HOUSE
COMMITTEE REPORT

(11)

Date referred: 4/1/86

FURTHER REFERRALS:

DATE: 4-14-86

The FINANCE Committee has considered HB 641

"An Act relating to generic drugs, pharmaceuticals, and the Board of Pharmacy; repealing the marijuana therapeutic research program; and providing for an effective date."

and recommends:

[ ] do pass

[ ] do not pass

[ ] do pass with attached amendment(s)

[ ] no recommendation

[X] replace with CS HB 641 (HESS) [X] same title [ ] new title

and recommends No Recommendation

[ ] further referral to the ______ Committee

and attaches:
[ ] letter of intent
[ ] first fiscal note
[ ] new fiscal note
[X] zero fiscal note 3/25/86 C.E.D. (same)

SIGNING DO PASS:

Albert P. Adams

SIGNING OTHER RECOMMENDATIONS:

J. Duncan No Rec
Mike Szymanski No Rec.
[illegible] No Rec.
[illegible] no rec
Rich Uehling (NO REC)
Steve Frank No Recommendation
Sam Cotten No Rec

Albert P. Adams

Chairman

STATE OF ALASKA 1986 LEGISLATIVE SESSION
FISCAL NOTE

Revision Date: _____

REQUEST

Bill/Resolution No.: CSHB 641 (HESS)
Title: An Act relating to generic drugs, pharmaceuticals, and the Board of Pharmacy;
Sponsor: Rep. Gruenberg
Requester: House HESS
Date of Request: _____

FISCAL DETAIL

Agency Affected: Commerce & Economic Dev.
BRU: Occupational Licensing
Components: _____

EXPENDITURES / REVENUES: (Thousands of Dollars)

OPERATING	FY 86	FY 87	FY 88	FY 89	FY 90	FY 91
PERSONAL SERVICES		-0-	-0-	-0-	-0-	-0-
TRAVEL		-0-	-0-	-0-	-0-	-0-
CONTRACTUAL		-0-	-0-	-0-	-0-	-0-
SUPPLIES		-0-	-0-	-0-	-0-	-0-
EQUIPMENT		-0-	-0-	-0-	-0-	-0-
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING		-0-	-0-	-0-	-0-	-0-
CAPITAL						
REVENUE		-0-	-0-	-0-	-0-	-0-

FUNDING: (Thousands of dollars)

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

POSITIONS:

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

ANALYSIS: Attach a separate page if necessary.

The bill extends the Board of Pharmacy to June 30, 1989, grants pharmacists the authority to fill prescriptions using generic drugs, and repeals the Marijuana Therapeutic Research Program.

This bill is not expected to generate new costs or revenues.

Prepared by: Jennifer Strickler, Management Analyst — Phone: 465-2144
Division: Occupational Licensing — Date: 3-25-86

Approved by Commissioner: Loren H. Lounsbury — Date: 3/25/86
Agency: Commerce and Economic Development

Distribution (by Agency preparing fiscal note):
- Legislative Finance
- Legislative Sponsor
- Requestor
- Office of Management and Budget
- Impacted Agency(ies)

10/25/85

Offered: 4/1/86
Referred: Finance

Original sponsor: Gruenberg

IN THE HOUSE

BY THE HEALTH, EDUCATION AND SOCIAL SERVICES COMMITTEE

CS FOR HOUSE BILL NO. 641 (HESS)

IN THE LEGISLATURE OF THE STATE OF ALASKA

FOURTEENTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to generic drugs, pharmaceuticals, and the Board of Pharmacy; repealing the marijuana therapeutic research program; 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, 1989 [1985].

* 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) assist the department in inspections and investigations [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) adopt [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;

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

(8) [(9)] adopt requirements for licen ing in addition to the requirements set out in this chapter.

* Sec. 3. AS 08.80.295(a) is amended to read:

(a) Unless the prescription expressly states that it is to be dispensed only as written [EXCEPT AS LIMITED BY (b) AND (c) OF THIS SECTION, WITH THE CONSENT OF THE PURCHASER], the pharmacist may substitute a drug product with the same generic name in the same strength, quantity, dose and dosage form as the prescribed drug, provided the substitute drug [PRESCRIBED DRUG WHICH] is, in the pharmacist's professional opinion, therapeutically equivalent and meets the standards of (g) of this section. The [UPON SUBSTITUTION THE] pharmacist shall notify the purchaser [AND THE PERSON WHO PRESCRIBED THE DRUG] of the substitution, and shall record on the prescription and keep a record of the name and manufacturer of the drug substituted.

* Sec. 4. AS 08.80.295 is amended by adding new subsections to read:

(i) A pharmacist who substitutes a drug in compliance with this section incurs no greater liability in filling the prescription by dispensing the equivalent drug product than would be incurred in filling the prescription by dispensing the prescribed brand name drug.

(j) Every pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that "Under Alaska law a therapeutically equivalent but less expensive drug may, in some cases, be substituted for the drug prescribed by your doctor. Please consult your pharmacist or physician." The printing on the sign shall be in block letters not less than one inch in height.

* Sec. 5. AS 08.80.360 is amended to read:

Sec. 08.80.360. SALE OF DANGEROUS MATERIALS. Drugs that [OR MEDICAL SUPPLIES WHICH] contain poisonous, potent, habit-forming or deleterious ingredients may [SHALL] be dispensed only by a licensed pharmacist. At the time of the sale, the pharmacist shall make the nature of the drug or medical preparation known to the purchaser.

* Sec. 6. AS 08.80.480(2) is repealed and reenacted to read:

(2) "drug" means an article recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary; an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal; an article other than food, intended to affect the structure or function of the body of man or animal; and an article intended for use as a component of an article specified in this paragraph but does not include devices or their components, parts, or accessories;

* Sec. 7. AS 08.80.480 is amended by adding a new paragraph to read:

(21) "nonprescription drug" means a nonnarcotic medicine or drug that may be sold without a prescription and that is prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of the state and the federal government.

* Sec. 8. AS 11.71.030(a) is amended to read:

(a) Except as authorized in AS 17.30 [OR AS 17.35], a person commits the crime of misconduct involving a controlled substance in the third degree if the person

(1) manufactures or delivers any amount of a schedule IIA or IIIA controlled substance or possesses any amount of a schedule IIA or IIIA controlled substance with intent to manufacture or deliver;

(2) delivers any amount of a schedule IVA, VA_1 or VIA controlled substance to a person under 19 years of age who is at least three years younger than the person delivering the substance; or

(3) being 18 years of age or older, possesses any amount of a schedule IA or IIA controlled substance within the grounds of or on a parking lot immediately adjacent to a public or private preschool, elementary, junior high, or secondary school.

* Sec. 9. AS 11.71.040(a) is amended to read:

(a) Except as authorized in AS 17.30 [OR AS 17.35], a person commits the crime of misconduct involving a controlled substance in the fourth degree if the person

(1) manufactures or delivers any amount of a schedule IVA or VA controlled substance or possesses any amount of a schedule IVA or VA controlled substance with intent to manufacture or deliver;

(2) manufactures or delivers, or possesses with the intent to manufacture or deliver, one or more preparations, compounds, mixtures, or substances of an aggregate weight of one ounce or more containing a schedule VIA controlled substance;

(3) possesses

(A) any amount of a schedule IA or IIA controlled substance;

(B) 25 or more tablets, ampules, or syrettes containing a schedule IIIA or IVA controlled substance;

(C) one or more preparations, compounds, mixtures, or substances of an aggregate weight of three grams or more containing a schedule IIIA or IVA controlled substance;

(D) 50 or more tablets, ampules, or syrettes containing a schedule VA controlled substance;

(E) one or more preparations, compounds, mixtures, or

substances of an aggregate weight of six grams or more containing a schedule VA controlled substance; or

(F) one or more preparations, compounds, mixtures, or substances of an aggregate weight of one pound or more containing a schedule VIA controlled substance;

(4) being 18 years of age or older, possesses a schedule IIIA, IVA, VA, or VIA controlled substance within the grounds of or on a parking lot immediately adjacent to a public or private preschool, elementary, junior high, or secondary school;

(5) knowingly keeps or maintains any store, shop, warehouse, dwelling, building, vehicle, boat, aircraft, or other structure or place which is used for keeping or distributing controlled substances in violation of a felony offense under this chapter or AS 17.30;

(6) makes, delivers, or possesses a punch, die, plate, stone, or other thing which prints, imprints, or reproduces a trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of these upon a drug, drug container, or labeling so as to render the drug a counterfeit substance;

(7) knowingly uses in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person;

(8) knowingly furnishes false or fraudulent information in or omits material information from any application, report, record, or other document required to be kept or filed under AS 17.30;

(9) obtains possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge; or

(10) affixes a false or forged label to a package or other container containing any controlled substance.

* Sec. 10. AS 11.71.050(a) is amended to read:

(a) Except as authorized in AS 17.30 [OR AS 17.35], a person commits the crime of misconduct involving a controlled substance in the fifth degree if the person

(1) manufactures or delivers, or possesses with the intent to manufacture or deliver, one or more preparations, compounds, mixtures, or substances of an aggregate weight of one-half ounce or more containing a schedule VIA controlled substance;

(2) manufactures or delivers, or possesses with the intent to manufacture or deliver, one or more preparations, compounds, mixtures, or substances of an aggregate weight of less than one-half ounce containing a schedule VIA controlled substance, for remuneration;

(3) possesses

(A) less than 25 tablets, ampules, or syrettes containing a schedule IIIA or IVA controlled substance;

(B) one or more preparations, compounds, mixtures, or substances of an aggregate weight of less than three grams containing a schedule IIIA or IVA controlled substance;

(C) less than 50 tablets, ampules, or syrettes containing a schedule VA controlled substance;

(D) one or more preparations, compounds, mixtures, or substances of an aggregate weight of less than six grams containing a schedule VA controlled substance; or

(E) one or more preparations, compounds, mixtures, or substances of an aggregate weight of one-half pound or more containing a schedule VIA controlled substance; or

(4) fails to make, keep, or furnish any record, notification, order form, statement, invoice, or information required under

AS 17.30.

* Sec. 11. AS 11.71.060(a) is amended to read:

(a) Except as authorized in AS 17.30 [OR AS 17.35], a person commits the crime of misconduct involving a controlled substance in the sixth degree if the person

(1) uses or displays any amount of a schedule VIA controlled substance or possesses one or more preparations, compounds, mixtures, or substances of an aggregate weight of one ounce or more containing a schedule VIA controlled substance on a public street or sidewalk or on the premises of a public carrier or business establishment or in any other public place;

(2) knowingly possesses any amount of a schedule VIA controlled substance within the immediate control of that person while operating a propelled vehicle;

(3) being under 19 years of age, possesses one or more preparations, compounds, mixtures, or substances of an aggregate weight of less than four ounces containing a schedule VIA controlled substance;

(4) possesses one or more preparations, compounds, mixtures, or substances of an aggregate weight of four ounces or more containing a schedule VIA controlled substance; or

(5) refuses entry into a premises for an inspection authorized under AS 17.30.

* Sec. 12. AS 11.71.070(a) is amended to read:

(a) Except as authorized in AS 17.30 [OR AS 17.35], a person commits the offense of misconduct involving a controlled substance in the seventh degree if the person

(1) manufactures or delivers, or possesses with the intent to manufacture or deliver, one or more preparations, compounds,

mixtures, or substances of an aggregate weight of less than one-half ounce of a schedule VIA controlled substance; or

(2) possesses one or more preparations, compounds, mixtures, or substances of an aggregate weight of less than one ounce containing a schedule VIA controlled substance on a public street or sidewalk or on the premises of a public carrier or business establishment or in any other public place.

* Sec. 13. AS 08.80.295(b), (c), and (f); 08.80.480(3); and AS 17.35 are repealed.

* Sec. 14. This Act takes effect immediately in accordance with AS 01.-10.070(c).

R/O 4-14-86
Rec'd 4-16-86

STATE OF ALASKA 1986 LEGISLATIVE SESSION
FISCAL NOTE

Revision Date: _____

REQUEST

Bill/Resolution No.: HB641
Title: An act relating to generic drug pharmaceuticals and Board of Pharmacy and providing for an effective date.
Sponsor: Gruenburg
Requestor: _____
Date of Request: _____

FISCAL DETAIL

Agency Affected: Dept. of Health & Social Services
BRU: Medical Assistance Non-Facility
Components: GRM Non-Facility

EXPENDITURES/REVENUES : (Thousands of Dollars)

OPERATING	FY 86	FY 87	FY 88	FY 89	FY 90	FY 91
PERSONAL SERVICES						
TRAVEL						
CONTRACTUAL						
SUPPLIES						
EQUIPMENT						
LAND & STRUCTURES						
GRANTS, CLAIMS		-0-	-0-	-0-	-0-	-0-
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 Department has submitted to the Governor an FY87 Budget Amendment of $2.5 million for an FY87 Pharmacy Program. One of the assumptions included in the amendment was the substitution of generic drug ~~products~~ for more expensive brand name products.

Prepared by: Rod Betit, Director — Phone: 465-3355
Division: Medical Assistance — Date: 3/4/86

Approved by Commissioner: _____ Date: 3/6/86
Agency: Department of Health & Social Services

Distribution (by Agency preparing fiscal note):
Legislative Finance
Legislative Sponsor
Requestor
Office of Management and Budget

POSITION PAPER/Department of Health & Social Services

POSITION PAPER
COMMITTEE SUBSTITUTE FOR HOUSE BILL 641

I. PURPOSE OF HB 641

HB 641 has three primary objectives:

(1) To extend the Board of Pharmacy to 1989.
(2) To strengthen a pharmacist's discretion in substituting a lower cost drug for a more expensive product of equal quality.
(3) To eliminate the Marijuana Research Program.

II. SECTIONAL ANALYSIS

SECTION I:

This section extends the life of the Board of Pharmacy to June 30, 1989. The Board will expire on June 30, 1986 without this extension. The Department of Health and Social Services takes no position on this section as occupational boards fall under the purview of the Department of Commerce.

SECTION II:

This section permits a pharmacist to substitute an equally effective generic drug for a drug prescribed by a physician that is more expensive. The pharmacist must notify the purchaser of the substitution and keep a record of it.

It should be noted that this change does not shift the primary substitution responsibility from the physician to the pharmacist. Rather, HB 641 recognizes that pharmacists are capable of making this substitution decision, and should be permitted to do so unless the physician specifies that only one drug product is acceptable for his patient. This slight change will allow pharmacists to more efficiently extend the cost savings of generic drugs to their customers, while protecting the physician's right to specify a certain drug, and while protecting the individual's right to know that the substitution is being made.

This generic drug substitution provision would apply to all Alaskans who purchase a prescription drug. The cost savings associated with this section of HB 641 are particularly important to Alaska's elderly who are living on a fixed income.

SECTION III:

This section establishes that the pharmacist will incur no greater liability by substituting an equivalent drug product, and specifies the method of advertising to the public that such a substitution may be made.

POSITION PAPER/Department of Health & Social Services

SECTION IV:

This section does three things; 1) it repeals certain pharmacy restrictions that are no longer applicable if HB 641 becomes law (08.80.295 b,c,f), 2) it eliminates the Marijuana Research Program (AS 17.35) and 3) it repeals the authority for the Board of Pharmacy to investigate alleged violations by its members (AS 08.80.030 (3)).

III. Department Position:

The Department takes no position on Section I as this is in the domain of the Division of Occupational Licensing in the Department of Commerce.

The Department strongly supports Sections II and III of HB 641, and that part of Section IV that repeals AS 08.80.295 b, c, and f.

The Department takes no position on repeal of AS 17.35 or AS 08.80.030(3).

Recommended By: Kimberly Buscher for
Rod Betit, Director
Division of Medical Assistance

Date: 4/11/86

Approved By: John R. Pugh
John R. Pugh, Commissioner
Department of Health and
Social Services

Date: 4/11/86

HB 641

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

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

TABLE OF CONTENTS

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.

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.

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.

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.

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

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 of 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.

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.

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	$ 0	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.

BILL SHEFFIELD, GOVERNOR

DEPARTMENT OF COMMERCE & ECONOMIC DEVELOPMENT

OFFICE OF THE COMMISSIONER

POUCH D
JUNEAU, ALASKA 99811
PHONE: 465-2500

June 28, 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 Pharmancy 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

HB 641

A FOLLOW-UP REVIEW ON THE DEPARTMENT OF COMMERCE AND ECONOMIC DEVELOPMENT BOARD OF PHARMACY

(Originally Released May 17, 1983)

November 14, 1985

Audit Control Number

08-1250-86-R

Commissioner, Department of Commerce and Economic Development	Loren H. Lounsbury
Deputy Commissioners, Department of Commerce and Economic Development	Greg Baker Terry Elder

Members of the Board of Pharmacy

President	William P. Larson
Secretary	Margaret D. Soden
Member	Joy H. Donelson
Member	Christy C. Nielsen
Member	Laura Kelley
Member	James H. McCorcle

STATE OF ALASKA

THE LEGISLATURE

BUDGET AND AUDIT COMMITTEE

AUDIT DIVISION
POUCH W
JUNEAU, ALASKA 99811

November 15, 1985

Members of the Legislative Budget
and Audit Committee:

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

A FOLLOW-UP REVIEW ON THE
DEPARTMENT OF COMMERCE AND ECONOMIC DEVELOPMENT
BOARD OF PHARMACY
(Originally Released May 17, 1983)

November 14, 1985

Audit Control Number

08-1250-86-R

Gerald L. Wilkerson

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), a follow-up review of the Board of Pharmacy was conducted to determine whether the recommendations presented in our report entitled, A Performance Report on the Board of Pharmacy, July 1, 1980 to February 28, 1983, have been implemented, and, if not, whether those recommendations are still pertinent.

Legislative intent requires consideration of this report during legislative oversight hearings to determine whether the Board of Pharmacy should be reestablished. The Board terminated June 30, 1985 and has until June 30, 1986 to conclude its affairs.

SCOPE

The major areas of our follow-up examination were the administration, complaint, and affirmative action functions of the Board, and the extent to which prior audit recommendations have been complied with. 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.
8. Current issues raised during sunset review and other legislative committee hearings.

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 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.

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 finding describes an area where a weakness or conflict exists. We have made recommendations which, if implemented, will improve the efficiency and effectiveness of the Board.

FINDING AND RECOMMENDATION

Recommendation No. 1

The Board of Pharmacy, in conjunction with the Division of Occupational Licensing (OL), should consult the Department of Law in order to determine the necessity of State registration of professionals with access to controlled substances. If possible, the Board should recommend legislation that will allow administration of their responsibilities under the Controlled Substances Act without State registration.

Alaska Statute 17.30.020(a) requires:

> ... A person who manufactures, distributes, dispenses, or conducts research with a controlled substance in the state or who proposes to manufacture, distribute, or dispense a controlled substance in the state, shall register annually with the board in accordance with regulations adopted under AS 17.30.010.

Alaska Statute 17.30.010(b) further provides:

> ... Regulations adopted under this chapter by the board shall be patterned after federal law so that the legitimate manufacture, distribution, and dispensing of controlled substances is subject to regulations regarding registration, record keeping, order forms and prescription requirements that are identical to those required by federal law or regulations.

Since 1982, when the legislation was passed, the Board has been developing and adopting the necessary regulations to carry out their responsibilities under the statute. Due to the time taken in establishing these regulations, registration of individuals did not begin until May 1985. As of the date of this report, approximately half of the individuals affected by this requirement have registered.

We question whether State registration, by the Board of Pharmacy, is necessary to effectively carry out the Board's responsibilities under the Controlled Substances Act (the Act) due to the following:

1. Duplication of Effort - The Drug Enforcement Administration (DEA) of the U.S. Department of Justice currently registers individuals involved in the manufacture, distribution, and dispensing of controlled substances. Under the Act, individuals registered with DEA are entitled to registration with the State. The State's application for registration requires no information

not already available through the DEA registration or OL's current licensee files. Additionally, people such as doctors and dentists resent this separate State registration that requires the same information submitted to DEA.

2. Unnecessary for Litigation - In October of 1983, former State Chief Prosecutor Dan Hickey told the Board that a separate application form was not necessary from a prosecution standpoint. He stated that his office felt that they would be able to successfully prosecute under regulations whereby a person simply submitted a copy of their DEA registration application and certification.

   Additionally, the Chief Investigator of OL has stated that a duplicate State registration was not necessary for the Division's investigations.

3. OL Workload - In a September 1984 report, the Office of Management and Budget reported that between FY 81 and FY 84 the workload of OL had increased greatly, measured by the applications received, exams administered, licenses issued, and responses to public inquiries. The paperwork involved in establishing an annual registration system adds another responsibility to an already strained OL licensing staff.

It appears that the statute would allow the Board to use the DEA registration under the general provisions of the Act. Alaska Statute 17.30.150 allows the Board to rely on the "results, information, and evidence received from the [DEA]..." in carrying out its regulatory functions. However, in informal discussions with the Department of Law, we have been told that the statute as a whole contemplates a separate registration, therefore requiring amendment to eliminate the State registration.

The State registration of individuals is duplicative, unnecessary, and costly to the State, and provides little or no additional public benefit or protection. The Board and OL's time and resources could be better spent administering their controlled substance regulatory responsibilities by using DEA information to the extent possible, rather than monitoring and enforcing an ongoing, separate registration system. Accordingly, we recommend that the Board and OL consult with the Department of Law and pursue a remedy that would allow the Board to pursue its regulatory responsibilities in a more efficient and effective manner.

PRIOR AUDIT RECOMMENDATIONS

Prior Recommendation No. 1

The Board of Pharmacy should allow the Division of Occupational Licensing (OL) to performs its administrative duties as described in AS 08.01.150 to improve documentation and file management.

The secretary of the Board received license fees and applications, kept applicant files, sent notification of exam results, and issued temporary permits. Each of these responsibilities have been assigned by the Legislature to the Department of Commerce and Economic Development, Division of Occupational Licensing.

Current Status

The Board of Pharmacy has complied with this recommendation. Currently, all applications, license fees, and exam results are being sent directly to OL, allowing that division to carry out its administrative duties and improve their documentation and file management.

Prior 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.

Current Status

The Board of Pharmacy has complied with this recommendation. Effective August 24, 1985, the continuing education regulations for licensed pharmacists were revised and simplified. With the repeal of 12 AAC 52.220-.280, the specific criteria by which continuing education courses were approved for credit, was deleted. In lieu of these criteria, the adoption of 12 AAC 52.215 provides that only programs administered by providers approved by the American Council on Pharmaceutical Education (ACPE) will be accepted by the Board as qualifying for continuing education credits.

Regulation 12 AAC 52.310, excusing a licensee from continued competency requirements, has also been repealed. Through 12 AAC 52.320 the Board will now ensure that all license renewals are contingent upon proof of the professional's continued competency.

Prior Recommendation No. 3

The Board of Pharmacy and OL 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.

Current Status

The Board of Pharmacy and OL have not introduced legislation that clarifies these statutes. However, we have determined that the friction caused due to this statutory conflict has been reduced considerably. The Board is no longer conducting its own investigations. Consumer complaints are referred by the Board to OL for investigation. The working relationship in this area appears to be much improved.

Prior 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 had 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 have served twelve and ten years at the end of their terms on March 31, 1984 and March 31, 1985, respectively.

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

We recommended the Office of the Governor ensure that Board members were appointed in accordance with statute.

Current Status

In large part, the findings behind this recommendation have been adequately addressed by the Office of the Governor. The individual who had served sixteen years as of March 31, 1983 was replaced by a new appointee. Likewise, the individual with twelve years of service as of March 31, 1984 was not reappointed. However, as of the date of this letter no appointment has been made to the Board to replace the individual whose term expired March 31, 1985.

AUDITOR'S COMMENTS

Marijuana Therapeutic Research Program

The 1982 Legislature, as an attachment to the Controlled Substances Act, enacted legislation that would permit the use of marijuana and its active derivative ingredient of tetrahydrocannabinol (THC) for use in the treatment of the ill effects of glaucoma, cancer chemotherapy, and radiology. Under the legislation, THC would be made available through controlled therapeutic research projects approved by the Board of Pharmacy. The Board was directed to adopt regulations to implement the program and establish a Patient Qualification Review Committee (PQRC) to review applicants and their licensed physician for appropriate admittance to the program.

The Board of Pharmacy and OL were slow in adopting the necessary regulations to carry out their new responsibilities. The legislation was approved by the Governor in May 1982 and was effective January 1, 1983. According to OL files, the drafting of regulations did not begin until almost a year after the approval of the legislation. Then, due to confusion between the Department of Law, OL, and the Board, the regulations were not finally approved until November 1984, twenty-nine months after the bill had been approved.

In March 1985 the Board directed OL to organize and schedule the first meeting of PQRC. The PQRC, consisting of four medical doctors, including the chairman of the State Medical Board and the Director of the Providence Cancer Therapy Center, were scheduled to meet in June 1985. No PQRC members attended. At the Board of Pharmacy's June meeting they were informed that it was the consensus opinion of the PQRC that the marijuana therapeutic research program was unnecessary and should be abandoned. In written comments submitted to OL, two PQRC members cited the lack of interest in the medical community and the availability of superior, more effective and less costly substances as reasons for their position.

In testimony at the PQRC meeting, it was further reported by the Manager of the Providence Hospital Pharmacy that a new THC drug, Marinol, had been approved by the Food and Drug Administration (FDA) and was to be released in August 1985. Marinol's pending availability has led the National Cancer Institute to close its marijuana research program. Based on this information and the letters from PQRC members, the Board recommended that the State's marijuana research program statutes be repealed. Recommended repeal legislation has been submitted to the Commissioner of the Department of Commerce and Economic Development for his consideration and review, prior to submittal to the Legislature.

As of the date of this report, Marinol is not yet available. We have been informed that the current projected release date is January 1986. It has been over three years since approval of legislation that would have allowed Alaskans access to THC. However, due to a lack of timely adoption of regulations and the promised availability of an FDA approved THC drug, the original purpose of, and perhaps the need for, the legislation has diminished or has been rendered obsolete.

Medicaid Drug Program

During the 1985 legislative session, HB 209 was introduced by the Rules Committee at the request of the Governor. The purpose of the bill was to allow the State to request participation in the Federal Medicaid prescribed drug program. Medicaid offers a program by which it will pay half of the costs of prescribed drugs for covered individuals. Under this program Medicaid allows payment of a dispensing fee in addition to the cost of the prescribed drug. This dispensing fee would be established by the State based on a variety of factors. In effect, under this bill the State would be telling pharmacists how much they can charge for prescribed drugs paid for under the Medicaid program.

We can find no evidence that the Board of Pharmacy formally opposed HB 209. While many pharmacists, including past and present Board members, testified against HB 209 before both the House Finance and the House Health, Education, and Social Services Committees, they have done so on their own behalf and not at the formal request of the Board.

Currently, prescribed drugs for qualified individuals are paid for by the State under the General Relief Medical (GRM) program, which is funded entirely by the General Fund. Under the General Relief Medical program, prescribed drugs are paid for at the price set by the pharmacist. If HB 209 is adopted, the costs would be split with the Federal government. Alaska is only one of two states who do not participate in this program. The Department of Health and Social Services (DHSS) estimates that the cost savings to the State, by enactment of this bill, would be approximately $1.4 million annually.

At the end of the 1985 session, HB 209 had been passed by the House, but not the Senate. In September 1985, DHSS met with pharmacists and tentatively agreed to a collection of alternative cost saving measures in lieu of HB 209. If these measures are implemented, the State's General Relief program would save approximately $700,000.

Although the proposed compromise between DHSS and the Pharmacy Association would reduce the cost of the prescribed drug program to GRM, all expenditures would still be General Fund monies. In our opinion the implementation of HB 209

would be preferable to this compromise. Participation in the Medicaid program would allow the State to provide eligible recipients the same level and quality of service at almost half the cost to the General Fund. Using schedules prepared by DHSS's Division of Medical Assistance, we determined that if the Medicaid Drug program had been in effect during FYs 84 and 85, the State would have saved over $2 million.

Executive Secretary

In recent years, the Board of Pharmacy has been seeking funding for an Executive Secretary that would answer directly to the Board, rather than OL. In 1984, the legislation extending the Board of Pharmacy also provided funding for an Executive Secretary, but was vetoed by the Governor. During the 1985 legislative session the issue was again debated, during sunset hearings. Proponents cited the Board's increased responsibilities under the Controlled Substances Act (the Act) as justification for such a position.

At the hearings, Carol Derfner from the Office of the Governor testified that the Governor remained opposed to the Executive Secretary concept and may veto any legislative appropriation or bill that made provision for one. Accordingly, OL also felt that the position was unnecessary. By late February 1985, the Board apparently recognized that its insistence of an Executive Secretary could endanger its status during the sunset process. The Board narrowly adopted, by a 3-2 vote, a resolution that "If given the choice between having an Executive Secretary or sunsetting, the Board would rather have an active body."

Currently, we believe that the need for an autonomous Executive Secretary, as opposed to utilizing OL staff, is not warranted for the following reasons:

1. Implementation of Recommendation No. 1, repealing the need to establish a separate State registration, would significantly reduce the duties of a contemplated Executive Secretary.

2. As of the date of this report, the Board has yet to formally consider the nature and extent, if any, of its further responsibilities and duties under the Act beyond registration.

3. As discussed in the previous section, if the Marijuana Therapeutic Research Program is repealed, as recommended by the Board, the duties of an Executive Secretary would be further reduced.

We recognize that the Board of Pharmacy and OL staff have been criticized in public testimony for inadequately investigating complaints submitted to them and the Board. However, the degree to which OL is or is not functioning should not, in and of itself, be related to the need for an Executive Secretary. We are reviewing OL investigatory procedures and effectiveness as part of a performance audit of OL currently being conducted.

BILL SHEFFIELD, GOVERNOR

DEPARTMENT OF COMMERCE & ECONOMIC DEVELOPMENT

DIVISION OF OCCUPATIONAL LICENSING

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

December 23, 1985

Mr. Gerald L. Wilkerson
Legislative Auditor
Division of Legislative Audit
Pouch W
Juneau, AK 99811

Dear Mr. Wilkerson:

Thank you for the opportunity to comment on your follow-up review report regarding the Board of Pharmacy.

We concur with your findings and recommendation. We also support reestablishment of the Board of Pharmacy.

As mentioned in earlier correspondence, it is important to note that statutes regarding the Marijuana Therapeutic Research Program failed to provide guidance or to identify an objective of the research program other than establishment of a committee to certify participation in the program. Also, the drug THC was already available through the Cancer Research Institute at Providence Hospital in Anchorage prior to establishment of the Marijuana Therapeutic Research Program by statutes. The research program added a layer of control by the State to an already existing federal program.

We fully concur that the controlled substance registration is a duplication of effort and have maintained this position since inception of the statutes.

Thank you once again for the opportunity to comment on your audit.

Sincerely,

for Loren H. Lounsbury
Commissioner

LHL/mst3050m
120985a

08-H8LH

CARRS
QUALITY CENTERS

1341 Fairbanks Street Anchorage, Alaska 99501 (907) 277-6639

October 29, 1985

Mr. Marc Moulton
Senior Auditor
Division Of Legislative Audit
Pouch W
Juneau, Alaska 99811

Dear Mr. Moulton:

I appreciate the opportunity to comment on the findings of the legislative audit of the Pharmacy Board, but must disagree with many of these findings:

Recommendation No. 1

Although I was appointed to the Board Of Pharmacy since the Controlled Substances Act was passed, I believe I know some of the history involved in this bill's passage.

Dan Hickey, former Chief Prosecutor, was very instrumental in getting this bill passed and gave the Board considerable guidance in not only adopting regulations, but taking a personal interest in the wording and format of the application for registration to assure that all legal requirements were met to allow prosecution without undue duplication with the federal registration. The reason we need a state registration is not to conduct investigation, as the Chief Investigator states, but to give the state an enforcement tool when a problem occurs.

The problem with the Controlled Substances registration has not been compliance nearly as much as it has been confusion with the way the applications were mailed.

Initially, OL sent the application along with a short note with the heading "ATTENTION" with nothing in the way of explanation as to why or who was required to register. I, then, at the request of the Board, drafted a letter explaining the reasons for registration and who was required to register. I asked OL to mail the letter along with an application form to all registrants. The letter was sent, but the application form was not.

I have personally talked to at least two hundred (200) registrants all requesting the application form so they could register. I have had only three (3) cases where the registrants complained and two (2) of the three (3) had already registered. Therefore, I do not believe the Board should opt for use of the federal registration, but for more communication and cooperation with DOL.

The above brings to mind another disagreement I have with the legislative audit findings. In one area of the finding you say, and I quote, "... an already strained OL licensing staff." Yet, in another section in reference to the Executive Secretary, "OL also felt the position was unnecessary." How can OL say they are strained yet can take on the huge responsibility of a qualified drug expert or "Executive Secretary."

During testimony last February on HB 123 when the Director Of OL, Harry Traegor, was asked if they had any expertise on pharmacy in OL, he said the only expertise they had was the Board Of Pharmacy. I, therefore, feel that If OL is already strained with their current workload, they will require additional personnel to run the Controlled Substances program. There might just as well be a qualified person to run the program as three (3) or four (4) incompetents who will not know what they are doing. I feel the Controlled Substances Bill is made up of three (3) portions: Registration, investigation, and enforcement. The "pharmacy expert" would be required to work in all these areas.

Recommendation No. 2

The continuing education regulations were re-evaluated and recommended changes approved at the June, 1985 meeting and so I have no further comment.

Recommendation No. 3

As you state, AS 08.01.050 (19) places responsibility for performing investigation with the Division and AS 08.80.030 (3) gives the Board the authority to conduct investigations, which would indicate a direct conflict. I believe legislative intent was to give the Division investigative authority only if the Board statute did not address the issue. Since the Board Of Pharmacy is specifically given investigative authority, their statute supersedes the vague statute giving the Division the investigative authority.

Recommendation No. 4

I agree with the recommendation to make two (2) additional appointees in a timely manner. Although a current Board member's term does not expire until he/she has been replaced. The three (3) vacancies we had were all resignations. I also fail to see what the intent was of including the information about AS 08.80.020 and the long terms of service in a report auditing the current Board. I believe these people should be complemented for their years of service, not criticized. I also believe the individuals mentioned and DOL were not in agreement and by including the information in your report you re-open old wounds. This serves no purpose.

Medicaid Drug Program

It has been the Board Of Pharmacy's position to remain neutral on HB 209 as it is essentially an economic issue among the federal government, state government, and private enterprise. All testifying on this bill by Board members past and present has been done as individuals and businessmen and during all testimony association with the Board has been avoided. I believe that legislative audit has no business including any reference to HB 209 in their findings and this section should be omitted.

Executive Secretary

Although I briefly discussed the Executive Secretary on page two, I have a few more comments to add here.

If we repeal the entire Controlled Substances Bill, there would be no need for an Executive Secretary or if the responsibility for running the Controlled Substances Bill were transferred to someone other than the Board Of Pharmacy, there would be no need for an Executive Secretary responsible to the Board. As it stands now, even if the registration portion is repealed, the Board is still responsible for investigation and enforcement and this cannot be done without a qualified, trained individual responsible to the Board Of Pharmacy.

Under the current administration's policy of not re-appointing Board members, there is lack of continuity from year to year. All current Board members are of four (4) years or less and are not familiar with the history of many of the problems facing the Board. By limiting Board meetings to one (1) a year as mandated by statute and budget restraints, by the time a Board member is comfortable with the problems, his term has expired. With an Executive Secretary, the Board would have continuity and still live with AS 08.80.020.

I appreciate this opportunity to express my views on this legislative audit and if I can be of any further assistance, do not hesitate to contact me.

Sincerely,

William P. Larson

William P. Larson, R.Ph.
President
Board Of Pharmacy
7731 E. Northern Lights Blvd.
Anchorage, Alaska 99504

WPL:ceb

HB 641

Controlled Substances Act amendment--registering professionals who handle drugs.

Recommendation #1 from Follow Up Audit.

* Section 1. AS 17.30.020(a) is amended to read:

(a) A person who manufactures, distributes, dispenses, or conducts research with a controlled substance in the state or who proposes to manufacture, distribute, or dispense a controlled substance in the state, shall comply with the registration requirements of the federal Controlled Substances Act, 21 U.S.C. sec. 811 -- 830, and the regulations adopted under those sections, 21 C.F.R. 1301 -- 1316. [REGISTER ANNUALLY WITH THE BOARD IN ACCORDANCE WITH REGULATIONS ADOPTED UNDER AS 17.30.010.]

* Sec. 2. AS 17.30.020(b) is amended to read:

(b) A person registered under federal law [THIS CHAPTER] to manufacture, distribute, dispense, or conduct research with controlled substances in the state may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by the person's registration and in conformity with the other provisions of this chapter.

* Sec. 3. AS 17.30.020(f) is repealed and re-enacted to read:

(f) A peace officer may enter a registrant's premises at reasonable times and in a reasonable manner to inspect the premises and records required to be maintained under federal law. An inspection shall not extend to financial data, pricing data, or sales data, other

than shipment data, unless the owner, operator, or agent in charge of the premises consents.

* Sec. 4. AS 17.30.020 is amended by adding a new subsection to read:

(g) Upon request from a peace officer, a person who manufactures, distributes, dispenses, or conducts research with a controlled substance in the state shall provide evidence of current registration under the federal Controlled Substances Act, 21 U.S.C. sec. 811 -- 830, and the regulations adopted under those sections, 21 C.P.R. 1301 -- 1316.

* Sec. 5. AS 17.30.060 is amended to read:

Sec. 17.30.060. RECORDS OF REGISTRANTS. A person registered under federal law to manufacture, distribute, dispense, or conduct research with controlled substances in the state [UNDER THIS CHAPTER] shall keep records and maintain inventories in conformance with the record keeping and inventory requirements of federal law [AND IN CONFORMANCE WITH ADDITIONAL REGULATIONS ADOPTED BY THE BOARD].

* Sec. 6. AS 17.30.080 is amended by adding a new subsection to read:

(b) A person who violates (a) of this section, or who otherwise manufactures, distributes, dispenses, or conducts research with a controlled substance in Alaska without fully complying with the federal Controlled Substances Act, 21 U.S.C. 811 -- 830, and regulations adopted under it, 21 C.F.R. 1301 -- 1316, is guilty of misconduct involving a controlled substance under AS 11.71.010 -- 11.71.070 in the degree appropriate to the circumstances as described in those sections.

* Sec. 7. AS 17.30.100 is amended to read:

Sec. 17.30.100. POWERS OF THE DEPARTMENT OF PUBLIC SAFETY [COOPERATIVE ARRANGEMENTS]. (a) The commissioner of public safety shall enforce this chapter and shall cooperate with other state and

federal agencies in the discharge of their responsibilities pertaining to illicit traffic in controlled substances and in suppressing the abuse of controlled substances. Under this section, the powers of the commissioner of public safety include but are not limited to the following:

(1) arranging for the exchange of information among government officials concerning illicit traffic in and abuse of controlled substances;

(2) coordinating training programs pertaining to controlled substances at both local and state levels; [AND]

(3) cooperating th the Drug Enforcement Administration of the United States Department of Justice by establishing a centralized unit to accept, catalog, file, and collect statistics, including records of persons who have violated the provisions of this chapter or AS 11.71 in the state and making the information available for federal, state, and local law enforcement purposes; and

(4) instituting in the superior court, actions for injunctions against continued manufacture, distribution, dispensation, or research with a controlled substance in the state by a person who violates the federal Controlled Substances Act, 21 U.S.C. 811 -- 830, or the regulations adopted under it, 21 C.F.R. 1301 -- 1316.

(b) The commissioner of public safety may not furnish the name or identity of a patient or research subject whose identity could not be obtained under AS 17.30.155.

* Sec. 8. AS 17.30.150 is amended to read:

Sec. 17.30.150. RELIANCE ON DRUG ENFORCEMENT ADMINISTRATION. Results, information, and evidence received from the Drug Enforcement Administration of the United States Department of Justice relating to the enforcement [REGULATORY] functions of this chapter, including

results of inspections conducted by it, may be relied on and acted on by the Department of Public Safety [BOARD] in the exercises of its enforcement [REGULATORY] functions under this chapter.

* Sec. 9. AS 17.30.155 is amended to read:

Sec. 17.30.155. CONFIDENTIALITY OF CERTAIN INFORMATION. A practitioner engaged in medical practice or research may not disclose [FURNISH] the name or identity of a patient or research subject [TO THE BOARD. THE PRACTITIONER MAY NOT OTHERWISE DISCLOSE THE NAME OR IDENTITY OF AN INDIVIDUAL] that the practitioner is required to keep confidential unless ordered by a court to disclose it within the context of a criminal investigation or proceeding.

* Sec. 10. AS 17.30.010, AS 17.30.020(c) -- (e), AS 17.30.030, AS 17.30.040, AS 17.30.050, AS 17.30.130, and AS 17.30.900 are repealed.

BILL SHEFFIELD, GOVERNOR

REPLY TO:

☐ 1031 W 4th AVENUE
SUITE 200
ANCHORAGE, ALASKA 99501
PHONE: (907) 276-3550

☐ 1st NATIONAL CENTER
100 CUSHMAN ST.
SUITE 400
FAIRBANKS, ALASKA 99701
PHONE: (907) 452-1568

☑ POUCH K - STATE CAPITOL
JUNEAU, ALASKA 99811
PHONE: (907) 465-3600

DEPARTMENT OF LAW

OFFICE OF THE ATTORNEY GENERAL

March 6, 1986

M E M O R A N D U M

TO: Nancy Bennett, Legislative Aide
House HESS Committee

FROM: Peter B. Froehlich
Assistant Attorney General

RE: Attached proposed amendment to HB 641 re controlled substances

At your request, on behalf of Co-chairman Gruenberg, I have undertaken to assimilate suggestions from both the criminal and civil divisions of the Department of Law on how best to amend AS 17.30 on controlled substances in response to the findings and recommendations on pages 7 and 8 of the November 14 Follow-up Review on the Board of Pharmacy by the division of legislative audit.

I have consulted with Assistant Attorney General Gayle Horetski of the criminal division, Gwen Byington, Special Assistant to the Controlled Substances Advisory Committee in the criminal division, and Assistant Attorney General Kay Gouwens of the Anchorage commercial section of the civil division of the Department of Law as well as with the division of occupational licensing in the Department of Commerce and Economic Development.

The consensus is in agreement with the Follow-up Review that the state controlled substance registration now required by AS 17.30 unnecessarily duplicates federal registration, is unduly burdensome upon registrants, and just does not seem workable now, four years after the 1982 enactment of AS 17.30. That enactment incidentally was based on a 1970 uniform act which the NCCUSL is apparently starting to reevaluate this year. Nonetheless, we do not believe that all AS 17.30.010 -- 17.30.080 should simply be repealed because the federal Controlled Substances Act is not actively enforced in Alaska by the federal DEA. That federal Act and the regulations adopted under it are all that would be left to deal with the problem of illicit diversion of controlled substances from the legitimate market.

We have therefore taken the approach of amending AS 17.30 to impose a state requirement that people who handle controlled substances in Alaska comply with the federal law and

provide the Department of Public Safety with a copy of their federal registration. This allows what amounts to state enforcement of the federal requirements to fill the gap left by federal inaction. The second basic ingredient of our approach is to eliminate the occupational licensing Board of Pharmacy from any enforcement function and replace it with the department which is already involved in the enforcement and implementation of much of the rest of AS 17.30. The department would keep records, inspect, initiate criminal prosecutions, and seek injunctions against continued violations of the federal law.

I have listed the changes in the bill to deal with AS 17.30 in amendment form as you requested. The amendment departs from normal drafting technique by setting out repeals in numerical order by statutory section rather than all at the end, to simplify reading the amendment.

We are providing copies of this memorandum and the attached amendment to various interested people and agencies and encourage their input on our proposals. We look forward to working with you and the committee to define an acceptable middle ground approach which is short of repealing all of AS 17.30.

HMB:PBF:pjg

cc w/enc.: Sandra Schubert
Assistant to Senate HESS Committee

Nancy Dunn, Director
Division of Occupational Licensing
Dept of Commerce & Econ. Development

Gayle Horetski, Asst. Attorney General
Criminal Division, Department of Law
Juneau

Kay Gouwens, Asst. Attorney General
Civil Division, Department of Law
Juneau

Gwen Byington, Special Assistant
Criminal Division, Department of Law
Anchorage

Rhonda Butterfield Roberson
Asst. District Attorney -- Anchorage

Hein

A M E N D M E N T

Offered in the HOUSE FINANCE CMTEE. By Szymanski

TO: CSHB 641(HESS)

Page 1, line 7:

Before "and" insert "pharmacy assistants, pharmacy clerks,"

Page 2, after line 4, insert new bill sections to read:

"* Sec. 3. AS 08.80.040 is amended to read:

Sec. 08.80.040. DUTIES OF THE BOARD. The board shall

(1) examine qualified applicants for registration as pharmacists;

(2) grant certificates of registration;

(3) [Repealed

(4)] report to the legislature on the condition of pharmacy in the state; the report shall include a resume of the proceedings of the board during the year and the names of all persons registered under this chapter;

(4) [(5)] maintain a record of the name and place of business of each person registered under this chapter, together with evidence adequate to justify registration;

(5) [(6)] issue a list of potentially dangerous medicinal ingredients or preparations that may be sold only under the direct supervision of a licensed pharmacist; the failure to include an ingredient or preparation in this list does not affect any law or

regulation, which prohibits or restricts the sale of the ingredient or preparation;

(6) [(7) Repealed

(8)] adopt regulations insuring that renewal of licenses occurs every four years and is contingent upon proof of continued competency;

(7) [(9)] hold hearings and order disciplinary sanctions against a person who violates this chapter or the regulations of the board;

(8) [(10)] provide for the regulation of controlled substances under AS 17.30;

(9) adopt regulations for the training and certification of pharmacy assistants and pharmacy clerks.

* Sec. 4. AS 08.80.160 is amended to read:

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

(1) examination;

(2) reexamination;

(3) investigation for licensing by credentials;

(4) pharmacist license;

(5) temporary license;

(6) wholesale drug dealer license;

(7) retail pharmacy license;

(8) pharmacy intern registration;

(9) emergency permit;

(10) hospital pharmacy license (inpatient and outpatient);

(11) hospital drug room license (inpatient);

(12) nursing home and related facilities license for inpatient dispensing;

(13) license amendment or replacement;

(14) pharmacy assistant certificate;

(15) pharmacy clerk certificate.

* Sec. 5. AS 08.80 is amended by adding new sections to read:

Sec. 08.80.211. QUALIFICATIONS FOR CERTIFICATION AS PHARMACY ASSISTANT. (a) An applicant for certification as a pharmacy assistant must have

(1) been awarded a high school diploma or G.E.D.; and

(2) completed

(A) an academic program for pharmacy assistant training approved by the board; or

(B) on-the-job training meeting guidelines approved by the board.

(b) The board may not certify as a pharmacy assistant a person who has been convicted of violating a law relating to controlled substances or the practice of pharmacy.

Sec. 08.80.212. SUPERVISION, FUNCTIONS, AND IDENTIFICATION OF PHARMACY ASSISTANTS. (a) A certified pharmacy assistant under the direct supervision of a licensed pharmacist may assist the pharmacist in performing manipulative, nondiscretionary functions associated with the practice of pharmacy.

(b) A pharmacy assistant may not perform the following functions:

(1) consultation with a prescriber regarding a patient and the patient's prescription;

(2) receipt of an unwritten prescription other than refill approval or denial from a prescriber;

(3) consultation with a patient regarding a prescription, both before and after filling the prescription, and regarding information contained in a patient medication record system;

(4) interpretation and identification of the contents of a prescription document;

(5) determination of the product required for a prescription;

(6) extemporaneous compounding of a prescription, except under regulations of the board that ensure that the accuracy, correct procedure and preparation, and safety of pharmaceutical constituents are verified by the supervising pharmacist;

(7) interpretation of data in a patient medication record system;

(8) final check on all aspects of the completed prescription and assumption of the responsibility for the filled prescription, including the accuracy of drug, strength, labeling, and proper container;

(9) dispensing of a prescription to a patient; or

(10) a duty required by law or regulation to be performed only by a licensed pharmacist.

(c) A pharmacy assistant, while on duty, shall wear a badge provided by the board that clearly identifies the person wearing it as

a pharmacy assistant. The badge shall be worn conspicuously.

(d) In this section, "direct supervision" includes visual or physical proximity that ensures adequate safety controls.

Sec. 08.80.213. PHARMACY ASSISTANT TRAINING PROGRAMS. (a) The board shall establish standards for the approval of pharmacy assistant training programs. The board shall reevaluate approved programs at intervals determined by the board. Approval shall be continued or withdrawn after each reevaluation.

(b) The director of a pharmacy assistant program

(1) must be a licensed pharmacist;

(2) shall submit to the board, with an application for initial approval, a description of the course of training offered, including subject taught, methods of teaching and testing, and practical experience provided; and

(3) shall inform the board of proposed significant changes in an approved training program and must receive board approval before implementing the changes.

(c) The board shall maintain a registry of approved programs and make the registry available at the request of interested persons.

Sec. 08.80.214. QUALIFICATIONS OF PHARMACY CLERKS. (a) The board may not establish age, education, or training requirements for pharmacy clerks. The supervising pharmacist shall instruct the pharmacy clerk of the limitations on the clerk's functions under AS 08.-80.215.

(b) The board may not certify as a pharmacy clerk a person who has been convicted of violating a law relating to controlled

substances or the practice of pharmacy.

Sec. 08.80.215. SUPERVISION, FUNCTIONS, AND IDENTIFICATION OF PHARMACY CLERKS. (a) A certified pharmacy clerk under the supervision of a licensed pharmacist may perform the functions of typing prescription labels, filing, refiling, bookkeeping, pricing or determination of cost or charge, stocking, delivery, nonprofessional phone inquiries, documentation of third-party reimbursements, and other clerical duties specified by the supervising pharmacist.

(b) A pharmacy clerk, while working in a pharmacy and having contact with patients or the general public, shall wear a badge provided by the board that clearly identifies the person wearing it as a pharmacy clerk. The badge shall be worn conspicuously.

Sec. 08.80.216. APPLICATIONS FOR PHARMACY ASSISTANT OR CLERK CERTIFICATION. An application for certification as a pharmacy assistant or pharmacy clerk shall be on a form provided by the board. The application must include

(1) the appropriate fee established under AS 08.80.160; and

(2) a statement by the applicant, under penalty of perjury, that the applicant has not been convicted of a violation of a law relating to controlled substances or the practice of pharmacy.

Sec. 08.80.217. EMPLOYMENT OF PHARMACY ASSISTANT OR CLERK. (a) The owner or manager of a licensed pharmacy shall notify the board of an intent to employ a certified pharmacy assistant or pharmacy clerk. The notification must describe the manner in which the pharmacy assistant or pharmacy clerk is to be used and supervised, including a job description and other information that may be required by the board.

(b) A pharmacy may not employ or use a person to perform the functions of a pharmacy assistant or pharmacy clerk unless the person is certified under this chapter.

* Sec. 6. AS 08.80.261 is amended by adding a new subsection to read:

(b) The board may, after a hearing, impose a disciplinary sanction on a person certified as a pharmacy assistant or pharmacy clerk under this chapter if the board finds that the person

(1) secured the certificate through deceit, fraud, or intentional misrepresentation;

(2) engaged in deceit, fraud, or intentional misrepresentation in the course of performing functions of a pharmacy assistant or pharmacy clerk;

(3) has been convicted of a felony or other crime that affects the person's ability to continue to perform competently and safely as a pharmacy assistant or pharmacy clerk; or

(4) violated a regulation relating to pharmacy assistants or pharmacy clerks.

* Sec. 7. AS 08.80.266(a) is amended to read:

(a) <u>If</u> [WHEN] it finds that a <u>person licensed or certified under this chapter</u> [LICENSEE] is guilty of an offense under AS 08.80.261, the board may impose the following sanctions singly or in combination:

(1) permanently revoke a license <u>or certificate</u>;

(2) suspend a license <u>or certificate</u> for a determinate period of time;

(3) censure <u>the person</u> [A LICENSEE];

(4) issue a letter of reprimand;

(5) place the person [A LICENSEE] on probationary status and require the person [LICENSEE] to

(A) report regularly to the board upon matters involving the basis of probation;

(B) limit practice or employment under the license or certificate to those areas prescribed;

(C) continue professional education until a satisfactory degree of skill has been attained in those areas determined by the board to need improvement;

(6) impose limitations or conditions on the practice or employment of the person that is regulated under the license or certificate [A LICENSEE].

* Sec. 8. AS 08.80.266(c) is amended to read:

(c) The board may summarily suspend a license or certificate before final hearing or during the appeals process if the board finds that the person licensed or certified [LICENSEE] poses a clear and immediate danger to the public health and safety if the person [LICENSEE] continues in the regulated [TO] practice or employment. A person whose license or certificate is suspended under this section shall be entitled to a hearing by the board no later than seven days after the effective date of the order. The person may appeal the suspension after a hearing to a court of competent jurisdiction.

* Sec. 9. AS 08.80.266(d) is amended to read:

(d) The board may reinstate a license or certificate that has been suspended or revoked if the board finds after a hearing that the applicant is able to practice or perform regulated functions with

skill and safety.

* Sec. 10. AS 08.80.270 is amended to read:

Sec. 08.80.270. REPORT OF EMPLOYEE. (a) An owner or manager of a pharmacy shall report to the board at the time the board directs, but not more often than twice each year, the names of all pharmacists, pharmacy assistant, and pharmacy clerks employed in that pharmacy.

(b) An owner or manager of a pharmacy shall forward to the board a change of employee notice within 10 days of hiring or dismissing a pharmacist, pharmacy assistant, or pharmacy clerk."

Renumber remaining bill sections accordingly.

Page 3, before line 1. insert new bill sections to read:

"* Sec. 13. AS 08.80.340 is amended to read:

Sec. 08.80.340. WHO MAY PREPARE PRESCRIPTIONS. Except as provided under AS 08.80.212, only [NO PERSON EXCEPT] a licensed pharmacist or a licensed intern pharmacist under the direct supervision of a licensed pharmacist may compound and dispense the prescription of a physician. However, this section does not limit the authority of a licensed medical doctor to compound and dispense medicinal preparations.

* Sec. 14. AS 08.80.440 is amended to read:

Sec. 08.80.440. DENIAL OF EXAMINATION, CERTIFICATE, OR LICENSE. The board may deny an applicant the opportunity to be examined, may deny a license to an applicant who has successfully completed the prescribed examination, [OR] may deny a license to an applicant for

licensure [REGISTRATION] by reciprocity, deny a certificate to an applicant, or institute proceedings to suspend, revoke or otherwise terminate a license or certificate [REGISTRATION], but only upon the basis of a specific complaint. Complaints shall be in the form of an affidavit and shall be filed in duplicate with the secretary of the board.

* Sec. 15. AS 08.80.450 is amended to read:

Sec. 08.80.450. DISCIPLINARY ACTION. The board may consider a complaint based upon the alleged violation of a [ANY] provision of this chapter, and may by a majority vote of a quorum dismiss the complaint, reprimand a person holding a license or certificate [LICENSEE], or take other punitive action as the nature of the facts warrant. Orders issued by the board shall be in writing, signed by a majority, and filed with the secretary of the board. The accused shall receive an authenticated copy of the order."

Renumber remaining bill sections accordingly.

Alaska State Legislature

House of Representatives

COMMITTEE ON HEALTH. EDUCATION
AND SOCIAL SERVICES

OFFICIAL BUSINESS

POUCH V
JUNEAU. AK 99811
465-3759

March 25, 1986

Representative Ben Grussendorf
Speaker of the House
P.O Box V
Juneau, Alaska 99811

Dear Mr. Speaker:

The House Committee on Health, Education and Social Services has considered the Sunset Review of the Board of Pharmacy, and recommends that the board be continued. Representative Max Gruenberg, Co-Chair of the committee, has introduced HB 641, to fulfill some of the findings of the Division of Legislative Audit.

As required by AS 44.60.050 (c), the Committee submits the following findings:

(1) the extent to which the board, commission or program has operated in the public interest.

The board has held three public meeetings a year, administers a yearly licensing examination and has passed regulations concerning dangerous drugs, continuing education as proof of continued comptency, false or misleading advertising of drugs and prepackaging of drugs in hospital drug rooms.

(2) 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.

Prior audit recommendation (1983) was that continuing competency regulations are too stringent and should be changed. The regulations require nonacademic programs to have an examination or another method of assuring satisfactory completio.. of the program before credit will be given. Continued competency regulations may also be waived for chronic illness, retirement, military service or hardship.

The 1985 audit states that the board believes the regulations to be arbitrary or unreasonable and should be changed since the board has deviated from their written policy in accepting nonregulation credits. Legislative Audit also believes it is more reasonable to require

individuals who have been chronically ill, retired or in the military to demonstrate continued compentency than those who have not interrupted their practice. These recommendations were accomplished by the board in August of 1985.

(3) the extent to which the board, commission or agency has recommended statutory changes which are generally of benefit to the public interest.

The board succeeded in having various obsolete or vague statutory requirements repealed which provided for smoother operation of the board. The board also was instrumental in passage of the controlled substances registration and the Marijuana Therapeutic Research Program which are currently recommended, by Legislative Audit, for repeal.

(4) 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.

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.

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

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

(6) 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 the board or commission is administratively assigned, or with the office of the ombudsman have been processed or resolved.

No problems were found by Legislative Audit.

(7) the extent to which the board or commission which regulates entry into an occupation or profession has presented qualified applicants to serve the public.

The board has licensed 83 pharmacists in the last three years, all but eight were licensed by credentials. Legislative Audit found no instances where the board licensed unqualified practitioners.

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

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

(9) 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 the factors enumerated in this subsection.

Legislative Audit found that state registration under the Controlled Substances Act is duplicative of the Federal Drug Enforcement Agency, unnecessary for litigation and costly for the state and that the board should recommend legislation to eliminate state registration.

The 1983 Audit recommendation that legislation be introduced to clarify the investigatory powers of the board and the Division was never accomplished, but has been incorporated into CSHB 641 (HESS)

The Audit also recommends repeal of the Marijuana Therapeutic Research Program since it was not accomplished in a timely fashion. The repeal is included in CSHB 641.

As required by AS 44.60.050 (d), the Committee submits the following findings:

(1) an identification of the problems or the needs that the programs and activities of the board, commission or agency are intended to address.

The board should recommend legislation to regulate pharmacy technicians. Although the Legislative Audit recommended the repeal of controlled substances registration, the committee has not addressed that issue, feeling that it will require further study.

(2) a statement, to the extent practicable, of the objectives of the program of the board, commission, or agency program, and its anticipated accomplishments.

The purpose of the board is to license qualified applicants, inspect pharmacies and adopt needed regulations.

(3) an identification of any other programs having similar, conflicting or duplicate objectives.

There are no other agencies which license pharmacists. The Department of Public Safety is the lead agency in enforcement of the Controlled Substances Act, and should be given the responsibilities currently assigned to the Board of Pharmacy which are necessary and do not duplicate federal DEA activity.

(4) an assessment of alternative methods of achieving the purposes of the program.

The Committee did not consider any alternatives for licensure. The Committee did consider the recommendations of the Departments of Law, Public Safety and Commerce and Economic Development for rewriting aspects of the Controlled Substances Act, but did not adopt these provisions because of opposition from members of the board, reserving the issue for possible future legislation.

(5) an assessment of the consequences of eliminating the board, commission or program and consolidating its activities with another program, or of funding it at a lower level.

Eliminating the board would remove licensing mechanisms, which are designed to assure that practitioners are competent to practice. The Committee did not consider funding for the board since legislation was passed last year to require licensing boards to alter fees in order to support board expenses.

(6) a justification for the recommended continuation or extension of the board, commission or program, and an explanation of the manner in which it avoids duplication of or conflict with other efforts.

The board should be continued because the regulation and licensing of qualified professional pharmacists is necessary to protect the public's health, safety and welfare. There are no other agencies which regulate pharmacists.

(7) any other information which, in the opinion of the committee, would improve the performance of the board, commission or agency with respect to its representation of and responsiveness to the public interest.

The Committee has no further recommendations.

Representative Max F. Gruenberg, Jr., Co-Chair
House Health, Education and Social Services Committee

Representative Willo Koponen, Co-Chair
House Health, Education and Social Services Committee

Offered: 4/1/86
Referred: Finance

Original sponsor: Gruenberg

IN THE HOUSE BY THE HEALTH, EDUCATION AND SOCIAL SERVICES COMMITTEE

CS FOR HOUSE BILL NO. 641 (HESS)

IN THE LEGISLATURE OF THE STATE OF ALASKA

FOURTEENTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to generic drugs, pharmaceuticals, and the Board of Pharmacy; repealing the marijuana therapeutic research program; 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, 1989 [1985].

* 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) assist the department in inspections and investigations [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) adopt [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;

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

(8) [(9)] adopt requirements for licensing in addition to the requirements set out in this chapter.

* Sec. 3. AS 08.80.295(a) is amended to read:

(a) Unless the prescription expressly states that it is to be dispensed only as written [EXCEPT AS LIMITED BY (b) AND (c) OF THIS SECTION, WITH THE CONSENT OF THE PURCHASER], the pharmacist may substitute a drug product with the same generic name in the same strength, quantity, dose and dosage form as the prescribed drug, provided the substitute drug [PRESCRIBED DRUG WHICH] is, in the pharmacist's professional opinion, therapeutically equivalent and meets the standards of (g) of this section. The [UPON SUBSTITUTION THE] pharmacist shall notify the purchaser [AND THE PERSON WHO PRESCRIBED THE DRUG] of the substitution, and shall record on the prescription and keep a record of the name and manufacturer of the drug substituted.

* Sec. 4. AS 08.80.295 is amended by adding new subsections to read:

(i) A pharmacist who substitutes a drug in compliance with this section incurs no greater liability in filling the prescription by dispensing the equivalent drug product than would be incurred in filling the prescription by dispensing the prescribed brand name drug.

(j) Every pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that "Under Alaska law a therapeutically equivalent but less expensive drug may, in some cases, be substituted for the drug prescribed by your doctor. Please consult your pharmacist or physician." The printing on the sign shall be in block letters not less than one inch in height.

* Sec. 5. AS 08.80.360 is amended to read:

Sec. 08.80.360. SALE OF DANGEROUS MATERIALS. Drugs that [OR MEDICAL SUPPLIES WHICH] contain poisonous, potent, habit-forming or deleterious ingredients may [SHALL] be dispensed only by a licensed pharmacist. At the time of the sale, the pharmacist shall make the nature of the drug or medical preparation known to the purchaser.

* Sec. 6. AS 08.80.480(2) is repealed and reenacted to read:

(2) "drug" means an article recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary; an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal; an article other than food, intended to affect the structure or function of the body of man or animal; and an article intended for use as a component of an article specified in this paragraph but does not include devices or their components, parts, or accessories;

* Sec. 7. AS 08.80.480 is amended by adding a new paragraph to read:

(21) "nonprescription drug" means a nonnarcotic medicine or drug that may be sold without a prescription and that is prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of the state and the federal government.

* Sec. 8. AS 11.71.030(a) is amended to read:

(a) Except as authorized in AS 17.30 [OR AS 17.35], a person commits the crime of misconduct involving a controlled substance in the third degree if the person

(1) manufactures or delivers any amount of a schedule IIA or IIIA controlled substance or possesses any amount of a schedule IIA or IIIA controlled substance with intent to manufacture or deliver;

(2) delivers any amount of a schedule IVA, VA, or VIA controlled substance to a person under 19 years of age who is at least three years younger than the person delivering the substance; or

(3) being 18 years of age or older, possesses any amount of a schedule IA or IIA controlled substance within the grounds of or on a parking lot immediately adjacent to a public or private preschool, elementary, junior high, or secondary school.

* Sec. 9. AS 11.71.040(a) is amended to read:

(a) Except as authorized in AS 17.30 [OR AS 17.35], a person commits the crime of misconduct involving a controlled substance in the fourth degree if the person

(1) manufactures or delivers any amount of a schedule IVA or VA controlled substance or possesses any amount of a schedule IVA or VA controlled substance with intent to manufacture or deliver;

(2) manufactures or delivers, or possesses with the intent to manufacture or deliver, one or more preparations, compounds, mixtures, or substances of an aggregate weight of one ounce or more containing a schedule VIA controlled substance;

(3) possesses

(A) any amount of a schedule IA or IIA controlled substance;

(B) 25 or more tablets, ampules, or syrettes containing a schedule IIIA or IVA controlled substance;

(C) one or more preparations, compounds, mixtures, or substances of an aggregate weight of three grams or more containing a schedule IIIA or IVA controlled substance;

(D) 50 or more tablets, ampules, or syrettes containing a schedule VA controlled substance;

(E) one or more preparations, compounds, mixtures, or

substances of an aggregate weight of six grams or more containing a schedule VA controlled substance; or

(F) one or more preparations, compounds, mixtures, or substances of an aggregate weight of one pound or more containing a schedule VIA controlled substance;

(4) being 18 years of age or older, possesses a schedule IIIA, IVA, VA, or VIA controlled substance within the grounds of or on a parking lot immediately adjacent to a public or private preschool, elementary, junior high, or secondary school;

(5) knowingly keeps or maintains any store, shop, warehouse, dwelling, building, vehicle, boat, aircraft, or other structure or place which is used for keeping or distributing controlled substances in violation of a felony offense under this chapter or AS 17.30;

(6) makes, delivers, or possesses a punch, die, plate, stone, or other thing which prints, imprints, or reproduces a trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of these upon a drug, drug container, or labeling so as to render the drug a counterfeit substance;

(7) knowingly uses in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person;

(8) knowingly furnishes false or fraudulent information in or omits material information from any application, report, record, or other document required to be kept or filed under AS 17.30;

(9) obtains possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge; or

(10) affixes a false or forged label to a package or other container containing any controlled substance.

AS 17.30.

* Sec. 11. AS 11.71.060(a) is amended to read:

(a) Except as authorized in AS 17.30 [OR AS 17.35], a person commits the crime of misconduct involving a controlled substance in the sixth degree if the person

(1) uses or displays any amount of a schedule VIA controlled substance or possesses one or more preparations, compounds, mixtures, or substances of an aggregate weight of one ounce or more containing a schedule VIA controlled substance on a public street or sidewalk or on the premises of a public carrier or business establishment or in any other public place;

(2) knowingly possesses any amount of a schedule VIA controlled substance within the immediate control of that person while operating a propelled vehicle;

(3) being under 19 years of age, possesses one or more preparations, compounds, mixtures, or substances of an aggregate weight of less than four ounces containing a schedule VIA controlled substance;

(4) possesses one or more preparations, compounds, mixtures, or substances of an aggregate weight of four ounces or more containing a schedule VIA controlled substance; or

(5) refuses entry into a premises for an inspection authorized under AS 17.30.

* Sec. 12. AS 11.71.070(a) is amended to read:

(a) Except as authorized in AS 17.30 [OR AS 17.35], a person commits the offense of misconduct involving a controlled substance in the seventh degree if the person

(1) manufactures or delivers, or possesses with the intent to manufacture or deliver, one or more preparations, compounds,

mixtures, or substances of an aggregate weight of less than one-half ounce of a schedule VIA controlled substance; or

(2) possesses one or more preparations, compounds, mixtures, or substances of an aggregate weight of less than one ounce containing a schedule VIA controlled substance on a public street or sidewalk or on the premises of a public carrier or business establishment or in any other public place.

* Sec. 13. AS 08.80.295(b), (c), and (f); 08.80.480(3); and AS 17.35 are repealed.

* Sec. 14. This Act takes effect immediately in accordance with AS 01.-10.070(c).

Introduced: 2/17/86
Referred: Labor & Commerce
Health, Education & Social
Services and Finance

IN THE HOUSE BY GRUENBERG

HOUSE BILL NO. 641

IN THE LEGISLATURE OF THE STATE OF ALASKA

FOURTEENTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to generic drugs, pharmaceuticals, and the Board of Pharmacy; repealing the marijuana therapeutic research program; 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, 1989 [1985].

* Sec. 2. AS 08.80.295(a) is amended to read:

(a) Unless the prescriber expressly states that a prescription is to be dispensed only as written [EXCEPT AS LIMITED BY (b) AND (c) OF THIS SECTION, WITH THE CONSENT OF THE PURCHASER], the pharmacist may substitute a drug product with the same generic name in the same strength, quantity, dose and dosage form as the prescription, provided the substitute drug [PRESCRIBED DRUG WHICH] is, in the pharmacist's professional opinion, therapeutically equivalent and meets the standards of (g) of this section. The [UPON SUBSTITUTION THE] pharmacist shall notify the purchaser [AND THE PERSON WHO PRESCRIBED THE DRUG] of the substitution, and shall record on the prescription and keep a record of the name and manufacturer of the drug substituted.

* Sec. 3. AS 08.80.295 is amended by adding new subsections to read:

(i) A pharmacist who substitutes a drug in compliance with this section incurs no greater liability in filling the prescription by dispensing the equivalent drug product than would be incurred in

filling the prescription by dispensing the prescribed brand name drug.

(j) Every pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that "Under Alaska law a therapeutically equivalent but less expensive drug may, in some cases, be substituted for the drug prescribed by your doctor. Please consult your pharmacist or physician." The printing on the sign shall be in block letters not less than one inch in height.

* Sec. 4. AS 08.80.030(3), 08.80.295(b), (c), and (f); and AS 17.35 are repealed.

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