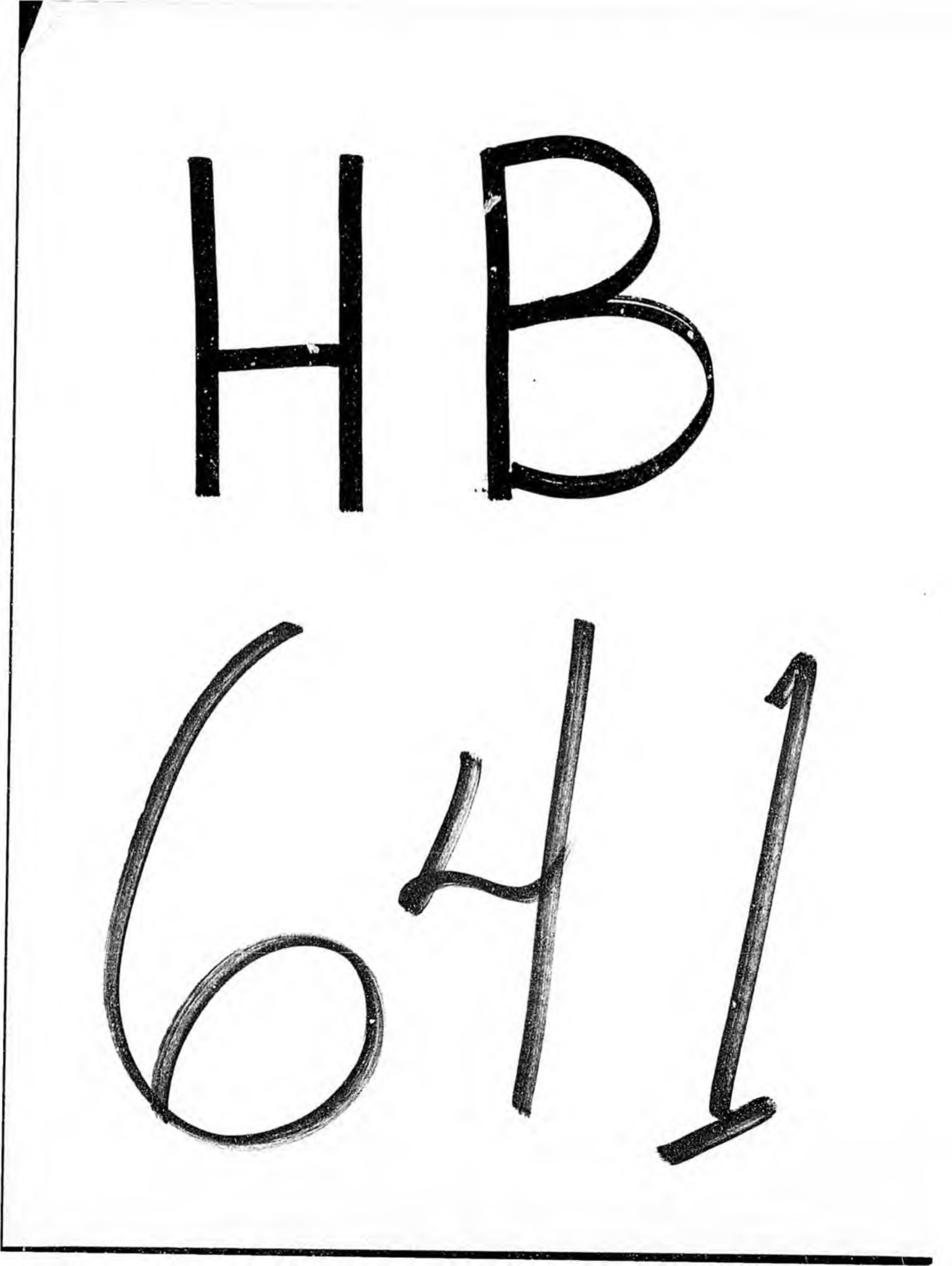
HB
641

Senate Health, Education and Social Services Committee

Legislation Checklist

Bill number: HB 641

Sponsor: Gruenberg

Date referred to committee: 4/30/86

Synopsis completed:

Fiscal note:

Further referrals:

CONTACTS:

Jackie Warren 562-2211 Mgr, Providence Hospital pharmacy re marijuana

✓Gruenberg, sponsor - x3759

✓Rod Betit, DHSS x3355

✓Rick Urion, Medical Assoc. 364-2315

✓Nancy Dunn (Jenny Strickler) x2534
5/1/86 will notify Bd. of hearing.

✓Pete Fraehlich, A.G. x3600

✓Jim Vaden, 4-22 Public Safety

STATE OF ALASKA
THE LEGISLATURE

POUCH Y - STATE CAPITOL
JUNEAU, ALASKA 99811
907-465-3800

LEGISLATIVE AFFAIRS AGENCY

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May, 1986

Copies of minutes listed below were originally included in this file. The minutes are available on the STAIRS date base CM 14. In order to save space copies of minutes have not been left in the files.

Jeanie Henry

Senate Health Education & Social Services Committee 2/20/86, 1:36 pm
" " " " " " 5/8/86, 1:25 pm

COMMITTEE REPORT

SENATE

FURTHER:

4/30/86

Date 5-8-86

Mr. President

The Committee on HESS considered CSHB 641(HESS)am

relating to generic drugs, pharmaceuticals, and the Board of Pharmacy; repealing the marijuana therapeutic research program; efd.

and (a majority of the committee) (the committee) reports it back with the following recommendations:

[ ] do pass

[ ] do pass with attached amendment(s)

[X] replace with/or adopt SCS for CSHB 641 (HESS) am
[ ] new title
[O] same title and recommends Do Pass

[ ] and attached a "LETTER OF INTENT" [ ] NEW FISCAL NOTE

[ ] reports it back without recommendation

[ ] recommends referral to _____ Committee

MEMBERS SIGNING
DO PASS

Lee P. Stephens
Carlton Stanley
Edna MacKie

MEMBERS HAVING
OTHER RECOMMENDATIONS

Chairman

Chairman recommendation

17-1

HB 641 EXTEND THE BOARD OF PHARMACY

1. EXTEND BOARD OF PHARMACY TO 1989. THIS IS THEIR WIND-DOWN YEAR. WILL TERMINATE IF NOT EXTENDED NOW.

2. REPEALS THE MARIJUANA THERAPEUTIC RESEARCH PROGRAM. THIS CALLED ON THE BOARD TO APPROVE PATIENTS FOR EXPERIMENTAL USE OF MARIJUANA IN CANCER THERAPY AND GLAUCOMA TREATMENT. SINCE THE LAW WAS PASSED IN 1982, MUCH NATIONAL RESEARCH HAS BEEN DONE AND THE FEDS. RECENTLY APPROVED MARINOL (SYNTHETIC MARIJUANA) AS A CONTROLLED SUBSTANCE. (ie. - it's no longer considered experimental) PHYSICIANS CAN NOW PRESCRIBE IT, AND REQUIRING THE BOARD TO APPROVE PATIENTS TO USE IT IS JUST AN EXTRA BUREAUCRATIC STEP. LEGISLATIVE AUDIT AND BOARD SUPPORT REPEAL.

3. ALLOWS A PHARMACIST TO SUBSTITUTE A GENERIC DRUG UNLESS THE DOCTOR SPECIFICALLY PRESCRIBES OTHERWISE OR UNLESS THE PATIENT OBJECTS. (Josephson amendment in Senate HESS) INTENT: COST SAVINGS TO THE CONSUMER. CURRENTLY, GENERIC DRUG CAN ONLY BE SUBSTITUTED IF THE DOCTOR SPECIFICALLY REQUESTS IT.

ADDED IN SENATE HESS (4.) REMOVES THE REQUIREMENT THAT PEOPLE WHO HANDLE CONTROLLED SUBSTANCES MUST REGISTER BOTH WITH THE STATE AND WITH THE FEDS. INSTEAD, WE'VE AMENDED STATE LAW TO REQUIRE PEOPLE TO COMPLY WITH THE FEDERAL REGISTRATION, AND MADE IT A STATE VIOLATION TO VIOLATE THE FEDERAL LAW (SO OUR STATE POLICE CAN ENFORCE IT).

Under this provision, as under current law, police officers would investigate violations of the Act. During the investigation, pharmacists would have to show the police officer their federal registration. This does not mean police officers would be routinely inspecting pharmacists to see if they're registered - only upon a report of a violation, as for other criminal activities

CONCERN: THIS IS THE OLD EXECUTIVE SECRETARY ARGUMENT. THE BOARD HAS WANTED TO MAINTAIN THE REGISTRATION -- HIRE AN EXECUTIVE SECRETARY -- HAVE THE SECRETARY INSPECT PHARMACY'S RECORDS FOR VIOLATIONS OF THE CONTROLLED SUBSTANCES ACT. GOVERNOR AND LEGISLATURE HAVE NEVER CHOSEN TO FUND AN EXECUTIVE SECRETARY, DESPITE YEARS OF LOBBYING BY THE BOARD. THEIR GOAL IS TO BE AN INDEPENDENT BOARD (IDEALLY WITH NO TIES TO THE DEPARTMENT), AND THEY SEE THIS AMENDMENT AS TAKING SOME OF THEIR "POWER" AWAY. (& their continuing argument for a secretary!)

Senate changes: page 2, line 27
pages 8-11 (Sec. 13-21)

Original sponsor: Gruenberg

Sectional Analysis Attached

IN THE HOUSE

BY THE HEALTH, EDUCATION AND SOCIAL SERVICES COMMITTEE

SENATE CS FOR 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, with the consent of the purchaser, 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, with your consent, be substituted for the drug prescribed by your doctor unless your doctor has specified otherwise. Please consult your pharmacist or physician." The printing on the sign shall be in block letters not less than one inch in height.

Josephson amendment in H+ss

* 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 tructure 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.

* 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 VI 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 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 21 U.S.C. 811 - 830 (Controlled Substances Act), and the regulations adopted under those sections [REGISTER ANNUALLY WITH THE BOARD IN ACCORDANCE WITH REGULATIONS ADOPTED UNDER AS 17.30.010].

* Sec. 14. 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. 15. AS 17.30.020(f) is repealed and reenacted 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 may 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.

CONTROLLED SUBSTANCE LANGUAGE ADDED IN HESS

* Sec. 16. 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 21 U.S.C. 811 - 830 (Controlled Substances Act) and the regulations adopted under those sections.

* Sec. 17. 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. 18. 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 the state without fully complying with 21 U.S.C. 811 - 830 (Controlled Substances Act), and regulations adopted under those sections, 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.

* Sc. 19. AS 17.30.100(a) 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 with 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 21 U.S.C. 811 - 830 (Controlled Substances Act) or the regulations adopted under those sections.

* Sec. 20. 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 exercise of its enforcement [REGULATORY] functions under this chapter.

* Sec. 21. 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. 22. AS 08.80.295(b), (c), and (f), 08.80.480(3); AS 17.30.010, 17.30.020(c), (d), and (e), 17.30.030, 17.30.040, 17.30.050, 17.30.130, 17.30.900(b); and AS 17.35 are repealed.

* Sec. 23. This Act takes effect immediately in accordance with AS 01.-10.070(c).

Marijuana Therapeutic Research Program

Alaska State Legislature

P O BOX V
STATE CAPITOL
JUNEAU, ALASKA 99811
(907) 465-3834
(907) 465-3762

Senate Committee on
Health, Education and Social Services

SECTIONAL ANALYSIS

changes in pen were made by Senate HESS.

May 7, 1986

CSHB 641 (HESS) am Relating to generic drugs, pharmaceuticals, and the board of pharmacy; repealing the marijuana therapeutic research program.

Section 1 Continues the Board of Pharmacy until 1989.

Section 2 Amends 08.80.030 (3), POWERS OF THE BOARD, to clarify investigation procedures as recommended by the 1983 and 1985 Legislative Audits of the board.

Section 3 Amends existing generic drug provisions to provide that generics may be substituted unless the prescriber expressly states that the prescription is to be filled as written or unless the purchaser objects.

Section 4 Adds two new subsections to existing law providing that a pharmacist incurs no greater liability in substituting generic drugs than in dispensing name brand drugs, and requiring a sign to be posted in all pharmacies indicating that Alaska law allows the use of generic drugs.

Sections 5-7 Updates the definitions of "drug" and "nonprescription drug" in accordance with the model pharmacy act.

Sections 8-12 Conforming amendments to the repeal of the Marijuana Therapeutic Research program in section 10.

Section ~~13~~ 22 Repeals the Marijuana Therapeutic Research Program and provisions of Title 8 that are in conflict with the generic drug provisions in sections 3 and 4. & provisions of title 17 that are in conflict with repeal of the controlled substance registration

Section ~~14~~ 23 Immediate effective date.

Sec. 13-21 The proposed amendment would clarify that people who handle controlled substances in Alaska must comply with the registration requirements of the federal law, and would remove the current state registration requirements. The Legislative Auditors and the Department of Law have determined that the state registration is duplicative, as persons must now register both with the Pharmacy Board and the federal Drug Enforcement Agency. Enforcement would continue to be handled by the Department of Public Safety.

On Thursday, May 8, 1986 from 1:30-3:30 p.m. in the Beltz Room, the Senate Committee on Health, Education and Social Services will hear the following bills:

CSHB 641 (HESS) am Relating to generic drugs, pharmaceuticals, and the Board of Pharmacy; repealing the marijuana therapeutic research program.

HB 641 would extend the Board of Pharmacy through 1989 and make other revisions to the pharmacy statute as recommended by the legislative audit:

1) Repeal the Marijuana Therapeutic Research Program, under which the Board is to approve patients for the use of marijuana and its active ingredient (THC) in the treatment of glaucoma and in cancer chemotherapy. The need for the program has been diminished by recent FDA approval of Marinol, a new THC drug, which is currently available through Providence Hospital in Anchorage.

2) Provide that a generic drug may be substituted unless the prescriber expressly states that the prescription is to be filled as written. Current statute allows substitution only if the prescriber specifically requests it.

(adopted by Senate HESS)

The attached amendment would remove the requirement that people who handle controlled substances in Alaska register with both the state and federal governments, and amend state law to specifically provide that federal registration requirements must be met. This was recommended by the legislative audit.

At its March 5 sunset review of the Board, the Senate Committee on Health, Education and Social Services did recommend its continuation. The Board terminated June 30, 1985 and has until June 30, 1986 to conclude its affairs.

HCR 61 am Relating to access to basic health care services for Alaskans.

HCR 61 requests the Governor to direct the Department of Health and Social Services to identify potential means and costs of providing for the health care needs of Alaskans who do not have adequate health care protection. It is anticipated that funding support for the study will come from a grant from the Robert Wood Johnson Foundation, and that the House Research Agency and legislative staff will cooperate in the effort. The resolution calls for the results of the study to be submitted to the legislature by March 1, 1987.

SB 415 Relating to school board composition.

SB 415 would exempt Rural Education Attendance Areas (REAAs) that convert to city or borough school districts from statutory provisions that govern the number of members who may serve on a city/borough school board. Current statute provides, for city/borough districts with less than 5000 students, a 5 member board; for city/borough districts with more than 5000 students, a 7, 9, or 11-member board; and for REAAs, a 5, 7, 9, or 11-member board.

The bill is intended to address the conversion of the Northwest Arctic REAA in Kotzebue to a borough school district. The REAA currently has an 11-member board; existing statute would require that the board be reduced to five members.

Chapter 35. Marijuana Therapeutic Research Program.

Section
10. Legislative purpose
20. Marijuana therapeutic research program
30. Patient qualification review committee
40. Sources, distribution and possession of marijuana
50. Report to the governor and legislature
500. Definitions

Cross references. — For declaration for legislative purpose, see § 1, ch. 45, SLA 1982 in the 1982 Temporary and Special Acts and Resolves.

Sec. 17.35.010. Legislative purpose. The legislature finds that recent research has shown that the use of marijuana may alleviate the nausea and ill effects of cancer chemotherapy and radiology, and, additionally, may alleviate the ill effects of glaucoma. The legislature further finds that there is a need for further research and experimentation regarding the use of marijuana under strictly controlled circumstances. (§ 5 ch 45 SLA 1982)

Sec. 17.35.020. Marijuana therapeutic research program. (a) A therapeutic research program is established in the Board of Pharmacy. The program shall be administered by the board. The board shall adopt regulations necessary for the proper administration of this chapter. Before adopting regulations, the board shall consider pertinent regulations adopted by the Drug Enforcement Administration of the United States Department of Justice, the federal Food and Drug Administration, and the National Institute on Drug Abuse.

(b) Except as provided in AS 17.35.030(e), the therapeutic research program is limited to cancer chemotherapy and radiology patients and glaucoma patients, who are certified to the Patient Qualification Review Committee by a practitioner. A patient may not be admitted to the therapeutic research program without full disclosure by the practitioner of the experimental nature of this program and of the possible risks and side effects of the proposed treatment.

(c) The board shall provide by regulation for a program of registration of therapeutic research projects. (§ 5 ch 45 SLA 1982)

Sec. 17.35.030. Patient qualification review committee. (a) The board shall appoint a Patient Qualification Review Committee to serve at its pleasure. The committee shall consist of four members with the following qualifications:

(1) two physicians licensed to practice medicine in the state, one of whom specializes in the practice of ophthalmology;

Bethye Board just recently adopted regs (3 yrs. after law was passed) Never approved anyone to use marijuana.

(2) a physician licensed to practice medicine in the state who specializes in the practice of psychiatry; and

(3) a physician licensed to practice medicine in the state who specializes in the practice of radiology.

(b) Members of the Patient Qualification Review Committee receive no salary but are entitled to per diem for travel and expenses authorized by law for boards and commissions.

(c) The Patient Qualification Review Committee shall review all applicants for the therapeutic research program and their licensed practitioners and certify their participation in the program.

(d) The Patient Qualification Review Committee and the board shall protect the privacy of individuals who participate in the therapeutic research program by withholding the names and other identifying characteristics of those individuals from all persons who are not connected with the research. Persons authorized to engage in research under the therapeutic research program may not be compelled in any civil, criminal, administrative, legislative, or other proceeding to identify the individuals who are the subjects of research for which the authorization was granted unless necessary to permit the board to determine whether the research is being conducted in accordance with the authorization.

(e) The Patient Qualification Review Committee may include other disease groups for participation in the therapeutic research program. However, a practitioner must present pertinent medical data to both the committee and the board before a disease group may be added. The participation of a disease group must be approved by the board consistent with applicable regulations adopted by the Drug Enforcement Administration of the United States Department of Justice, the federal Food and Drug Administration, and the National Institute on Drug Abuse. (§ 5 ch 45 SLA 1982)

Sec. 17.35.040. Sources, distribution and possession of marijuana. (a) A patient who is certified to participate in the therapeutic research program by the Patient Qualification Review Committee may obtain and possess marijuana, its derivatives, or its active ingredients, whether synthetic or natural, for the patient's own use.

(b) The board shall establish procedures by which a person authorized under this section to possess marijuana, its derivatives or active ingredients, whether synthetic or natural, may do so, subject to applicable regulations adopted by the Drug Enforcement Administration of the United States Department of Justice, the United States Food and Drug Administration, and the National Institute on Drug Abuse. (§ 5 ch 45 SLA 1982)

Sec. 17.35.050. Report to the governor and legislature. The board, in conjunction with the Patient Qualification Review Committee, shall report its findings and recommendations to the governor and the legislature regarding the effectiveness of the therapeutic research program by March 1, 1984. (§ 5 ch 45 SLA 1982)

Sec. 17.35.500. Definitions. In this chapter

(1) "board" means the Board of Pharmacy;

(2) "marijuana" has the meaning set out in AS 11.71.900(14);

(3) "practitioner" means a physician authorized to practice medicine in the state under AS 08.64. (§ 5 ch 45 SLA 1982)

Revisor's notes. — Enacted as AS 17.35.060. Renumbered in 1982.

HB641

The Board of Pharmacy, consisting of seven members, regulates and licenses pharmacists, retail and wholesale pharmacies, hospital pharmacies, and drug rooms. The Board terminated June 30, 1985 and has until June 30, 1986 to conclude its affairs. The Legislative Audit report recommends that the Board be reestablished. The Audit report also recommends that the Board review the controlled substance registration statute for duplication of existing federal registration requirements. In addition, the audit supports the Board's recommendation to repeal the Marijuana Therapeutic Research Program, which permits the use of marijuana in the treatment of cancer. According to the medical community, the availability of superior, less costly substances diminishes the need for the program.

Copies of the audits are attached. Also attached are resumes of appointments to these two boards which have been referred to the committee for confirmation. The hearing will be teleconferenced to Anchorage and Fairbanks.

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
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STATE OF ALASKA

AUDIT DIVISION
POUCH W
JUNEAU, ALASKA 99811

THE LEGISLATURE

BUDGET AND AUDIT COMMITTEE

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, 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.

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REPORT CONCLUSION

Policy Issues

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

Report Conclusion

In our opinion, the [redacted] 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 perforrns 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 Recommer ıation 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.

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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

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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

adopted

PROPOSED AMENDMENT

DEPARTMENT OF LAW

DRAFT

DATE:

BOOKPROOFED:

APPROVED:

[redacted]

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

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

(a) A person who manufactures, distributes, dispenses, or con ducts research with a controlled substance in the state or who pro poses to manufacture, distribute, or dispense a controlled substan in the state, shall comply with the registration requirements of th federal Controlled Substances Act, 21 U.S.C. sec. 811 -- 830, and th regulations adopted under those sections, 21 C.F.R. 1301 -- 1318 [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] t manufacture, distribute, dispense, or conduct research with controlle substances in the state may possess, manufacture, distribute, dis pense, or conduct research with those substances to the exten authorized by the person's registration and in conformity with th 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 reason able times and in a reasonable manner to inspect the premises an records required to be maintained under federal law. An inspectio shall not extend to financial data, pricing data, or sales data, othe

Board had this authority in past.

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.F.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 pertainin to illicit traffic in controlled substances and in suppressing th abuse of controlled substances. Under this section, the powers of th commissioner of public safety include but are not limited to th 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 with 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

DEPARTMENT OF LAW

DRAFT

DATE:

BCOMPROOFED:

APPROVED:

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

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

Sec. 17.30.155. CONFIDENTIALITY OF CERTAIN INFORMATION.
practitioner engaged in medical practice or research may not disclos
[FURNISH] the name or identity of a patient or research subject [T
THE BOARD. THE PRACTITIONER MAY NOT OTHERWISE DISCLOSE THE NAME O
IDENTITY OF AN INDIVIDUAL] that the practitioner is required to kee
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.

delete reference to Board in controlled substance statute

MEMORANDUM

TO: ALL MEMBERS OF THE HOUSE
FROM: REPRESENTATIVE MAX F. GRUENBERG, JR.
DATE: APRIL 25, 1986
RE: THE MARIJUANA THERAPEUTIC RESEARCH PROGRAM

The 1982 Controlled Substances legislation contained provisions setting up the Marijuana Therapeutic Research Program to permit the use of marijuana and its active derivative ingredient (THC) in the treatment of glaucoma, in cancer chemotherapy and radiology. Under the legislation, the Board of Pharmacy was to develop regulations and set up a Patient Qualification Review Committee (PQRC), by which patients and their physicians would be reviewed for admittance to the program.

The regulations for the program were not approved until 29 months after the legislation was passed, and the PQRC has never met. In fact, the PQRC has recommended that the program is unnecessary and should be abandoned.

On the federal level, the new THC drug, Marinol, has been approved by the Food and Drug Administration and is currently awaiting re-classification as a Controlled Substance II so that it can be made available in local pharmacies. During the interim, Providence Hospital in Anchorage has the authority from the FDA to dispense investigational drugs (the current category of Marinol), and can obtain Marinol for patients from the National Cancer Institute. However, since Alaska law requires approval of the PQRC for a patient to obtain the drug, and this is <u>not</u> a federal requirement, no patient in Alaska has been able to obtain the drug because the committee has never met.

Repeal of the Marijuana Therapeutic Research Program would allow physicians in the state to request this drug for their patients directly from Providence Hospital pharmacy.

The manager of Providence Hospital Pharmacy, Jackie Warren, will be happy to speak with any legislator or staff on the subject. She can be reached from 7:00 a.m. to 3:30 p.m. at 562-2211.

SENATE H.E.S.S. COMMITTEE FEBRUARY 20, 1986

TELECONFERENCED TO ANCHORAGE AND FAIRBANKS: NO OTHER SITES AVAILABLE.

SUNSET REVIEW OF BOARD OF PHARMACY; CURRENTLY IN ITS WIND-DOWN YEAR.

TO TESTIFY: Nancy Dunn JENNY STRICKLER, DIV. OCCUPATIONAL LICENSING

BILL LARSON, BOARD PRESIDENT (ANCHORAGE)

TOM MIKLAUTSCH (HE'S IN ANCHORAGE)

RICK URION, MEDICAL ASSOCIATION

AUDIT RECOMMENDS:

1. CONTINUE BOARD
2. REPEAL CONTROLLED SUBSTANCE REGISTRATION. (DUPLICATES FEDERAL LAW. INVESTIGATION AND ENFORCEMENT BY DEPT. PUBLIC SAFETY WILL CONTINUE. A.G. RECOMMENDS ADDING LANGUAGE REFERENCING THE FEDERAL REGISTRATION.)
3. REPEAL MARIJUANA THERAPEUTIC RESEARCH PROGRAM (NOT USED. SYNTHETIC MARIJUANA CAPSULES APPROVED BY F.D.A. AS PRESCRIPTION DRUG. LESS CHANCE OF ABUSE WITH THIS SUBSTANCE.)

AUDIT DOES NOT RECOMMEND FUNDING AN EXECUTIVE SECRETARY FOR THE BOARD. BOARD HAS EMPHASIZED THAT PUTTING PHARMACEUTICALS INTO THE MEDICAID PROGRAM IS A SEPARATE ISSUE AND SHOULD NOT BE TIED TO CONTINUATION OF THE BOARD.

HOUSE HAS INTRODUCED:

HB 566 (MARROU) EXTEND 1 ADDITIONAL YEAR.

HB 641 (GRUENBERG) EXTEND 4 YEARS, ADD GENERIC DRUGS, REPEAL CONTROLLED SUB.

LATEST FIGURES AVAILABLE ARE FOR FY 82:

REVENUES	$ 42,763
EXPENDITURES	$ 46,166
LICENSE FEE	$50/YEAR

Collateral references. — 25 Am. Jur. 2d, Drugs, Narcotics, and Poisons, §§ 7, 10-15.

28 C.J.S. Supp., Drugs and Narcotics, §§ 28, 29.

Article 1. The Board of Pharmacy.

Section

10. Creation and membership of Board of Pharmacy
20. Term of office
30. Powers of the board
40. Duties of the board
45. Nonprescription drugs
50. Applicability of Administrative Procedure Act
60. Meetings of the board
70. Quorum
80. Expenses of members
90. Disposition of fees
100. [Repealed]
105. Removal of board members

Sec. 08.80.010. Creation and membership of Board of Pharmacy. There is created the Board of Pharmacy, composed of seven members, five of whom shall be pharmacists licensed in the state who have been actively engaged in the practice of pharmacy in the state for a period of three years immediately preceding their appointment. Two shall be persons with no direct financial interest in the health care industry. Whenever possible, the board shall include at least one member from each judicial district. (§ 3 ch 194 SLA 1955; am § 25 ch 102 SLA 1976)

Cross references. — As to constitutionality of ch. 102, SLA 1976, see notes to AS 09.55.536 and Alas. Const., art. II, § 14.

Sec. 08.80.020. Term of office. Members of the board are appointed by the governor, and confirmed by the legislature in joint session, for overlapping terms of four years, or until their successors are appointed and qualified. The terms of the public members shall be staggered so that they do not expire at the same time. An appointment to fill a vacancy is for the unexpired term. The term of office begins on April 1 of each year. A person who has served two successive complete terms may not be reappointed until four years from the expiration of the second term. (§ 3 ch 194 SLA 1955; am § 26 ch 102 SLA 1976; am § 3 ch 166 SLA 1980)

Effect of amendments. — The 1980 amendment substituted "four" for "five" preceding "years" in the first sentence, "not" for "no" preceding "expire" in the second sentence, and added the present fourth sentence.

Sec. 08.80.030. Powers of the board. The board may

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

(2) examine applicants for registration as pharmacists;

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

(4) adopt regulations and do whatever else is necessary and advisable to carry out the purposes of this chapter;

(5) promulgate regulations to carry out the purposes of this chapter;

(6) Repealed by § 21 ch 166 SLA 1980.

(7) register intern pharmacists and promulgate rules relating to their minimum experience requirements;

(8) promulgate regulations to ensure adequate security for all dangerous drugs;

(9) adopt requirements for licensing in addition to the requirements set out in this chapter. (§ 4 ch 194 SLA 1955; am § 1 ch 72 SLA 1969; am § 9 ch 69 SLA 1970; am § 1 ch 206 SLA 1972; am § 1 ch 187 SLA 1976; am §§ 4, 21 ch 166 SLA 1980)

Effect of amendments. — The 1980 amendment added paragraph (9), and repealed paragraph (6), which read: "Examine applicants for shopkeeper permits."

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 by § 21 ch 166 SLA 1980.

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

(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;

(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;

(7) Repealed by § 21 ch 166 SLA 1980.

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

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

(10) **[Effective January 1, 1983]** provide for the regulation of controlled substances under AS 17.30. (§ 5 ch 194 SLA 1955; am § 2 ch 206 SLA 1972; am §§ 5, 6, 21 ch 166 SLA 1980; am § 7 ch 45 SLA 1982)

Effect of amendments. — The 1980 amendment deleted "each examination shall be graded by a member who resides in a judicial district other than the district in which the applicant resides" following "pharmacists" at the end of paragraph (1), added paragraphs (8) and (9), and repealed paragraphs (3) and (7), which read, respectively: "(3) initiate prosecution of any person violating this chapter," and "(7) issue shopkeeper permits in accordance with § 380 of this chapter."

The 1982 amendment, effective January 1, 1983, added paragraph (10).

Sec. 08.80.045. Nonprescription drugs. (a) Except as provided in (b) of this section the board may not regulate the sale of patent or nonprescription drugs which are prepackaged for use by the consumer, are in their original, unbroken packaging, and are labeled in accordance with requirements of the federal government.

(b) The board may regulate the sale and distribution of patent or nonprescription drugs under AS 44.62.250 when the regulation is required by an emergency to protect the public health and safety. (§ 7 ch 166 SLA 1980)

Sec. 08.80.050. Applicability of Administrative Procedure Act. The board shall comply with the Administrative Procedure Act (AS 44.62).

Sec. 08.80.060. Meetings of the board. The board shall meet at least once each year at the call of the president for the transaction of business properly before it. The president shall also call the board into session when requested in writing by at least two members. The secretary shall give at least 30 days written notice to all members before a meeting. (§ 6 ch 194 SLA 1955)

Sec. 08.80.070. Quorum. Four members constitute a quorum for the transaction of business. However, when the board meets for the purpose of examining applications for registration, three members of the board constitute a quorum. (§ 6 ch 194 SLA 1955; am § 27 ch 102 SLA 1976)

Cross references. — As to constitutionality of ch. 102, SLA 1976, see notes to AS 09.55.536 and Alas. Const., art. II, § 14.

Sec. 08.80.080. Expenses of members. Members of the board are entitled to reimbursement for actual travel expenses incidental to the discharge of their duties and, while in the performance of their duties, are entitled to the per diem expenses allowed by law. (§ 7 ch 194 SLA 1955)

Sec. 08.80.090. Disposition of fees. The fees collected by the secretary of the board shall be deposited in the general fund of the state. (§ 21 ch 194 SLA 1955)

Sec. 08.80.100. Board secretary as certifying officer. Repealed by § 3 ch 59 SLA 1966.

Editor's notes. — The repealed section derived from § 21, ch. 194, SLA 1955.

Sec. 08.80.105. Removal of board members. A member of the board may be removed from office by the governor for cause. The board may by regulation provide that unexcused absences from meetings constitute cause for removal. (§ 8 ch 166 SLA 1980)

Article 2. Licensing and Registration.

Section
110. Qualifications for registration
115. [Repealed]
116. License of pregraduate and postgraduate intern pharmacist
117. [Repealed]
120. Grading and content of examination
130. Reexamination
140. License by credentials
150. Temporary license
155. Emergency permit
157. Retail and wholesale licenses
160. Fees

Section
170—210. [Repealed]
220. Prescription department required for issuance of license
230. Sanitary conditions required for issuance of license
240. Form and display of registration certificate and license
250—260. [Repealed]
261. Grounds for imposition of disciplinary sanctions
265. [Repealed]
266. Disciplinary sanctions

Collateral references. — 25 Am. Jur. 2d, Drugs, Narcotics, and Poisons, §§ 10-15.

28 C.J.S., Supp. Drugs and Narcotics, §§ 29, 30.

Sec. 08.80.110. Qualifications for registration. An applicant for registration as a pharmacist shall

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

(2) furnish the board with at least two affidavits from reputable citizens, that the applicant has known for at least one year, attesting to the applicant's good moral character and freedom from addiction to the use of drugs or alcoholic liquors;

(3) be a graduate of a college of pharmacy recognized by the National Association of Boards of Pharmacy;

(4) pass an examination by a board of pharmacy which has been approved by the National Association of Boards of Pharmacy;

(5) have completed at least 1,500 hours of internship training under the direct supervision of a licensed pharmacist in a licensed pharmacy, 160 hours of which must have been completed after graduation. (§ 8 ch 194 SLA 1955; am § 1 ch 24 SLA 1968; am § 2 ch 72 SLA 1969; am

§§ 3, 4 ch 206 SLA 1972; am § 16 ch 127 SLA 1974; am §§ 9, 10 ch 166 SLA 1980)

Effect of amendments. — The 1980 amendment deleted "board" preceding "has been approved" in paragraph (4), and substituted "160" for "540" in paragraph (5).

Editor's notes. — This section was redrafted by the revisor of statutes to remove personal pronouns in conformity with AS 01.05.031(c) and § 4, Chapter 58, SLA 1982.

NOTES TO DECISIONS

Cited in Hicklin v. Orbeck, Sup. Ct. Op. No. 1435 (File No. 3025), 565 P.2d 159 (1977).

Sec. 08.80.115. Registration of pregraduate and postgraduate intern pharmacist.

Repealed by § 40 ch 177 SLA 1978.

Editor's notes. — The repealed section derived from § 5, ch. 206, SLA 1972.

As to purpose of repealing act, see § 1, ch. 177, SLA 1978 as amended by § 7, ch. 46, SLA 1982, in the 1982 Temporary and Special Acts and Resolves.

Sec. 08.80.116. License of pregraduate and postgraduate intern pharmacist. (a) An applicant for license as a postgraduate intern pharmacist must meet the requirements of AS 08.80.110(1) — (3) and pay the required fee.

(b) An applicant for license as a pregraduate pharmacist must meet the requirements of AS 08.80.110(1) and (2) and must be enrolled in a pharmacy school recognized by the National Association of Board of Pharmacy as a junior. An applicant may be on recognized vacation from the pharmacy school. However, the vacation may not exceed one quarter or one semester. The pregraduate internship pharmacist shall pay the required fee.

(c) The license of a postgraduate or pregraduate internship pharmacist is valid for one year and may be renewed upon application. (§ 6 ch 94 SLA 1980; § 11 ch 166 SLA 1980)

Sec. 08.80.117. Malpractice insurance.

Repealed by § 7 ch 94 SLA 1980 and § 21 ch 166 SLA 1980.

Editor's notes. — The repealed section derived from § 28, ch. 102, SLA 1976.

Sec. 08.80.120. Grading and content of examination. To pass the state pharmacy examination each applicant must attain a general average of not less than 75 percent and a grade of not less than 60 per cent in any one category of the National Association of Board of Pharmacy Standard Examinations for licensure or an equivalent examina-

tion given by the board. (§ 89 ch 194 SLA 1955; am § 2 ch 24 SLA 1968; am § 6 ch 206 SLA 1972; am § 1 ch 50 SLA 1974)

Sec. 08.80.130. Reexamination. An applicant unsuccessful in an initial examination may take a second examination within one year without further application and upon payment of the reexamination fee. If the applicant fails to take a second examination within one year, the applicant must submit a new application for any examination. (§ 8 ch 194 SLA 1955; am § 7 ch 206 SLA 1972)

Editor's notes. — This section was redrafted by the revisor of statutes to remove personal pronouns in conformity with AS 01.05.031(c) and § 4, Chapter 58, SLA 1982.

Sec. 08.80.140. License by credentials. The board may license an applicant who has been certified as a registered pharmacist by the National Association of Boards of Pharmacy if the applicant meets the requirements under AS 08.80.110 and passes the state jurisprudence examination. (§ 8 ch 194 SLA 1955; am § 3 ch 24 SLA 1968; am § 3 ch 72 SLA 1969; am § 8 ch 206 SLA 1972; am § 12 ch 166 SLA 1980)

Effect of amendments. — The 1980 amendment substituted "license" for "register without examination" and "under AS 08.80.110 and passes the state jurisprudence examination" for "of AS 08.80.110(1) — (4)."

Sec. 08.80.150. Temporary license. The board, or a member of the board, may issue a temporary license to an applicant applying for a license under AS 08.80.140 upon written or oral examination before a member of the board and certification by the member to the secretary of the board that the applicant is competent to receive a temporary license. The temporary license is valid for three months, or until the next regular meeting of the board, whichever is longer. A temporary license is not renewable, but at the discretion of the issuing board member may be extended for a period not to exceed 60 days, and an applicant may not receive more than one temporary license. An applicant whose license has been denied by the board is not eligible to receive a temporary license. (§ 9 ch 194 SLA 1955; am § 9 ch 206 SLA 1972; am § 13 ch 166 SLA 1980)

Effect of amendments. — The 1980 amendment substituted "or a member of the board, may" for "shall," at the beginning of the section, "a license under AS 08.80.140" for "registration as a pharmacist under AS 08.80.140," near the beginning of the section, and "license" for "registration" in the last sentence.

Sec. 08.80.155. Emergency permit. (a) The board, or a member of the board, may grant an emergency permit to a pharmacist for the purpose of providing coverage in a pharmacy which is temporarily without the services of a pharmacist due to death, illness or other emergency circumstances.

(b) A pharmacist applying under (a) of this section must submit proof that the pharmacist holds a license in good standing in a state recognized by the National Association of Boards of Pharmacy, and pay the fee required under AS 08.80.160.

(c) A permit issued under this section is valid for a period not to exceed 60 days. (§ 10 ch 206 SLA 1972; am § 14 ch 166 SLA 1980)

Effect of amendments. — The 1980 amendment inserted "or a member of the board," and deleted "in its discretion" preceding "grant an emergency permit" near the beginning of subsection (a).

Editor's notes. — This section was redrafted by the revisor of statutes to remove personal pronouns in conformity with AS 01.05.031(c) and § 4, Chapter 58, SLA 1982.

Sec. 08.80.157. Retail and wholesale licenses. (a) If an applicant furnishes proof satisfactory to the board that the applicant is equipped with land, facilities, and equipment, in fee or leased, necessary to carry on the business described in the application and the applicant complies with this chapter, applicable regulations adopted by the board, and pays fees provided for under AS 08.80.160, the board may issue

(1) a wholesale drug dealer license to an applicant who manufactures or distributes noncontrolled legend drugs to licensed retail pharmacists, dentists, physicians, surgeons, or veterinarians, who may legally purchase noncontrolled legend drugs at a wholesale level, or to government agencies which may legally purchase noncontrolled legend drugs at a wholesale level;

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

(3) a license to a retail pharmacy.

(b) A license under this section may not be issued to a person who has been convicted of a wilful violation of a federal law or a law of any state relating to a drug or controlled substance, or who is addicted to a drug or controlled substance. A license may not be issued to a corporation with a managing officer who has been convicted of a wilful violation of a federal law or a law of any state relating to a drug or controlled substance, or who is addicted to a drug or controlled substance. (§ 15 ch 166 SLA 1980)

Editor's notes. — This section was redrafted by the revisor of statutes to remove personal pronouns in conformity with AS 01.05.031(c) and § 4, Chapter 58, SLA 1982.

Sec. 08.80.160. Fees. The following fees shall be imposed under this chapter when applicable:

(1) examination fee	$ 50
(2) reexamination fee	$ 15
(3) investigation fee for licensing by credentials	$ 25

Chapter 80. Pharmacy Act.

Article
1. The Board of Pharmacy (§ 08.80.090)
2. Licensing and Registration (§ 08.80.160)
3. Duties of Licensed Pharmacists (§ 08.80.295)

Article 1. The Board of Pharmacy.

Section
90. [Repealed]

Sec. 08.80.090. Disposition of fees. [See postponed repeal note.]

Postponed repeal. — The 1985 repeal of this section is effective upon the adoption of regulations under AS 08.01.065.

Article 2. Licensing and Registration.

Section
160. Fees

Sec. 08.80.160. Fees [See effective date note]. 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. (§ 10(a) ch 194 SLA 1955; am § 4 ch 24 SLA 1968; am § 11 ch 206 SLA 1972; am §§ 16, 21 ch 166 SLA 1980; am § 45 ch 37 SLA 1985)

Effect of amendments. — The 1985 amendment rewrote this section, which included a fee schedule.

Effective dates. — The 1985 amendment to this section is effective upon the adoption of regulations under AS 08.01.065. For the law until that date, see the main pamphlet.

(4) pharmacist license fee and renewal fee due every four years $200
(5) temporary license fee . . . . . $ 20
(6) wholesale drug dealer license fee and renewal fee due every four years $200
(7) retail pharmacy license fee and renewal fee due every four years $200
(8) pharmacy intern license fee . . . . . $ 10
(9) emergency permit fee . . . . . $ 10
(10) hospital pharmacy license fee and renewal fee due every four years (in and outpatient) $200
(11) hospital drug room license fee and renewal fee due every four years (inpatient) $100
(12) nursing home and related facilities license fee and renewal fee due every four years for inpatient dispensing . . $100
(13) Repealed by § 21 ch 166 SLA 1980.
(14) license amendment or replacement fee . . . . . $ 10.

(§ 10(a) ch 194 SLA 1955; am § 4 ch 24 SLA 1968; am § 11 ch 206 SLA 1972; am §§ 16, 21 ch 166 SLA 1980)

Effect of amendments. — The 1980 amendment, in paragraph (3), deleted "reciprocity" preceding "investigation fee," and added "for licensing by credentials"; in paragraph (4), deleted "biennial" preceding "pharmacist" and added "and renewal fee due every four years"; in paragraphs (6), (7), and (10) — (12), deleted "biennial" preceding "license fee" and added "and renewal fee due every four years"; in paragraph (8), substituted "license" for "registration"; substituted "$200" for "$50" in paragraphs (4), (6), (7), and (10); substituted "$20" for "$10" in paragraph (5); substituted "$100" for "$25" in paragraphs (11) and (12); substituted "$10" for "$2" in paragraph (14); and repealed former paragraph (13), which read: "shopkeepers biennial permit fee . . . . . $10."

Secs. 08.80.170 — 08.80.210. Fees.

Repealed by § 7 ch 24 SLA 1968.

Editor's notes. — The repealed sections derived from §§ 10 (b) — 10(f), ch. 194, SLA 1955.

Sec. 08.80.220. Prescription department required for issuance of license. The board shall issue a license to operate a pharmacy only to an establishment which operates a bona fide prescription department. (§ 10 ch 194 SLA 1955)

Sec. 08.80.230. Sanitary conditions required for issuance of license. Failure to have proper sanitary appliances and to maintain orderly and sanitary premises are grounds for refusing a license to a pharmacy. (§ 10 ch 194 SLA 1955)

Sec. 08.80.240. Form and display of registration certificate and license. The registration certificate and license shall be in the form, and issued in the manner prescribed by the board. The license and certificate shall be conspicuously displayed in the premises for which issued or in which the licensee is employed. (§ 10 ch 194 SLA 1955)

Secs. 08.80.250 — 08.80.260. Renewal of lapsed registration; grounds for refusing or revoking a license.

Repealed by § 21 ch 166 SLA 1980.

Cross references. — As to grounds for imposition of disciplinary sanctions, see AS 08.80.261.

Editor's notes. — The repealed sections derived from §§ 10, 14, ch. 194, SLA 1955; §§ 5, 6, ch. 24, SLA 1968; § 12, ch. 206, SLA 1972; § 33, ch. 177, SLA 1978.

Sec. 08.80.261. Grounds for imposition of disciplinary sanctions. The board may, after a hearing, impose a disciplinary sanction on a person licensed under this chapter when the board finds that the licensee

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

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

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

(4) has been convicted of a felony or other crime that affects the licensee's ability to continue to practice competently and safely;

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

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

(7) continued to practice after becoming unfit due to

(A) professional incompetence;

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

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

(D) physical or mental disability;

(8) engaged in lewd or immoral conduct in connection with the delivery of professional service to patients;

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

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

(11) violated state or federal regulations pertaining to the provision of adequate security for dangerous drugs. (§ 17 ch 166 SLA 1980; AS 08.80.260; am § 9 ch 59 SLA 1982)

Effect of amendments. — The 1982 amendment, effective May 28, 1982, redrafted this section to conform to current drafting style.

Editor's notes. — This section was enacted as AS 08.80.260 but was renumbered by the revisor of statutes pursuant to AS 01.05.031(b).

This section was redrafted by the revisor of statutes to remove personal pronouns in conformity with AS 01.05.031(c) and § 4, Chapter 58, SLA 1982.

Collateral references. — What amounts to conviction within statute making conviction a ground for refusing or cancelling license or special privilege. 113 ALR 1179.

Revocation or suspension of license or permit to practice pharmacy or operate drugstore because of improper sale or distribution of narcotic or stimulant drugs. 17 ALR3d 1408.

Sec. 08.80.265. Limits or conditions on license; discipline.

Repealed by § 21 ch 166 SLA 1980.

Cross references. — As to disciplinary sanctions, see AS 08.80.266.

Editor's notes. — The repealed section derived from § 28, ch. 102, SLA 1976.

Sec. 08.80.266. Disciplinary sanctions. (a) When it finds that a 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;

(2) suspend a license for a determinate period of time;

(3) censure a licensee;

(4) issue a letter of reprimand;

(5) place a licensee on probationary status and require the licensee to

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

(B) limit practice 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 of a licensee.

(b) The board may withdraw probationary status if it finds that the deficiencies that required the sanction have been remedied.

(c) The board may summarily suspend a license before final hearing or during the appeals process if the board finds that the licensee poses a clear and immediate danger to the public health and safety if the licensee continues to practice. A person whose license 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.

(d) The board may reinstate a license that has been suspended or revoked if the board finds after a hearing that the applicant is able to practice with skill and safety.

(e) The board shall seek consistency in the application of disciplinary sanctions, and significant departure from prior decisions involving similar situations shall be explained in findings of fact or orders. (§ 18 ch 166 SLA 1980; AS 08.80.265; am § 10 ch 59 SLA 1982)

Effect of amendments. — The 1982 amendment, effective May 28, 1982, redrafted this section to conform to current drafting style.

Editor's notes. — This section was enacted as AS 08.80.265 but was renumbered by the revisor of statutes pursuant to AS 01.05.031(b).

This section was redrafted by the revisor of statutes to remove personal pronouns in conformity with AS 0.05.031(c) and § 4, Chapter 58, SLA 1982.

Article 3. Duties of Licensed Pharmacists.

Section
270. Report of employee
280. Responsibility for goods sold
290. Affixing of label
295. Substitution
297. Prescription prices available to consumer
300. Record of prescriptions
310. Record of sales
320. Pharmacist required
330. Licensed pharmacist as manager
340. Who may prepare prescriptions
350. Technical aids required
360. Sale of dangerous materials
365. Partial closure of pharmacy

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 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. (§ 11(a) ch 194 SLA 1955; am § 13 ch 206 SLA 1972)

Editor's notes. — This section was redrafted by the revisor of statutes to remove personal pronouns in conformity with AS 01.05.031(c) and § 4, Chapter 58, SLA 1982.

Sec. 08.80.280. Responsibility for goods sold. An owner, or, if the owner is not a licensed pharmacist, a manager of a pharmacy, is responsible for the quality of drugs, chemicals and other medicines sold or dispensed by the owner or manager, except those sold in the original packages of the manufacturer, and except those articles and preparations known as patent or proprietary medicines. (§ 11(b) ch 194 SLA 1955)

Editor's notes. — This section was redrafted by the revisor of statutes to remove personal pronouns in conformity with AS 01.05.031(c) and § 4, Chapter 58, SLA 1982.

Collateral references. — 25 Am. Jur. 2d, Drugs, Narcotics, and Poisons, §§ 8, 9.

28 C.J.S., Supp. Drugs and Narcotics, §§ 32-35.

Sec. 08.80.290. Affixing of label. At the time of dispensing a prescription, there shall be affixed to the container of a prescription, a label bearing the name and address of the pharmacy compounding the prescription, the serial number of the prescription, the name and directions of the prescriber, the name of the patient, the date of dispensing, and the initials of the registered pharmacist who compounded the prescription. In addition a pharmacist shall indicate on the drug container the name and strength of the drug contained in it, unless specifically directed otherwise by the prescribing physician, osteopathic physician, dentist or veterinarian. If a drug is a mixture of pharmacologically active substances, only the name of the mixture need be indicated on the container, or in the absence of a name, the term "physician's mixture" may be used. (§ 11(c) ch 194 SLA 1955; am § 14 ch 206 SLA 1972)

Sec. 08.80.295. Substitution. (a) 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 which is, in the pharmacist's professional opinion, therapeutically equivalent and meets the standards of (g) of this section. Upon substitution the pharmacist shall notify the purchaser and the person who prescribed the drug of the substitution and of the drug substituted.

(b) A person authorized to prescribe drugs shall specify in writing or by oral communication whether or not the pharmacist may substitute a drug under (a) of this section. Written specification may be accomplished either by (1) the physician personally initialing or checking the appropriate box on a prescription order form labeled "DISPENSE AS WRITTEN" or "SUBSTITUTION ALLOWED"; or (2) by handwriting on the prescription order. If the physician fails or neglects to give written specification, the prescription shall be dispensed as written. If the person communicating the specification does so orally, the pharmacist shall indicate that fact in handwriting on the written copy of the prescription order.

(c) Preprinted prescription order forms used by a person authorized to prescribe drugs shall contain boxes labeled "DISPENSE AS WRITTEN" and "SUBSTITUTION ALLOWED" to be checked or initialed by the person issuing the prescription.

(d) A pharmacist shall substitute a drug product under (a) of this section only when there will be a savings in cost to the purchaser.

(e) For a period of two years following September 16, 1976, 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.

Article 3. Duties of Licensed Pharmacists.

Section
295. Substitution

Sec. 08.80.295. Substitution. (a) 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 which is, in the pharmacist's professional opinion, therapeutically equivalent and meets the standards of (g) of this section. Upon substitution the pharmacist shall notify the purchaser and the person who prescribed the drug of the substitution and of the drug substituted.

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(c) Preprinted prescription order forms used by a person authorized to prescribe drugs shall contain boxes labeled "DISPENSE AS WRITTEN" and "SUBSTITUTION ALLOWED" to be checked or initialed by the person issuing the prescription.

(d) A pharmacist shall substitute a drug product under (a) of this section only when there will be a savings in cost to the purchaser.

(e) *[Repealed, § 31 ch 6 SLA 1984.]*

(f) If a person authorized to prescribe drugs is temporarily unavailable, the pharmacist may, if the pharmacist cannot supply the drug requested, substitute a drug or preparation of approximately equal therapeutic value so long as the pharmacist notifies the author of the prescription at an early opportunity. The pharmacist in all cases of substitution, except when specifically indicated to the contrary by the prescriber, shall relate the nature of the change to the purchaser.

(g) A pharmacist may not substitute a product under the provisions of this section unless it has been manufactured with the following minimum good manufacturing standards and practices:

(1) maintain quality control standards equal to those of the Food and Drug Administration;

(2) comply with regulations promulgated by the Food and Drug Administration;

(3) mark products with identification code or monogram;

(4) label products with expiration date;

(5) provide reasonable services to accept returned goods that have reached their expiration date;

(6) maintain 24-hour resources for product information where practicable and financially feasible;

(7) maintain recall capabilities for unsafe or defective drugs;

(8) shall not refuse to sell to any proper[ly] licensed pharmacy.

(h) As used in this section, unless the context requires otherwise,

(1) "brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug, its container, label or wrapping at the time of packaging;

(2) "generic name" means the official title of a drug or drug ingredients published in the latest edition of a nationally recognized pharmacopoeia or formulary;

(3) "substitute" means to dispense without prescriber's express authorization a different drug product in place of the drug ordered or prescribed;

(4) "therapeutically equivalent" means drugs that will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen. (§ 15 ch 206 SLA 1972; am § 2 ch 187 SLA 1976; am § 8 ch 94 SLA 1980; am § 31 ch 6 SLA 1984)

Effect of amendments. — The 1984 amendment repealed former subsection (e), relating to pharmacies posting a sign as to substitution of drugs.

Chapter 84. Physical Therapists Practice Act.

Article
2. Registration (§§ 08.84.032, 08.84.050, 08.84.100)

Article 2. Registration.

Section
32. Foreign-trained physical therapy or physical therapy assistant applicants
50. Fees
100. Renewal of license

Sec. 08.84.032. Foreign-trained physical therapy or physical therapy assistant applicants [See effective date note]. To be eligible for licensure by the board as a physical therapist or physical therapy assistant, an applicant who is a graduate of a school of physical therapy that is located outside of the United States shall

(1) have completed, to the satisfaction of the board, a resident course of study and professional instruction equivalent to that provided by a school approved by the Council on Medical Education and Hospitals of the American Medical Association or the American

(f) If a person authorized to prescribe drugs is temporarily unavailable, the pharmacist may, if the pharmacist cannot supply the drug requested, substitute a drug or preparation of approximately equal therapeutic value so long as the pharmacist notifies the author of the prescription at an early opportunity. The pharmacist in all cases of substitution, except when specifically indicated to the contrary by the prescriber, shall relate the nature of the change to the purchaser.

(g) A pharmacist may not substitute a product under the provisions of this section unless it has been manufactured with the following minimum good manufacturing standards and practices:

(1) maintain quality control standards equal to those of the Food and Drug Administration;

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(5) provide reasonable services to accept returned goods that have reached their expiration date;

(6) maintain 24-hour resources for product information where practicable and financially feasible;

(7) maintain recall capabilities for unsafe or defective drugs;

(8) shall not refuse to sell to any properly licensed pharmacy.

(h) As used in this section, unless the context requires otherwise,

(1) "brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug, its container, label or wrapping at the time of packaging;

(2) "generic name" means the official title of a drug or drug ingredients published in the latest edition of a nationally recognized pharmacopoeia or formulary;

(3) "substitute" means to dispense without prescriber's express authorization a different drug product in place of the drug ordered or prescribed;

(4) "therapeutically equivalent" means drugs that will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen. (§ 15 ch 206 SLA 1972; am § 2 ch 187 SLA 1976; am § 8 ch 94 SLA 1980)

Revisor's note. — Subsection (e) is apparently obsolete.

Effect of amendments. — The 1980 amendment substituted "(g)" for "(f)" near the end of the first sentence of subsection (a).

Editor's notes. — This section was redrafted by the revisor of statutes to remove personal pronouns in conformity with AS 01.05.031(c) and § 4, Chapter 58, SLA 1982.

Sec. 08.80.297. Prescription prices available to consumer. A pharmacist shall disclose the price of filling any prescription when requested by the consumer. (§ 3 ch 187 SLA 1976)

Sec. 08.80.300. Record of prescriptions. Each pharmacy shall maintain a record of every prescription compounded or dispensed. The record shall be kept for a period of not less than five years, and shall be open at all times to inspection by the board, its members, agents or employees, and by the medical doctor who issued the prescription. (§ 11(d) ch 194 SLA 1955)

Sec. 08.80.310. Record of sales. (a) The owner, or, if the owner is not a licensed pharmacist, the manager, of every drug store, shall maintain in that place of business a record in which sales of the following items shall be entered: the compounds and salts of arsenic and mercury (calomel excepted); caustic hydrates of sodium and potassium; the concentrated mineral acids; hydrocyanic acids and their salts; yellow phosphorous; the essential oils of pennyroyal, tansy and savine; croton oil, aconite; carbolic acid; and the poisonous alkaloids or alkaloidal salts.

(b) The record shall state the quantity and date of purchase, the purpose for which it is to be used, and the name and address of the buyer. The record shall be available during hours of business and subject to inspection by the attorney general, a federal, state or municipal peace officer, acting within the area of the attorney general's or peace officer's jurisdiction, and an authorized agent of the board. A record of each sale shall be retained for a period of five years from the date of the sale. (§ 11(e) ch 194 SLA 1955; am § 16 ch 206 SLA 1972)

Editor's notes. — This section was redrafted by the revisor of statutes to remove personal pronouns in conformity with AS 01.05.031(c) and § 4, Chapter 58, SLA 1982.

Sec. 08.80.320. Pharmacist required. (a) A pharmacy shall have a pharmacist, licensed and registered under this chapter, on duty during the hours that the pharmacy is open for business.

(b) In communities which have one licensed pharmacy, the owner of the pharmacy shall have a pharmacist, licensed and registered under this chapter, on duty, or on call, at all times that the pharmacy is open for business. (§ 11(f) (i) ch 194 SLA 1955; am § 17 ch 206 SLA 1972)

Collateral references. — Construction of statutes in relation to operation of drugstore, pharmacy or chemical store. without registered pharmacist. 74 ALR 1084.

Sec. 08.80.330. Licensed pharmacist as manager. (a) If the owner of a pharmacy is not a licensed pharmacist, the owner shall place a licensed pharmacist, designated the manager, in full charge and control of the pharmacy. The manager shall insure compliance with all laws, rules and regulations governing the operation of the pharmacy. A licensed pharmacist appointed as manager of a pharmacy shall immediately advise the board of that appointment.

(b) A license may not be issued to a pharmacy unless there is a licensed registered pharmacist in charge whose name appears on the face of the license. (§ 11(g) ch 194 SLA 1955; am § 18 ch 206 SLA 1972)

Editor's notes. — This section was redrafted by the revisor of statutes to remove personal pronouns in conformity with AS 01.05.031(c) and § 4, Chapter 58, SLA 1982.

Sec. 08.80.340. Who may prepare prescriptions. 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. (§ 11(h) ch 194 SLA 1955; am § 19 ch 206 SLA 1972)

Sec. 08.80.350. Technical aids required. Each licensed pharmacy shall have on the premises a copy of the most recent revision of the "United States Dispensatory" or "Remington's Practice of Pharmacy" or both the "National Formulary" and the "United States Pharmacopoeia." In addition, each pharmacy shall have sufficient technical equipment to properly compound prescriptions and pharmaceutical preparations. No license may be issued until the requirements of this section are met. (§ 11(j) ch 194 SLA 1955; am § 20 ch 206 SLA 1972)

Sec. 08.80.360. Sale of dangerous materials. Drugs or medical supplies which contain poisonous, potent, habit-forming or deleterious ingredients 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. (§ 11(k) ch 194 SLA 1955)

Sec. 08.80.365. Partial closure of pharmacy. A pharmacy or pharmacy drug department which is open for business at times different than the remainder of the store or building in which the pharmacy is located shall

(1) be accessible to the remainder of the store or building only through an entrance which is capable of being locked;

(2) Repealed by § 21 ch 166 SLA 1980.

(3) be locked during nonbusiness hours; and

(4) have all keys to the pharmacy or drug department in the possession of a pharmacist, licensed and registered under this chapter. (§ 21 ch 206 SLA 1972; am § 21 ch 166 SLA 1980)

Effect of amendments. — The 1980 amendment repealed paragraph (2), which read: "be advertised by the methods described in §§ 420 and 430 of this chapter only if the signs or symbols are attached or located within the portions of the store or building where the pharmacy is located."

Article 4. Unlawful Acts.

Section
370. Vending machine sales prohibited
380. [Repealed]
390. Pharmacists required in hospitals and clinics
400. Practice of medicine not affected
410. Use of term "pharmacist" prohibited
420. Certain advertising prohibited
430. Use of pharmacy symbols prohibited
440. Denial of examination or license
450. Disciplinary action
460. Violation

Collateral references. — 25 Am. Jur. 2d, Drugs, Narcotics, and Poisons, §§ 7, 14.

28 C.J.S., Supp. Drugs and Narcotics, §§ 40-42.

Sec. 08.80.370. Vending machine sales prohibited. No mechanical device or vending machine wherever located, may be used to dispense a drug, medicine or preparation containing poison. (§ 12 ch 194 SLA 1955)

Sec. 08.80.380. Issuance of shopkeepers permits.

Repealed by § 21 ch 166 SLA 1980.

Cross references. — For present provisions relating to prohibition of regulation by the board of non-prescription drugs, see AS 08.80.045.

Editor's notes. — The repealed section derived from § 12, ch. 194, SLA 1955; § 22, ch. 206, SLA 1972.

Sec. 08.80.390. Pharmacists required in hospitals and clinics. (a) A hospital, clinic, nursing home, infirmary or related facility which dispenses drugs for outpatient treatment shall have a licensed pharmacist in charge of the dispensary, except that prescriptions may be compounded and dispensed by or under the supervision of the prescribing physician.

(b) The board shall issue a license to a hospital drug room, nursing home drug room or related facility which dispenses drugs from bulk supply for inpatient treatment, providing the facility employs a licensed pharmacist on a continual or consultant basis. (§ 12 ch 194 SLA 1955; am § 23 ch 206 SLA 1972)

Sec. 08.80.400. Practice of medicine not affected. This chapter does not affect the practice of medicine by a licensed medical doctor, and does not limit a licensed medical doctor in supplying a patient with any medicinal preparation or article which the licensed medical doctor considers proper. (§ 12 ch 194 SLA 1955)

Editor's notes. — This section was redrafted by the revisor of statutes to remove personal pronouns in conformity with AS 01.05.031(c) and § 4, Chapter 58, SLA 1982.

Sec. 08.80.410. Use of term "pharmacist" prohibited. It is unlawful for a person to assume or use the title "pharmacist," or any variation of the title, or to hold out to be a pharmacist, without being registered. (§ 13(a) ch 194 SLA 1955)

Cross references. — For professional designation requirements for registered pharmacists, see AS 08.02.010.

Editor's notes. — This section was redrafted by the revisor of statutes to remove personal pronouns in conformity with AS 01.05.031(c) and § 4, Chapter 58, SLA 1982.

Sec. 08.80.420. Certain advertising prohibited. (a) It is unlawful for a person to use or exhibit the title "pharmacist," "assistant pharmacist," or "druggist," or the descriptive term "pharmacy," "drug store," "drug sundries," or other similar title or term containing the word "drug," in any business premises, or in an advertisement through the media of press, or publication, or by radio or television, unless the business has a licensed pharmacist in regular and continuous employment.

(b) Repealed by § 21 ch 166 SLA 1980. (§ 13(b) ch 194 SLA 1955; am § 24 ch 206 SLA 1972; am § 21 ch 166 SLA 1980)

Effect of amendments. — The 1980 amendment repealed former subsection (b), which read: "A person may not advertise in any manner, prices, percentiles of prices or discounts for drugs requiring a prescription."

Sec. 08.80.430. Use of pharmacy symbols prohibited. It is unlawful for a person to display in a place of business the characteristic pharmacy symbol of bottles, or globes, which are colored or contain colored liquids unless the business has a pharmacist licensed and registered under this chapter on duty under AS .08.80.320. (§ 13(c) ch 194 SLA 1955; am § 25 ch 206 SLA 1972)

Sec. 08.80.440. Denial of examination 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 registration by reciprocity, or institute proceedings to suspend, revoke or otherwise terminate a 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. (§ 15 ch 194 SLA 1955)

Sec. 08.80.450. Disciplinary action. The board may consider a complaint based upon the alleged violation of any provision of this chapter, and may by a majority vote of a quorum dismiss the complaint, reprimand a 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. (§ 17 ch 194 SLA 1955)

Sec. 08.80.460. Violation. (a) A person who violates a provision of this chapter is guilty of a class B misdemeanor.

(b) A person who violates the provisions of AS 08.80.295 is punishable by a civil fine in an amount established by the board in a schedule or schedules establishing the amount of civil fine for a particular violation. The schedule or schedules shall be adopted by the board by regulation. Any civil fine imposed under this section may be appealed in the manner provided for appeals in the Administrative Procedure Act (AS 44.62). (§ 19 ch 194 SLA 1955; am § 26 ch 206 SLA 1972; am § 4 ch 187 SLA 1976; am § 19 ch 166 SLA 1980)

Effect of amendments. — The 1980 amendment, in subsection (a), deleted "for which no punishment is provided" following "of this chapter," and "and is punishable by a fine not to exceed $1,000, or by imprisonment for a period not to exceed three months or by both" following "misdemeanor," and inserted "class B."

Cross references. — For penalties for misdemeanors, see AS 12.55.135.

Article 5. General Provisions.

Section	Section
470. Construction	480. Definitions
475. Exception	490. Short title

Sec. 08.80.470. Construction [Effective until January 1, 1983]. Nothing in this chapter amends, modifies, repeals or otherwise changes any provision of the Uniform Narcotic Drug Act (AS 17.10) or the Alaska Food, Drug and Cosmetic Act (AS 17.20).

[Effective January 1, 1983]. Nothing in this chapter amends, modifies, repeals or otherwise changes any provision of AS 11.71, AS 17.30, or the Alaska Food, Drug and Cosmetic Act (AS 17.20). (§ 20 ch 194 SLA 1974; am § 8 ch 45 SLA 1982)

Effect of amendments. — The 1982 amendment, effective January 1, 1983, substituted "AS 11.71, AS 17.30" for "the Uniform Narcotic Drug Act (AS 17.10)."

Editor's notes. — For declaration of legislative purpose, see § 1, ch. 45, SLA 1982 in the 1982 Temporary and Special Acts and Resolves.

Sec. 08.80.475. Exception. This chapter does not apply to the safe storage, preservation, dispensing, or control of drugs in any federally operated hospital or institution. (§ 1 ch 49 SLA 1974)

Sec. 08.80.480. Definitions. As used in this chapter, unless the context otherwise requires,

(1) "board" means the Board of Pharmacy;

(2) "drug" or "drugs" means drugs or medical supplies which contain poisonous, potent, habit-forming or deleterious ingredients, or medicines containing ingredients which may be considered dangerous or harmful if taken in overdose;

(3) "medical supplies" means items for the cure or treatment of disease or injury which do not require prescription by a physician and which do not contain poisonous, potent, habit-forming or deleterious ingredients, or an ingredient which may be considered dangerous or harmful if taken in overdose;

(4) "owner" means the owner of a place of business for wholesaling, retailing, compounding or dispensing drugs, medicines or poisons;

(5) "pharmacy" includes "drug store" and "pharmacy or drug department" and means a place of business in which physicians' prescriptions are compounded or dispensed and in which drugs and medicines are compounded or dispensed;

(6) Repealed by § 11 ch 53 SLA 1973.

(7) "recognized college of pharmacy" means a college, school or department of pharmacy whose entrance requirements and courses of study are approved by the National Association of Boards of Pharmacy;

(8) "manager" means a licensed pharmacist in charge of a pharmacy or drug store, or of a pharmacy or drug department, where the owner is not a licensed pharmacist;

(9) "retail" means sale to the ultimate user;

(10) "retail pharmacist" means a person who sells to the ultimate user;

(11) "sell" means to possess in violation of the intent of this chapter, exchange, barter, give away or otherwise dispose of;

(12) "wholesale" means sale by a manufacturer, wholesale dealer, distributor, or jobber to a person who sells, or intends to sell, directly to the user;

(13) "wholesale drug dealer" means a manufacturer, wholesale dealer, distributor or jobber;

(14) "bulk supply" means drugs in original containers not labeled as required by AS 08.80.290;

(15) "drug room" means an area provided only for the proper and safe storage, preservation and control of bulk supply drugs and which is under the responsibility of a continuously employed or consultant pharmacist;

(16) "hospital pharmacy" means and includes a pharmacy, licensed by the board, located within any hospital, institution or establishment which maintains and operates organized facilities for the diagnosis, care and treatment of human illness and provides for the obtaining, storage and dispensing of drugs to both inpatients and outpatients and which is under the responsibility of a staff pharmacist;

(17) "outpatient dispensing" means dispensing drugs for administration outside of the hospital pharmacy's control;

(18) "prescription department" means that section of a business in which prescriptions for medications are compounded, filled and dispensed by a licensed pharmacist;

(19) Repealed by § 21 ch 166 SLA 1980.

(20) **[Effective until January 1983]** "controlled substance" means a narcotic drug as defined in AS 17.10.230(13) or a depressant, hallucinogenic or stimulant drug as defined in AS 17.12.150(3).

[Effective January 1, 1983] "controlled substance" has the same meaning set out in AS 11.71.900(4). (§ 2 ch 194 SLA 1955; am §§ 27 — 29 ch 206 SLA 1972; am § 11 ch 53 SLA 1973; am §§ 20, 21 ch 166 SLA 1980; am § 9 ch 45 SLA 1982)

Effect of amendments. — The 1980 amendment added paragraph (20), and repealed former paragraph (19), which read "'shopkeeper' means a retail dealer who sells over the counter medicinal preparations in original unbroken packaging which do not require a prescription for dispensing."

The 1982 amendment, effective January 1, 1983, rewrote paragraph (20).

Editor's notes. — For declaration of legislative purpose, see § 1, ch. 45, SLA 1982 in the 1982 Temporary and Special Acts and Resolves.

Sec. 08.80.490. Short title. This chapter may be known as the Pharmacy Act. (§ 1 ch 194 SLA 1955)

Chapter 84. Physical Therapists Practice Act.

Article

1. State Physical Therapy Board (§§ 08.84.010 — 08.84.020)
2. Registration (§§ 08.84.030 — 08.84.120)
3. Unlawful Acts (§§ 08.84.130 — 08.84.185)
4. General Provisions (§§ 08.84.190 — 08.84.200)

Collateral references. — 61 Am. Jur. 2d, Physicians, Surgeons and Other Healers, §§ 11, 86.

70 C.J.S., Physicians and Surgeons, §§ 6, 13.

Article 1. State Physical Therapy Board.

Section

10. State Physical Therapy Board
20. Applicability of Administrative Procedure Act

Sec. 08.84.010. State Physical Therapy Board. (a) There is created the State Physical Therapy Board, which consists of five members appointed by the governor. The membership consists of one physician licensed to practice medicine in the state, three physical therapists licensed in the state or two physical therapists and a physical therapy assistant licensed in the state, and one lay person with no direct financial interest in the health care industry. Members of the board

Sandra

added on House floor (Rep. Goll)

Offered: 4/1/86
Referred: Finance

Original sponsor: Gruenberg

controlled substance act

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

CS FOR HOUSE BILL NO. 641 (HESS) am House-passed version.

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, with the consent of the purchaser, 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, with your consent [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.

* 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)] required physician to request generic 08.80.480(3); definition of medical supplies and AS 17.35 marijuana are repealed.

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

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

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PURPOSE AND SCOPE OF THE REPORT

PURPOSE

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

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

SCOPE

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

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

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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.

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

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

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

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

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

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

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

Recommendation No. 2

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

The following requirements of continuing education should be reviewed.

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

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

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

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

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

Recommendation No. 3

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

Alaska Statute 08.01.050(19) places the responsibility for

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

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

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

Recommendation No. 4

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

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

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

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

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

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

ANALYSIS OF PUBLIC NEED

Limited Analysis

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

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

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

B. The Board administers the pharmacy test yearly.

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

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

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

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

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

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

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

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

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

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

A. We found no problems in this area.

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

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

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

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

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

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

Please refer to the recommendation section of this report.

APPENDIX A

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

(UNAUDITED)
(Note 1)

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

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

Note 1

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

Note 2

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

Note 3

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

BILL SHEFFIELD, GOVERN

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

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

RECOMMENDATION #3.

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

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

RECOMMENDATION #4.

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

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

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

Sincerely,

Richard A. Lyon
Commissioner

RAL/cw#23DD1
62883B

file Pharmacy Bd

Offered: 4/1/86
Referred: Finance

Original sponsor: Gruenberg

superseded

BY THE HEALTH, EDUCATION AND SOCIAL SERVICES COMMITTEE

IN THE HOUSE

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 am nded 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.

* 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 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).

Sandra

5-7-86

HB 6411

Nancy Dunn — Bill Larson + Jay Donaldson

- Bd will support repeal of controlled substance registration. "If don't do registration, don't need Executive Secretary."
- Duplicative. Has been leverage in Bd's effort to get Exec Sec.
- Waste of $ costs $10 to register in state
- Occ Lic + Dept Law support repeal. Leg Aud't proposes repeal.
- Dept must enforce registration that has no purpose

Bd, Bd, Bd support repeal

-Public Safety does enforcement -

don't need registration. Do need to be able to call a federal violation a state one. DEA isn't enforcing fed. laws in state — Public Safety.

Pb Safe calls DEA to see if guy federally registered Occ Lic has copy of fed. reg.

Gail Horetski or * Pete Haelich (* preferred) ← Bd. concerned about controlled substance 'cause thought would bog down continuation bill.

Marijuana Therapeutic Research

has been determined marijuana isn't the drug of preference for glaucoma treatment, feds. have now scheduled marijuana substitute — available w/out going through committee process.

Alaska State Legislature
House of Representatives
COMMITTEE ON HEALTH, EDUCATION
AND SOCIAL SERVICES

OFFICIAL BUSINESS

POUCH
JUNEAU, AK 998
465-375

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 completion 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 Niilo Koponen, Co-Chair
House Health, Education and Social Services Committee

Sandra
2-18-86

Pharmacy Audit

never used – 1 physician who wanted to – patient died before Bd got everything worked out.

other substances w/ less chance of abuse

x 2534 Occ. Lic., DCED Jenny Strickler

LARSON – REPEAL

propose repeal: 1) marijuana therapeutic program for cancer-glaucoma

Marinol, synthetic marijuana capsule – approved by FDA. Will be available thru pharmacy – prescription.

IF NO STATE REGISTRATION, NO AUTHORITY TO ENFORCE. FED. INVESTIGATOR WOULD HAVE TO DO IT – DON'T HAVE MANPOWER.

2) controlled substance registration really pushed by Chuck Rush, past member. He's still determined.

+ no on exec sec – Bd. won't propose. Very controversial

This is why Bd. is in wind-down year!

fill out form when purchase controlled substance. Who responsible for investigate/enforce?

If repeal registration, repeal whole Controlled Substance Act.

~~Bd~~ on books since 1980 – never been implemented.

338-5035 William Larson, DCED

(less) $200/4 yrs.

1 bd. mtng. yr.
Div Occ's investigators not familiar w/ pharmacy.
Linked to Controlled Substances Act.

x 3830 Legislative Audit Jerry Wilkerson

Notified. Will not attend.

Tom Miklautsch W 456-8679 H 456-7606

out of town this week. Gave info. to his secretary.

Lt. Tom Sterns

~~Frank Cochran~~ 269-5505 – Narcotics Coordinator, Pub. Safe

~~Lt. Sterns, Narcotics coordinator wouldn't want to keep.~~

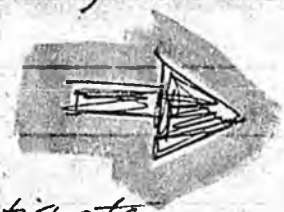
State unable to enforce if don't register? NO

Public Safety investigate & enforce

Fed gov. requires records be kept by pharmacists

If overprescribing controlled substances, DPS investigate.

Work closely w/ fed. gov. in investigating.



360° Rita Taelich, A.G. working w/ Gail Horetski – repeal registration only, not whole statute. Add lang. saying need federal registration + affirmative defense in criminal code that has fed. number. Public safety does investigation & enforced.

House bills: Marron & Gruenberg

last yr. HB 122 extended → '85; we have HB 123 in Committee (do same)

teleconference Fbx. & Anch.

Called back 2/20/86. Gwen Byington, Anch.
Had spoken to DEA + Dept. Law

Feds. want drug enforcement control at state level.
repeal of Article I? ~~Concerns~~ Wouldn't affect Public Safety's ability to do investigation + enforcement.
Duplicating fed-gov.'s efforts.
If DEA feds pull out of investigation altogether, would be beneficial to have records at state level (to facilitate investigation).

Bd's role only to keep records + check application backgrounds on people.
After fed or state criminal action, bd. could revoke license, etc.
Only kind of investigation involved in is falsification of applications.

DEA has no cases in Alaska in this regard.
No contact w/ Pharmacy Bd. in the 3 yrs. he's headed the narcotics division.

Pete received memo from criminal division (2/27/86) He's preparing memo to committee.
In Article I, only section .080 should be retained.
↳ He should have memo to us by Tues, March

STATE OF ALASKA

BILL SHEFFIELD, GOVERNOR

DEPARTMENT OF COMMERCE & ECONOMIC DEVELOPMENT

DIVISION OF OCCUPATIONAL LICENSING

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

March 5, 1986

Honorable Bettye Fahrenkamp
Chairman
Health, Education and Social
Services Committee
Alaska State Senate
P O Box V
Juneau, AK 99811

Dear Senator Fahrenkamp:

At the request of your aide, Sandra Schubert, we have prepared a chronology of the implementation of the Controlled Substances Act with respect to the original fiscal note; current status of funding for items included in that fiscal note; responsibilities of the Investigator initially funded by that fiscal note; and adoption of the regulations.

We hope the committee will find this information useful. If we can be of further assistance, please contact this office.

Sincerely,

Nancy Dunn
Director

ND/sal694s
30686a

Enclosures

08-H8LH

CONTROLLED SUBSTANCES ACT

PASSAGE OF BILL

CCSSB 190:
5/05/81 - SB 190 passed the Senate
4/20/82 - CSSB 190 passed the House with Letter of Intent
4/22/82 - CCSSB 190 approved by the Senate, sent for enrollment, and notification to the House
5/20/82 - Approved by the Governor, Chapter 45, SLA 1982
1/01/83 - Effective date

FISCAL NOTE (HB 180 version)

$155.6 vetoed down to $75.0 (Ch. 139, SLA 1982)

-Regulations Specialist	$ 21.5
-Patient Qualification Review Committee	3.6
-Investigator III	49.9
	$ 75.0

Administration Component:

Regulations Specialist - Hired 4/13/83 to 6/30/84
(Position authorized for 12 months, however, funding under the veto was reduced to six months.)

Personal Services	$ 15.9
Contractual	2.9
Equipment	2.1
Space Rent	.6
	$ 21.5

(Funding for this position were deleted from the FY 85 budget.)

Board Component:

Travel for Patient Qualification - Review Committee $ 3.6

(Funds were deleted in the FY 85 budget; authorized total went from $160.4 in FY 84 to $95.0 in FY 85.)

Investigations Component:

Two Investigator III positions were authorized by the HB 180 fiscal note however, the veto deleted funding for one of the two positions.

Investigator III - Hired 6/28/84 to present. (This position is currently funded in Occupational Licensing.)

Personal Services	$ 43.8
Travel	1.6
Equipment	3.3
Space rental	1.2
	$ 49.9

(Funds for Equipment and Space Rental were deleted from the FY 85 budget.)

INVESTIGATOR ACTIVITIES

The Investigator funded by the fiscal note is responsible for Pharmacy investigations in addition to all drug-related cases which may also involve Medical Doctors, Nurses, Dentists and Veterinarians.

FY 86:	Current Pharmacy case load	5 ongoing cases 2 in litigation
FY 85:	Pharmacy Investigative case load:	18 Opened 16 Closed
	Litigation:	1 hearing completed, license denied 2 hearings were pending

Current statistics reflect the following case load and percent of investigative activity as it applies to the health care fields with drug-related issues:

	ONGOING CASES	LITIGATION	% OF TOTAL DIVISION INVESTIGATIONS ACTIVITY
Pharmacy	5	2	9.00%
Medical	30	5	29.05%
Nursing	9	11	11.57%
Dental	6	2	4.88%
Veterinary	0	1	0.77%

REGULATION PROJECT:

5/2/83	Regulation Specialist began drafting regulations required by AS 17.30 and AS 17.35.
6/28/83	Board approved draft regulations at June 28, 1983 board meeting.
7/13/83	Regulation project was public noticed; and a copy of the regulation project and public notice was sent to the Regulations Attorney in the Department of Law for review.
8/22/83	Joe D. Digangi, AAG was assigned to the regulation project.
9/26, 27, 28, and 30, 1983	Public hearings were conducted.
10/28/83	Board adopted proposed registration form.
10/31/83	Kay Gouwens, new AAG, assigned to take over the regulation project.

12/5/83	Complete regulation project was sent to the Department of Law for review and filing.
12/21/83	Letter from Kay Gouwens, AAG to Chairman of the Pharmacy Board was sent stating that the regulation project was disapproved for filing because of inconsistency with the authorizing statute.
12/30/83	Regs. Specialist received a copy of a letter from Kay Gouwens, AAG to the Chairman of the Pharmacy Board with a revised proposed draft of the regulations.
2/7/84	Regs. Specialist met with Kay Gouwens to combine Ms. Gouwens' draft with the draft adopted by the board on October 28, 1983.
2/17/84	Regs. Specialist received a typed version of the combined draft from Ms. Gouwens. The typed version was not the version that was prepared and agreed upon at the 2/7/84 meeting.
2/22/84	Regs. Specialist submitted to the board: a) the draft she prepared using Kay Gouwens' suggestions; b) Kay Gouwens revised proposal.
2/23/84	The board adopted (b) Kay Gouwens' revised proposal.
3/13/84	The complete file was sent to the Department of Law for review and filing.
4/17/84	Regs. Specialist received a copy of an entirely new rewrite of the regulations from Kay Gouwens consisting of all previous versions of the regulation project including the drafts adopted by the board on 10/28/83 and 2/23/84, in addition to new changes. Changes to the content and meaning of the regulation project were substantial and differed from the public notice. At this point, the regulation project remained in the Attorney General's Office for further action.
11/30/84	The regulations were reviewed by Pete Froehlich, AAG and filed with the Lieutenant Governor.
12/30/84	Effective date of regulations.

References:

Senate Journal 1981, pg. 957
Senate Journal 1982, pg. 983
Senate Journal 1982, pg. 1010
Session Laws Sec. 23, Ch. 45, SLA 1982
Fiscal Note HB 180 version
Conference Committee Report for 1983, pgs. 16-21
Chapter 139, SLA 1982 (CSSB 746(Fin) am H)
May 2, 1984 memorandum from Marion Hardy, Regs. Spec. to Harry Treager, Director
March 4, 1984 note from Darrell Miller, Regs. Spec. to Harry Treager, Director
November 30, 1984 memo from Pete Froehlich, AAG to Richard Lyon, Commissioner, Department of Commerce and Economic Development

0051m

Alaska State Legislature

file HB 641

P.O. BOX V
STATE CAPITOL
JUNEAU, ALASKA 99811
(907) 465-3834
(907) 465-3762

Senate Committee on Health, Education and Social Services

Sandra

M E M O R A N D U M

TO: Members, Senate Committee on Health, Education and Social Services

FROM: Committee Staff

RE: Committee Meeting, May 8, 1986

DATE: May 7, 1986

On Thursday, May 8, 1986 from 1:30-3:30 p.m. in the Beltz Room, the Senate Committee on Health, Education and Social Services will hear the following bills:

CSHB 641 (HESS) am Relating to generic drugs, pharmaceuticals, and the Board of Pharmacy; repealing the marijuana therapeutic research program.

HB 641 would extend the Board of Pharmacy through 1989 and make other revisions to the pharmacy statute as recommended by the legislative audit:

1) Repeal the Marijuana Therapeutic Research Program, under which the Board is to approve patients for the use of marijuana and its active ingredient (THC) in the treatment of glaucoma and in cancer chemotherapy. The need for the program has been diminished by recent FDA approval of Marinol, a new THC drug, which is currently available through Providence Hospital in Anchorage.

2) Provide that a generic drug may be substituted unless the prescriber expressly states that the prescription is to be filled as written. Current statute allows substitution only if the prescriber specifically requests it.

The attached amendment would remove the requirement that people who handle controlled substances in Alaska register with both the state and federal governments, and amend state law to specifically provide that federal registration requirements must be met. This was recommended by the legislative audit.

At its March 5 sunset review of the Board, the Senate Committee on Health, Education and Social Services did recommend its continuation. The Board terminated June 30, 1985 and has until June 30, 1986 to conclude its affairs.

HCR 61 am Relating to access to basic health care services for Alaskans.

HCR 61 requests the Governor to direct the Department of Health and Social Services to identify potential means and costs of providing for the health care needs of Alaskans who do not have adequate health care protection. It is anticipated that funding support for the study will come from a grant from the Robert Wood Johnson Foundation, and that the House Research Agency and legislative staff will cooperate in the effort. The resolution calls for the results of the study to be submitted to the legislature by March 1, 1987.

SB 415 Relating to school board composition.

SB 415 would exempt Rural Education Attendance Areas (REAAs) that convert to city or borough school districts from statutory provisions that govern the number of members who may serve on a city/borough school board. Current statute provides, for city/borough districts with less than 5000 students, a 5 member board; for city/borough districts with more than 5000 students, a 7, 9, or 11-member board; and for REAAs, a 5, 7, 9, or 11-member board.

The bill is intended to address the conversion of the Northwest Arctic REAA in Kotzebue to a borough school district. The REAA currently has an 11-member board; existing statute would require that the board be reduced to five members.

STATE OF ALASKA 1986 LEGISLATIVE SESSION
FISCAL NOTE

Revision Date: _____

REQUEST | **FISCAL DETAIL**

Bill/Resolution No.: CSHB 641

Title: An Act relating to generic drugs, pharmaceuticals, and the Board of Pharmacy;

Sponsor: Rep. Gruenberg

Requester: House HESS

Date of Request: _____

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

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 Servi

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 — cc

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
- Impacted Agency(ies)

Alaska State Legislature

BETTYE FAHRENKAMP, Chairman
ARLISS STURGULEWSKI, Vice Chairman
JOE JOSEPHSON
PAUL FISCHER
EDNA ARMSTRONG-DE VRIES

P. O. BOX V
STATE CAPITOL
JUNEAU, ALASKA 99811
(907) 465-3834
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Senate Committee on
Health, Education and Social Services

M E M O R A N D U M

TO: Senator Bennett, Senate President

FROM: Senator Fahrenkamp, Chairman
Senate Committee on Health, Education and Social Services

RE: Board of Pharmacy

DATE: March 5, 1986

Pursuant to your referral under AS 44.60.050 and AS.03.010, the Senate Committee on Health, Education and Social Services has had under review the Board of Pharmacy.

As required by statute, a public hearing was held on the review of this Board. The Committee considered the findings and recommendations of the Legislative Audit Division and has examined the proposed budget for the Board.

After careful analysis, the Committee is recommending that the Board of Pharmacy be extended for another four year period. Legislation to extend the Board has been introduced.

Senator Fahrenkamp, Chairman

Bettye Fahrenkamp

Senator Devries

Edna DeVries

Senator Sturgulewski, Vice Chairman

Arliss Sturgulewski

Senator P. Fischer

Paul Fischer

Senator Josephson

Joe Josephson

prepared Leg Audit
2-1986

BOARD OF PHARMACY INFORMATION

	FY 84	FY 85
Number of Meetings	1 Anchorage 2 Juneau	1 Anchorage 1 Juneau
Total	3	2
Number Taking Exam	2 Pass 0 Fail	1 Pass 1 Fail
Total	2	2

The exam is given once a year in June. The number of licenses at the end of FY 85 was 428. During FY 85 there were 26 licenses issued (24 by reciprocity).

Phar. Bd

Alaska State Legislature

BETTYE FAHRENKAMP, Chairman
ARLISS STURGULEWSKI, Vice Chairman
JOE JOSEPHSON
PAUL FISCHER
EDNA ARMSTRONG-DE VRIES

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Senate Committee on Health, Education and Social Services

March 25, 1986

Jacki Warren
Alaska Pharmaceutical Association
P.O. Box 10-1185
Anchorage, AK 99510

Dear Jacki:

Thank you for your recommendations regarding the State Board of Pharmacy.

As you may know, the Senate Committee on Health, Education and Social Services, which I chair, has recommended that the Board be continued for another four years. The legislation that would accomplish this, and that also addresses the findings of the sunset audit, is currently under review by the House. I do expect it to be referred to my committee once it reaches the Senate, and assure you I will keep your views in mind as we begin our deliberations on it.

Again, I appreciate receiving your comments.

Sincerely,

Bettye Fahrenkamp
Chairman

BF/ss

MAR 1 4 1986

ALASKA PHARMACEUTICAL ASSOCIATION

Box 10-1185 Anchorage, Alaska 99510

Letters P 14

March 11, 1986

The Honorable Bettye Fahrenkamp
United States Senator
Capitol Room 125
Post Office Box V
Juneau, Alaska 99811

Dear Senator Fahrenkamp:

The Board of the Alaska Pharmaceutical Association agrees with the recommendation of the State's follow-up "sunset" review which states that the State Board of Pharmacy should be re-established. Please consider also our comments on the findings and recommendations of this review. Basic to our comments is the realization that funding of the Board is extremely limited and actions expected of the Board must keep this in mind.

Recommendation #1: State Registration for Controlled Substances

While much confusion surrounded this first attempt at State registration, the process itself is very simple and not burdensome. The license should be treated as permission to do work, not as an information source as the review seems to do. The basic issue is - can the State Board of Pharmacy restrict the manufacture, distribution and dispensing of a Controlled Substance within the State without state registration. The Senate Health, Education and Social Services Committee should know the answer to the question "How will the State Board of Pharmacy restrict the privileges of a pharmacist, physician or dentist who is abusing controlled substances if the individual is practicing under a federal rather than state license." If the answer is clear, then the recommendation is reasonable.

Prior Recommendation #3:

Investigational responsibility still seems less than clear. Expert knowledge is essential to a fair investigation. The Association is not aware of any such expertise within the Department of Occupational licensing.

Prior Recommendation #4:

The Association wholly supports this recommendation. It is essential that new members are appointed promptly to promote continuity and communications within the Board and the profession.

Medicaid Drug Program:

This is not a State Board of Pharmacy issue and there is no justification for it being addressed in this report. The report simply served as an inappropriate vehicle to express the opinion of the legislative auditor. All reference to it should be stricken.

Executive Secretary:

State registration under the Controlled Substances Act and the ability to conduct adequate and fair investigations are central to this staffing issue. As previously stated, the Association has not been made aware of any such expertise in existence in the Department of Occupational Licensing. This expertise is essential to the regulation of the profession and the Controlled Substance Act.

Thank you very much for your consideration of our opinions.

Sincerely,

Jacki Warren

Jacki Warren
Immediate Past President
Alaska Pharmaceutical Association

cc: Senator Jan Faiks

William P. Larson, Pharmacist
President, State Board of Pharmacy

file Pharmacy Bd

March 7, 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 revised 1st page of proposed amendment to HB 641 re controlled substances

As I mentioned to you this morning, after further consultation with the Department of Public Safety, we have a change to page 1 of the amendment attached to my memo to you yesterday. A new page 1 is therefore attached.

The change was agreed upon by Deputy Commissioner James Vaden and Narcotics Unit Sgt. James Grimes of the Department of Public Safety in conversations with special assistant Gwen Byington of the criminal division of the Department of Law. It would eliminate the requirement that controlled substances registrants provide evidence of their federal registration to a state agency. This eliminates a burden on both the registrant and the state agency without infringing on the efficiency of enforcement. Investigators could ask either the registrants or the DEA for evidence of registration and other records when necessary.

We apologize for this late change, but it is definitely a further improvement.

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

cc w/enc.: (continued)

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

James Vaden, Deputy Commissioner
Department of Public Safety

William Larson, R.Ph., President
Board of Pharmacy

T.L. Conley, M.D., Chair
State Medical Board

Paul Buxton, D.D.S., Chair
Dental Board

Pam Tuomi, D.V.M., Acting Chair
Veterinary Board

Eileen Montano, R.N., Chair
Nursing Board

PROPOSED AMENDMENT
Department of Law, 3/6/86

Offered in the HOUSE HESS COMMITTEE By _____

TO: HB 641

Page 1, line 7, following "Pharmacy":

Insert "amending the controlled substances Act;"

Page 2, between lines 8 and 9:

Insert the following:

* Sec. 4. AS 17.30.010 is repealed.

* Sec. 5. 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 [REGISTER ANNUALLY WITH THE BOARD IN ACCORDANCE WITH REGULATIONS ADOPTED UNDER AS 17.30.010] comply with the requirements of the federal Controlled Substances Act, 21 U.S.C. sec. 811 -- 830, and the regulations adopted under those sections, 21 CFR 1301 -- 1311.

* Sec. 6. AS 17.30.020(b) -- (e) are repealed.

* Sec. 7. AS 17.30.020(f) is amended to read:

(f) The Department of Public Safety [BOARD] may inspect the establishment of a registrant [OR APPLICATION FOR REGISTRATION IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE BOARD].

* Sec. 8. AS 17.30.030 is repealed.

* Sec. 9. AS 17.30.040 is repealed.

* Sec. 10. AS 17.30.050 is repealed.

* Sec. 11. AS 17.30.060 is amended to read: