requirement appears to be to protect public health by allowing consumers to avoid drug products manufactured in countries that may not have the same standards as the United States. Since the requirement applies across the board to all drug products, the requirement applies evenhandedly and does not appear to have any goal of economic protectionism. The effect of the requirement on interstate commerce appears to be an incidental effect on interstate commerce, since the requirement does not discriminate against interstate commerce.[4/]

Here again the burden of the requirement on interstate commerce would need to be balanced against the anticipated local benefits. A court would examine the need for a consumer to have the information. This probably would include an inquiry into whether the federal law regulating the quality of drug products that are manufactured in foreign countries is sufficient to cover the concern that drug products in some foreign countries do not have the same quality as those produced in the United States. Since the federal government appears to regularly inspect drug product plants in foreign countries and to impose the same quality standards on foreign drug products as to domestic drug products, the actual benefits to citizens of Alaska of the labelling requirement appear to be questionable. The public would be able, however, to choose whether or not to purchase products from foreign countries. The requirement would assist a person who does not believe that the quality of the drug products from certain countries is very good to avoid those products. The state may believe that this is an important goal.

[4/]See fn. 2 on this point.

A court would also examine the nature and extent of the burden that would be imposed on interstate commerce. The initial burden would be significant, since some products would have to be relabelled especially for Alaska. The ongoing burden does not seem to be very heavy, because a company could substitute one address for another when printing its labels.

When balancing the benefits with the burden, although the state benefits do not seem to be very significant, the burden on interstate commerce does not appear to be clearly excessive in relation to the anticipated local benefits. In that case, the requirement would not violate the commerce clause.

If you would like me to review other requirements for pharmacies or if I may be of other assistance, please advise.

TLB:gc
91-404.glc

STATE OF ALASKA
THE LEGISLATURE
LEGISLATIVE AFFAIRS AGENCY

POUCH Y STATE CAPITOL
JUNEAU ALASKA 99811
907 465 3800

MEMORANDUM February 6, 1990

SUBJECT: Pharmacy licensing requirements in other states (Work Order No. 6-2115)

TO: Representative Curt Menard
Attn: Iola

FROM: John B. Gaguine JBG
Legislative Counsel

Per your request, I have been looking at the pharmacy licensing requirements in some of the other Western states. In all of the statutes I have examined, a pharmacy can be licensed if it complies with the pharmacy laws, which is essentially the same requirement as is found in AS 18.-80.157. (Sometimes there are minor additional requirements, such as the North Dakota requirement that a pharmacy must possess the standard pharmaceutical reference book to get licensed.) However, the majority of the other statutes I looked at regulate pharmaceutical practices considerably more closely than do Alaska's laws and regulations, and all of them regulate at least as closely as Alaska. For your interest I am enclosing some of the statutes of Nevada (since that is the location of the mail-order pharmacy under the revised state employee health care program) and Washington (since Seattle pharmacies can logically be expected to enter the mail-order prescription drug business).

Incidentally, I found that Wyoming has adopted an out-of-state pharmacy law that is also apparently based on the California statute on which I modeled W.O. 6-2018A. North Dakota, on the other hand, takes a different approach, requiring out-of-state pharmacies doing mail-order business in that state to get a license from the North Dakota board. I am enclosing a copy of the North Dakota statute. I think that the approach taken by the California law is better, since I do not think that the Alaska board (or the North Dakota board, for that matter) would be able to effectively

regulate an out-of-state pharmacy. Hence requiring it to get an Alaska license would not, in my opinion, accomplish much.

If I may be of further assistance, please advise.

JBG:lmb
L9/095

Enclosures

STATE OF ALASKA
THE LEGISLATURE

LEGISLATIVE AFFAIRS AGENCY

POUCH V STATE CAPITOL
JUNEAU, ALASKA 998
[illegible]

MEMORANDUM January 26, 1990

SUBJECT: Out-of-state pharmacies and licensing requirements (Work Order No. 6-2018)

TO: Representative Curt Menard
Attn: Iola Young

FROM: John B. Gaguine JBG
Legislative Counsel

You have asked for a bill that would require out-of-state pharmacies doing business within the state (primarily out-of-state pharmacies soliciting and filling mail orders) to meet the requirements of licensing for in-state pharmacies. I am writing this memo to explain that there are essentially no requirements for in-state pharmacies, and that control of out-of-state mail order pharmacies can probably be better achieved through a different bill.

Under AS 08.80, the Board of Pharmacy regulates and licenses both pharmacies and pharmacists. Unlike the stringent requirements for issuance of a pharmacist license, however, there are virtually no requirements for a pharmacy license. AS 08.80.157 provides:

> (a) If an applicant furnishes proof satisfactory to the board that the applicant is equipped with land, facilities, and equipment, in fee or leased, necessary to carry on the business described in the application and the applicant complies with this chapter, applicable regulations adopted by the board, and pays fees provided for under AS 08.80.160, the board may issue
>
> > (1) a wholesale drug dealer license to an applicant who manufactures or distributes noncontrolled legend drugs to licensed retail pharmacists, dentists, physicians, surgeons, or veterinarians, who may legally purchase noncontrolled legend drugs at a wholesale level, or to government

agencies which may legally purchase noncontrolled legend drugs at a wholesale level;

(2) a wholesale drug dealer license to a qualified applicant who is in compliance with the Federal Controlled Substance Act of 1969 as amended;

(3) a license to a retail pharmacy.

(b) A license under this section may not be issued to a person who has been convicted of a wilful violation of a federal law or a law of any state relating to a drug or controlled substance, or who is addicted to a drug or controlled substance. A license may not be issued to a corporation with a managing officer who has been convicted of a wilful violation of a federal law or a law of any state relating to a drug or controlled substance, or who is addicted to a drug or controlled substance.

The specific requirements listed in subsection (a) - land, facilities, and equipment - obviously would be met by any out-of-state pharmacy capable of filling orders in Alaska. The "no conviction" provision of (b) is likely equally meaningless, as such a provision is likely found in virtually all state licensing acts. (I examined the pharmacy licensing statutes of several states, and they all had such a provision.) The other provisions in AS 08.80 concerning pharmacies, rather than pharmacists, are so vague as to be useless in regulating out-of-state pharmacies; see, e.g., AS 08.80.230 (pharmacy must have proper sanitary appliances and maintain orderly and sanitary premises). Most important, the Board of Pharmacy, which could issue regulations giving some meaning to these vague provisions, has to date not done so, likely because there have been major problems with duty pharmacies.

I would suggest instead an approach along the line of California's, which requires the out-of-state pharmacy to submit proof of compliance with the licensing laws of the pharmacy's state of residence, and also allows the California board to request information. I am enclosing

copies of the relevant California statutes. If this approach appeals to you, I can draft a bill based on those statutes (but likely far simpler). Or I can draft a bill along the lines of your request, that an out-of-state pharmacy must meet Alaska qualifications, in the hope that the Board of Pharmacy will someday issue the necessary regulations.

JBG:gc
G13/071

Enclosure

Department of Commerce & Economic Development / POSITION PAPER

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: 3/20/91

GAO/RPB/JS/wfd2162W
31891b

STATE OF ALASKA

DEPARTMENT OF ADMINISTRATION
DIVISION OF RETIREMENT & BENEFITS
PLEASE REPLY TO:

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Public Employees Retirement System
Teachers Retirement System
Judicial Retirement System
Elected Public Officers Retirement System
National Guard Retirement System
Territorial Retirement System
Retirees Voluntary Dental-Vision-Audio Plan
Supplemental Benefits System
Group Health/Life Insurance Benefits
Deferred Compensation Plan
Public Employers Social Security Contributions

STEVE COWPER, GOVERNOR

March 19, 1990

The Honorable Curt Menard
Alaska House of Representatives
P.O. Box V
Juneau, AK 99811

Dear Representative Menard:

Your staff requested an analysis from this division of the impact HB 508 would have on the health insurance plan for State of Alaska employees.

The health insurance plan that was negotiated last summer by the Alaska State Employees Association (ASEA) includes a provision for prescription drugs to be obtained through the mail. I have reviewed HB 508 and do not see any provisions that would be at cross purposes with the current negotiated agreement with ASEA or increase the cost of health insurance premiums.

The mail order prescription drug plan is provided by National Pharmacies, Inc. through a subcontract with Aetna, our health insurance carrier. I have also discussed the bill's requirements with Aetna and have been informed that National Pharmacies would currently be able to satisfy these requirements.

Sincerely,

Mike Coughlin

Michael B. Coughlin
Deputy Director

MBC/ksl
cc: Sally Smith
Director
Division of Retirement and Benefits

Lynn Withrow
Aetna Life Insurance
Seattle, WA 98111

Note: Please Include Your Social Security Number in All Correspondence & Requests Concerning Your Benefits.

cc: (continued)

Frank S. Baxter, CPA
Commissioner
Department of Administration

Gary Bader
Deputy Commissioner
Services to State Agencies
Department of Administration

Sioux Plummer
Special Assistant
Department of Administration

RB90-017

AARP PHARMACY SERVICE

RETIRED PERSONS SERVICES, INC.

March 25, 1991

The Honorable Curt Menard
Senate of Alaska
State Capitol
P.O. Box V
Juneau, Alaska 99811

Re: Support for SB.125--Pharmacies Located Outside of the State

Dear Senator Menard:

I am writing in my capacity as Director of Governmental Affairs of the AARP Pharmacy Service and its Oregon subsidiary, the Oregon Retired Persons Pharmacy of Beaverton, Oregon. Our Oregon facility provides service to approximately 5,000 AARP members living in Alaska. This is to commend you for authoring and introducing SB.125, a bill to require the registration of out-of-state pharmacies which provide pharmacy services to residents of Alaska. The AARP Pharmacy Service strongly supports the enactment of SB.125.

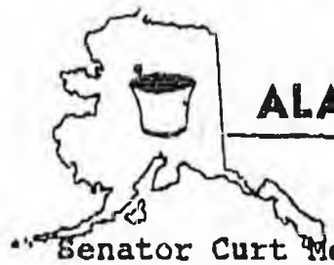
Your bill represents a significant contribution toward enhancing and improving professional relations between pharmacies engaged in interstate commerce and the Alaska Board of Pharmacy. Just as important, the bill will serve to improve cooperation and communication between the Alaska Board and the boards of other states. Finally, the regulatory framework adopted by SB.125 is reasonable, realistic and based on sound constitutional principles.

Very truly yours,

F. Nicholas Willard
Director, Governmental Affairs

cc: AARP Alaska State Legislative Committee

500 Montgomery Street
Alexandria, Virginia 22314-1563
(703) 684-0244 Fax: (703) 684-0246



ALASKA PHARMACEUTICAL ASSOCIATION

Box 10-1185 Anchorage, Alaska 99510

Senator Curt Menard
Alaska State Legislature
Juneau, Alaska FAX 465-3756

March 25, 1991

Dear Senator Menard:

The members of the Alaska Pharmaceutical Association wish to convey to you their support of your bill SB 125. Mail-order pharmacy involves many significant realities, especially in the state of Alaska.

One very important reality is that the State has the duty to protect the health and welfare of its citizens. SB 125 addresses that duty with respect to those pharmacy businesses which are not resident in the state of Alaska and which do a preponderance of their prescription volume through mail-order dispensing.

The issue of mail-order pharmacy is of great concern to the members of the Alaska Pharmaceutical Association. The Associaiton and its Board of Directors appreciate your efforts to address this concern. It is gratifying to have a Senator who not only listens to his constituents, but who also acts.

The Association will particpate in your hearings tomorrow (March 26th) through Katy Fishel, Past President of the Association. We will continue to watch the progress of SB 125 with interest and support.

Please contact me if I can be of help as SB 125 continues toward passage, hopefully this term. I can be reached at 261-3078 or via FAX 261-3048. Or, you may write to me at the Association's address given above.

Sincerely,

Lynn E. Rodda
President, Alaska Pharmaceutical Association

cc: Association Board of Directors

EMENS, HURD, KEGLER & RITTER CO., L.P.A.

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March 18, 1991

The Honorable Curt Menard
Alaska State Legislature
P.O. Box V
Juneau, Alaska 99811

RE: Nonresident Pharmacy Legislation/Senate Bill 125

Dear Senator Menard:

I am writing this letter in my capacity as Regulatory Counsel for Medco Containment Services, Inc., to include each of its regionally located mail service pharmacies, and with respect to the Alaska State Legislature's consideration of licensure, or registration, requirements for nonresident pharmacies. In this regard, Medco is pleased to support Senate Bill 125 upon the following terms and conditions:

I. Background Statement

The regulation of nonresident pharmacies, and particularly those engaged in the practice of mail service pharmacy, has been the subject of frequent, often emotional and sometimes even misinformed debate over the last several years. No issue of this debate has engendered more interest than whether a state has the power to compel a nonresident pharmacy to be locally licensed. Evidenced by legislative and administrative initiatives in any number of states, the lines of debate are well-drawn and range from arguments supporting regulation by restrictive licensure to enacted licensure requirements consistent with legal, policy and practice standards. At the center of debate is Art. 1, Sec. 8, cl. 3 of the Constitution of the United States of America, the Commerce Clause, granting Congress the power "(t)o regulate commerce . . . among the several states . . . ." Advocates on either side cannot avoid the impact of the Commerce Clause upon the regulation of the interstate delivery of prescription drugs

and its special relevance to those pharmacies who regularly and uniformly dispense prescription drugs from one state to another.

If a state chooses to regulate that portion of the business of a nonresident pharmacy which is engaged in interstate commerce, the Commerce Clause cannot be relied upon to suggest that the state is without the power to impose licensure requirements. This concept is too often lost in the rhetoric of the debate but essential to any dialogue. Rather, the Commerce Clause can be correctly relied upon to suggest that the nature and extent of the conditions of licensure must satisfy the basic criteria for determining the validity of state action which affects interstate commerce. The Commerce Clause of the Constitution of the United States of America prohibits states from enacting legislation that would have an unduly burdensome impact upon interstate commerce. When a state statute, or administrative rule promulgated thereunder, directly regulates interstate commerce, or when its effect is to discriminate against out-of-state interests, the statute, or administrative rule, is per se invalid under the Commerce Clause. When a state statute has only indirect impact on interstate commerce and regulates evenhandedly, the United States Supreme Court has employed a balancing approach to determine whether the regulation substantially impedes the free flow of commerce.

There is generally no clear line which separates a statute that satisfies the balancing approach and a statute that otherwise fails to conform to the constitutional standards mandated by this approach. On the issue of licensure requirements for nonresident pharmacies, specifically those engaged in the practice of mail service pharmacy, the search for that line is made easier by the development of an objective pattern of facts. This pattern has proven mail service pharmacy to be a safe, effective means of dispensing prescription drugs for chronic and long-term conditions, adequately regulated by present licensing protocols, particularly when complimented by reasonable licensure requirements, and, a discipline consistent with legitimate local objectives. Indeed, the day-to-day operations of a mail service pharmacy favorably compares with the Standards of Practice of the American Pharmaceutical Association. And not one fiction, if established as fact, would be avoided or resolved by restrictive licensure. Numerous objective, third-party authorities, from governmental agencies (e.g. FDA, Federal Trade Commission, Michigan State Legislature) to academia (e.g. Brandeis University, University of Texas College of Pharmacy) to professional bodies (e.g. American Medical Association), have so contributed to a formal record in the legislative and

administrative forums of the states that support these conclusions.

It is significant, and a clear indication of the obvious trend of choice in the regulation of mail service pharmacy on this issue, that the California Disclosure Legislation, adopted in 1988, has now been enacted, or implemented in original form or with reasonable modifications, in an increasing number of states, to this <u>past</u> year include Kentucky, Maine, Missouri, South Carolina, Virginia and Wyoming. A number of other states are expected to do likewise this year. If mail service pharmacy is truly a form of discipline consistent with the high standards of pharmacy, then the California Disclosure Legislation shall be the extent of licensure requirements necessary to be consistent with legal, policy and practice standards. On the other hand, if the advocates of restrictive licensure are correct, then the California Disclosure Legislation provides the best vehicle to gather together those facts necessary to satisfy the Supreme Court's balancing approach and, thereby, support their position and advance more restrictive licensure requirements. The history of the regulation of mail service pharmacy, and indeed nonresident pharmacies as an identifiable group suggests that the California Disclosure Legislation is now, and shall be in the future, the reality of state licensure requirements.

<u>II Senate Bill 125</u>

The proposed legislation appears to be consistent with the California Disclosure Legislation and to the extent modifications raise legal, policy or practice concerns, these concerns are satisfactorily addressed <u>so long as</u> the nonresident pharmacy would not be required to violate the law and regulation of its home jurisdiction. As drafted, Senate Bill 125 does not appear to cause the nonresident pharmacy to violate the law and regulation of its home jurisdiction. With this consideration in mind, Medco is supportive of Senate Bill 125.

In closing, it is the hope of Medco that the substance of this letter can serve to encourage a broader, more comprehensive dialogue on the issue. It is through dialogue, not debate, that regulators, nonresident pharmacies, and even those who advocate restrictive licensure can work toward a common, practical, constitutionally viable end, all of which can only benefit the object of our mutual concern -- the patient.

Thank you for the opportunity to comment and the consideration of this letter.

Very truly yours,

Robert D. Marotta

Attachment (California Disclosure Legislation)

cc: Medco Containment Services, Inc.

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Senate Bill No. 2213

CHAPTER 1424

An act to amend Section 4084.6 of, to add Sections 4050.1 and 4383 to, and to add and repeal Section 4350.6 of, the Business and Professions Code, relating to pharmacy, and making an appropriation therefor.

[Approved by Governor September 26, 1988. Filed with Secretary of State September 27, 1988.]

LEGISLATIVE COUNSEL'S DIGEST

SB 2213, Craven. Pharmacy.

Under existing law, it is unlawful for any person to, among other things, sell or dispense any prescription of a medical practitioner unless the person is a registered pharmacist under specified provisions of the Business and Professions Code. The law requires an out-of-state pharmacy which conducts the business of selling or distributing drugs in this state to be licensed by the Board of Pharmacy.

This bill would require any pharmacy, as specified, located outside this state which ships, mails, or delivers any controlled substances or dangerous drugs or devices into this state to register with the board, disclose specified information to the board, and meet other conditions.

The bill would authorize the board to deny, revoke, or suspend a nonresident pharmacy registration for failure to comply with specified provisions of California law and, until January 1, 1992, for conduct which causes serious bodily or psychological injury to a resident of this state if the regulatory agency in the state where the pharmacy is located fails to initiate an investigation into the matter within 45 days of being notified by the board.

The bill also would prohibit specified advertisements with regard to unregistered, nonresident pharmacies.

Existing provisions of the Business and Professions Code continuously appropriate the moneys in the Pharmacy Board Contingent Fund. Because this bill would increase the amount of moneys in the fund, it would constitute an appropriation.

A violation of those provisions of the Business and Professions Code constitutes a misdemeanor.

This bill would impose a state-mandated local program by creating or revising a crime.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this

act for a specified reason.

Appropriation: yes.

The people of the State of California do enact as follows:

SECTION 1. (a) The Legislature finds and declares that the practice of pharmacy is a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use and drug related therapy.

(b) The Legislature recognizes that with the proliferation of alternate methods of health delivery, there has arisen among third-party payers and insurance companies the desire to control the cost and utilization of pharmacy services through a variety of mechanisms, including the use of mail order pharmacies located outside the State of California.

(c) As a result, the Legislature finds and declares that to continue to protect the California consumer-patient, all out-of-state pharmacies that provide service to California residents shall be registered with the board, disclose specific information about their services, and provide pharmacy services at a high level of protection and competence.

SEC. 2. Section 4050.1 is added to the Business and Professions Code, to read:

4050.1. (a) Any pharmacy located outside this state which ships, mails, or delivers, in any manner, controlled substances or dangerous drugs or devices into this state shall be considered a nonresident pharmacy, shall be registered with the board, and shall disclose to the board all of the following:

(1) The location, names and titles of all principal corporate officers and all pharmacists who are dispensing controlled substances or dangerous drugs or devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or pharmacist.

(2) That it complies with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(3) That it maintains its records of controlled substances or dangerous drugs or devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs

dispensed.

(b) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(c) The registration fee shall be the fee specified in subdivision (a) of Section 4416.

(d) The registration requirements of this section and Sections 4350.6 and 4383, shall apply only to a nonresident pharmacy which only ships, mails, or delivers controlled substances and dangerous drugs and devices into this state pursuant to a prescription.

SEC. 3. Section 4084.6 of the Business and Professions Code is amended to read:

4084.6. No out-of-state manufacturer, wholesaler, or pharmacy doing business in this state who has not obtained a certificate, license, permit, registration, or exemption from the board and who sells or distributes drugs in this state through any person or media other than a wholesaler who has obtained a certificate, license, permit, registration, or exemption pursuant to the provisions of this chapter or through a selling or distribution outlet which is licensed as a wholesaler pursuant to the provisions of this chapter, shall conduct the business of selling or distributing drugs in this state without obtaining an out-of-state drug distributor's license from the board or registering as a nonresident pharmacy.

Applications for an out-of-state drug distributor's license or a nonresident pharmacy registration, under this section shall be made on a form furnished by the board. The board may require such information as the board deems is reasonably necessary to carry out the purposes of the section.

The board may deny, revoke, or suspend such out-of-state distributor's license for any violation of this chapter or for any violation of Division 21 (commencing with Section 26001) of the Health and Safety Code. The license or nonresident pharmacy registration shall be renewed annually on or before the first day of January of each year.

The Legislature, by enacting this section, does not intend a license or nonresident pharmacy registration issued to any out-of-state manufacturer, wholesaler, or pharmacy pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any out-of-state manufacturer, wholesaler, or pharmacy.

The Legislature, by enacting this section, does not intend a license or nonresident pharmacy registration, issued to any out-of-state manufacturer, wholesaler, or pharmacy pursuant to this section to

serve as any evidence that such out-of-state manufacturer, wholesaler, or pharmacy is doing business within this state.

SEC. 4. Section 4350.6 is added to the Business and Professions Code, to read:

4350.6. (a) The board may deny, revoke, or suspend a nonresident pharmacy registration for failure to comply with any requirement of Section 4050.1 or 4383 or for any failure to comply with Section 11164 of the Health and Safety Code.

(b) The board may deny, revoke, or suspend a nonresident pharmacy registration for conduct which causes serious bodily or serious psychological injury to a resident of this state if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to initiate an investigation within 45 days of the referral. The board shall obtain and maintain a record of referrals pursuant to this subdivision and any action taken thereon and shall report its findings to the Legislature on or before March 31, 1991.

This section shall be operative until January 1, 1992, and as of that date, is repealed unless a later enacted statute deletes or extends that date.

SEC. 5. Section 4350.6 is added to the Business and Professions Code, to read:

4350.6. The board may deny, revoke, or suspend a nonresident pharmacy registration for failure to comply with any requirement of Section 4050.1 or 4383 or for any failure to comply with Section 11164 of the Health and Safety Code.

This section shall become operative on January 1, 1992.

SEC. 6. Section 4383 is added to the Business and Professions Code, to read:

4383. It is unlawful for any nonresident pharmacy which is not registered pursuant to Section 4050.1 to advertise its services in this state, or for any person who is a resident of this state to advertise the pharmacy services of a nonresident pharmacy which has not registered with the board, with the knowledge that the advertisement will or is likely to induce members of the public in this state to use the pharmacy to fill prescriptions.

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs which may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, changes the definition of a crime or infraction, changes the penalty for a crime or infraction, or eliminates a crime or infraction.

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

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

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.