HB

1123

2/15

COMMITTEE REPORT

HOUSE

(7)

HEALTH, EDUCATION AND SOCIAL SERVICES

FURTHER: ~~FINANCE~~

1/25/85

Date: Feb 14 1985

The Committee on LABOR & COMMERCE has had HB 123

"An Act extending the termination date of the Board of Pharmacy; and providing for an effective date."

under consideration and recommends:

[X] do pass [ ] do not pass

[ ] do pass with attached amendments(s)

[ ] replace with CS for ______ [ ] same title [ ] new title

and recommends ______

[ ] AND attaches a "Letter of Intent" [ ] New Fiscal Note

[ ] Zero Fiscal Note Attached

[ ] reports it back without recommendation

[ ] referred to the ______ Committee

MEMBERS SIGNING DO PASS

Mike Navarre

Mike Davis

Mike Kopp

MEMBERS HAVING OTHER RECOMMENDATIONS:

- No rec

Faye Hanley - No Rec.

Mike Navarre

CHAIRMAN

HB 123 FILE CONTENTS

1) Summary of HB 123 --Legislative Reporting Service

2) Overview -- Committee Staff

3) Overview of Board and Board Members -- Boards and Commissions

4) Transmittal Letter from Governor

5) Fiscal Note -- Dept. of Commerce, Occupational Licensing Div.

6) Operating Budget Request -- Dept. of Commerce

6) Governor's Veto Message of Last Year

7) Legislative Budget & Audit Report

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8) Additional Materials Dated February 11, 1985 Supplied to Committee from Harry Traeger of Occupational Licensing in response to questions by Rep. Hanley in February 6, 1985 hearings.

HB 122, (cont'd)

1. their function has been absorbed by another entity;
2. they have lacked funding by legislative appropriations more than two years in a row;
3. the specific need for which they were established no longer exists.

Despite their dormant state, these entities exist on the books of the Alaska Statutes. The purpose of this bill is to abolish these entities and repeal the statutes governing their operation. The cultural facilities development fund, AS 44.33.401 -- 44.33.417, which was to be handled by the Advisory Council on Cultural Facilities, is also repealed; no money has been appropriated to the fund, and no grants have been awarded.

I urge your prompt and favorable action on this measure, to clean up the statutes and to clear up public confusion about these entities.

Board of Pharmacy (extending)

HOUSE BILL NO. 123, by the Rules Committee by Request of the Governor. Extends the Board of Pharmacy until June 30, 1988 (currently set to terminate June 30, 1984,. Act takes effect immediately.

Introduced January 25 and referr d to Labor & Commerce, Health, Education & Social Services, then Finance.

In his message transmitting the bill, Governor Sheffield stated:

Under the authority of art. III, sec. 18, of the Alaska Constitution, I am transmitting a bill extending the termination date of the Board of Pharmacy for four more years.

Under AS 08.03.010(c)(4), the board terminated on June 30, 1984. Under AS 08.03.020, however, the board is authorized to continue its activities, with no reduction in its powers or authority, until June 30, 1985. If the board's termination date is not extended before June 30, 1985, the board must cease its activities. Because of the valuable examination and oversight functions of the Board of Pharmacy, I believe the public interest would be best served by continuing the existence of the board.

The attached bill, therefore, amends AS 08.03.010(c)(4) to extend the life of the board until June 30, 1988.

Last session, I vetoed CSHB 716(L&C), which, in part, would also have extended the board's termination date until June 30, 1988. That bill, however, contained other provisions that I felt were administratively undesirable. I noted in my veto message that the legislature could still accomplish extension of the board before June 30, 1985.

Older Alaskans Commission (extending)

HOUSE BILL NO. 124, by the Rules Committee by Request of the Governor. Extends the Older Alaskans Commission until June 30, 1989 (currently set to terminate June 30, 1985). Takes effect immediately.

Introduced January 25 and referred to State Affairs, then Health, Education & Social Services.

M E M O R A N D U M

TO: All Members, House Labor and Commerce Committee

FROM: Committee Staff

DATE: February 5, 1985

SUBJECT: Overview; HB 123

On Wednesday, February 6, 1985, beginning at 1:15 pm, the House Labor and Commerce Committee meets on HB 123, "An Act extending the termination date of the Board of Pharmacy."

There is no companion legislation in the Senate. However, this bill was submitted last year as HB 716 by the House Labor and Commerce Committee. This bill not only extended the sunset date in a manner similar to the current bill, but in addition expanded the powers of the Board and asked for a full-time executive staff person to cover additional responsibilities under the Uniform Control Substances Act. This was done under a lot of pressure from pharmacists throughout the state, and there is considerable correspondence from last year asking that the position be added. The legislature ultimately granted the position in the bill, but did not provide funds for it, leaving it instead to the Department.

The Administration has a general policy which they applied here, to cut back on permanent staff for all Boards and have Departmental staff serve this need as being more cost effective. Further, they felt that the responsibilities in question could be covered through new regulations and in-house staff instead of through an executive secretary. Hence, the Governor vetoed this bill after it had passed both houses last session. A copy of his veto message is attached.

The termination date of the Board is one year from June 30, 1984 if the Governor's veto remains in effect. This new legislation would extend the Board's activity, but without the addition of a permanent staff person.

This bill is in effect then, an extension of the sunset hearings from last year. The file contains the Legislative Budget and Audit report on the Board, and they favored extending the Board's existence. The LB&A recommendations in regards to the Board were responded to by Commissioner Lyon in a letter dated June 28, 1983 on the last page of the report.

A PERFORMANCE REPORT ON THE BOARD OF PHARMACY

July 1, 1980 to February 28, 1983

Audit Control Number

08-1114-51-83-R

Commissioner, Department of Commerce and Economic Development	Richard A. Lyon
Deputy Commissioners, Department of Commerce and Economic Development	Vincent O'Reilly Terry Elder

Members of the Board of Pharmacy

Chairman	Eldon Ulmer
Secretary	Margaret Soden
Member	Susan Roberts
Member	Robert Snider
Member	James McCorcle
Member	Charles Rush
Member	Sidney Fry

STATE OF ALASKA

DIVISION OF LEGISLATIVE AUDIT

STATE OF ALASKA

AUDIT DIVISION
POUCH W
JUNEAU, ALASKA 99811

THE LEGISLATURE

BUDGET AND AUDIT COMMITTEE

May 17, 1983

Members of the
Legislative Budget and Audit Committee:

In accordance with the provisions of Titles 24 and 44 of the Alaska Statutes (sunset), the attached report is submitted for your review.

A PERFORMANCE REPORT
ON THE
BOARD OF PHARMACY

July 1, 1980 to February 28, 1983

Gerald L. Wilkerson, CPA
Legislative Auditor
Division of Legislative Audit

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PURPOSE AND SCOPE OF THE REPORT

PURPOSE

In accordance with the intent of Titles 24 and 44 of the Alaska Statutes (sunset legislation), we have reviewed the activities of the Board of Pharmacy for the past three fiscal years. Our examination was conducted to determine if the Board has been operating in an efficient and effective manner.

Legislative intent requires consideration of this report during legislative oversight hearings to determine whether the Board of Pharmacy should be reestablished. The law now specifies that the Board will terminate June 30, 1984, and have one year from that date to conclude its affairs.

SCOPE

The major areas of our examination were the licensing, examination, administration, complaint, and affirmative action functions of the Board. We reviewed and evaluated the following:

1. Applicable statutes and regulations.
2. Interviews with the license examiners.
3. Tests of files and documents of licensees.
4. Complaints filed with the Division of Occupational Licensing, Human Rights Commission, Equal Employment Opportunity Office, Attorney General's Office, and the Ombudsman Office.
5. Discussions with Board members.
6. Minutes of Board meetings and Division correspondence files.
7. Attorney General Opinions applicable to professional boards.

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ORGANIZATION AND FUNCTION

The Board of Pharmacy is a regulatory board with seven members; two public members having no direct financial interest in the health care industry, and five professional members with three years practical experience and licensed in Alaska. Whenever possible, each judicial district should be represented by a Board member.

The Board regulates five types of licenses; pharmacists, retail pharmacies, wholesale pharmacies, hospital pharmacies and drug rooms. The Board sets the minimum standards to practice in Alaska by:

1. Examining and issuing licenses to qualified applicants.

2. Establishing, amending, or eliminating regulations controlling pharmacy practices.

3. Revoking, annulling or suspending licenses in accordance with the Administrative Procedures Act when a person has violated pharmacy statutes or regulations.

Applicants for registration as a pharmacist are required to pass the National Association of the Boards of Pharmacy Licensing Examination (NABPLEX), and a jurisprudence exam covering Alaska pharmacy law and the Federal Controlled Substance Act.

Pharmacists licensed to practice in another state who apply for licensure in Alaska, can be licensed by credentials, except for those applicants from California or Louisiana. These two states require applicants to pass a state exam, not the national exam. Consequently, these applicants must take the national exam when applying in Alaska.

The Board may also issue temporary or emergency permits. Temporary permits allow qualified applicants to practice until the Board can formally license them; emergency permits allow pharmacists licensed in another state to practice in Alaska in an emergency. Both permits are limited in their duration and application.

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REPORT CONCLUSION

Policy Issues

This report contains policy issues raised as a result of our evaluation of various Board practices. The final policy decisions affecting these practices are not within the scope of this report but require legislative consideration. In debating these issues, the oversight committees should take into consideration the findings and recommendations presented in this report so the potential impact of policy changes can be evaluated.

Report Conclusion

In our opinion, the Board of Pharmacy should be reestablished. The regulation and licensing of qualified professionals is necessary to protect the public's health, safety, and welfare. The Board provides this service by establishing minimum educational and experience requirements that provide reasonable assurance that persons licensed are qualified. Also, assurances that those licensed act in a competent manner is provided by active investigation of complaints and revocation or suspension of licenses where appropriate.

However, the following findings describe areas where weaknesses or conflicts exist. We have made recommendations which, if implemented, will improve the efficiency and effectiveness of the Board.

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FINDINGS AND RECOMMENDATIONS

Recommendation No. 1

The Board of Pharmacy should allow the Division of Occupational Licensing (OL) to perform its administrative duties as described in AS 08.01.050 to improve documentation and file management.

The Secretary of the Board receives license fees and applications, keeps applicant files, sends notification of exam results, and issues temporary permits. Each of these responsibilities has been assigned by the Legislature to the Department of Commerce and Economic Development, Division of Occupational Licensing. The above situation exists because the previous Secretary believed he could be more efficient in maintaining the files and processing the applications. We disagree.

The Division of Occupational Licensing is able to provide continuous, uninterrupted service while Board membership changes causing address changes and file transfers.

Additionally, the Secretary of the Board may not be equipped with the space or security needed to maintain confidentiality of files and to safeguard State assets. Furthermore, applicants become confused about where to send their documents.

Noncompliance with AS 08.01.050 is the major cause of the following problems:

A. In seven of ten files reviewed for proper permanent licensure, we were unable to assure ourselves the applicant had passed the jurisprudence exam.

B. In two of the files, we were unable to verify the applicants had satisfied the internship requirement. The Board reviewed these files and was unable to satisfy us that the requirements had been met. One file was missing documentation and the other file had documentation we considered insufficient in relation to that required of other applicants. Most applicants were required to have certified copies of hours worked from supervising pharmacists. In this case, documentation consisted of an internship permit issued by the Board with no evidence any hours had been worked.

C. Temporary permits are being issued by individual Board members without complete documentation on file in DOL. This procedure has resulted in inconsistent issuances of temporary permits. Furthermore, it allows for the possibility of unqualified individuals being licensed.

Prior to the February 1983 Board meeting, we reviewed each application for permanent licensure scheduled for Board consideration. Each applicant had already been issued a temporary permit. In five of eleven cases, there was insufficient documentation in the applicant's file to show that all requirements for temporary licensure had been met.

By the time of the February 1983 meeting, all necessary documentation to support issuance of temporary permits, except for a jurisprudence exam, had either been received by OL or brought to the meeting by the Secretary of the Board. With the additional documentation, we determined that no temporary permit had been issued to an unqualified applicant. However, the possibility exists for a person to be improperly licensed for a short time.

The Board should ensure all documentation is sent directly to OL. When the file is complete, a member of the Board can either issue the permit or direct OL to issue the permit. This procedure will ensure that all necessary documentation is on file at OL before issuance of temporary permits.

D. Alaska Statute 08.80.157 requires proof that an applicant for a retail or wholesale pharmacy license has the land, facilities and equipment necessary to carry on business. Also, that the applicant be free of any conviction of a federal or state drug offense and free of any addiction.

We reviewed seven pharmacy files and none of the files contained sufficient documentation to issue a license. We discussed our finding with the Board and determined it was not their policy to include this documentation. They knew who had the facilities and relied on a telephone call from the Drug Enforcement Administration to satisfy the conviction requirement.

We believe the Board should adopt a policy to document satisfaction of the licensing requirements. The procedures need not be elaborate, but should supply sufficient proof that the applicant complies with law.

We recommend the Board ensure that all files, applications, fees and exam results are sent directly to OL. Also, that temporary permits are only issued after all documentation has been received by OL.

Recommendation No. 2

The Board of Pharmacy should reevaluate its regulations governing continuing education.

The following requirements of continuing education should be reviewed.

A. Regulations require nonacademic programs to have an examination or another method of assuring satisfactory completion of the program before continuing education credit will be given. The Board allowed continuing education credit to be given to an individual when the nonacademic requirement had not been met. The reason given for allowing these credits was that the regulations were too stringent.

   If the Board believes its regulations to be arbitrary or unreasonable, those regulations should be changed before accepting nonregulation continuing education credits. Compliance with existing regulations will ensure that all licensees are treated equally and consistently until changes can be made.

B. The Board has described four instances when they will excuse a licensee from continued competency requirements. These causes are chronic illness, retirement, military service, or hardships as individually determined by the Board.

   In our opinion, it is more reasonable to require individuals who have been chronically ill, retired or in the military to demonstrate their continued competency, than those who have not interrupted their practice. We also understand that those persons who have been chronically ill should not be penalized for their illness.

   However, the Board has the ability, under the hardship clause, to determine each case individually. They should evaluate the changes in the profession and develop a plan for the individual that would allow him or her to practice while fulfilling the continuing education requirements. This would fulfill the Board's primary purpose to protect the public while not unduly penalizing the professional.

Recommendation No. 3

The Board of Pharmacy and the Division of Occupational Licensing should introduce legislation that will clarify certain statutory requirements.

Alaska Statute 08.01.050(19) places the responsibility for

performing investigations with the Division; Alaska Statute 08.01.070 assigns to the Board the requesting authority. However, AS 08.80.030(3) also gives the Board the authority to conduct investigations. This conflict has caused friction between the Division and the Board.

The Board is concerned that the Division is not informing them of complaints or investigations concerning pharmacy, while the Division is concerned that the Board not become involved in the investigation to such an extent as to prejudice the case. Also, the Board must remain impartial in case they become involved in any disciplinary action against the licensee.

Legislation is necessary to clarify the responsibilities of the Board and the Division so both will be confident they are properly performing their statutory duties.

Recommendation No. 4

The Office of the Governor should ensure that Board members are properly appointed.

In July of 1980, the Legislature limited the number of consecutive terms a Board member could serve to two and reduced the term from five years to four. The intent of AS 08.80.020 as amended, was to make service on the Board accessible to more individuals in the profession.

In discussions with Legislative Affairs' attorneys, it became clear that the intent of the Legislature was to include service prior to July, 1980, in determining the limitation. Three members of the Board of Pharmacy have served longer than is allowed when prior service is applied.

One member has served for sixteen years as of March 31, 1983, thirteen of those years prior to July, 1980. This same member was reappointed after the effective date of AS-08.80.020. At the end of his present term, he will have served nineteen years. Two other members will have served twelve and ten years at the end of their present terms on March 31, 1984 and March 31, 1985. respectively.

Additionally, three members of the Board appointed after the effective date of the legislation, have been appointed for five year terms instead of four.

We recommend the Office of the Governor ensure that Board members are appointed in accordance with statute.

ANALYSIS OF PUBLIC NEED

Limited Analysis

The following analyses indicate both positive and negative factors as they relate to the public need as defined in the "sunset" law. These analyses are not intended to be comprehensive, but to address those areas we were able to cover during our review.

I. The extent to which the board, commission or program has operated in the public interest.

A. The Board has held public meetings three times a year.

B. The Board administers the pharmacy test yearly.

C. The Board has passed regulations concerning dangerous drugs, continuing education as proof of continued competency, false or misleading advertisement of drugs, and prepackaging of drugs in hospital drug rooms.

D. The Board was instrumental in passage of the Controlled Substance Act and the Marijuana Therapeutic Research Program.

II. The extent to which the operation of the board, commission, or agency program has been impeded or enhanced by existing statutes, procedures, and practices which it has adopted, and any other matter, including budgetary, resource, and personnel matters.

A. The Board adopted continuing education regulations that may be too stringent. The Board is reconsidering these regulations (see Recommendation No. 2).

III. The extent to which the board, commission or agency has recommended statutory changes which are generally or benefit to the public interest.

A. The Board actively supported passage of the Controlled Substance Act; it became effective January 1, 1983.

B. The Board succeeded in having various obsolete or vague statutory requirements repealed which provided for smoother operation of the Board.

IV. The extent to which the board, commission or agency has encouraged interested persons to report to it concerning the effect of its regulations and decisions on the effectiveness of service, economy of service, and availability of service which it has provided.

A. Board meetings are announced to the public. Comments on regulation changes are solicited by announcement in public newspapers. The Board does not actively solicit comments on its effectiveness.

V. The extent to which the board, commission or agency has encouraged public participation in the making of its regulations and decisions.

A. The Board announces proposed regulation changes or additions in newspapers according to the Administrative Procedures Act.

VI. The efficiency with which public inquiries or complaints regarding the activities of the board, commission or agency filed with it, with the department to which a board, or commission is administratively assigned, or with the Office of the Ombudsman have been processed and resolved.

A. We found no problems in this area.

VII. The extent to which a board or commission which regulates entry into an occupation or profession has presented qualified applicants to serve the public.

A. We found no instances where the Board had licensed unqualified practitioners.

B. The Board has licensed 83 pharmacists in the last three years, all but eight were licensed by credentials.

VIII. The extent to which state personnel practices, including affirmative action requirements, have been complied with by the board, commission or agency to its own activities and the area of activity or interest.

A. Applications for licensure as a pharmacist require information and photographs which the Division of Equal Employment Opportunity (EEO) believes may not be necessary to determine the qualifications of the applicant.

IX. The extent to which statutory, regulatory, budgeting or other changes are necessary to enable the agency, board or commission to better serve the interests of the public and to comply with factors enumerated in this subsection.

Please refer to the recommendation section of this report.

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APPENDIX A

BOARD OF PHARMACY
REVENUES COMPARED WITH EXPENDITURES
For the Fiscal Year Ended June 30, 1982

(UNAUDITED)
(Note 1)

Average Revenues (Note 2)	$42,763
Less: Expenditures (Note 3)	46,166
Excess of Expenditures Over Revenues	$ 3,403

Revenue Type	Amount	Collection Time
Examination Fee	$ 50	With application
Re-examination Fee	15	With application
Investigation Fee	25	With application
Pharmacist Fee	200	With license issuance
Pharmacist Renewal Fee	200	Every four years
Temporary License Fee	20	With permit issuance
Wholesale Drug Dealer Fee	200	With license issuance
Wholesale Drug Dealer Renewal Fee	200	Every four years
Retail Pharmacy Fee	200	With license renewal
Retail Pharmacy Renewal Fee	200	Every four years
Pharmacy Interim Fee	10	With license issuance
Emergency Permit Fee	10	With permit issuance
Hospital Pharmacy Fee	200	With license issuance
Hospital Pharmacy Renewal Fee	200	Every four years
Hospital Drug Room Fee	100	With license issuance
Hospital Drug Room Renewal Fee	100	Every four years
Nursing Home and Related Facility Fee	100	With license issuance
Nursing Home and Related Facility Renewal Fee	100	Every four years
License Amendments or Renewal Fee	10	When applicable

Note 1

This revenue/expenditure comparison was prepared from available records and discussions with Occupational Licensing personnel. The records were not audited by us and accordingly we do not express an opinion on the Board's Revenues Compared with Expenditures.

Note 2

The majority of the revenues collected are composed of license renewal fees. These fees are collected by most boards once every two or four years and causes revenues in one year to be much greater than the revenues collected in the next year. Therefore, we calculated and reported an average of the revenues collected in Fiscal Years 1981 and 1982 in order to obtain a more accurate representation of revenues collected.

Note 3

Expenditures include those made by board members, such as travel and per diem, and an allocated percentage (estimated) of total administrative expenses of the Division of Occupational Licensing. They do not include expenditures for efforts of other departments (such as the Department of Law) assisting the boards and the Division.

(Intentionally left blank)

BILL SHEFFIELD, GOVERNOR

DEPARTMENT OF COMMERCE &
ECONOMIC DEVELOPMENT

OFFICE OF THE COMMISSIONER

POUCH D
JUNEAU, ALASKA 99811
PHONE: 465-2500

June 23, 1983

Mr. Gerald Wilkerson, CPA
Legislative Auditor
Audit Division
Pouch W
Juneau, Alaska 99811

Dear Mr. Wilkerson:

Re: Board of Pharmacy -
Performance Report

Thank you for the opportunity to respond to the performance audit of the Board of Pharmacy and the Division of Occupational Licensing which is dated July 1, 1980 to February 28, 1983.

We concur with your evaluation that the Board of Pharmacy should continue to exist in interest of the public's health and safety. Your suggestions will be evaluated for implementation. Those determined to improve the efficiency and effectiveness of the division and the board will be strongly supported and recommended. We have reviewed each of your recommendations and will provide you with this agency's position if we do not agree.

RECOMMENDATION #1.

The board of Pharmacy should allow the Division of Occupational Licensing (DOL) to perform its administrative duties as described in AS 08.01.050 to improve documentation and file management.

We concur in this recommendation, and cooperative efforts have recently improved. As mandated by legislation, and in the interest of efficiency, DOL is committed to assisting the Board of Pharmacy in all areas.

RECOMMENDATION #2.

The Board of Pharmacy should reevaluate its regulations governing continuing education.

08-H2LH

This agency is continuing a review on requirement of continuing education by licensing agencies (boards). We do not agree that continued education ensures continued competency. As a licensing agency we determine that competency is the most important. Competency ensures the safety of the consumer. We also take the position that initial licensing is based on minimum qualifications; retesting on the entrance level may serve the purpose of ensuring continued competency. Continued education would, or should, be viewed as the professional association's responsibility to ensure knowledgeable professionals. This would also be in keeping with less government regulations and letting industry regulate itself.

RECOMMENDATION #3.

The Board of Pharmacy and the Division of Occupational Licensing should introduce legislation that will clarify certain statutory requirements.

We concur with this recommendation. This agency has been working with the Legislative Code Revision Committee in rewriting Title 8. This would have deleted the fragmentation throughout Title 8 and the various chapters. This effort was resisted by the board as an effort to diminish its authority. We will seek to have legislation submitted to clarify the issue of conflict within the statutes.

RECOMMENDATION #4.

The Office of the Governor should ensure that board members are properly appointed.

We would assure the auditors this has been addressed by the Governor's Office and by the Department of Law.

Again, thank you for the opportunity to respond to your report. Please feel free to contact this agency or the Division of Occupational Licensing if additional information or clarification is needed. Be assured, we determine your comments and findings to be fair and in the best interest of Alaskan consumers and professional pharmacist.

Sincerely,

Richard A. Lyon
Commissioner

RAL/cw#23D01
628838

BOARD: PHARMACY, BOARD OF

TITLE: Board of Pharmacy

DEPT: Department of Commerce and Economic Development

AUTHORITY: AS 08.80.010

STATUS: ACTIVE

REQUIREMENTS: LEGISLATIVE CONFIRMATION

PROHIBITIONS: Cannot serve more than two successive complete terms

TERM: 4-year - overlapping

DESCRIPTION: 7 members appointed by Governor: 5 licensed pharmacists actively engaged in practice in Alaska for 3 years immediately preceding appointment; 2 public members (staggered terms) with no direct financial interest in health care industry; when possible, one member should represent each judicial district; terms begin April 1; members elect President.

SPECIAL FACTS: Quorum - 4 members (3 when examining applications for registration); report to Legislature; members may be removed for cause

FUNCTION: Controls certification, revocation of applicants; promulgates regulations to ensure adequate security for dangerous drugs.

COMPENSATION: Actual travel expenses and standard per diem

MEETINGS: 3 times per year; 9 days total

*FOR FURTHER INFORMATION CONTACT: Licensing Examiner, Division of Occupational Licensing, Dept. of Commerce and Economic Development, Pouch D, Juneau, AK 99811 - 465-2541

Pharmacy

MEMBER	APPT	REAPPT	TERM
Joy H. Donelson, RPh 908 "R" Street Anchorage 99501 Pharmacist	83/12/27		86/03/31
William P. Larson, RPh SRA Box 562 Anchorage 99516 Pharmacist	84/03/30		88/03/31
James H. McCorcle, RPh P.O. Box 450 Juneau 99802 Pharmacist - Chair	80/04/15		85/03/31
Christy C. Nielson, RPh SR Box 20124-A Fairbanks 99701 Pharmacist	83/12/27		87/03/31
Sue Roberts Mile 153 Sterling Highway Anchor Point 99556 Public	81/03/05		86/03/31
Robert K. Snider 2122 Forest Park Drive Anchorage 99503 Public	80/04/15		85/03/31
Margaret D. Soden, RPh 3222 Anella Avenue Fairbanks 99701 Pharmacist	81/03/19		86/03/31

JUNEAU

January 25, 1985

The Honorable Ben Grussendorf
Speaker of the House
Alaska State Legislature
Pouch V
Juneau, AK 99811

Dear Representative Grussendorf:

Under the authority of art. III, sec. 18, of the Alaska Constitution, I am transmitting a bill extending the termination date of the Board of Pharmacy for four more years.

Under AS 08.03.010(c)(4), the board terminated on June 30, 1984. Under AS 08.03.020, however, the board is authorized to continue its activities, with no reduction in its powers or authority, until June 30, 1985. If the board's termination date is not extended before June 30, 1985, the board must cease its activities. Because of the valuable examination and oversight functions of the Board of Pharmacy, I believe the public interest would be best served by continuing the existence of the board.

The attached bill, therefore, amends AS 08.03.010(c)(4) to extend the life of the board until June 30, 1988.

Last session, I vetoed CSHB 716(L&C), which, in part, would also have extended the board's termination date until June 30, 1988. That bill, however, contained other provisions that I felt were administratively undesirable. I noted in my veto message that the legislature could still accomplish extension of the board before June 30, 1985.

I urge your prompt action or this bill.

Sincerely,

Bill Sheffield
Governor

REQUEST

Bill/Resolution No.: HB 125

Title: An Act relating to the continuation of the Board of Pharmacy

Sponsor:

Requestor:

Date of Request:

FISCAL DETAIL

Agency Affected: Commerce & Econ. Dev.

Program Category Affected: Consumer Protection

BRU, Program or Subprogram(s) Affected: Occupational Licensing

EXPENDITURES/REVENUES: (Thousands of Dollars)

	FY 85	FY 86	FY 87	FY 88	FY 89	FY 90
OPERATING						
100 PERSONAL SERVICES						
200 TRAVEL						
300 CONTRACTUAL						
400 SUPPLIES						
500 EQUIPMENT						
600 LAND & STRUCTURES						
700 GRANTS, CLAIMS						
800 MISCELLANEOUS						
TOTAL OPERATING		-0-	-0-	-0-	-0-	-0-
CAPITAL						
REVENUE						

FUNDING: (Thousands of Dollars)

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

POSITIONS:

FULL-TIME						
PART-TIME						
TEMPORARY						

ANALYSIS: Attach a separate page if necessary

The bill extends the function of the Board of Pharmacy which was sunsetted and expected to terminate on June 30, 1985. Funding for operating costs of the board is included in the agency's FY '86 budget request.

Prepared By: Jennifer Strickler, Management Analyst Phone: 465-2144

Division: Occupational Licensing Date: 10/9/84

Approved by Commissioner: Richard A. Lyon Date: 12/11/84

Agency: Commerce and Economic Development

Distribution (by Agency preparing fiscal note):

Legislative Finance
Legislative Sponsor
Requestor
Office of Management and Budget
Impacted Agency(ies)

7/1/84

Board of Pharmacy - Allocations

The total Division budget request for FY 86 is:

ADMINISTRATION Component 1197.8

Of this amount, 12.3 is for 35% of a Licensing Examiner for the Pharmacy Board.

BOARD Component (Travel/and Per diem) 161.0

The base budget request was 95.0. Of this amount, 2.4 would be allocated to the Pharmacy Board. An additional budget increment of 56.0 was requested. Additional funding of 4.8 would be added to the Pharmacy Board if the increment is approved.

INVESTIGATIONS Component 638.8

This component provides all costs for investigations and hearings. There is no prior allocated amount to any particular board, however, Pharmacy cases are listed as life threatening and are given priority in allocated resources.

February 6, 1985

CSHB 685(Loans)

and the Alaska renewable resources investment fund; and providing for an effective date.)

Chapter 161, SLA 1984

CSHB 716(L&C)

The following letter dated July 6, 1984, was received:

Re: CSHB 716(L&C)
(An Act relating to the Board of Pharmacy)

"Dear Mr. Speaker:

Under the authority granted in art. II, sec. 15 of the Alaska Constitution, I have vetoed Committee Substitute for House Bill No. 716 (L&C), concerning the Board of Pharmacy.

This bill would have authorized the Board of Pharmacy to hire its own executive secretary. This would have been an undesirable departure from the consolidation and uniformity of the occupational licensing system under AS 08.01. It would have set a disturbing precedent for other boards in securing autonomous staff, outside of the division of occupational licensing in the Department of Commerce and Economic Development.

Another important reason for my veto is that the legislature failed to appropriate any money to fund the fiscal requirements of this position which was estimated by the department in a fiscal note to be $135,000 this year.

Rather than allow this unfunded and administratively flawed bill to become law, I have directed the Department of Commerce and Economic Development and the Department of Law to review methods of better and more quickly implementing AS 17.30 concerning controlled substances. That chapter, which was enacted in 1982, gave the Board of Pharmacy some new powers and duties which have not been fully implemented, even though they largely overlap the board's continuing powers and duties under AS 08.80.

I believe that there are other better ways to implement the controlled substances legislation without unnecessarily disrupting the structure of the occupational licensing system. I am confident that the review I have directed will produce recommendations for alternatives that can be accomplished by the end of the next budget cycle, if the legislature will fund them.

Meanwhile even though this vetoed bill included a provision to extend the board's termination date from June 30, 1984 to June 30, 1988, under AS 08.03.020(a), the board will continue until June 30, 1985. Before that date the next

CSHB 716(L&C)

session of the legislature can extend the board without granting it the power to hire an executive secretary.

Sincerely,

/s/

Bill Sheffield
Governor"

STATE OF ALASKA

BILL SHEFFIELD, GOVERNOR

DEPARTMENT OF COMMERCE &
ECONOMIC DEVELOPMENT

DIVISION OF OCCUPATIONAL LICENSING

POUCH D
JUNEAU, ALASKA 99811
PHONE: (907) 465-2534

February 11, 1985

The Honorable Alyce A. Hanley
Alaska House of Representatives
Pouch V
Juneau, Alaska 99811

Dear Representative Hanley:

Re: Controlled Substance Act
(Chapter 45, SLA 1982)

During a recent committee hearing of the House Labor and Commerce Committee you requested two responses from this agency. They were:

1. how executive secretaries are addressed in other states; and

2. a short commentary on the efforts to implement the Controlled Substances Act.

For ease in review, enclosed is a synopsis of other states who have an executive secretary assigned to their boards of pharmacy. It is important to note the number of licensees vs. approximately 438 in the State of Alaska.

The following list is a compilation of the efforts expended to implement the Controlled Substances Act. The Board of Pharmacy's statutory mandate is set out in AS 17.30 and AS 17.35. This includes registering all practitioners who are authorized by the Drug Enforcement Agency (DEA), Department of Justice, to manufacture, dispense or distribute controlled substances.

1. Hired a regulation specialist in April 1983 for 16 months primarily for the development of regulations pertaining to registration.

2. Held numerous public hearings and teleconferences relating to the regulations project (12 AAC 52.400-455).

3. Developed a staff working relationship with staff of DEA. State began receiving DEA information on State practitioners currently licensed and registered with DEA.

08-H8LH

4. Established a coordinated program with DEA personnel to receive a quarterly report on use of all controlled substances in Alaska.

5. Established additional programs on current computer program to include DEA registration number (for doctors, dentists, pharmacy registrants, veterinarians).

6. Forms design. Developed two forms, the first for applicants (physicians) who desire to be appointed to the patient qualification committee; the second was the registration form for all practitioners with DEA numbers.

7. Completed first regulation project in June 1983 forwarded to Pharmacy Board. Began second project (12 AAC 52.610 to 630. - Marijuana Therapeutic Research Program).

8. Designed and developed a "pyramid" warning system in Southeast. The system is to notify pharmacists of a dangerous drug or when a registrant's license is revoked, or cancelled.

9. February 1984 investigative staff trained in Seattle by DEA personnel. Emphasis on pharmacy inspections and prescription inventory.

10. Established an additional program receipts procedure for registration under 12 AAC 52.400 to 455.

11. New investigator for Pharmacy Board hired in Anchorage.

12. December 1984, regulations approved by Department of Law for filing.

13. Coordinated efforts for the Board of Pharmacy to become registered to obtain an IND registration number (Investigational Exemption for New Drug).

Other tasks completed by the board:

Appointment of physicians to the patient qualification review committee.

Designated Providence Hospital as the location for dispensing THC.

I trust the above information will assist you in your reviews. If this agency can be of additional assistance, feel free to contact us.

Sincerely,

Harry D. Treager
Director

HDT/val0111V
21185A
Enclosure
cc: Representative Mike Navarre, Chairman
House Labor and Commerce Committee

STATE OF ALASKA
BOARD OF PHARMACY
APPLICATION FOR REGISTRATION UNDER CONTROLLED SUBSTANCES ACT

Mail the white and yellow copies of this form with attachments to

State of Alaska
Board of Pharmacy
Pouch D
Juneau, Alaska 99811

Retain pink copy for your records and future reference. A validated form will be returned as your certificate and must be posted conspicuously in your place of practice.

Name _____

Location _____

Mailing Address _____

_____

_____

Telephone: _____

1. Alaskan Professional License Number: _____
2. DEA Number _____
3. DEA Number registered for use in Alaska — Yes ☐ No ☐
4. Has the applicant been convicted of a felony in connection with controlled substances under State or federal law; or if the applicant is a corporation, association or partnership, has any officer or partner been convicted of a felony in connection with controlled substances under State or federal law? Yes ☐ No ☐

   If answer to question #4 is YES, attach a letter setting forth the circumstances.

I certify under penalty of perjury that the above information furnished is true and correct.

Warning: Alaska Statute 11.56.210 states that any person who knowingly or intentionally furnishes false or fradulent information in this application has committed a Class A misdemeanor.

_____ Print Name

_____ Signature

_____ Date

Attached hereto must be:

1. $10.00 Registration Fee
2. A photocopy of current federal registration certificate; or, a photocopy of application for a federal registration along with proof from U.S. Drug Enforcement Agency that the registration has been unduly delayed.

   Note: All attachments must be signed by the applicant

BELOW FOR DEPARTMENT USE ONLY

Alaska Controlled Substance Act Authorization Number: _____

Authorized Business Activity

A. ☐ Retail Pharmacy
B. ☐ Hospital Clinic
C. ☐ Teaching Institution
D. ☐ Practitioner
E. ☐ Researcher
F. ☐ Analytical Laboratory

Drug Schedules

A. Schedule II ☐ Narcotic ☐ Nonnarcotic
B. Schedule III ☐ Narcotic ☐ Nonnarcotic
C. Schedule IV
D. Schedule V

Expiration Date: _____

Date	Receipt	Amount	Initials

1. White: Certificate (must be validated)
2. Yellow: Board of Pharmacy
3. Pink: Applicant Retain

12 AAC 52 is amended by adding new sections to read:

ARTICLE 5

REGULATION OF MANUFACTURE, DISTRIBUTION, PRESCRIPTION AND DISPENSING OF CONTROLLED SUBSTANCES

Section

12 AAC 52.400. PERSONS REQUIRED TO REGISTER. Each person who manufactures, distributes, dispenses, or conducts research with a controlled substance in this state, or who proposes to do so, shall register annually with the board unless exempted by AS 17.30.020(c) or 12 AAC 52.405. Only a person actually engaged in these activities is required to register. A related or affiliated person who does not engage in the activities is not required to register. (Eff. 12/30/84, Reg. 92)

Authority: AS 17.30.010
AS 17.30.020(a) and (b)

12 AAC 52.405. PERSONS EXEMPT UNDER FEDERAL LAW. (a) A person who is exempt from federal registration under the federal Controlled Substances Act of 1970, as amended 21 U.S.C. secs. 321 -- 392, is also exempt from registration with the board.

(b) If a person exempted by this section also engages as a private individual in any activity for which registration is required, the person shall register for the private activity. (Eff. 12/30/84, Reg. 92)

Authority: AS 17.30.010
AS 17.30.020(a) and (b)
AS 17.30.030

12 AAC 52.410. SEPARATE REGISTRATION FOR INDEPENDENT ACTIVITIES. (a) A person must obtain a separate certificate of registration for each group of independent activities in which the person engages.

(b) The following groups of activities are considered to be independent of each other:

(1) manufacturing controlled substances listed in U.S. Drug Enforcement Administration Schedules I -- V;

(2) distributing controlled substances listed in U.S. Drug Enforcement Administration Schedules I -- V;

(3) dispensing controlled substances listed in U.S. Drug Enforcement Administration Schedules I -- V;

(4) conducting research with controlled substances listed in U.S. Drug Enforcement Administration Schedules I -- V;

(5) conducting instructional activities with controlled substances listed in U.S. Drug Enforcement Administration Schedules I --V;

(6) conducting a narcotic treatment program using any narcotic drugs listed in U.S. Drug Enforcement Administration Schedules I -- V;

(7) conducting chemical analysis with controlled substances listed in U.S. Drug Enforcement Administration Schedules I -- V;

(8) importing controlled substances listed in U.S. Drug Enforcement Administration Schedules I -- V;

(9) exporting controlled substances listed in U.S. Drug Enforcement Administration Schedules I -- V;

(10) compounding controlled substances listed in U.S. Drug Enforcement Administration Schedules I -- V;

(c) A person registered for a group of activities may engage in those activities with respect to all controlled substances in each schedule identified in that group of activities. However a person registered to conduct research with Schedule I controlled substances under (b)(4) of this section may conduct those activities only with the particular controlled substances identified on a research protocol that has been approved by the U.S. Drug Enforcement Administration. (Eff. 12/30/84, Reg. 92)

Authority: AS 17.30.010
AS 17.30.020(a)
AS 17.30.030(a)
AS 17.30.070(c)

12 AAC 52.415. SEPARATE REGISTRATION FOR SEPARATE LOCATIONS. A separate registration is required for each principal place of business or professional practice and for each office or other facility where controlled substances are manufactured, distributed, dispensed, or stored by a person. However, no separate registration is required for the following facilities:

(1) a warehouse where controlled substances are stored by or on behalf of a registered person, and from which the substances are distributed only to the registered person's principal place of business;

(2) an office used by agents of a registered person, at which the purchase or sale of controlled substances is solicited, made, or supervised, but which neither contains any controlled substances, other than for display purposes or for lawful distribution as samples only, nor serves as a distribution point for filling purchase or sales orders; and

(3) an office, used by a registered person with another principal place of business, from which controlled substances are prescribed but not administered or otherwise dispensed as a regular part of the professional practice of the registered person, and at which no supplies of controlled substances are maintained. (Eff. 12/30/84, Reg. 92)

Authority: AS 17.30.010
AS 17.30.020(a) and (e)
AS 17.30.030(a)

12 AAC 52.420. REGISTRATION RENEWAL. A person's state registration expires annually, on the date the person's then-current registration with the U.S. Drug Enforcement Administration expires. Application for renewal of state registration must be filed with the board not later than 30 days before expiration of the current registration. (Eff. 12/30/84, Reg. 92)

Authority: AS 17.30.010
AS 17.30.020(d)

12 AAC 52.425. APPLICATION. (a) Application for registration and renewal must be made on forms provided by the board. The board will mail an application to known licensed professionals in the the state who are registered with the U.S. Drug Enforcement Administration. However, each person required to be registered is responsible for requesting an application if one is not received, and failure of the board to mail an application does not excuse a person from timely registering under 12 AAC 52.400 -- 12 AAC 52.455. Applications may be obtained at the offices of the Department of Commerce and Economic Development, division of occupational licensing, during normal business hours, or by writing to the State of Alaska, Board of Pharmacy, Pouch D, Juneau, Alaska 99811.

(b) Each applicant shall return the original copy of the application form with proof of federal registration and the registration fee, to the board, retaining the duplicate of the form for the applicant's records. Each applicant must include all information called for unless an item is not applicable, in which case this fact must be indicated.

(c) Each application, attachment, or other document filed as part of an application must be signed by the applicant, if the applicant is an individual; by an authorized partner, if the applicant is a partnership; or by an appropriate officer, if the applicant is a corporation, corporate division, association, trust, or other entity.

(d) Each application must be accompanied by the proof of federal registration required by 12 AAC 52.430, and by the registration fee required by 12 AAC 52.435, and must be submitted for filing to the State of Alaska, Board of Pharmacy, Pouch D, Juneau, Alaska 99811.

(e) A person required to obtain more than one certificate of registration may submit all applications in one package. Each application must be complete by itself and may not refer to an accompanying application for required information. (Eff. 12/30/84, Reg. 92)

Authority: AS 17.30.010
AS 17.30.020(a)
AS 17.30.030

12 AAC 52.430. PROOF OF FEDERAL REGISTRATION. (a) An applicant must prove that the applicant is registered under the federal Controlled Substance Act of 1970, as amended. Proof of federal registration must accompany each application.

(b) An applicant may prove the applicant's federal registration by submitting

(1) a photocopy of the applicant's current federal registration certificate; or

(2) a photocopy of the applicant's application for a new or renewed federal registration along with proof from the U.S. Drug Enforcement Administration that the applicant's federal registration has been unduly delayed. (Eff. 12/30/84, Reg. 92)

Authority: AS 17.30.010
AS 17.30.020(a)
AS 17.30.030

12 AAC 52.435. REGISTRATION FEE. (a) For each registration or renewal the applicant must pay a fee of $10.

(b) Payment must be made in the form of a personal, certified, or cashier's check or money order made payable to the "State of Alaska". Payment in the form of stamps, foreign currency or third party endorsed checks will not be accepted. If the application is not accepted for filing or if it is denied, the payment will be refunded to the applicant. (Eff. 12/30/84, Reg. 92)

Authority: AS 17.30.010(a) and (b)
AS 17.30.020(a)

12 AAC 52.440. ACTION ON APPLICATIONS. (a) Complete correct applications will be dated upon receipt by the board. An application failing to comply with the requirements of 12 AAC 52.400 -- 12 AAC 52.455 will not be accepted for consideration by the board. An incomplete or defective application will be returned to the applicant, and may be completed or corrected and resubmitted at any time.

(b) The board will decide whether to grant or deny an application within a reasonable period of time after the complete correct application has been received by the board. (Eff. 12/30/84, Reg. 92)

Authority: AS 17.30.010
AS 17.30.020(a)

12 AAC 52.445. CERTIFICATE OF REGISTRATION. (a) Successful applicants will receive a certificate of registration. The certificate of registration will include

(1) the name, address, and registration number of the registrant;

(2) the activity authorized by the registration;

(3) the schedules of the controlled substances which the registrant is authorized to handle;

(4) the amount of the fee paid; and

(5) the expiration date of the registration.

(b) The registrant shall display the certificate of registration in a prominent place at the registrant's place of business and shall permit inspection of the certificate by any official, agent, or employee of any federal, state, or local, agency engaged in enforcement of laws relating to controlled substances. (Eff. 12/30/84, Reg. 92)

Authority: AS 17.30.010
AS 17.30.020(a) and (e)

12 AAC 52.450. TERMINATION OF REGISTRATION. A registration terminates when the registrant dies, ceases legal existence, or discontinues business or professional practice. A registrant who ceases legal existence or discontinues business or professional practice shall notify the board promptly of that fact. (Eff. 12/30/84, Reg. 92)

Authority: AS 17.30.010
AS 17.30.020(a) and (b)

12 AAC 52.455. SURRENDER OF REVOKED OR SUSPENDED CERTIFICATE OF REGISTRATION. (a) Upon service of an order of the board suspending or revoking a registration, a registrant shall immediately deliver the state certificate of registration to the board and shall deliver all controlled substances and order forms in his or her possession to the nearest office of the Department of Public Safety, or to the authorized agents of the U.S. Drug Enforcement Administration, or to an authorized municipal law enforcement agency designated by the commissioner of public safety, as instructed by the board.

(b) If revocation or suspension is limited to a particular controlled substance or substances, the registrant will be given a new certificate or registration for all substances not affected by the revocation or suspension. No fee will be required for the new certificate of registration. The registrant shall deliver to the board the old certificate of registration and, if appropriate, any order forms in his or her possession. All controlled substances affected by the revocation or suspension must be surrendered as provided by (a) of this section. (Eff. 12/30/84, Reg. 92)

Authority: AS 17.30.010
AS 17.30.020(a)
AS 17.30.030
AS 17.30.040(b) and (c)
AS 17.30.050(b)

12 AAC 52 is amended by adding a new article to read:

ARTICLE 6

MARIJUANA THERAPEUTIC RESEARCH PROGRAM

Section
610. Application for appointment to committee
620. Terms of committee members
630. Action by the committee

12 AAC 52.610. APPLICATION FOR APPOINTMENT TO COMMITTEE. (a) The board will prepare and mail application forms to practitioners who request appointment to the patient qualification review committee. All applications for appointment must be submitted to the Board of Pharmacy, Pouch D, Juneau, Alaska 99811.

(b) All applications will be reviewed by the board. The board will, in its discretion, verify the qualifications of applicants and will, on its own motion, invite a practitioner to apply for appointment to the committee.

(c) Each individual selected by the board for membership will be sent a letter stating the specialty of his or her appointment, if applicable, and the term of his or her appointment.

(d) The letter of appointment will be signed by the president of the board and attested to by the secretary of the board. (Eff. 12/30/84, Reg. 92)

Authority: AS 17.35.020
AS 17.35.030

12 AAC 52.620. TERMS OF COMMITTEE MEMBERS. (a) The member of the patient qualification review committee with no required specialty serves for one year and is chairman of the committee.

(b) The committee member specializing in psychiatry serves for two years.

(c) The member specializing in ophthamology serves for three years.

(d) The member specializing in radiology serves for four years.

(e) Each member of the patient qualification review committee may be considered for reappointment at the end of his or her term. Application for reappointment must be submitted to the board three months before the expiration date of the member's current term.

(f) A member may be removed by the board with or without cause.

(g) Vacancies occurring on the committee will be filled by the board as quickly as practicable. (Eff. 12/30/84, Reg. 92)

Authority: AS 17.35.020(a)
AS 17.35.030(a)

12 AAC 52.630. ACTION BY THE COMMITTEE. (a) A meeting of the committee may be called by the board, the chairman of the committee or by any two committee members. The committee may conduct business only if a quorum of at least two members is present.

(b) A patient's involvement in the therapeutic research program is certified if it is approved by a majority of the members in a meeting at which a quorum is present. Where an even number of members are present, the chairman or acting chairman may not vote except to break a tie.

(c) The committee shall administer procedures established by the board under AS 17.35.040(b). (Eff. 12/30/84, Reg. 92)

Authority: AS 17.35.020(a)
AS 17.35.030(a) and (c)
AS 17.35.040(b)

January 3, 1984

C. J. Sternlagen, M.D.
Cancer Treatment Center
Providence Hospital
3200 Providence Drive
Anchorage, Alaska 99504

Dear Dr. Sternlagen:

Re: Patient Qualification Review Committee

Enclosed for your perusal are copies of Alaska Statute Title 17, Chapter 35 and the regulations 12 AAC 52, Chapter 6, titled "Marijuana Therapeutic Research Program."

The regulations became effective on December 30, 1984.

The Alaska Board of Pharmacy should meet with your committee in the near future to set guidelines and adopt further regulations to comply with the various sections in the statutes. (Ex. AS 17.35.020(a), AS 17.35.020(c), AS 17.35.030(e) and AS 17.35.040(b))

This correspondence is to advise you the division is your administrative support, with offices in Anchorage and Juneau. We have one staff person, Ms. Barbara Branson, who works with the general pharmacy licensing function in Juneau. There are also other staff resources to assist you when the needs arise, such as a regulation specialist. I would request you review the statutory authority (AS 17.35) and formulate some thoughts and ideas as to how you would accomplish your committee's work. There are some legislative guidelines, such as confidentiality, which must be adhered to. We are here to assist you in starting the program.

If you have any questions regarding the governmental involvement, feel free to contact me. I look forward to meeting and working with you in the near future.

Sincerely,

Harry D. Treager
Director

HDT/mst1256&7m
010284a
Enclosures
cc: Margaret Soden, Pharmacy Board

January 3, 1984

Thomas L. Conley, M.D.
3615 Tongass
Ketchikan, Alaska 99901

Dear Dr. Conley:

Re: Patient Qualification Review Committee

Enclosed for your perusal are copies of Alaska Statute Title 17, Chapter 35 and the regulations 12 AAC 52, Chapter 6, titled "Marijuana Therapeutic Research Program."

The regulations became effective on December 30, 1984.

The Alaska Board of Pharmacy should meet with your committee in the near future to set guidelines and adopt further regulations to comply with the various sections in the statutes. (Ex. AS 17.35.020(a), AS 17.35.020(c), AS 17.35.030(e) and AS 17.35.040(b))

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If you have any questions regarding the governmental involvement, feel free to contact me. I look forward to meeting and working with you in the near future.

Sincerely,

Harry D. Treager
Director

HDT/mst!256&7m
010284a
Enclosures
cc: Margaret Soden, Pharmacy Board

January 3, 1984

Kenneth T. Richardson, M.D.
542 West 2nd Avenue
Anchorage, Alaska 99501

Dear Dr. Richardson:

Re: Patient Qualification Review Committee

Enclosed for your perusal are copies of Alaska Statute Title 17, Chapter 35 and the regulations 12 AAC 52, Chapter 6, titled "Marijuana Therapeutic Research Program."

The regulations became effective on December 30, 1984.

The Alaska Board of Pharmacy should meet with your committee in the near future to set guidelines and adopt further regulations to comply with the various sections in the statutes. (Ex. AS 17.35.020(a), AS 17.35.020(c), AS 17.35.030(e) and AS 17.35.040(b))

This correspondence is to advise you the division is your administrative support, with offices in Anchorage and Juneau. We have one staff person, Ms. Barbara Branson, who works with the general pharmacy licensing function in Juneau. There are also other staff resources to assist you when the needs arise, such as a regulation specialist. I would request you review the statutory authority (AS 17.35) and formulate some thoughts and ideas as to how you would accomplish your committee's work. There are some legislative guidelines, such as confidentiality, which must be adhered to. We are here to assist you in starting the program.

If you have any questions regarding the governmental involvement, feel free to contact me. I look forward to meeting and working with you in the near future.

Sincerely,

Harry D. Treager
Director

HDT/mst1256&7m
010284a
Enclosures
cc: Margaret Soden, Pharmacy Board

January 3, 1984

David H. Williams, M.D.
Anchorage Community Health Center
3944 Spenard Road
Anchorage, Alaska 99503

Dear Dr. Williams:

Re: Patient Qualification Review Committee

Enclosed for your perusal are copies of Alaska Statute Title 17, Chapter 35 and the regulations 12 AAC 52, Chapter 6, titled "Marijuana Therapeutic Research Program."

The regulations became effective on December 30, 1984.

The Alaska Board of Pharmacy should meet with your committee in the near future to set guidelines and adopt further regulations to comply with the various sections in the statutes. (Ex. AS 17.35.020(a), AS 17.35.020(c), AS 17.35.030(e) and AS 17.35.040(b))

This correspondence is to advise you the division is your administrative support, with offices in Anchorage and Juneau. We have one staff person, Ms. Barbara Branson, who works with the general pharmacy licensing function in Juneau. There are also other staff resources to assist you when the needs arise, such as a regulation specialist. I would request you review the statutory authority (AS 17.35) and formulate some thoughts and ideas as to how you would accomplish your committee's work. There are some legislative guidelines, such as confidentiality, which must be adhered to. We are here to assist you in starting the program.

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Sincerely,

Harry D. Treager
Director

HDT/mst1256&7m
010284a
Enclosures
cc: Margaret Soden, Pharmacy Board

Aloys J. Daack, M. D.

Physician and Surgeon

Chicken, Alaska

July 22, 1983

TO: Richard A. Lyon, Commissioner
State of Alaska
Department of Commerce and
Economic Development
Board of Pharmacy
Office of the Commissioner
Pouch D
Juneau, AK 99811-0800

FROM: Dr. Aloys J. Daack, M.D.
No: AA 00497
Chicken, Alaska

Dear Mr. Lyon:

I have your State of Alaska public notice before me. Such is quite confusing.

I do not have all the articles, sections, and amendments that are mentioned in this long two page brief.

The main question that I would ask of you, how does it affect me as a practicing physician.

Sincerely submitted,

Aloys J. Daack, M.D.

AJD:mr

cc: file

Asst Secy + Stat Book
7/29/83

PHARMACEUTICAL MANUFACTURERS Association

1100 FIFTEENTH STREET, N.W.
WASHINGTON, D.C. 20005
AREA CODE (202) 835-3523
CABLE: PHARM, WASHINGTON, D.C.
TWX: 710 0229494-PMA-WSH

CHARLES R. GREZLAK, Ph. D.
MANAGER OF ISSUE DEVELOPMENT &
REGIONAL DIRECTOR
STATE GOVERNMENT RELATIONS

September 26, 1983

Department of Commerce
and Economic Development
Division of Occupational Licensing
Board of Pharmacy - Regulations
Century Plaza
142 East 3rd Avenue
Anchorage, Alaska 99501

Re: Proposed Changes in Regulations Regarding Controlled Substances/Title 12, Alaska Administrative Code, Chapter 52.

Dear Sirs:

The Pharmaceutical Manufacturers Association (PMA), representing 140 companies engaged in the research and development of prescription drugs, appreciates the opportunity to offer the following comments regarding the recent regulatory proposals by the Board of Pharmacy.

PMA recognizes the important public purpose served by Alaska's controlled substances statute, which is patterned after the Uniform Controlled Substances Act, and the regulations that are being proposed to implement this law. At the same time, we would hope that these regulations would be interpreted in such a manner by the Board of Pharmacy so as not to inhibit the legitimate activities of interstate pharmaceutical manufacturers. Specifically, we believe that the Alaska Controlled Substances Act and the proposed regulations do not require registration of out-of-state manufacturers, or their sales representatives, and should not be interpreted to require such registration.

Regarding the issue of registration of company sales representatives, it is significant that the federal Controlled Substances Act does not require company representatives who handle drugs to register individually so long as they are employees of federally registered manufacturers. Moreover, the Uniform Controlled Substances Act contains the advisory comment that registration of manufacturers' agents "would be extremely burdensome and afford little increase in protection against diversion." State registration of company representatives would

not provide any useful information that is not already available from drug manufacturers, who are required by the federal Drug Enforcement Administration to keep detailed records concerning controlled substances. Additional state registration of sales representatives would therefore be unnecessary, as well as costly to the State of Alaska to implement. Most importantly, we also note that Section 17.30.020(c) of the Alaska Controlled Substances Act specifically exempts "agents" of registered manufacturers from registration.

The second issue of concern to PMA is the possible interpretation of the proposed rules to require registration of out-of-state manufacturers, which we do not believe is necessary or desirable under these proposed regulations. The Alaska statute authorizing the Board to promulgate these regulations does in fact specify in Section 17.30.020(a) that persons who manufacture "in the state" are required to register, thereby implying that out-of-state manufacturers are not subject to this requirement.

While PMA does not oppose the registration of drug manufacturers located in the state, we do oppose proposals that would require out-of-state manufacturers to be registered, when their activities are limited mainly to taking orders in the state and shipping their products to purchasers. Individual state registration requirements for such activities would serve no demonstrable public purpose. The federal Food, Drug and Cosmetic Act already imposes strict registration requirements on interstate manufacturers of drugs and medical devices. These registration requirements assure accountability and responsibility. In addition, for manufacturers of controlled substances, even more accountability is required by the federal Drug Enforcement Administration (DEA), including detailed records of all transactions involving Schedule I, II and III controlled substance drugs. Such information is regularly made available by DEA to various state agencies.

For the above reasons, PMA requests that the Board of Pharmacy, in interpreting the proposed regulations, refrain from taking such action that might require the registration of either manufacturer sales representatives or out-of-state companies. We believe that such registration requirements would be contrary to the language included in the Alaska Controlled Substances Act, and would be unnecessary as well as duplicative of federal requirements.

We would appreciate your consideration of these comments in interpreting the proposed regulations of the Board of Pharmacy. In recognition of the important role played by the Board in carrying out the requirements of the Controlled Substances Act, I also would like to express our readiness to provide whatever assistance we can in this regard.

Sincerely,

Charles R. Grezlak

Charles R. Grezlak

Aurora Animal Clinic
1651 College Road
Fairbanks, Alaska 99701
(907)452-6055

Dear Dept. of Commerce -

I am writing this letter to express my opposition to the proposed changes in the Board of Pharmacy Regulations - article 5.

These proposed changes needlessly duplicate existing Federal Regulations and the bureaucratic structure required to implement and enforce the changes cannot be justified for the State of Alaska at this time.

I feel that the legislature is asking the Board of Pharmacy to create a bureaucratic mess.

Thanks for listening

Steve Lee

Interior Alaska Veterinary Medical Association

800 Collage Road

FAIRBANKS, ALASKA
99701

September 27, 1983

Department of Commerce
Division of Occupational Licensing
Board of Pharmacy-Regulations
Century Plaza
142-E 3rd Ave.
Anachorage, Alaska. 99501

To Whom It May Concern:

On behalf of the Interior Veterinary Medical Association, I wcul like to express our opposition to the proposed legislation requiring Alaska licensed practicioners to register and pay State fees for the verifications of their DEA registration.

We feel the additional paperwork an unnessary burden for the State, and that the registration/revenue only duplicates our federal registration and federal fee payment.

Please consider the proposal a duplication of responsibility that we have already satisfied on the federal level and delate it from the statutes.

Sincerely,

Kate Klause, DVM

Kate Klause, D.V.M
President IVMA

KK/mj

Russell A. Lee, DVM

9-23-83

Aurora Animal Clinic
1651 College Road
Fairbanks, Alaska 99701
(907)452-6055

To Whom it May Concern:

In reference to the proposal to require a state licensure of persons handling controlled substances, I feel that it is a duplication of the program already being conducted by the U.S. Drug Enforcement Administration. This would be unnecessary and would only cost the taxpayers, the State, and the individuals concerned additional money and time both in setting up the program and in operating it on a yearly basis. In this time of austerity, this type of program only adds to an already inefficient bureaucracy, and is totally unneeded in my opinion.

Respectfully,

Russell A. Lee, DVM

Aurora Animal Clinic
1651 College Road
Fairbanks, Alaska 99701
(907)452-6055

attn: Dr Zittner

28 September 1983

To Whom It May Concern,

This letter is written in reference to the proposed requirement for the state pharmacy board to register all persons handling controlled substances. As a licensed veterinarian, I feel this to be a wasteful duplication of effort since federal law already requires, supervises and controls such registration. I can honestly see no real benefit to such a requirement and consider the time spent both on the part of the administrators and the applicants to be not only an obvious futility but also a great waste of the taxpayer's money. I am wholeheartedly against the implementation of this needless duplication of effort and earnestly hope that this proposal, to me just another example of bureaucratic by regulated strangulation, not be adopted.

Sincerely,

Adam Cook Zittner Jr V.M.D.

Ketchikan Medical Clinic, Inc.

3612 TONGASS
KETCHIKAN, ALASKA 99901

H.J. Henrickson, M.D.
D.E. Johnson, M.D.
T.L. Conley, M.D.
M.E. Bloom, M.D.

Phone 225-5144
Phone 225-5145

December 19, 1983

Board of Pharmacy
Occupational Licensing Division
Dept. of Commerce & Economic Development
Pouch D
Juneau, Alaska 99811

Gentlemen:

At its regular meeting on the 8th and 9th of December, 1983, the State Medical Board considered at some length the proposed changes to 12AAC 52. In question were the proposed additions of Chapter 5 on controlled substance registration and Chapter 6 on the marijuana therapeutic research program. The Medical Board has directed me to communicate its comments to you.

In regard to the proposed addition of Chapter 5 on registration for the use and distribution of controlled substances, the State Medical Board concluded that this program serves no useful purpose. It is noted that the federal government already has a program for this purpose in place. Formation of a State program to perform the same function simply adds another level of bureaucracy that benefits no one as far as we can see. We would also remark that within its own frame of reference, the program is deficient in the sense that it does not provide for registration of temporary medical personnel and those holding locum tenes licenses. Since these license holders provide a significant proportion of the medical care in Alaska, failure to include them within the program creates chaos.

An additional consideration is the fact that the program proposed will add additional expense at a time when the Department's budget is being cut back both in absolute terms and by inflation. To spend money on a program that serves no discernable function seems doubly undesirable at this time.

Our feelings about Chapter 6 of the proposed regulations, the formation of a marijuana therapeutic research program are a bit more complicated. We recognize the need to provide some sort of a mechanism to insure the availablity of the substance in question to practioners who are treating patients with malignancies as they undergo chemotherapy and perhaps patients with glaucoma. Presently, short sided federal regulations make this at least difficult. The obvious solution to the problem is of course to make the substance available on prescription like any other controlled

substance. Surely, if physicians are given authority to prescribe narcotics which have enormous potential for abuse, they should be given the authority to prescribe marijuana and its derivatives which have considerably less potential for abuse, at least within the medical setting. That of course is a whole philisophical discussion with numerous social ramifications that we do not wish to get into at this time. Nonetheless, the program envisioned by Chapter 6 does not seem to be a particularly rational solution to the problem either.

In talking to physicians in other parts of the country who are dealing with programs such as the present law envisions, one comes to the inescapable conclusion that the law would tend to substitute one form of illegal behavior for another. At the present time, physicians treating individuals with malignancies who wish to prescribe marijuana and its derivitives usually indicate to the patient that they should acquire the material on their own. Granted, this is illegal, but it is at least practical. The system that the law proposes would set up a board that would have to pass on each individual case. Considering the nature of bureaucracy and the infrequency with which the board could meet to consider each individual case, it is likely that physicians will be induced to request permission for the use of the substance for patient A with the full knowledge that when the permission and the drug finally become available, they will administer it to patient B because patient A is either finished with his or her course of therapy or has already expired. In talking to physicians in other parts of the country, this is indeed exactly what happens. One could perhaps argue that this is less of a deception than simply advising the patient to acquire his or her own supply of the substance in question but substituting one illegality for another hardly seems like a reasonable course for the State to espouse. The answer thus does not seem to lie at a State level but rather would seem to lie at the federal level. We would therefore feel that getting involved in this matter on a State level is at least inadvisable. Additionally, the arguments relative to the expenditure of funds at a time when State revenues are declining both in real dollars and by inflation would apply to this program too.

The State Medical Board realizes that the Pharmacy Board is in a difficult position in regard to both of these programs. You have been directed by the legislature, as a result of recent enactments of law to go in this direction. We realize that you have relatively little discretion in the matter. It would therefore be our proposal to inform the legislature and the Governor's office of our feelings in the matter with the recommendation that the legislature either not vote funding for either of these programs or that when the funding proposals come to the Governor's office, he line item veto the expenditures.

We realize that this is a fairly unusual response to your proposed regulations, but feel that it is the only rational one available at the present time. We will look forward to further discussion of this matter at the conjoint meeting of the Boards of Nursing, Pharmacy and Medicine in Juneau in February of 1984.

Sincerely,

Thomas L. Conley, M.D.
Secretary
Alaska State Board of Medicine

TLC:dp

cc: Jeffrey A. Partnow, M.D.
Hugh Gellert, Chairman
George C. Brenneman, M.D.
Thomas Kinsella
George S. Ryneer, M.D.
Office of the Management of the Budget
Governor's Office

Ketchikan Medical Clinic, Inc.

3612 TONGASS
KETCHIKAN, ALASKA 99901

Phone 225-5144
Phone 225-5145

H.J. Henrickson, M.D.
L E. Johnson, M.D.
T.L. Conley, M.D.
M.E. Bloom, M.D.

TO Office of the Governor
Office of the Management of the Budget

FROM Alaska State Medical Board

DATE December 21, 1983

RE Proposed Regulatory Changes

Enclosed is a letter from the Alaska State Medical Board to the Alaska State Board of Pharmacy. It discusses proposed regulatory changes to 12 AAC 52. Copies of our comments are forwarded to you because we have a rather unusual proposal for these regulations.

At the last meeting of the Alaska State Medical Board, we heard from Commissioner Lyon relative to budetary limitations during the coming fiscal year. As we understand it, the budget for occupational licensing will actually be reduced slightly at a time when inflation and increasing responsibilities make it very difficult to insure that ends meet. In this regard, we have significant problems with the proposed action envisioned by 12 AAC 52. It envisions the formation of programs that, as far as we can see, serve no useful function. In addition to serving no useful function, they will further drain the treasury at a time when this can be ill afforded.

Unfortunately, enactments of law during the last legislative session, namely the omnibus drug bills, have more or less mandated the programs that are envisioned in the regulatory changes. Again, we would stress they have little or no relevance to Alaska and attempt to attack on a State level, problems which basically are national rather than local problems. The registration requirement for the dispensing of a controlled substance is a particularly redundant and to most physicians repugnant act on the part of the State government. It also seems, at least in the regulations, to be very poorly conceived.

That being the case, it has been our proposal that for both practical reasons and for reasons of economy, these programs not go into effect. Since they are on the books, there seems to be little that can be done about them at the present time other than not funding them. We would

therefore propose both to the Office of the Management of the Budget on the legislative side, and to the Office of the Governor on the administrative side, that you give serious consideration to preventing funding of these programs.

Sincerely,

Thomas L. Conley, M.D.
Secretary
State Medical Board
by direction

TLC:dp

Enclosure

KILA, Inc.

Locally Controlled
Integrated and Coordinated
Human Services

Fairbanks Alternative
Placement Center

Detention
Furlough
Re-Entry

Fairbanks Substance
Abuse Center

Education
Outreach
Prevention
Training
Treatment

3098 Airport Way
Fairbanks, Alaska 99701-5599
(907) 452-5972

December 26, 1983

Darrel Miller
Regulations Specialist
Department of Commerce & Economic Development
Pouch D
Juneau, Alaska 99811

Dear Mr. Miller,

I just recently came into possession of the proposed regulations promulgated by the Board of Pharmacy (as required by AS 17.30.010 as passed under SB 190).

I have no overwhelming opposition to the proposed regulations developing, but I do need to ask why it only costs $5/year to get registered with the feds and $10/year to get registered with the State of Alaska? Why is registration with the State deemed desirable? Why not just get a listing of those registered with the feds from the feds? I am concerned only because the need for such registration evades my reading of the proposed regulations. Section 12 AAC 52.425 (6) is already covered under federal law and regulations; why does the state need to engage in such realms?

I would suggest that programs falling under the jurisdiction of the federal government's agencies (FDA and/or DEA) be exempted from having to secure a state license also. Why does the Board of Pharmacy want jurisdiction over programs it has succeeded in ignoring for the past 10+ years? The program to include us under the Board of Pharmacy is wasteful and of questionable value. Most important: Why is the Board committed to the growth of some state bureaucracy when the issues are already well covered by the federal government's bureaucracy?

Thank you for the opportunity to respond to the proposed regulations. It is indicative of the genuine interest in programs such as ours that the proposed regulations only just now arrived in this office--and then from an agency other than the Board of Pharmacy.

Sincerely yours,

Frank J. Gold, EdD
Executive Director & Staff Psychologist

FJG:ss

cc: SOADA
Fairbanks Delegation

Miller

Ketchikan Medical Clinic, Inc.

3612 TONGASS
KETCHIKAN, ALASKA 99901

H.J. Henrickson, M.D.
D.E. Johnson, M.D.
T.L. Conley, M.D.
M.E. Bloom, M.D.

Phone 225-5144
Phone 225-5145

March 23, 1984

Board of Pharmacy
Occupational Licensing Division
Dept. of Commerce and Economic Development
Pouch D
Juneau, Alaska 99811

Dear Pharmacy Board Members:

This is in follow-up to our letter of December 19, 1983, suggesting non-funding of the mechanisms necessary to implement the changes envisioned in the addition of Chapters 5 and 6 to 12AAC52 (controlled substance registration and creation of the Marijuana Therapeutic Research Program, respectively). It reflects consideration of the material presented by your Board at the combined Medicine, Nursing and Pharmacy Board meeting of February 23, 1984 and subsequent reflection on the matter by the Medical Board at its meeting on February 24, 1984.

It was disturbing to us to learn that the federal Bureau of Narcotic and Dangerous Drugs programs for registration of practitioners, retail pharmacies, wholesale pharmacies and manufacturers is a virtual sham -- perhaps becoming more of a sham as it moves from the general (manufacturer) to particular (practitioner) and that the federal government is abrogating its responsibility in this matter without publicly announcing the fact. Additionally disturbing was your assertion -- offered we might note without proof -- that 50% of the illicit drugs available "on the streets" are being diverted from legitimate sources.

Disturbing as all this might be, the Medical Board found it to be a giant leap, unsupported by documentation, to suppose that a State registration of all practitioners was in order. If indeed there is massive diversion of controlled substances to the illicit market it is reasoned that the bulk of it is likely leaking at the level of manufacturer (none in Alaska) and wholesaler. There may therefore be a rational for registration and control by another level of bureaucracy at the supra-pharmacy level. One is less than sure that this is justified at the retail and prescribing level as adequate controls in other formats in such a small state already seem to function quite well as recent prosecutions and investigations would indicate. Additionally, the original presentation of this idea about a year ago by the State's chief prosecutor, Mr. Hickey, left the Board very concerned that considerations of due process and humane inquiry, especially as they applied to terminal patients being prescribed significant amounts of controlled substances might well be ignored and trampled upon by the overzealous.

The Medical Board is, of course, not so naive as to believe that there is no diversion of illicit drugs by individual pharmacists and medical practitioners but rather wonders if you are not proposing that we acquire a big stick to swat a mosquito. We feel some time and careful inquiry is needed to determine just how necessary the program might be.

With this in mind, the State Medical Board would like to urge a "go slow" policy. Rather than adopting the registration idea on a permanent basis, we would suggest instead funding of a trial program to run for say two years. During that time we (the Pharmacy and Medicine Boards) would determine if such a program identifies any significant number of bad actors and whether it actually benefits the State. If it does fine; if it doesn't it gives us the option of bowing out of the program before it does permanent harm. Such a trial program takes cognizance of the fact that permanent legistation, whether of benefit or not, tends to create bureaucracies that servive on pure inertia.

The Medical Board also reconsidered the Marijuana Therapeutic Research Program in light of the simplification proposed by the utilization of the federally recognized pharmacy program at Providence Hospital in Anchorage to supply tetrahydrocanabinol capsules to practitioners treating cancer patients undergoing chemotherapy. The idea has merit and we approve.

However, in light of the simplification, we fail to understand why the State needs to spend money creating yet another board to administer the program and certify various physicians as investigators qualified to receive controlled substances from the federally designated pharmacy. Surely the already constituted Pharmacy and Medical Boards, either alone or in concert, are adequate to this rather simple task. It is felt that very few of the State's physician's will apply for such authority, and we could even limit it to a specified number by geographical location. Therefore, we don't understand the necessity for a special commission with all the attendant administrative support, travel, etc. to carry out this function. It seems manifestly a dreadful waste of money and the time of the proposed commissioners.

Sincerely,

Thomas L. Conley
Secretary
Alaska State Board of Pharmacy

TLC:dp

4/8/84 applied
Miller & Hald

TO: Office of the Governor
Legislative Office of the Management of the Budget

FROM: Alaska State Medical Board

RE: Proposed Regulatory Changes to 12AAC52

DATE: March 23, 1984

Enclosed is a reconsideration of proposed changes to 12AAC52 (Pharmacy Board Regulations) by the State Medical Board. Reference is made to our memo to you of December 21, 1983. The reconsideration arises out of a conjoint meeting of the Boards of Medicine, Nursing and Pharmacy on February 24, 1984 in Juenau, and a subsequent meeting of the Medical Board on February 24, 1984.

The jist of the reconsideration is a proposal to undertake registration of State health care providers (in the use of controlled substances) on a limited, two-year trial basis to see if it is of benefit to the State before committing ourselves to it permanently and at significant cost. Additionally, there is a reconsideration of the Marijauana Therapeutic Research Program with a proposal that the State save money by employing already constituted and functioning State agencies to administer the program rather than squandering funds to create a new, and as far as we can see unnecesary commission.

Functionally, the way to accompliah this would be the non-funding of the program needed to establish the Marijuana Therapeutic Research Program either at a legislative level or by line-item veto at the Executive level.

We will be happy to answer any questions on our suggestions in this regard. (Contact person: T. L. Conley, M.D., Secretary, Alaska State Medical Board, 3612 Tongass Avenue, Ketchikan, Alaska 99901, 907-225-5146).

Thomas L. Conley
Secretary

TLC/dp

Enclosure

CTS #4167320

KILA, Inc.

Fairbanks Alternative Placement Center

Detention
Furlough
Re-Entry

Locally Controlled
Integrated and Coordinated
Human Services

3098 Airport Way
Fairbanks, Alaska 99701-5599
(907) 452-5972

Fairbanks Substance Abuse Center

Education
Outreach
Prevention
Training
Treatment

June 12, 1984

Governor Bill Sheffield
Pouch A
Juneau, Alaska 99811

Dear Governor Sheffield,

Attached find copies of the correspondence between this office and the Division of Occupational Licensing regarding the proposed regulations to be implemented by the Board of Pharmacy.

Note that we are not opposed to registration, but we are opposed to multiple registration. At this time, the Fairbanks Substance Abuse Center is registered with the US Food & Drug Administration, the US Drug Enforcement Administration, and the Alaska Office of Alcoholism & Drug Abuse. A fourth agency is not perceived as particularly welcome. More important, each of these agencies sees fit to come through the program and examine the dispensing records, the patient files, etc. To be very direct about this issue, we are not impressed with having to set aside still more time to deal with visitors who are coming to check what has already been checked by another visitor!

We are requesting that the regulations be modified to exempt certain agencies, like the Fairbanks Substance Abuse Center, who already are multiply registered. The examinations can be secured by the Board of Pharmacy (if they so desire) from each of our current examiners--and the state can save many dollars by not engaging in a quadruplication of effort.

Thank you for considering our view.

Sincerely yours,

Frank J. Gold, EdD
Executive Director & Staff Psychologist

[redacted]ORDOVA COMMUNITY HOSPITAL — Cordova, Alaska

December 3, 1982

MEMORANDUM

TO: CITY MANAGER

FROM: HOSPITAL ADMINISTRATOR

SUBJECT: PHARMACY REGULATIONS

This memo is to report to you the difficulties this small rural hospital experiences when we try to meet the needs of our patients and comply with pharmacy regulations.

Drugs such as demeral,codeine, valium, etc., can only be issued to patients by order of a licensed physician. That is no problem and the way it should be. However, the problem arises after working hours and on weekends. A nurse can issue only one dose of the above class drugs in our emergency room unless a physician or pharmacist is present. Therefore, if more than one dose is needed the patient must return to the emergency room for another one dose.

As you know we do not have a pharmacist on duty at all times, and in many cases, the patient does not require the direct service of a physician/dentist.

If the patient is a fisherman or on a boat that will not be in Cordova when the drug store will open, then either the physician or dentist must come to the hospital to be present before the drug can be lawfully given to the patient. This means that the patient must needlessly pay for an after hours physician call or pay $25.00 to the pharmacist for him to be called to the hospital. This problem is the same for all rural hospitals in Alaska.

RECOMMENDATION:

The pharmacy regulations should be changed so that a hospital emergency room nurse could issue these class drugs to patients in accordance with a physician/dentist prescription regardless whether a physician or pharmacist is available.

Box 1210 602 Railroad Avenue
Cordova, Alaska 99574
Phone: (907) 424-3237
or 424-3238

"The Friendly City"

OC# 3004134

RECEIVED
DEC 29 '82

December 21, 1982

Governor Bill Sheffield
Office of the Governor
Pouch V
Juneau, AK 99811

Dear Governor Sheffield:

Enclosed find a recommendation submitted by the Cordova Community Hospital Administrator, Ed Zeine, regarding Pharmacy Regulations.

Would appreciate your consideration of this recommendation.

Best wishes to you, your family and staff for a Merry Christmas and Happy New Year!

Very truly yours,

Perry D. Lovett
City Manager

Enclosure

Alaska Dental Society
3400 Spenard Road, Suite 10
Anchorage, Alaska 99503
(907) 277-4675

July 20, 1983

Richard A. Lyon, Commissioner
Department of Commerce and Economic Development
Division of Occupational Licensing
Board of Pharmacy - Regulations
Century Plaza
142 East 3rd Ave.
Anchorage, Alaska 99501

Dear Commissioner Lyon:

I have received and read the public notice of proposed changes in the regulations of the Department of Commerce and Economic Development, Board of Pharmacy. Of concern to me is Title 12, Alaska Administrative Code, Chapter 52, Sections 410 and 415. (12 ACC 52.410 and 12 ACC 52. 415) I expect these also concern other practitioners in the healing arts who write prescriptions and have obligations in dealing with controlled substances.

An interpretation of proposed changes in 410 and 415 by medical and dental practitioners could be that another unnecessary bureaucracy is to be created. Why? The U.S. Treasury Department has been doing a fine job for many years. They have a large staff and a lot of money. These changes would call for hiring additional personnel and maintaining additional office space. (Costs for the remainder of 1984 - $17,500 and for 1985 $26,700). It seems a duplication of effort and a waste of dwindling state monies.

As president of the Alaska Dental Society, I will be questioned about this regulation by our membership. I would like to offer more of an explanation than is offered in the material sent out over your signature on July 11, 1983. Please help me understand the rationale behind these proposed changes. As presented, they seem dangerously incumbering, unnecessary and presumptuous in that you are entering the domain of the U.S. Treasury Department.

Sincerely,

Edward G. Wilkinson D.D.S.

Edward G. Wilkinson, D.D.S.
President
Alaska Dental Society

Ketchikan Medical Clinic, Inc.

3612 TONGASS
KETCHIKAN, ALASKA 99901

H.J. Henrickson, M.D.
D.E. Johnson, M.D.
T.L. Conley, M.D.
M.E. Bloom, M.D.

Phone 225-5144
Phone 225-5145

July 26, 1983

Department of Commerce & Economic Development
Division of Occupational Licensing
Board of Pharmacy - Regulations
Century Plaza, 142 East Third Avenue
Anchorage, Alaska 99501

RE: 12 AAC 52 New Article #5
REGULATION AND MANUFACTURER DISTRIBUTION, PRESCRIPTION AND DISPENSING OF CONTROLLED SUBSTANCES

Gentlemen:

Thank you for this opportunity to again comment on the proposed regulation changes creating what is in effect a mini-DEA in the State of Alaska.

As I stated before. I find myself somewhat irritated by this whole procedure. We already have a national registration for drug control through the Drug Enforcement Administration in Washington, D.C. It totally escapes me what possible purpose could be served by creating a parallel organization in the State of Alaska. It creates a new level of bureaucracy, charges practitioners a fee of $10 for no good purpose, and most importantly, squanders $20,000 to $30,000 a year of state funds in a useless effort.

I realize that the state legislature has essentially directed the Board of Pharmacy to come up with some regulations to make sure that everyone is registered. I do not pretend to understand their purpose in this. After watching the legislature over the last several years, I suspect they do not understand their purpose either. I realize, however, that it is a hassle and you probably have to do something. Perhaps, however, we could be imaginative about this, and deliver to the legislature the appearance without the reality. After all, that is all they ever really seem to care about anyway. It strikes me that at the next conjoint pharmacy, nursing and medical board meeting we might look at the possibility of registering everyone automatically at the time they are issued a license in the various disciplines. This could be construed as conforming to the letter of the law without getting ourselves involved in futile expenditures of time, effort and public resources.

I am quite aware that there is a significant problem with illicit drugs in the State of Alaska. I certainly agree that we should expend effort, time and public funding on trying to combat this problem. However, the proposed regulations, which I understand grew out of legislative desire to do something, are totally irrelevant to the problem and represent only bureaucratic handwringing. In any case I say, enough of this. Surely we have better things to do with our time.

Sincerely.

Thomas L. Conley, M.D.
Alaska State Board of Medicine

TLC:dg

cc: Mr. Hugh Gellert
406 "G" Street
Anchorage, Alaska 99501

HARRIET JACKSON SCHIRMER, M.D.
BOX 773
WRANGELL, ALASKA 99929
874-3368

July 28, 1983

Richard A. Lyon, Commissioner
Department of Commerce and
Economic Development
Board of Pharmacy

Dear Sir:

I have just received your public notice of proposed changes in regulations, and notice that under article number five, 12 AAC 52.400, provides that every person who dispenses any controlled substance, or proposes to do so, must obtain a certificate of registration with the Board of Pharmacy. Are you suggesting that there be a double registration business for narcotics and controlled substances, or that physicians would have a federal and a state registration? What about nurses who in the course of their activity in a hospital do dispense controlled substances?

I would appreciate your letting me know what this means.

Yours sincerely,

Harriet J. Schirmer, M.D.

HJS:kaw

Susitna Valley Veterinary Clinic

Kenneth Aadsen, D.V.M. *Valerie Shepard, D.V.M.*

Mile 48.2 Parks Highway Star Route 2100 Wasilla, Alaska 99687 Phone 376 - 2141

August 12, 1983

Department of Commerce and Economic Development
Division of Occupational Licensing
Borad of Pharmacy Regulations
Century Plaza
142 East 3rd Avenue
Anchorage Alaska 99501

Dear Sirs,

The Board of Veterinary Examiners at its last meeting, August 8, 1983, voted to oppose adoption of the proposed amendment to 12AAC52 designated Article 5, "Regulation of Manufacture, Distribution, Prescription, and Dispensing for Controlled Substances."

Board memebers had been approached by veterinarians and other individuals opposed to the adoption of these regulations prior to the meeting and had an opportunity to review the text of the proposed amendment as well as the new statute under Chapter 17.30 "Controlled Substances." Ms. Marian Hartley, Regulations Specialist, spoke to us regarding the development of the proposed regulations.

The Board listed the following reasons for it's opposition:

1. Implementation of this regulation would merely duplicate the registration system already adequately administered by the Federal Drug Enforcement Agency.
2. The cost of this duplication would place an unnecessary financial burden on the citizens and proposed licensees of this state.
3. Other than compliance with Chapter 30 of Title 17, there has been no demonstrated need for such registration nor would its implementation appear to improve upon the already existing Federal system.
4. The requirement that all distributors register with the state may decrease the availability of some controlled substances utilized by veterinarians who ordinarily order such drugs from distributors located outside of Alaska.

The Board further suggested that the entire question of Statutorily mandated registration be reexamined by the Legislator with regard to eliminating unnecessary duplication of the Federal registration system.

We trust that the Board of Pharmacy will consider these comments along with others it might receive at the scheduled public hearing, and suggest that you move to withdraw the adoption order for Article 5.

Valerie Shepard DVM
Board of Veterinary Examiners

FAITH HOSPITAL
CENTRAL ALASKAN MISSIONS, INC.
GLENNALLEN, ALASKA 99588
PHONE 822-3203

August 26,1983

I feel a Marijuana Therapeutic Research Program is a waste of time and money. Pharmacologically the effects of marijuana are no more beneficial than currently prescribed medications. For example, the use of marijuana in cancer patients or those with glaucoma has been shown to be less effective and more expensive. Research programs such as these will more than likely only promote the legalization of marijuana. I believe the legalization of marijuana would promote detrimental consequences to our already "mood altering" society.

Heidi Roth R.Ph.
Box 369
Glennallen, Alaska 99588

Box 8515
Ketchikan, Alaska
9/10/83

To: Board of Pharmacy
Concerning - Marijuana Research Program
From - Betty J. Wilson, President, Ketchikan Families in Action

Ketchikan Families in Action is a group concerned about drug use and abuse in Ketchikan and in the state of Alaska. For over two and one half years we have been studying the current research on Marijuana because we have observed what it is doing to our teenagers and friends.

The purpose of the legislation pertaining to the Alaska Therapuetic Research Act is not a good enough reason for Alaska to spend its time and money researching Marijuana as a medicine. The Federal government has been researching this for several years. We do not believe that Alaska has better methods for conducting this research therefor let us let the Federal government do it.

The research that has been done has shown Marijuana to have some problems and that it was notsuperior to other medicines for controlling nausea and helping Glaucoma. Dr. Richard Gralla of Memorial Sloan Kettering Cancer Center has conducted a comprehensive study using Metoclopramide to control Nausea in cancer chemotherapy patients. He found that 1. It was safe to administer at high doses, 2. Side affects are mild, 3. very effective in controlling nausea. Marijuana is none of the above. It has many unpleasant side affects, some are incoordination, dizziness, ataxia, paranoia and hallucination.

Another study was done comparing THC, a placebo and compazine. It was found that patients on THC and compazine did about as well except that they had many more side effects on THC, especially the older patients.

There are certain types of cancer therapy drugs on which THC does not work. One is cisplatinum, used against ovarion, testicular cancer as well as lung, bladder and prostat

There is lots of evidence that NORML the organization for reform of Marijuana laws is working hard in all states to get them to make pot available for therapuetic use since they have not had good luck in legalizing it. This is one more way of improving Marijuana's social acceptance.

In Ketchikan marijuana is already socially acceptable with all the problems that a psychologically addictive drug can cause a community and its people. We need this money that it would cost to implement this research to help Alaska's people know that Marijuana is a dangerous drug and can get them hooked. The legislature has cut funds for drug prevention, and treatment . We need in-patient treatment facilities for youth and adequate out-patient counselling for youth and their families.

Another concern we have is that the bill says that the patient may possess Marijuana, its derivatives or its active ingredients, synthetic or natural. I believe federal law says that only THC capsules are legal. I sincerely hope that we will follow federal law . We are now in conflict with the federal law by allowing 4 oz. of marijuana for personal use. If we are not very careful we may well compound this offense.

Please thoughtfully consider the ramifications of this legislation.

Betty J. Wilson

Alaska Veterinary Clinic, Inc.
300 EAST FIREWEED LANE
ANCHORAGE, ALASKA 99503

Department of Commerce
Division of Occupational Licensing
Board of Pharmacy - Regulations
Century Plaza
142 East 3rd Ave.
Anchorage, Ak. 99501

Sirs;

I wish to comment on the proposed r. lations regarding manufacture distribution, prescription, and dispensing f controlled substances.

Unless the regulation specifies "for human use", I feel it places an unnecessary burden on members of the Veterinary profession. It appears that before I could order a controlled substance from a distributor, the manufacturer, distributor and myself would have to possess a permit from the Board of Pharmacy.

Please bear in mind that veterinarians use numerous anesthetic agents, sedatives, and analgesics on a daily basis, many of which are controlled substances which are purchased from numerous sources throughout the country. Veterinarians, of course, must possess a federal DEA Registration Number to utilize controlled substances. Additional state regulations and interference in the conduct of everyday practice are absolutely unwarranted and would only contribute to the growing state bureaucracy.

In summary, I wish to register my protest to the adoption of Article 5.

Yours Truly,

David W. Law D.V.M.

	OREGON	WYOMING	CALIFORNIA	COLORADO	FLORIDA	WASHINGTON
TITLE	Executive Director	Executive Director	Executive Officer	Program Administrator	Executive Director	Executive Secretary
APPOINTED BY (Hire/Fire)	Pharmacy Board	Interviewed by the Board, but in accordance with hiring procedures of the State.	Pharmacy Board	Director of the Division of Registration.	Director of the Division of Professions.	Pharmacy Board
RESPONSIBLE TO	Pharmacy Board	Pharmacy Board	Pharmacy Board	Director of the Division of Registration.	Director of the Division of Professions.	Pharmacy Board
AUTONOMOUS OR UMBRELLA AGENCY	Autonomous	Autonomous	Board operates as an autonomous board but falls under the Dept. of Consumer Affairs.	Umbrella Agency - Division of Registration in the Dept. of Regulatory Boards.	Umbrella Agency - Division of Professions in the Dept. of Professional Regulation.	Autonomous
NUMBER OF LICENSEES	10,000 of this, 2,900 pharmacies	110,000	117,500 - pharmacists 5,000 - pharmacies	4,100 - pharmacists 800 - pharmacies 275 - interns 1,000 -other drug related categories.	13,000 - pharmacists 3,600 - community & institutional pharmacies.	8 to 9,000
SIZE OF STAFF	7 (including the Exec. Director) 3 are inspectors who are pharmacists, full-time board staff.	3 (Exec. Director, Secretary, & Inspector who is a pharmacists.)	30 (4 Inspectors & one supervising inspector for the Northern region; 12 Inspectors & one supervising inspector for the Southern region.)	7 (3 clerical, and 4 inspectors who are pharmacists, hired be the program administrator.	6 full-time 1 part-time 1 Exec. Director *NO INSPECTORS UNDER THE EXEC. DIRECTOR (see below)	6 Office staff 9 Inspector
NUMBER OF OFFICES (Statewide)	1 Central Office	1 Central Office	2 (Sacramento & LA)	1 Central Office	1 Central Office 10 (Investigative field offices)	1 Central Office
NUMBER OF BOARD MEMBERS	7 (2 public members)	6 (3 public members)	10 (2 public members)	7 (2 public members)	7 (2 public members)	7
AMOUNT OF BUDGET	not available	$130,000. (annually)	$2.4 million (annual)	$366,982 (annually)	not available	$1.0 million (biennial) on odd-numbered years Supplements may be requested on even-numbered years.

	OREGON	WYOMING	CALIFORNIA	COLORADO	FLORIDA	WASHINGTON
SOURCE OF FUNDING	Revenues	$45.0 from revenues; $85.0 - 10% from licensing fees, & 90% from general funds.	Revenues	General funds allocated by the Dept. All revenues collected are deposited to the Department.	Revenues	General funds
EMPLOYMENT OF STAFF	Exec. Director hires staff under State employees personnel rules.	Same procedure as employment of the Executive Director.	Executive Officer in compliance with State personnel rules. All employees are classified as 'civil service' employees. Executive - Officer is the only exemption, as that person is responsible to the Board.	Program Administrator hires staff. NOTE: The Program Administrator is assigned various licensing professions by the Director of Registration, and can be changed at any time.	Executive Director employs staff under the Division of Professions with the approval of the Division Director. Inspectors are hired by the Chief Inspector with the approval of the Director of the Division of Investigative Services. *NOTE: A seperate Division of Investigative Services provide enforcement. Within the Division of Investigative Services are full-time pharmacy inspectors.	Executive Secretary hires staff in accordance with the State personnel system.

Offered: 5/25/84
Referred: Rules

Original sponsor: Labor and Commerce Committee

IN THE HOUSE BY THE LABOR AND COMMERCE COMMITTEE

SENATE CS FOR CS FOR HOUSE BILL NO. 716 (L&C)

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTEENTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to the Board of Pharmacy; and providing for an effective date."

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

* Section 1. AS 08.03.010(c)(4) is amended to read:

(4) Board of Pharmacy (AS 08.80.010) -- June 30, 1988 [1984].

* Sec. 2. AS 08.80.030 is amended to read:

Sec. 08.80.030. POWERS OF THE BOARD. The board may

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

(2) examine applicants for registration as pharmacists;

(3) investigate individually, collectively, or through its agent, for violations of this chapter, or of any other state or federal statute relating to the practice of pharmacy;

(4) adopt regulations [AND DO WHATEVER ELSE IS NECESSARY AND ADVISABLE] to carry out the purposes of this chapter;

(5) [PROMULGATE REGULATIONS TO CARRY OUT THE PURPOSES OF THIS CHAPTER;

(6) Repealed

(7)] register intern pharmacists and adopt regulations [PROMULGATE RULES] relating to their minimum experience requirements;

(6) adopt [(8) PROMULGATE] regulations to ensure adequate security for all dangerous drugs;

(7) [(9)] adopt requirements for licensing in addition to

the requirements set out in this chapter.

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

Sec. 08.80.095. EXECUTIVE SECRETARY. The board may hire an executive secretary to assist in implementing this chapter and in regulating controlled substances under AS 17.30. The executive secretary shall be a member of the partially exempt service under AS 39.25.120.

Sec. 08.80.097. DUTIES OF THE EXECUTIVE SECRETARY. The executive secretary shall

(1) serve as liaison with the national association of boards of pharmacy;

(2) under the supervision of the board, administer the state pharmacy examination;

(3) serve as liaison with the Drug Enforcement Administration on all matters pertaining to the legitimate use of controlled substances by members of the medical community;

(4) maintain files and records approved by the board; and

(5) perform other duties required by the board.

Sec. 08.80.099. INVESTIGATIONS. (a) The executive secretary, under the supervision of the board, may inspect pharmacies and investigate complaints to determine whether any person has violated this chapter or AS 17.30 or a regulation adopted under either chapter or to secure information useful in the administration of either chapter.

(b) If the executive secretary believes that a person may have engaged in or be about to engage in an act or practice in violation of this chapter or AS 17.30 or a regulation adopted under either chapter, the executive secretary shall investigate the matter in accordance with this chapter or AS 17.30 and immediately send written notice of

the investigation to each board member and to the department.

* Sec. 4. AS 39.25.120(c) is amended to read:

(c) The following positions in the state service constitute the partially exempt service:

(1) deputy and assistant commissioners of the principal departments of the executive branch, including the assistant adjutant general of the Department of Military Affairs;

(2) the directors of the major divisions of the principal departments of the executive branch and the regional directors of the Department of Transportation and Public Facilities;

(3) attorney members of the staff of the Department of Law and of the public defender agency;

(4) one private secretary for each head of a principal department in the executive branch;

(5) employees of councils, boards, or commissions established by statute in the Office of the Governor or the office of the lieutenant governor, unless a different classification is provided by statute;

(6) the executive director, deputy director, hearing officers, and administrative law judges of the Alaska Public Utilities Commission;

(7) the director, deputy director, staff legal counsel, and hearing officers of the Alaska Transportation Commission;

(8) not more than two special assistants to the commissioner of each of the principal departments of the executive branch, but the number may be increased if the partially exempt service is extended under AS 39.25.130 to include the additional special assistants;

(9) the principal executive officer of the following

boards, councils, or commissions:

(A) Alaska Public Broadcasting Commission;

(B) Professional Teaching Practices Commission;

(C) Parole Board;

(D) Board of Nursing;

(E) Real Estate Commission;

(F) Alaska Royalty Oil and Gas Development Advisory Board;

(G) Alaska Historical Commission;

(H) Alaska State Council on the Arts;

(I) Alaska Police Standards Council;

(J) Council on Science and Technology;

(K) Older Alaskans Commission;

(L) Board of Pharmacy;

(10) Alaska Pioneers' Home managers;

(11) hearing examiners in the Department of Revenue;

(12) the comptroller in the division of treasury, Department of Revenue;

(13) investment officers in the Department of Revenue;

(14) airport managers in the Department of Transportation and Public Facilities employed at the Anchorage and Fairbanks International Airports;

(15) the deputy director of the division of tourism and the deputy director of the division of insurance in the Department of Commerce and Economic Development;

(16) the executive director and staff of the Alaska Public Offices Commission;

(17) the director, deputy director, personnel analysts II, labor relations analysts I, labor relations analysts II, senior

negotiators, and research directors of the division of labor relations in the Department of Administration;

(18) the rehabilitation administrator of the Workers' Compensation Board.

* Sec. 5. This Act takes effect immediately in accordance with AS 01.-10.070(c).

RECORDS CERTIFICATION

I, the undersigned, an employee of the State of Alaska, do hereby certify that the microfilm images on this microform are accurate reproductions of the original records of the State of Alaska as accumulated during the regular course of business, and that it is the established policy and practice of this State to microfilm its records and to dispose of the original records after microfilm reproductions have been made.

James O. Smith
Signature of Camera Operator

9/5/89
Date

02-519 (REV 8/78)