ALASKA LEGISLATURE COMMITTEE FILES 1985-1986 8672

3229 HHESS HB 641

105

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Signature of Camera Operator

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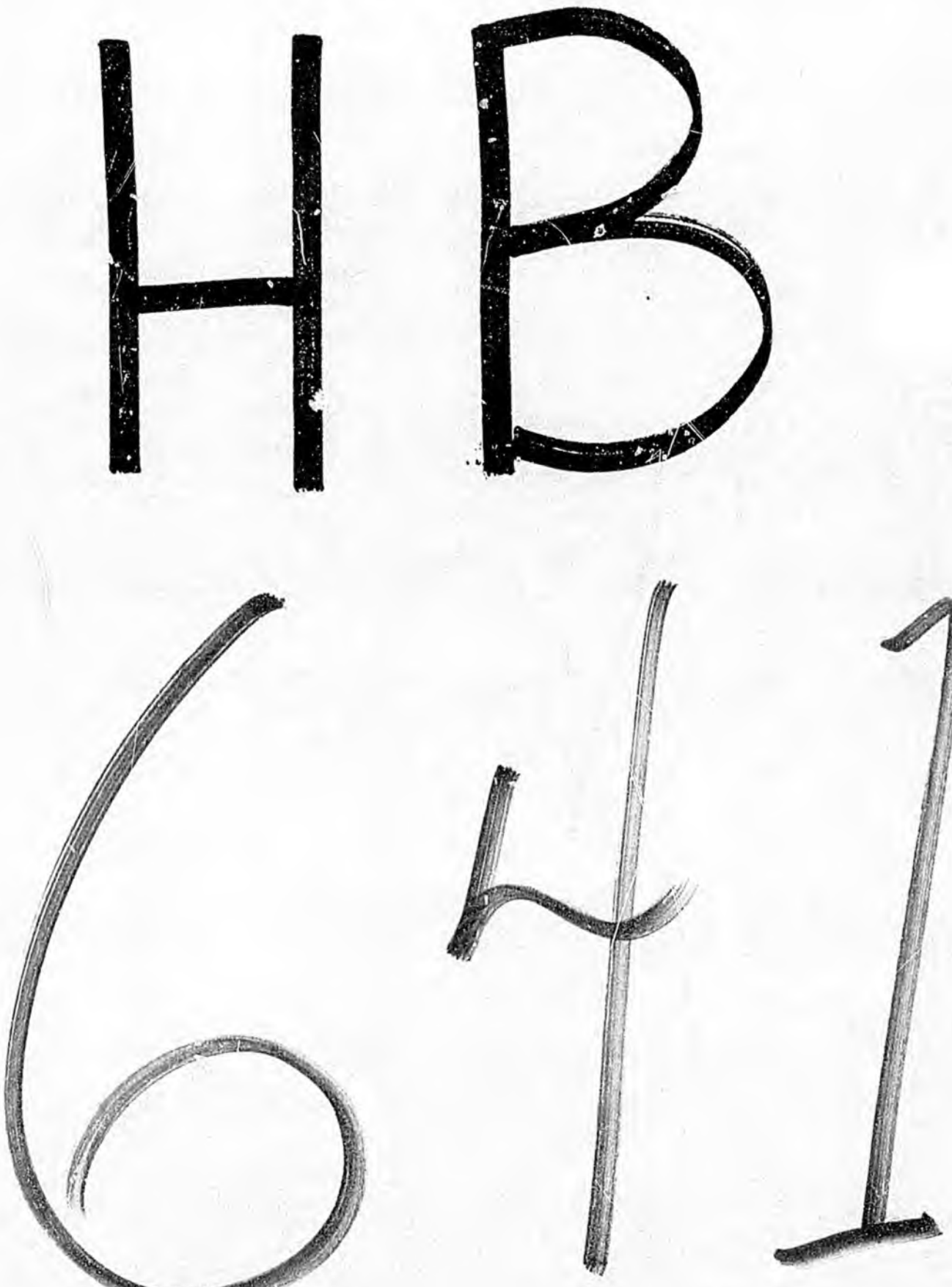
02-519 (REV 8/78)


HB
641

HOUSE
COMMITTEE REPORT

(7)
Date referred: 2/26/86
(L&C waived 2/26)

FURTHER REFERRALS: FINANCE

DATE: March 26, 1986

The HEALTH, EDUCATION AND SOCIAL SERVCIES Committee has considered HB 641

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

and recommends:

[ ] do pass

[ ] do not pass

[ ] do pass with attached amendment(s)

[ ] no recommendation

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

do pass [ ] new title

and recommends ~~Do Not Pass~~

[ ] further referral to the _____ Committee

and attaches: [ ] letter of intent
[ ] first fiscal note
[ ] new fiscal note
2 [✓] zero fiscal note

SIGNING DO PASS:

Mike Greenberg
Willie Kopanas II
Robin L. Taylor
Katie Hurley

SIGNING OTHER RECOMMENDATIONS:

NO REC
NO REC
Bruce Hayley NO REC

Co-Chairman
Willie Kopanas II
Co-Chairman

Hein
3/25/86

Original sponsor: Gruenberg

IN THE HOUSE

BY THE HEALTH, EDUCATION AND SOCIAL SERVICES COMMITTEE

CS FOR HOUSE BILL NO. 641 (HESS)

IN THE LEGISLATURE OF THE STATE OF ALASKA

FOURTEENTH LEGISLATURE - SECOND SESSION

A BILL

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

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

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

(4) Board of Pharmacy (AS 08.80.010) -- June 30, 1989 [1985].

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

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

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

(2) examine applicants for registration as pharmacists;

(3) assist the department in inspections and investigations [INVESTIGATE INDIVIDUALLY, COLLECTIVELY, OR THROUGH ITS AGENT,] for violations of this chapter, or of any other state or federal statute relating to the practice of pharmacy;

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

(5) adopt [PROMULGATE] regulations to carry out the purposes of this chapter;

(6) [REPEALED

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) possesses

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) possesses

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

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

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

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

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

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

AS 17.30.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

STATE OF ALASKA 1986 LEGISLATIVE SESSION
FISCAL NOTE

Revision Date: _____

REQUEST

Bill/Resolution No.: CSHB 641

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

Sponsor: Rep. Greenberg

Requester: House HESS

Date of Request: _____

FISCAL DETAIL

Agency Affected: Commerce & Economic Dev.

BRU: Occupational Licensing

Components: _____

EXPENDITURES / REVENUES: (Thousands of Dollars)

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

FUNDING: (Thousands of dollars)

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

POSITIONS:

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

ANALYSIS: Attach a separate page if necessary.

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

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

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

Division: Occupational Licensing Date: 3-25-86

Approved by Commissioner: Loren H. Lounsbury Date: 3/25/86

Agency: Commerce and Economic Development

Distribution (by Agency preparing fiscal note):

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

10/25/85

PUBLIC OPINION MESSAGE

TO: REPRESENTATIVE MAX F. GRUENBERG

FROM: BILL LARSON
13400 BAYWIND DRIVE
ANCHORAGE, ALASKA 99516
338-5035

BILL NO: HB 641

SUBJECT: GENERIC DRUGS; EXTEND BOARD OF PHARMACY

MESSAGE:

THE BOARD OF PHARMACY IS IN FAVOR OF PASSAGE OF CSHB 641 AND AGREES WITH THE AMENDMENT CONCERNING 08.80.030 (3).

BILL LARSON - PRESIDENT OF STATE BOARD OF PHARMACY

DATE: 03/25/86 TIME: 14:38:24 SENT BY: ANCHORAGE LIO

COPIES TO: HOUSE HEALTH, EDUCATION & SOCIAL SERVICES

Ron's Apothecary Shoppe
P.O. Box 2007
Juneau, Alaska 99803
(907) 789-0458

MARCH 21, 1987

REP. Max Gruenberg
Capitol, Rm 114
Pouch V
Juneau, Alaska 99811

Dear Rep. Gruenberg,

I am writing in regard to the amendments to HB 641 proposed by the Proprietary Association.

I have been in communication with representatives of the Alaska Board of Pharmacy, the Alaska Pharmaceutical Association and several individual pharmacists around the state regarding these amendments. All agree that the two definition changes are acceptable if you wish to add them but the third change suggested (re: emergency powers of the Board of Pharmacy to regulate over-the-counter drugs) we find completely unacceptable. This aspect of the statute was discussed fully in hearings before various committees of the Legislature during a session in the early 1970's and the existing statute was the result of those hearings.

To make such changes at this time we feel would encumber HB 641 to the point that pharmacists would no longer be able to fully support its passage as we do at present.

We have a good piece of legislation at this point, please do not make changes to it only to satisfy a Washington, D.C. group whose interest is purely financial and not in regard to the public health and safety of Alaskan's.

Sincerely,

Ron Sedgwick, R.Ph.

MEMORANDUM

TO: HOUSE HESS COMMITTEE MEMBERS
FROM: NANCY BENNETT, COMMITTEE STAFF
RE: TODAY'S AGENDA
DATE: MARCH 12, 1986

WE HAVE TWO BILLS SCHEDULED FOR TODAY

HB 497 - RELATING TO CHILD CUSTODY, BIRTH CERTIFICATES

We have a draft committee substitute for this bill which makes the following changes:

1. deletes section 1 relating to minor shoplifting
2. Expands current section 1 (25.20.060) to specify how the court will review child custody arrangements.
3. Adds a new section 2 which allows the court to order visitation by grandparents and others and specifies that child support may be ordered under any custody arrangement.

There are also two Gruenebrg amendments in your file. One relates to priority of calendaring for chilc custody cases and the other would allow the court to order home studies by Health and Social Services and other agencies.

HB 641 - RELATING TO THE BOARD OF PHARMACY

This is our sunset review hearing. The audit recommedns:

1. State registration of professionals with access to controlled substances duplicates DEA requirements and should be repealed.
2. The board should allow Occupational Licensing to perform administrative duties required by statute to improve documentation and file management.
3. AS 08.80.030(3), assigning the board authority to conduct investigations, is in conflict with statutory provisions requiring Occupational Licensing to perform these functions.
4. The Marijuana Therapeutic Research Program should be repealed because the board did not respond in a timely fashion.

HB 641 continues the board of Pharmacy, repeals the Marijuana Therapeutic Research Program and 08.80.030(3) and contains the generic drug language passed by this committee last year in HB 209.

We also have the following proposed amendments:

THE PROPRIETARY ASSOCIATION

Suite 1200 1150 Connecticut Avenue, N.W. Washington, D.C. 20036
Phone (202) 429-9260 Telex 75-9293 (PA WSH)

Federal Express

March 7, 1986

Nancy Bennett
House Health, Education & Social Services Committee
State Capitol Building
4th & Main Streets, Room 112
Juneau, Alaska 99811

Dear Nancy:

I appreciate your taking the time to call me and request our suggested amendments to H.B. 641 the Alaska Pharmacy Act revisions. As I mentioned to you earlier, the Proprietary Association is the 105-year-old trade association which represents manufacturers of nonprescription, over-the-counter (OTC) medicines such as Bayer® Aspirin, Excedrin®, Contac®, Vicks Cough Syrup®, Pepto-Bismol®, and many others. These medicines are marketed in all 50 states in approximately 750,000 retail outlets, including food stores, pharmacies, discount and department stores and other convenient retail locations. Many of our members market products in Alaska, and we are therefore interested in H.B. 341.

Enclosed are three suggested amendments that we are submitting for the committee's consideration. Two of the amendments we have proposed are drawn from the National Association of Boards of Pharmacy (NABP) Model State Pharmacy Act: a modernized and updated definition of nonprescription, OTC drugs and an updated OTC exemption, which allows food stores and other non-pharmacy outlets to sell nonprescription drugs. The other amendment would conform the definition of "drug" contained in the Alaska Pharmacy Act with the standard definition found in the Alaska Food, Drug and Cosmetic Act, the Federal Food, Drug and Cosmetic Act, and most state statutes.

Over the past few years, a number of states have adopted these or similar drug provisions when rewriting their pharmacy acts (I've included a few of these for your reference), and in the interest of uniformity and clarity we would appreciate their inclusion in the Alaska Pharmacy Act.

1. The Department of Law has prepared a series of amendments to repeal the controlled substances registration while placing enforcement functions within the Department of Public Safety. (audit recommendation #1)

2. The Board has an amendment allowing them to promulgate regulations governing pharmacy technicians. (We also have a copy of Washington state law on this issue)

3. The Proprietary Association, of Washington D.C. representing manufacturers of over the counter drugs, has contacted us and submitted a request to revise drug definitions to comply with FDA definitions. Sue Stevenson of that organization will be testifying by teleconference.

THE PROPRIETARY ASSOCIATION

Suite 1200, 1150 Connecticut Avenue, N.W., Washington, D.C. 20036
Phone (202) 429-9260, Telex 75-9290 (PA WSH)

Federal Express

March 7, 1986

Nancy Bennett
House Health, Education & Social Services Committee
State Capitol Building
4th & Main Streets, Room 112
Juneau, Alaska 99811

Dear Nancy:

I appreciate your taking the time to call me and request our suggested amendments to H.B. 641 the Alaska Pharmacy Act revisions. As I mentioned to you earlier, the Proprietary Association is the 105-year-old trade association which represents manufacturers of nonprescription, over-the-counter (OTC) medicines such as Bayer® Aspirin, Excedrin®, Contac®, Vicks Cough Syrup®, Pepto-Bismol®, and many others. These medicines are marketed in all 50 states in approximately 750,000 retail outlets, including food stores, pharmacies, discount and department stores and other convenient retail locations. Many of our members market products in Alaska, and we are therefore interested in H.B. 641.

Enclosed are three suggested amendments that we are submitting for the committee's consideration. Two of the amendments we have proposed are drawn from the National Association of Boards of Pharmacy (NABP) Model State Pharmacy Act: a modernized and updated definition of nonprescription, OTC drugs and an updated OTC exemption, which allows food stores and other non-pharmacy outlets to sell nonprescription drugs. The other amendment would conform the definition of "drug" contained in the Alaska Pharmacy Act with the standard definition found in the Alaska Food, Drug and Cosmetic Act, the Federal Food, Drug and Cosmetic Act, and most state statutes.

Over the past few years, a number of states have adopted these or similar drug provisions when rewriting their pharmacy acts (I've included a few of these for your reference), and in the interest of uniformity and clarity we would appreciate their inclusion in the Alaska Pharmacy Act.

If you or any of the committee members have any questions or would like to discuss the amendments prior to the hearing on March 12, please give me a call. Otherwise, as we discussed, Don Magnusson will present the amendments for us at the hearing, and I will plan on participating by teleconference.

Thank you for your consideration of our views.

Sincerely yours,

Susan T. Stephenson
Assistant General Counsel / Director
of State Government Relations

Enclosures (4): Suggested Amendments to H.B. 641
Section 17.20.370(6), Alaska Food, Drug, & Cosmetic Act
Selected Provisions of the NABP Model State Pharmacy Act
Selected Provisions of other State Pharmacy Acts

cc: Don Magnusson
Ed Hessel

STS:cmc

The Proprietary Association

SUGGESTED AMENDMENTS TO H.B. 641

* Language to be added is underlined.

** Language to be deleted is [slashed and in brackets].

1. Definitions

Amend "Section 08.80.430. Definitions" as follows:

(a) Definition of Drug

(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;]

"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 component of an article specified in this paragraph but does not include devices or their components, parts, or accessories;

Comment:

The amendment conforms the definition of "drug" in the Alaska Pharmacy Act with the definition contained in the Alaska Food, Drug, and Cosmetic Act (Alaska FD&C Act).[1] It parallels that of the National Association of Boards of Pharmacy (NABP) Model State Pharmacy Act,[2] the Federal Food, Drug, and Cosmetic Act (Federal Act), and most state statutes.

(b) Definition of Nonprescription Drug

(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;]

"Nonprescription drug" means a non-narcotic medicine or drug which may be sold without a prescription and which is prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of this state and the federal government.

---

1 Section 17.20.370(6) of the Alaska FD&C Act (attached).

2 NABP Model State Pharmacy Act, p. 3. Relevant provisions of the Model Act are attached.

Comment:

The amendment defines a "nonprescription" drug in modernized language which has been drawn from the NABP Model State Pharmacy Act[3] and has been adopted by a number of states in the last few years. The term "medical supplies" in the current Alaska Pharmacy Act more appropriately refers to medical "devices", since "supplies" would not legally be considered "drugs" under either the Alaska FD&C Act or the Federal Act.

2. OTC Exemption

Amend "Section 08.80.045. Nonprescription Drugs" as follows:

> [(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.]
>
> It shall be lawful for any person to sell and distribute nonprescription drugs. Persons engaging in the sale and distribution of such items shall not be deemed to be improperly engaged in the practice of pharmacy. No rule or regulation will be adopted by the Board under this Act which shall require the sale of nonprescription drugs by a licensed pharmacist or under the supervision of a licensed pharmacist or otherwise apply to or interfere with the sale and distribution of such medicines.

Comment:

This amendment would modernize the existing "OTC exemption" in Alaska which insures that food stores and general retail merchants (other than pharmacies) are allowed to sell nonprescription drugs which are prepackaged and labeled for use by the consumer. It is drawn from the OTC exemption contained in the NABP Model State Pharmacy Act and has been adopted by a number of states in the last few years.[4] Wisconsin adopted similar language this year in the Pharmacy Act rewrite (S.B. 285) which has just gone to the Governor for signature.

The existing provision in the Alaska Pharmacy Act gives emergency authority to the Board to regulate the sale of nonprescription drugs which is duplicative of authority already given to the Commissioner of Health and Social Services under the Alaska Food, Drug, and Cosmetic Act.

---

3 Id., p. 5. Provisions of several other State Pharmacy Acts are attached.

4 Id., pp. 26-27. See also other Pharmacy Acts attached.

The Commissioner of Health has existing authority to regulate the "sale" of all drugs which is specified to include the

> "manufacture, production, processing, packing, exposure, offer, possession, and holding of them for sale; the sale, dispensing, and giving of them, and the supplying . . . of them in the conduct of a . . . drug . . . establishment." (Alaska FD&C Act, Section 17.20.340)

In addition, the Health Commissioner has authority to enforce the provisions of the act that deal with adulterated drugs (Section 17.20.080), misbranded drugs (false and misleading labeling, etc., Section 17.20.090), and new drugs (Section 17.20.110).

Parallel authority is also given to the U.S. Food and Drug Administration under the Federal Act.

STS:cc
3/7/86

Effect of amendments. — The 1981 amendment added "of environmental conservation or the commissioner of health and social services, as the case may be" following "commissioner" in the first sentence and added "appropriate" preceding "commissioner" in the second sentence.

Sec. 17.20.370. Definitions. In this chapter

(1) "advertisement" means a representation disseminated, other than by labeling, for the purpose of inducing, or which is likely to induce directly or indirectly the purchase of food, drugs, devices or cosmetics;

(2) "antiseptic", in the labeling or advertisement of a drug, is a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or other use involving prolonged contact with the body;

(3) "contaminated with filth" means food, drug, device, or cosmetic not securely protected from dust, dirt, and as far as necessary by all reasonable means, from foreign or injurious contamination;

(4) "cosmetic" means an article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance, and an article intended for use as a component of an article enumerated in this paragraph; except that the term does not include soap intended for cleansing purposes only;

(5) "device" except when used in AS 17.20.040(6), 17.20.090(3), 17.20.150(3), 17.20.290(10) and 17.20.300 means an instrument, apparatus, and contrivance, including its components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal; or to affect the structure or function of the body of man or animal;

(6) "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 component of an article specified in this paragraph but does not include devices or their components, parts, or accessories;

(7) "federal act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 — 392; 52 Stat. 1040 — 1059;

(8) "food" means an article used for food or drink for man or animal, chewing gum, and articles used for components of either of them;

(9) "immediate container" does not include a package liner;

(10) "label" means a display of written, printed or graphic matter upon the immediate container of an article; however, a requirement made by or under authority of this chapter that a word, statement, or other information appear on the label is not complied with unless the

The Model State Pharmacy Act and Model Regulations of the National Association of Boards of Pharmacy

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(over, please)

Section 108. Definitions.

1. "Board of Pharmacy" or "Board" means the _____ State Board of Pharmacy.

2. "Deliver" or "Delivery" means the actual, constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

3. "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, which is required under federal or state law to be prescribed by a Practitioner and dispensed by a Pharmacist.

Comment

The federal government exercises strict control over the production and sale of devices pursuant to the Federal Food Drug & Cosmetic Act (21 U.S.C.A. 360 et seq.). These federal restrictions are not applicable to pharmacies, however (21 U.S.C.A. 360 (g) (1)). The MSPA is made applicable only to these devices which are required to be dispensed by a pharmacist and it is contemplated that the Board would regulate only the dispensing aspects of devices. Boards must carefully avoid regulations that may be contrary to or pre-empted by federal law.

4. "Dispense" or "Dispensing" shall mean the preparation and delivery of a prescription drug pursuant to a lawful order of a Practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

5. "Distribute" means the delivery of a drug other than by administering or dispensing.

6. "Drug" means:

(i) Articles recognized as drugs in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopia, other drug compendium or any supplement to any of them;

(ii) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal;

(iii) Articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(iv) Articles intended for use as a component of any articles specified in clause (i), (ii) or (iii) of this subsection.

7. "Drug Outlet" shall mean all pharmacies, nursing homes, convalescent homes, extended care

facilities, drug abuse treatment centers, penal institutions, hospitals, family planning clinics, retail stores, wholesalers, manufacturers and mail order vendors with facilities located in this state which are engaged in dispensing, delivery or distribution of drugs.

8. "Labeling" shall mean the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer or distributor of a Non Prescription Drug or commercially packaged legend drug or device. Any such label shall include all information required by Federal and State law or regulation.

9. "Manufacture" shall mean the production, preparation, propagation, compounding, conversion, or processing of a Device or a Drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a drug by an individual for his own use or the preparation, compounding, packaging or labeling of a drug (i) by a pharmacist or practitioner as an incident to his administering or dispensing of a drug in the course of his professional practice or (ii) by a practitioner or by his authorization under his supervision for the purpose of or as an incident to research, teaching, or chemical analysis and not for sale.

10. "Manufacturer" shall mean a person engaged in the manufacture of drugs in facilities located within this state.

11. "Person" shall mean an individual, corporation, partnership, association or any other legal entity.

12. "Pharmacist" shall mean an individual licensed by this State to engage in the Practice of Pharmacy.

13. "Practitioner" shall mean a physician, dentist, veterinarian, scientific investigator or other person (other than pharmacists) licensed by this State and permitted by such license to dispense, conduct research with respect to or administer drugs in the course of professional practice or research in this state.

Comment

The definition of "Practitioner" anticipates that those persons other than pharmacists who are permitted to distribute, dispense, administer or otherwise work with drugs will be specifically so authorized in other legislation. The phrase ". . .other persons licensed by this state and permitted by such license to dispense . . ." is meant to include individuals not specifically named such as podiatrists, osteopaths, etc. Such individuals could, of course, be specifically included in this definition if such inclusion is deemed desirable.

14. "Prescription Drug or Legend Drug" shall mean a drug which, under Federal Law is required, prior to being dispensed or delivered, to be labeled with either of the following statements: (i) "Caution: Federal law prohibits dispensing without prescription;" (ii) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian;" or a drug which is required by any applicable Federal or State Law or regulation to be dispensed on prescription only or is restricted to use by

(over, please)

practitioners only.

15. "Prescription Drug Order" shall mean a lawful written or verbal order of a Practitioner for a drug.

16. "Non-Prescription Drug" shall mean non-narcotic medicines or drugs which may be sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of this State and the federal government.

17. "Wholesaler" shall mean a person with facilities located in this State, who buys drugs for resale and distribution to persons other than consumers.

Introductory Comment to Article V

The fifth and last substantive Article of the MSPA concerns registration of Drug Outlets. The registration requirements of this Article will provide a Board with knowledge of all facilities involved in the storage, distribution and sale of drugs within the state. They will permit a Board to better insure against drug diversion from the legitimate channels of intrastate commerce and provide the necessary data for effective recalls and the dissemination of information.

ARTICLE V

Registration of Facilities

Section 501. Registration.

(a) Registration. All Drug Outlets shall annually register with the Board of Pharmacy.

(b) Classification. (i) Each Drug Outlet shall apply for a certificate of registration in one of the following classifications:

(1) Retail Drug Outlet;
(2) Institutional Drug Outlet;
(3) Manufacturing Drug Outlet;
(4) Wholesale Drug Outlet.

(ii) No individual who is employed by a corporation which is registered under any classification listed above need register under the provisions of Article V.

(c) Rules and Regulations. The Board shall establish by rule or regulation under the powers granted to it under Section 212 and 214 of this Act the criteria which each Drug Outlet, that has employees or personnel engaged in the Practice of Pharmacy, must meet to qualify for registration in each classification designated above. The Board may issue various types of certificates with varying restrictions to such outlets referred to in this subparagraph (c) where the Board deems it necessary by reason of the type Drug Outlet requesting a certificate.

Comment

Section 501(c) contemplates that the criteria established in an individual Drug Outlet classification could differ. For example, the criteria that must be met by a nuclear pharmacist's outlet will certainly differ from that of the community pharmacist even though both may fall within the classification of Retail Drug Outlet. This type of latitude places the responsibility on the Board to adopt appropriate rules and regulations to meet the situation at hand. It also provides a forum for change to meet the changing concepts of the practice.

(d) [redacted] It shall be lawful for a Drug Outlet registered under this Section 501 to sell and distribute Non Prescription Drugs. Drug Outlets engaging in the sale and distribution of such items shall not be deemed to be improperly engaged in the Practice of Pharmacy. No rule or regulation

(over, please)

will be adopted by the Board under this Act which shall require the sale of Non Prescription Drugs by a licensed pharmacist or under the supervision of a licensed pharmacist or otherwise apply to or interfere with the sale and distribution of such medicines.

Section 502. Application.

(a) Procedures. The Board shall specify by rule or regulation the registration procedures to be followed, including but not limited to specification of forms for use in applying for such certificates of registration and times, places and fees for filing such application; provided, however, the annual fee for an original or renewal certificate shall not exceed $_____.

(b) Required Information. Applications for certificates of registration shall include the following information about the proposed Drug Outlet.

(i) Ownership.
(ii) Location.
(iii) Identity of pharmacist licensed to practice in the State, who shall be the pharmacist in charge of the Drug Outlet, where one is required by this Act, and such further information as the Board may deem necessary.

(c) Transferability. Certificates of registration issued by the Board pursuant to this Act shall not be transferable or assignable.

(d) Professional Responsibility. The Board shall specify by rule and regulation minimum standards for the professional responsibility in the conduct of any Drug Outlet that has employees or personnel engaged in the Practice of Pharmacy. The Board is specifically authorized to require that the portion of the facility to which such certificate of registration applies be operated only under the direct supervision of no less than one (1) pharmacist licensed to practice in this State and not otherwise, and to provide such other special requirements as deemed necessary.

Section 503. Notifications.

(a) Changes. All registered Drug Outlets shall report to the Board of Pharmacy the occurrence of any of the following changes:

(i) Permanent closing;
(ii) Change of ownership, management, location or pharmacist in charge;
(iii) Any and all other matters and occurrences as the Board may require by rules and regulations.

(b) Other Reportable Events. Disasters, accidents and emergencies which may affect the strength, purity or labeling of drugs, medications, devices or other materials used in the diagnosis or the treatment of injury, illness and disease shall be immediately reported to the Board.

COLORADO

Proprietary Medicine Definition

Title 12, Article 22, Sec. 12-22-102(20) - p. 20

12-20-102. Definitions.- (20) "Nonprescription drug" means a medicine or drug which may be sold without a prescription which is prepackaged for use by the consumer, prepared by the manufacturer or producer for use by the consumer, properly labeled and unadulterated in accordance with the requirements of the state food and drug law and the federal "Food, Drug, and Cosmetic Act". The term shall not apply to any drug that is designated under any law or regulation of this state or federal law or regulation as a habit-forming drug or a controlled substance, as defined in section 12-22-307(7). ***

(L. 59, p. 386, sec. 4; CRS 53, sec. 48-1-25; CRS 1963, sec. 48-1-24; L. 69, p. 340, sec. 16; L. 75, pp. 425, 426, sec.1,1; L. 76, p. 406, sec. 1; L. 79, p. 450, sec. 1; L. 81, pp. 706, 695, 734, sec. 26, 1, 3; L. 84, p. 1158, sec. 1.)

PA/LRS
1/86

Proprietary Medicine Exemption

Title 12, Article 22, Part 1, Sec. 12-22-120(5)- p. 23

12-22-120. Registration of facilities.- (1) All outlets with facilities in this state shall register annually with the board in one of the following classifications:

(a) Prescription drug outlet;
(b) Wholesale drug outlet;
(c) Manufacturing drug outlet;
(e) Other, as may be authorized by this article.

* * *

(5) It shall be lawful for a person to sell and distribute nonprescription drugs. Any outlet engaged in the sale and distribution of such drugs shall not be deemed to be improperly engaged in the practice of pharmacy, nor shall the board promulgate any rule or regulation pursuant to this part 1 which permits the sale of nonprescription drugs only by a licensed pharmacist or only under the supervision of a licensed pharmacist or which would otherwise apply to interfere with the sale and distribution of nonprescription drugs.
(L. 97, p. 161, Sec. 1; L. 81, pp. 706,699, Sec. 8, L. 84, Sec. 2.)

PA/LRS
10/85

U T A H

Proprietary Medicine Exemption

Title 58, Chapter 17, Sec. 58-17-18(1)

(1) Dietary foods and dietary food supplements, including vitamins and minerals or combinations of them, sold only to supplement or fortify the diet, all packaged nonprescription drugs and medicines, medical supplies, bottled or nonbulk chemicals when identified by and sold under a trademark, trade name, or other trade symbol privately owned or registered in the United States patent office, or as provided by the laws of Utah, and labeled with directions for use and with the name and address of the manufacturer or distributor, if the articles meet with the requirements of the Federal Food, Drug, and Cosmetic Act and the food and drug laws of Utah, may be sold by grocers, dealers, and other vendors generally without restriction. No rule may be adopted by the division under this chapter which requires the sale of nonprescription drugs by a licensed pharmacist or under the supervision of a licensed pharmacist or otherwise apply to or interfere with the sale or distribution of such medicines. (1985, ch. 39, Sec. 1)

Definition of Nonprescription Drugs

Title 58, Chapter 17, Sec. 58-17-2(24)

58-17-2. As used in this chapter:

(24) "Nonprescription drugs" means medicines or drugs which may be sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of this state and the Federal Government. (1985, ch. 39, Sec. 1)

1/86
PA/LRS

V E R M O N T

Proprietary Medicine Definition

Title 26, Chapter 36, Sec. 2022(9) - pp. 18-19

Sec. 2022. Definitions. -

* * *

(9) "Nonprescription drugs" shall mean non-narcotic medicines or drugs which may be sold without a prescription and which are pre-packaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of this state and the federal government. (1978, No. 266; 1982, No. 244, Secs. 1,18.)

Proprietary Medicine Exemption

Title 26, Chapter 36, Sec. 2032(f) - p. 20

Sec. 2032. Powers, Duties, Limitations. -

* * *

(f) It shall be unlawful for a drug outlet licensed under this act to sell and distribute nonprescription drugs. Drug outlets engaging in the sale and distribution of such items shall not be deemed to be improperly engaged in the practice of pharmacy. No rule or regulation will be adopted by the board under this chapter which shall require the sale of nonprescription drugs by a licensed pharmacist or under the supervision of a licensed pharmacist or otherwise apply to or interfere with the sale and distribution of such medicines. (1978, No. 266; 1979, No. 158, Sec. 4; 1982, No. 244, Sec. 4.)

10/85
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M I S S I S S I P P I

Proprietary Medicine Exemption

Title 73, Chapter 21, Sec. 73-21-123. p. 10b

Nothing in this act shall be construed to prevent, or in any manner interfere with, or to require a permit for the sale of nonnarcotic nonprescription drugs which may be lawfully sold under the United States Food, Drug and Cosmetic Act(21 USC 301 et seq. as now or hereafter amended) without a prescription, nor shall any rule or regulation be adopted by the board under the provisions of this act which shall require the sale of nonprescription drugs by a licensed pharmacist or in a pharmacy or otherwise apply to interfere with the sale or distribution of such drugs. (1983, Ch. 414, Sec. 27.)

10/85
PA/LRS

Wisconsin SB 295
Assembly Sub. 1

1985-86 Legislature STATE OF WISCONSIN LRBs0400/3
JM:bt

ASSEMBLY SUBSTITUTE AMENDMENT 1

TO 1985 SENATE BILL 285

January 23, 1986 - Offered by COMMITTEE ON COMMERCE and CONSUMER AFFAIRS.

AN ACT to amend 448.01 (11), 453.04 and 453.07; to repeal and recreate chapter 450; and to create 447.07 (3) (L) of the statutes, relating to revising the statutes governing the pharmacy examining board, granting rule-making authority and providing penalties.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 447.07 (3) (L) of the statutes is created to read:

447.07 (3) (L) A violation of ch. 161 or 450.

SECTION 2. 448.01 (11) of the statutes is amended to read:

448.01 (11) "Unprofessional conduct" means those acts or attempted acts of commission or omission defined as unprofessional conduct by the board under the authority delegated to the board by s. 15.08 (5) (b) and any act by a physician or podiatrist in violation of ch. 161 or 450.

SECTION 3. Chapter 450 of the statutes, as affected by 1985 Wisconsin Act 56, is repealed and recreated to read:

CHAPTER 450

PHARMACY EXAMINING BOARD

450.01 DEFINITIONS. In this chapter:

~~(b) The board may not adopt any rule which limits to a pharmacist the authority to sell in any way interferes with the sale of nonnarcotic nonprescription drugs that are prepackaged for consumer use and labeled in compliance with all applicable state and federal laws.~~

450.03 PHARMACIST; LICENSURE. (1) No person may engage in the practice of pharmacy or use the title "pharmacist" or sell, give away or barter drugs unless the person is licensed as a pharmacist by the board. This subsection does not apply to:

(a) The offer to sell or sale of contraceptive articles, as defined under s. 450.16 (1), by a professional nurse registered under s. 441.06.

(b) The sale of any nonprescription drug product, in an original unbroken package, which complies with 21 USC 301 to 392.

(c) The sale of pesticides which comply with ss. 94.67 to 94.71.

(d) The delivery of complimentary samples of drug products or devices to a practitioner by a manufacturer or its agent acting in the usual course of business.

(e) Any person lawfully practicing within the scope of a license, permit, registration, certificate or certification granted to practice professional or practical nursing or nurse-midwifery under ch. 441, to practice dentistry or dental hygiene under ch. 447, to practice medicine and surgery under ch. 448, to practice optometry under ch. 449 or to practice veterinary medicine under ch. 453, or as otherwise provided by statute.

(2) The board shall issue a license as a pharmacist to any person who files satisfactory proof of qualifications under s. 450.04 (3) and passes the examination under s. 450.04, except as provided under s. 450.10.

450.04 EXAMINATIONS. (1) Examinations for licensure as a pharmacist shall be designed to determine whether an applicant is competent to engage in the practice of pharmacy.

(2) Examinations shall be conducted at least semiannually.

State of Alaska

COMMITTEES
HOUSE HEALTH, EDUCATION
AND SOCIAL SERVICES
(Co-Chairman)
HOUSE JUDICIARY
HOUSE COMMUNITY AND
REGIONAL AFFAIRS

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Representative Max F. Gruenberg, Jr.
District 11
Spenard, Upper Midtown Anchorage

March 7, 1986

Ms. Betzi Woodman
3001 Widgeon Lane, Unit 8
Anchorage, Alaska 99508

RE: House bill 641

Dear Ms. Woodman: Betzi

Thank you very much for your letter of February 25, on the above legislation, copy enclosed. As you can see, this bill contains several provisions relating to the use of generic drugs. It will change current Alaska law to provide that generic drugs may be dispensed unless the prescription prohibits them. Under current Alaska law, they may not be dispensed unless the prescription specifically allows them. Second, the bill revives previous Alaska statute, which requires pharmacies to post notices that generics may be dispensed at a lower cost than brand name drugs. Third, the bill provides that a person dispensing generic drugs incurs no greater liability than he would for dispensation of a named brand drug.

This bill will be heard in the House HESS Committee, Room 112, Wednesday, March 12, 1986, at 4:30 pm. The hearing will be teleconferenced to Anchorage. If you would like to testify, you can do so by attending the hearing at the Legislative Information Office at 1024 W. 6th Ave, Anchorage, on the ground floor. I invite you to testify if you care to.

Again, thanks for writing. I found the article extremely interesting and will retain it in the bill file for use during the hearings and debates.

I hope you continue to correspond on issues of importance. Your advice is very much appreciated.

Cordially,

Max F. Gruenberg, Jr.

MFG/ddl

Enclosure

Betzi Woodman
3001 Widgeon Lane Unit 8
Anchorage, Alaska 99508

Betzi Woodman *Free Lance Writer/Photographer*

*Alaska Correspondent for:
Reuters News & Economic Services
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Feb. 25, 1986

Rep. Max F. Gruenberg, Jr.
Alaska State Legislature
Pouch V (MS 31100)
Juneau, AK 99811

Dear Reb. Grúenberg:

Noted your bill, HB 641 and thought the enclosed would be of interest to you. As you can see, there could be opposition by brandname manufacturers who believe a generic sale is an inroad into their market share.

I approve of your bill--what I've read about it. I have not read the bill itself yet, but as a senior citizen I would find it more hopeful to be able to get a generic product at less than the brand name cost. I shudder every time I see on TV the intense hardsell for the across the counter items--and it might be true that the manfacturers put pressures on pharmacists to use the name brand.

Sincerely,

Betzi Woodman

GENERIC VS. BRANDNAME DRUGS

The battle between brandname and generic manufacturers in the $16 billion/year prescription drug industry in the U.S. has erupted into a brawl. The Food and Drug Administration (FDA) has ordered Sandoz to correct unfair product promotion. It has singled out Pfizer, Abbott Laboratories, G.D. Searle and Berlex for unfair promotion and is currently investigating Ayerst Laboratories. Mylan Laboratories (Morgantown, W.Va.) is suing Sandoz in federal court for "false and misleading" statements. And Representative Henry Waxman (D., Calif.), chairman of the House subcommittee on health and environment, is planning hearings this spring to investigate the brandname "whispering campaign that generics aren't safe and effective."

Indeed, Waxman says the campaign is "purely an economic ploy to protect market share." And Judith I. Brown, health analyst for the American Assn. of Retired Persons (Washington, D.C.), calls it "despicable."

Inroads. The generic industry maintains that brandname makers are waging an unrelenting campaign. "It's virulent and ongoing and will exist as long as generics make inroads into brandname market share," says Jacob M. Schein, chairman and chief executive officer of Schein Pharmaceutical (Port Washington, N.Y.). And Harold Snyder, president of Biocraft Laboratories (Elmwood Park, N.J.), adds that each day the brandname companies "hold us back, they make more money." Dee Fensterer, president of the Generic Pharmaceutical Industry Assn. (New York City), attributes the brandname companies' promotion tactics to their quest for "the almighty dollar."

The brandname industry denies such a campaign. Gerald J. Mossinghoff, president of the Pharmaceutical Manufacturers Assn. (Washington, D.C.), flatly denies a "disinformation campaign." Individual companies are simply attempting to protect market share at the "time they're threatened," says La. R. Versteegh, Searle's director for regulatory affairs. And Paul Miller, Pfizer's associate general counsel, calls it a "difference of opinion over specific products and testing."

FDA also denies the existence of a concerted campaign. Brandname companies have not "banded together to wipe out the generic industry," says Peter H. Rheinstein, director of the agency's office of drug standards at Rockville, Md. The recent barrage of regulatory offenses by brandname companies, he says, is a function of the Drug Price Competition and Patent Term Restoration Act (DPCPTRA) of 1984, which allowed more generic products faster market access. What appears to be an industry-wide effort, says Rheinstein, is no more than a number of companies "independently but simultaneously" attempting to protect market share. That attempt has certainly included "aggressive promotion" by brandname companies, promotion that has tested the "limits FDA will allow," says Rheinstein.

But Rheinstein also has seen generic companies occasionally push FDA limits. That brandname makers appear to have committed more offenses, Rheinstein says, may simply reflect the fact that "brandname companies advertise more in places where FDA sees the ads." Brandname companies generally advertise in national trade publications, says Rheinstein, while generics often use direct mail and catalogs that FDA is "less likely to see."

'Many hats.' Rheinstein also points out that brandname companies are heavily involved in generics. Eli Lilly is the largest generic manufacturer in the U.S., he says, and SmithKline Beckman and Warner Lambert's Parke-Davis Div. also are major producers. Schein Pharmaceutical's Schein adds that brandname companies "wear many hats and have many faces." They advertise against generics, he says, but they also deal with generic companies in joint ventures and manufacturing.

Another FDA official who has essentially the same view as Rheinstein is Kenneth R. Feather, chief of the drug advertising regulation branch at Rockville, Md. He agrees that each company is attempting to protect its market. The driving force, he says, is "economics."

Feather also says that on a "few occasions" generic companies have "said something improper" about brandname products. But he adds that such tactics are unusual in the generic industry. "They're not trying to protect," he says. "They're trying to open the market."

Unquestionably, the generic market is growing. Generics had a 22.7% share of the 1984 prescription drug market, which brought them sales of $3.6 billion. That is projected to increase to a 25.6% share in 1989,

The post patent market for generics

Company	No. of products losing patent protection by 1989	Estimated 1984 sales (billion dollars)
Merck	13	$847
Lilly	10	839
American Home	7	557
Pfizer	8	542
Roche	3	395
SmithKline	2	363
Upjohn	5	363
Bristol-Myers	8	255
Johnson & Johnson	2	199
Warner-Lambert	4	137
Syntex	4	125
Searle	3	121
Schering-Plough	6	109
Abbott	2	102
Sandoz	3	102
Boehringer	2	101
Robins	1	68
Erbamont	1	68
Ciba-Geigy	3	58
Beecham	1	55
Boots	2	45
Merrell Dow	4	42
Glaxo	1	40
Burroughs	1	35
Squibb	1	34
Marion	1	28
American Cyanamid	2	28
Carter-Wallace	1	25
Smith Labs	1	20
Du Pont	1	17
Sterling	1	10
Total	104	$5.7

Source: David F. Saks.

epichlorohydrin, 8,000-10,000 m.t., is imported. The new unit will fill that demand and export the balance of the epoxy resin produced.

Salgema's expansion project has taken several years to get off the ground. The company received approval four years ago from Brazil's industrial planning agency, Conselho de Desenvolvimento Industrial (CDI) to start work on the complex. However, construction was delayed by a strong lobbying effort by environmentalists, who complained that the expansion would bring industrial activity too close to the growing residential areas of the city of Maceió.

The environmentalists blocked approval by regional authorities until changes were made in the plans for the complex. The most significant alteration required Salgema to build a greenbelt around the industrial area that would serve as a public park for the city. Once Salgema agreed to the changes, late last year, the $270 million expansion program was allowed to proceed.

Limited supply. One potential operating problem for the new complex is its limited ethylene supply, currently at 60,000 m.t./year, from an alcohol-fed plant at the Maceió site. An additional 40,000 m.t./year of the feedstock will have to be shipped to Maceió from Triunfo or Camaçari. Recently, Companhia Petroquimica do Sul (Copesul) announced plans to increase its olefins capacity at Triunfo by 25% (*CW, Feb. 5, p. 36*). The additional ethylene to be produced by Copesul could serve Maceió's estimated needs for a time. However, that may not provide long-term help, or even be available, since downstream expansions slated for Camaçari probably will consume the additional olefins.

Helio Meirelles Cardoso, former coordinator for CDI's chemical industry section, says that planners at the Maceió complex could take two different tacks to increase ethylene supplies. One would be to build a natural gas separation plant to produce ethane and methane streams. Apart from providing the raw materials for ethylene, Cardoso says, that could be the base for a host of plants for other products, such as methylene chloride, chloroform and carbon tetrachloride.

The other approach would be to build a plant similar to the existing alcohol-fed unit at Maceió. That project, Cardoso predicts, will become feasible if Brazil fails in its current attempts to land sizable long-term contracts for the sale of its surplus alcohol to the U. S.□

PAUL LYONS in Rio de Janeiro, with Paula M. Block

A bare-knuckles fight

or sales of $8.3 billion, according to Frost & Sullivan (New York City) in a new study, "Generic Drugs." In fact, recent FDA approval of generic versions of Hoffmann-La Roche's Valium diazepam alone, according to the study, should add $15-25 million to 1986 sales.

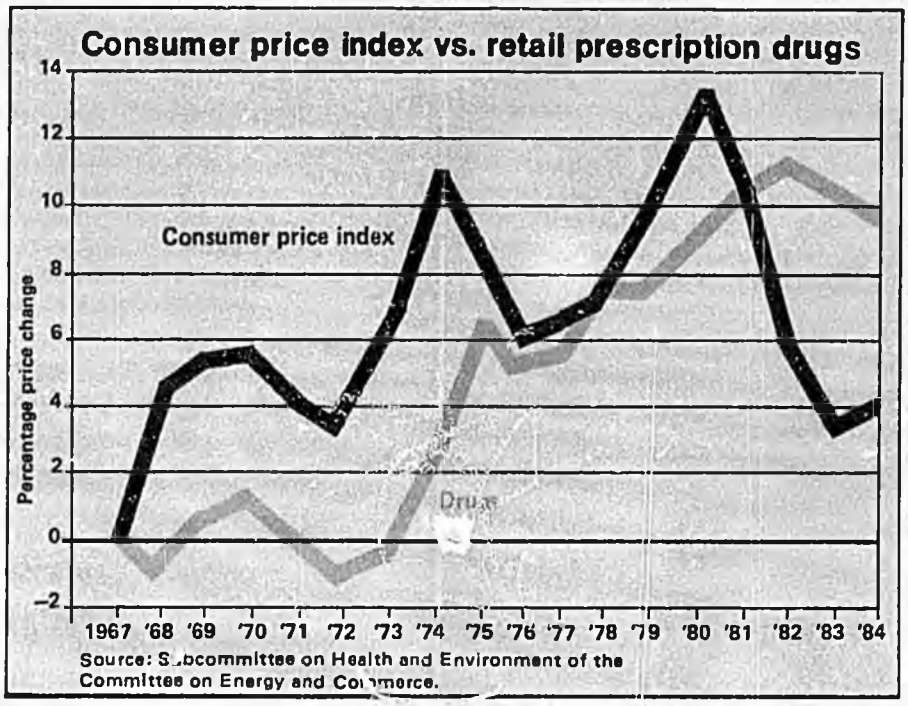
Others, however, believe that the generic market is even larger. Its share of the prescription drug market should expand to about 50% by 1990, says David F. Saks, senior vice-president for drugs, research and investment at Morgan Olmstead Kennedy & Gardner (New York City). Further, a "large reservoir" of 104 drugs, with sales of $5.7 billion, will come off patent by 1989, making them available for generic manufacture and sale, Saks says (*table, p. 28*). He adds that virtually all the top 100 U. S. prescription drugs will be subject to generic substitution within five years.

And Hemant K. Shah, vice-president for research at Nomura Securities International (New York City), sees the groundwork that generics have thus far laid as enabling more rapid market penetration. Such penetration could exceed 30% during the first year, he says.

Just how fast a generic can penetrate the market is demonstrated by Zenith Laboratories (Northvale, N. J.). Its tolazamide, used to stimulate insulin production in diabetics, is a generic form of Upjohn's Tolinase. In its first year, Zenith's product captured 50% of the unit market share, says James O. Leonard, Zenith's president and chief executive officer. He predicts 60% penetration this year and 80% longer term.

Big savings. A big attraction of generics is that they permit substantial savings for users. In 1984, consumers saved $130-236 million, or about 25% per prescription, reports the Federal Trade Commission in a new study entitled "Generic Substitution and Prescription Drug Prices." However, substitution occurred only about 15% of the time, says the study; the Frost & Sullivan study puts substitution at 22%.

Brandname drug prices, moreover, have risen sharply. After rising at rates below the consumer price index for a number of years, drug prices have recently soared (*graph, above*). While the consumer index rose 23% from January 1981 to June 1985, drug prices shot up 56%. Says Representative Waxman: "One can only conclude that what is going on in this industry is greed on a massive scale."



Certainly, pharmaceutical companies have consistently maintained higher profit rates than other U. S. manufacturers (*graph, p. 30*). From 1967 to 1984, after-tax profit per sales dollar for all U. S. manufacturing averaged 4.8%/year; profits for pharmaceutical companies averaged 11.5%/year, with the figure topping 13% in five of the past six years. Drug companies generally can maintain or increase sales even when raising prices, says Waxman, because of the "relatively inelastic demand" for most drugs and the ability to control prices of patented drugs. Waxman adds that, while drug companies say they have raised prices to finance research, there is concern whether prices have risen "far in excess of what is needed to support even the most lush and comprehensive" research budgets.

The campaign 'will exist as long as generics make inroads into brandname market share'

Waxman is one of the authors of DPCPTRA. That act, under certain circumstances, extends the 17-year period under which a new drug is protected by patent and, therefore, cannot be copied. To compensate for delays in regulatory approval, the act permits patent extension of up to five years, but it imposes a 14-year limit for exclusivity.

The law also speeds up approval of generic versions of drugs for which patents have expired. It allows use of abbreviated new drug applications (ANDA) for drugs with patents that expire after 1962. ANDA is a much simplified approval process for off-patent drugs. It requires only bioavailability and good manufacturing practice information, rather than full-blown clinical trials. Prior to DPCPTRA, ANDAs were permitted only for drugs that went off patent before 1962.

Armistice? In essence, by eliminating the requirement for new clinical trials, the act removed a huge financial barrier to generic manufacturers. In addition, as Waxman declared after the act took effect, the "war between generics and brandnames is over.'

Actually, the war is far from over. Brandname and generic companies are still battling ferociously, with attacks by brandname makers generally focusing on FDA's bioequivalency standards. Bioequivalency is determined predominantly on the basis of bioavailability, the extent to which a drug is available to the target tissue after administration. However, because measurement at

the precise target is impractical, bioavailability is determined by the measure of drug concentration in the blood plasma. FDA uses bioavailability tests in comparing generic and brandname drugs of the same strength and dosage.

Yet the agency allows blood level variations of 30% between equivalent drug products, because of physical differences between people and varied individual responses to the same drug. Such variations, FDA says, produce no clinically detectable differences. In fact, variations are observed from pill to pill in brandname products, says Shrikant V. Dighe, FDA's director for the division of bioequivalency at Rockville, Md. "Exactly the same" bioequivalency standards are applied to both generic and brandname products, says Dighe.

Bioequivalency. Indeed, bioequivalency sparked the flare-up between FDA and Sandoz, which lasted more than two years and ended in a corrective letter from Sandoz. The dispute centered on a Sandoz promotion campaign for its Mellaril thioridazine, a phenothiazine used to treat psychosis. FDA characterized the campaign as an attempt to "discredit competing thioridazine products without scientific basis" and called it a "flagrant, repeated and willful" violation of the Food, Drug and Cosmetic Act (FDCA). It threatened to seize misbranded products and issue an injunction to prevent future violations.

Sandoz, FDA said, was promoting the belief that substituting generic thioridazine would result in clinical failures. Among others, it cited a Sandoz ad that stated: "Different thioridazines given at the same dosage may produce widely varying blood levels in some patients." FDA insisted that Sandoz qualify those claims by stating that such variations were not clinically significant and that Mellaril produced similar blood level variations.

Lockout. For its part, Sandoz maintained that it had not said that generic thioridazine was less safe and effective. And it requested that all thioridazine products, including its own, be rated "BP" because of potential problems from interchange. A BP rating—which states that products are equally bioavailable but not bioequivalent—does not allow interchanging of products. However, such a rating would, "in effect, lock in Mellaril and lock out generics," says FDA's Feather. Sandoz also cited 66 reports of adverse drug reactions as evidence of clinical problems associated with interchanging thioridazine.

FDA stated that Sandoz's contention of bioinequivalence was unfounded and that adverse reactions to thioridazine are "far from unique to generic products." It cited 154 cases of such adverse reactions, of which 118 occurred in patients on Mellaril, compared with 36 in those on generic thioridazine. FDA concluded that the reactions were indicative of problems with the entire class of phenothiazines, specifically thioridazine.

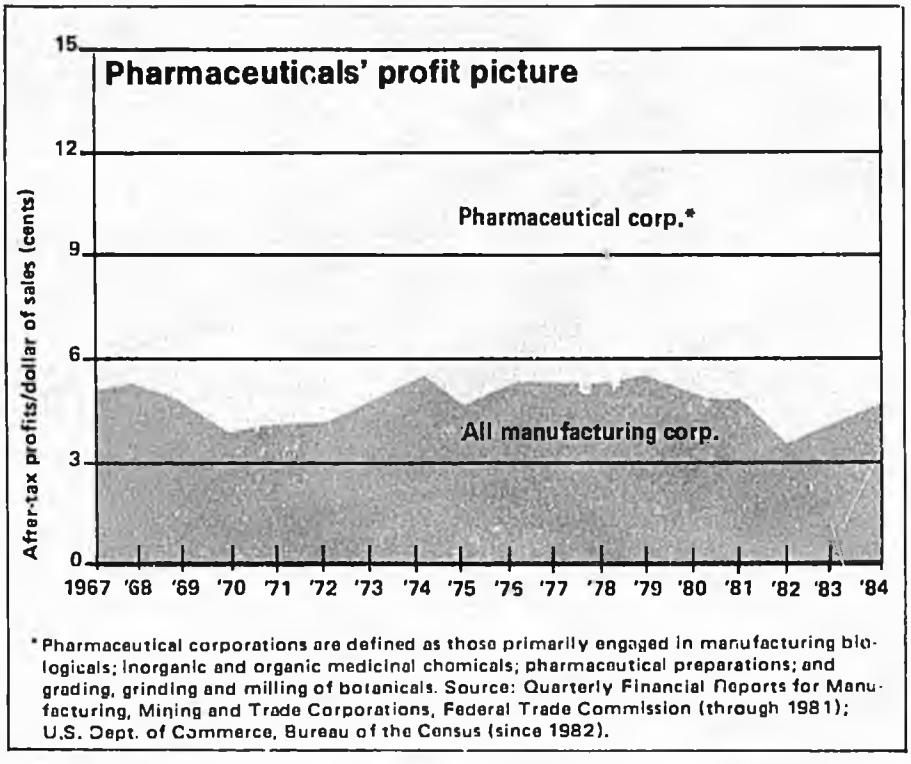
Sandoz also said that a "Dear Pharmacist" letter that it had written in May 1985—for which FDA specifically demanded corrective action—did not create a "market imbalance," as FDA said. The company cited an independent report that showed that the decrease in Mellaril's share of total thioridazine prescriptions actually accelerated in the four months following the letter. It also cited a similar "Dear Pharmacist" letter written by a "manufacturer of a brandname drug," following which no corrective action was demanded.

FDA responded that it had objected to a Pfizer letter about Diabinese chlorpropamide but that Pfizer immediately stopped all "such practices." That and the absence of any history of Pfizer's "engaging in related similar activities such as we have cataloged for Sandoz," were the reasons FDA did not demand corrective action.

Exception taken. The agency also took exception to Sandoz's claim that its "Dear Pharmacist" letter had no market impact. "Your activities," said FDA, "could just as legitimately have been construed as having been successful enough to have held down the generic share to a lower level than it would have normally reached."

Sandoz then said it would conduct "additional" clinical studies as "appropriate," and it issued a corrective letter to pharmacists and company sales representatives. The letter stated that Sandoz was "not aware" of any trials that demonstrated clinical difference in patient response to Mellaril and generic thioridazine. It said that persons using Mellaril exhibit blood level variations comparable with those "observed in [patients] using certain generic products," adding that no known significance was associated with these variations. Sandoz concluded by saying that its letter of May 1985 was sent in "good faith" and was not intended to "criticize or demean" generic thioridazine.

Although Pfizer's earlier wrangle with FDA did not result in corrective action, it did generate some heated exchanges. FDA expressed concern that an "apparent chance issuance" of three February 1985 promotional actions for Diabinese chlorpropamide, which controls blood sugar levels in diabetics, was "more than random chance." The actions included a "Dear Doctor" letter providing a form to report adverse reactions to chlorpropamide; a "Dear Formulary Committee" letter sent to the Illinois Dept. of Public Health suggesting superiority of Diabinese over gener-



* Pharmaceutical corporations are defined as those primarily engaged in manufacturing biologicals; inorganic and organic medicinal chemicals; pharmaceutical preparations; and grading, grinding and milling of botanicals. Source: Quarterly Financial Reports for Manufacturing, Mining and Trade Corporations, Federal Trade Commission (through 1981); U.S. Dept. of Commerce, Bureau of the Census (since 1982).

ic chlorpropamide; and several petitions supporting Diabinese from physicians to the state formulary committee .

FDA objected most strongly to the "Dear Formulary Committee" letter. The agency held that it contained claims that could "misleadingly suggest" that generic chlorpropamide could result in clinical failures. Two statements particularly irked FDA:

- Pfizer said that generic chlorpropamide does not conform to bioequivalence standards established by Pfizer for Diabinese. It failed to mention, however, said FDA, that "minor differences from your standards," while still meeting FDA requirements, will have "very little or no clinical impact."
- Pfizer said that its excipients in Diabinese are compendial grade, which, said FDA, can imply that excipients in generics are "something less." FDA pointed out that it requires compendial-grade excipients for all generic chemicals.

Stopped. FDA concluded that the "entire" letter was "without basis and an attempt to falsely malign" both the generic industry and FDA. It ordered the "practice" stopped, adding that continuation would "misbrand" Diabinese.

Concerning the petitions from Illinois physicians, FDA said that letters sent by certified mail from physicians in different cities were stamped with consecutive serial numbers. It added that many of the petitions were "virtually identical and even appear to be prepared by the same word-processing facility." The agency concluded that an "organized effort is behind this entire matter."

Pfizer responded that its sales representatives did approach physicians. However, the doctors wrote their own letters, Pfizer said, although sales reps supplied them with addresses and statutory citations and collected and mailed the letters "as a courtesy."

Pfizer also stated that it has "genuine concerns" about FDA's approval of generic chlorpropamide. As a result, it is studying diabetic patients controlled with Diabinese at the University of Washington (Seattle). This action, comments Pfizer, "resolved the issue."

FDA also locked horns with Abbott on the matter of brandname vs. generic drugs. Although it demanded corrective action over promotion of Abbott's antibiotic EES-400 erythromycin ethylsuccinate, FDA later backed down.

The objection concerned an Abbott letter, dated August 1985, to the Virginia Dept. of Health. The letter, said FDA, was "obviously an attempt" to keep generic erythromycin produced by Barr Laboratories off the Virginia formulary. The agency considered the letter labeling under FDCA, calling it "so obviously misleading that we should be obligated to initiate regulatory action."

In the letter, Abbott stated that serum concentrations from bioequivalence

'Brandname companies advertise more in places where FDA sees the ads'...

studies of Barr's product were "unduly low," adding that this could be due to "inadequacies in assay methodology." Abbott supported this contention by citing a 1981 FDA inspection that found deficiencies in "validation and conduct of erythromycin microbiological assays" conducted by Harris Laboratories, which performed Barr's bioequivalence study. The FDA inspection was conducted after the study comparing Barr's erythromycin with Abbott's. "Therefore, it must be assumed," said Abbott, "that there were deficiencies in the erythromycin assays for this study."

FDA said that this assumption was "false." It added that Abbott failed to state that the deficiencies were eventually determined by FDA not to affect acceptability of the erythromycin study.

'Faulty.' Abbott said that it continued to believe the bioequivalence assay "faulty," adding that because FDA held the assumption false, "does not require that we share that same conclusion." Further, it disagreed "strongly" that its letter constituted labeling, as it was not "upon" or "accompanying" the drug as FDCA requires. Abbott, moreover, refused to take corrective action.

FDA responded that it maintained its "stated position" on the definition of labeling, but added, "we will consider this to be a closed issue." FDA and Abbott "agreed to disagree," comments Donald Hudson, Abbott's director of regulatory affairs. He adds that the question of what constitutes labeling is a "legal

...while generics often use direct mail and catalogs that FDA is 'less likely to see'

issue that only the courts could decide."

In a recent action, FDA is taking a hard look at Ayerst Laboratories, a division of American Home Products, concerning a "Dear Pharmacist" letter dated last month. The letter reminded pharmacists that Inderal propranolol, a drug for hypertension, is the only propranolol indicated to reduce mortality following myocardial infarctions [MI]. It addressed the "potential liability" that could result from substituting generic propranolol for this indication.

The issue has not been "resolved in the courts," said the letter, adding that it is not "possible to determine, in advance, the outcome of a suit which may arise from such a situation." The letter continued: "It is clear, however, that litigation is troublesome, expensive and will generate adverse publicity. Although some generic product manufacturers may be willing to indemnify for monetary awards, no company could adequately compensate you for the trouble and negative publicity that may result from a court case."

The letter concludes that Ayerst believes that "consistent with prudent pharmacy practice, you will want to dispense Inderal tablets, the only propranolol product with the approved indication for reduction of mortality post-MI."

No threat is intended by the letter, comments Marvin A. Heuer, Ayerst's medical director. The sole intent, he says, is to "spell out" that Ayerst has done the study for the indication, while the "generics haven't." Heuer adds that the study cost Ayerst almost $4 million and that, although the "point of contention is technical," Ayerst "should be able to say something about it."

Exclusivity. The contention turns on a point in the new law. Generic propranolol cannot carry the indication because of a two-year exclusivity rule in DPCPTRA. Under that rule, any new use approved between Jan. 1, 1982, and Sept. 24, 1984—the date the law was enacted—gets two years without competition. The provision was a "last minute political compromise made in the Senate," says Waxman. Its intent was to protect companies that spent funds for approval of new uses shortly before the law took effect.

Waxman does not believe pharmacists would be liable. Generic propranolol is "therapeutically equivalent" for all Inderal indications, he says, and will be so labeled, beginning Sept. 24, 1986, without any change in the generic product. He adds that because so many pharmacists are "concerned," he will attempt to clarify the issue at his upcoming hearings.

But just how much Waxman's hearings can accomplish in cooling the war between generics and brandnames is moot. That war, says FDA's Feather, "won't go away as long as the generics don't go away." □

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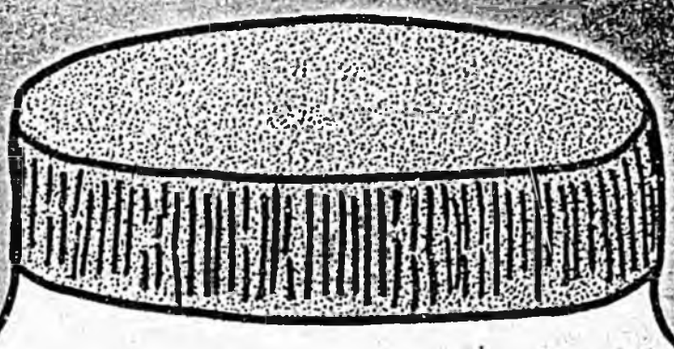


Rx How to purchase drugs at less cost

Cutting the cost of prescription drugs is important to Mary J. Newcomb, a Juneau senior.

Newcomb routinely takes prescription medication for diabetes, high blood pressure and arthritic pain. Her monthly drug bill added up to $72.

Two of the three medications Newcomb takes are available generically at a Juneau pharmacy. (The generic name refers to the drug's chemical make up while the brand name is chosen by the manufacturer.)

By taking these two generic prescription drugs, Newcomb monthly prescription drug costs would drop to $52.

Newcomb (not her real name) now orders all three medications in a generic form from the American Association of Retired Persons' pharmacy in Portland, Oregon.

Her monthly prescription drug bill is now $25, a savings of 65 percent.

Buying generic prescription drugs can save seniors money. Savings of up to half are common when generics are purchased.

William Larson, a member of the Alaska State Board of Pharmacy and pharmacy director for Carrs Quality Centers, said the main reason seniors should consider using generics is because of the cost savings.

"Anyone on a fixed income would benefit."

Customers at Carrs, an Anchorage area food and drug store chain, are encouraged to purchase generic prescription drugs, Larson said.

While the cost savings available when generics are purchased have been established, some seniors are reluctant to use them.

They sometimes think generics aren't as good as brand name prescription drugs.

The Food and Drug Administration's position on generics, however, is that they are equivalent to brand name drugs.

"FDA believes that the prescribing of generic drugs can offer consumers an opportunity to cut the costs of their health care while assuring that

Continued on page 12

GENERIC

"There are not two classes of medicines on the market. There is only one class and it is safe and effective."

FDA encourages consumers to talk to their doctors and pharmacists about obtaining generic drugs.

If a generic is therapeutically equivalent (has the same effect in controlling or curing a condition), it can be prescribed instead of a brand name drug.

Pharmacy law unclear

"Generic" can be a magic word leading to substantial savings when buying prescription drugs.

In Alaska, however, the state law allowing substitution of generics for brand name prescription drugs has a number of stumbling blocks for the potential generic purchaser. These pitfalls could prevent some seniors from realizing the financial savings available from generics.

Problem one: Pharmacists are not required to post a sign in the pharmacy letting consumers know an equivalent but less expensive drug may be substituted for the drug prescribed by their doctor.

Such signs inform consumers about generics and them of possible sav ch time they go to a pha .

The signs were required here in 1976 for a two-year period. The generic substitution law, originally passed in 1972, was amended at that time to include details on how substitutions should be made.

Problem two: Alaska's substitution law is not clear on what should be preprinted on prescription order forms, which prescribers have printed for themselves.

One section states the forms should have two boxes labled "dispense as written" and "substitution allowed" for prescribers to check each time they fill out a form.

However, another section gives prescribers the option of checking or initialing a box or handwriting the prescription order.

"It is truly confusing," said Diane C lvin, assistant attorney general for the Alaska's Department of Law. "You try to put the pieces together and it doesn't fit."

Colvin said the law needs to be amended. "What we have here is a badly drafted statute that should be revised."

Many physicians in Alaska do not have boxes on their preprinted forms.

If boxes are printed on all prescription blanks, physicians might consider the possibility of prescribing a generic each time they fill out a blank.

Physicians tend to think in terms of brand names when prescribing drugs because drug companies promote their products heavily and because brand names are easier to remember.

Problem three: Alaska's generic drug law discourages the substitution of generics.

In Oregon, a pharmacist is allowed to substitute a generic if there is nothing written on the prescription form that prohibits it, said William Frenzel, chief pharmacist for the Oregon Retired Persons Pharmacy, located in Beaverton, Oregon.

Not so in Alaska. If there is nothing about substitution on the prescription form, the pharmacist cannot substitute a generic unless he or she takes the time to call the physician for permission.

Buying generic drugs can save seniors money

Continued from page 11

the products they use meet the same FDA standards as brand name drugs for safety, strength, purity and effectiveness," the agency reported in the June 1979 issue of FDA Consumer.

"Consumers have been misled and are paying a lot more to the well established firms for prescription drugs when generics could be used," said Edward Nida, spokesperson for FDA, in a telephone interview from his Rockville, Maryland office.

"There are not two classes of medicines on the market. There is only one class and it is safe and effective."

FDA encourages consumers to talk to their doctors and pharmacists about obtaining generic drugs.

If a generic is therapeutically equivalent (has the same effect in controlling or curing a condition), it can be prescribed instead of a brand name drug.

Dr. Thomas P. Senter, president of the Anchorage Medical Society, said his organization's position on generic prescription drugs is the same as the American Medical Association's.

"For some people, generic drug use is fine; for others it's not. It's left to the discretion of the individual doctor."

Dr. LouAnn Feldman, a physician for the Anchorage Neighborhood Health Center, said she prescribes generics if they contain the same basic ingredients and if they are absorbed as rapidly as the brand name product.

"Most generics are OK," Feldman said.

Larson agrees. Generics must pass "pretty strict criteria (under state law) to be allowed in Alaska," Larson said.

However, Jacki Warren, president of the Alaska Pharmaceutical Association and a pharmacist for Providence Hospital, has reservations about generics.

Seniors should use caution when making decisions about generics and rely on the advice of their health care professionals, usually physicians and pharmacists, she said.

Warren thinks generics sold by large companies like Lederle Laboratories, Parke Davis and E.R. Squibb, companies that have developed brand name drugs, are better quality than generics sold by generic houses.

But FDA's Nida doesn't agree. "Generics are frequently not made by the large pharmaceutical firm whose name is on it."

"Some of the little firms make drugs for the big ones and vice versa," Nida said. "The products come from the same production lines."

Savings for consumers on generics from brand name houses are not usually as great as from companies specializing in generics.

While the pros and cons of using generics are still being debated, more people are buying generics prescription drugs each year. (See article Page 12)

The American Association of Retired Persons (AARP) encourages its members to buy generics.

The organization has 10 pharmacies throughout the U.S. and Alaska members can order prescriptions from AARP's Oregon Retired Persons Pharmacy, P.O. Box 2755, Portland, OR 97208.

Consumers can save money by asking for generic prescription drugs and comparing prices available from mail order firms, chain drug stores and neighborhood pharmacies.

nacy law unclear

by mail, checking or initialing a box or

How to save on drugs

- Check with your pharmacist to see if any of the medications you are now taking are available generically.
- Ask your physician to prescribe generic drugs when possible.
- Compare prices when buying prescription drugs and over-the-counter drugs.

gs in U.S.

30, nd nts. patent time remaining after FDA approval plus the extension may not be more than 14 years.

In congressional testimony, the American Association of Retired Persons (AARP) questioned the advisibility of extending patents.

"Though AARP is of the opinion that extension of brand name drugs' patent terms is unnecessary and undesirable, we realize that compromise is necessary in order to achieve a broad base of support essential for passage of this legislation," AARP officials said.

Just how big the growth of generics will be by the end of the decade is not known, but one thing is certain.

It's worthwhile for seniors to check to see if they can save money by using generic prescription drugs. (See main story page 1.)

patents

Patent expires 1985 Brand name	generic
Valium	Diazepam
Motrin	Ibuprofen
Triavil	Amitriptyline HCl perphenazine
Ludiomil	Maprotiline HCl

Frequently prescribed generics

Generic name	Type of drug	Brand name
Acetaminophen w/Codeine	Analgesic	Tylenol w/Codeine
Amitriptyline	Antidepressant	Elavil
Amoxicillin	Antibiotic	Lanotid, Amoxil
Ampicillin	Antibiotic	Principen
Aspirin w/Codeine	Analgesic	Empirin w/Codeine
Chlordiazepoxide	Tranquilizer	Librium
Chlorpromazine	Psychogenic	Thorazine
Chlorthalidone	Antihypertensive	Hygroton
Diphenozylate w/Atropine	Antidiarrheal	Lomotil
Dipyridamole	Vasodilator	Persantine
Erythromycin	Antibiotic	Erythrocin
Conjugated Estrogens	Estrogen	Premarin
Folic Acid	Hematinic	—
Furosemide	Cardiovascular	Lasix
Hydralazine	Hypertensive	Apresoline
Hydrochlorothiazide	Diuretic	Hydrodiuril
Imipramine	Antidepressant	Tofranil
Isosorbide Dinitrate	Cardiovascular	Isordil
Meprobamate	Tranquilizer	Equanil, Miltown
Metronidazole	Antibacterial, Antiprotozoal	Flagyl
Nitroglycerin	Cardiovascular	Nitro-Bid
Papaverine	Muscle Relaxant	Payabid
Paregoric	Antidiarrheal	-----
Penicillin G	Antibiotic	Pentids
Penicillin VK	Antibiotic	Pen-Vee K, V-Cillin K
Phenobarbital	Sedative	Luminal
Phenytoin Sodium	Antiepileptic	Dilantin
Potassium Chloride	Supplement	-----
Prednisone	Steroid	Meticortelone
Promethazine	Decongestant	Phenergan
Propoxyphene Compound-65	Analgesic	Darvon Compound-65
Quinidine Sulfate	Cardiovascular	-----
Spironolactone	Diuretic	Aldactone
Spironolactone w/ Hydrochlorothiazide	Diuretic	Aldactazide
Sulfisoxazole	Urogenital antiseptic	Gantrisin
Tetracycline	Antibiotic	Achromycin V, Sumycin
Thioridazine	Antipsychotic	Mellaril
Tolbutamide	Antidiabetic	Orinase
Trimethoprim w/ Sulfermethoxizol	Antibiotic	Bactrim, Septra
Trifluoperazine	Antipsychotic	Stelazine

Adapted from Chain Drug Review

It's a new era for generic drugs in U.S.

It's a new era for generic prescription drugs in the U.S.

With a new federal law cutting approval time for generics and many brand name drugs losing their patent protection, an avalanche of generics is expected to flood the market, according to drug company analysts.

The use of generic prescription drugs has grown substantially since the early 1960s.

Generics accounted for 21 percent of all the dispensed prescriptions at the retail level in 1984 — 418 million out of 1.99 billion, according to the January 14 issue of *Chain Drug Review.*

While about half of the top 200 prescription drugs dispensed in the U.S. are available generically now, the number of generics on the market is expected to increase dramatically in the next few years.

A new law passed last year has streamlined the Food and Drug Administration application process for the marketing of generics.

Now, to get generic drugs approved, firms will have only to show FDA that a product is equivalent to an already approved drug in ingredients, routes of administration and therapeutic effect, Nida said. The costly testing that was needed for approval of the original drug will not have to be duplicated.

This simplified application procedure plus the fact that a number of major prescription drugs are coming off patent protection, makes it likely that hundreds of new generics will flood the market in the next few years.

Over the next two years, patents on some of the nation's largest-selling drugs, like Motrin and Valium, are expiring. By 1990, most all of the 50 top-selling brand name drugs will lose their patents.

When a drug's patent protection has ended, other companies can then manufacture it.

Patent protection usually lasts 17 years, but the new law that simplified the FDA generic drug application process also gave manufacturers of brand name drugs more patent protection for new drugs they develop.

Drug companies apply for patents as soon as they have a drug with some medical effect in test animals and in humans, Nida said. Later, they apply for FDA approval to sell the drug and that review process could take two years or more.

The new drug law passed last year allows the patent time to be extended up to five years. But the patent time remaining after FDA approval plus the extension may not be more than 14 years.

In congressional testimony, the American Association of Retired Persons (AARP) questioned the advisibility of extending patents.

"Though AARP is of the opinion that extension of brand name drugs' patent terms is unnecessary and undesirable, we realize that compromise is necessary in order to achieve a broad base of support essential for passage of this legislation," AARP officials said.

Just how big the growth of generics will be by the end of the decade is not known, but one thing is certain.

It's worthwhile for seniors to check to see if they can save money by using generic prescription drugs. (See main story page 1.)

Expirations due for brand name patents

Patent expired 1984

Brand name	generic
Inderal	Propranolol HCL
Aldomet	Methyldopa
Diabinese	Chlorpropamide
	Methyldopa w/ Hydrochlorothiazide
Ativan	Lorazepam
Dalmane	Flurazepam HCl
Navane	Thiothixene
Meclomen	Meclofenamate sodium
Serax	Oxazepam
Depakene	Valproic acid
Tinactin	(not available)
Restoril	Temazepam
Zaroxolyn	Metolazone
Dymelor	Acetohexamide
Megace	Megestrol acetate

Patent expires 1985

Brand name	generic
Valium	Diazepam
Motrin	Ibuprofen
Triavil	Amitriptyline HCl perphenazine
Ludiomil	Maprotiline HCl
Desyrel	Trazodone HCl
Intal	Cromolyn sodium
Nubain	Nalbuphine HCl
Yutopar	Ritodrine HCl

AMENDMENT

OFFERED IN THE HOUSE

TO HB 641

ADD A NEW SECTION TO THE BILL TO READ:

AS 08.80.030. POWERS OF THE BOARD is amended by adding a new subsection as follows:

(10) promulgate regulations regarding the activities of pharmacy technicians

POSITION PAPER/Department of Health & Social Services

POSITION PAPER
HOUSE BILL 641

I. PURPOSE OF HB 641

HB 641 has three primary objectives:

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

II. SECTIONAL ANALYSIS

SECTION I:

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

SECTION II:

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

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

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

Two minor language changes are recommended in Section II.

(1) Insert the words "in writing on a prescription" after the word "states" on line 15, page 1.

(2) Substitute the words "prescribed drug" for the word "prescription" on line 19, page 1.

POSITION PAPER/Department of Health & Social Services

SECTION III:

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

SECTION IV:

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

III. Department Position:

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

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

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

Recommended By: Rod Betit

Rod Betit, Director
Division of Medical Assistance

Date: 3/4/86

Approved By: John R. Pugh

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

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 Servic
BRU : Medical Assistance Non-Facility

Components : GRM Non-Facility

EXPENDITURES/REVENUES : (Thousands of Dollars)

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

FUNDING : (Thousands of Dollars)

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

POSITIONS :

FULL-TIME						
PART-TIME						
TEMPORARY						

ANALYSIS : Attach a separate page if necessary

The Department has submitted to the Governor an FY87 Budget Amendment of $2.5 million for an FY87 Pharmacy Program. One of the assumptions included in the amendment was the substitution of generic drug ~~products~~ for more expensive brand name products.

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

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

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

10/25/85

CSHB 885(Loans)

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

Chapter 161, SLA 1984

CSHB 716(L&C)

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

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

"Dear Mr. Speaker:

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

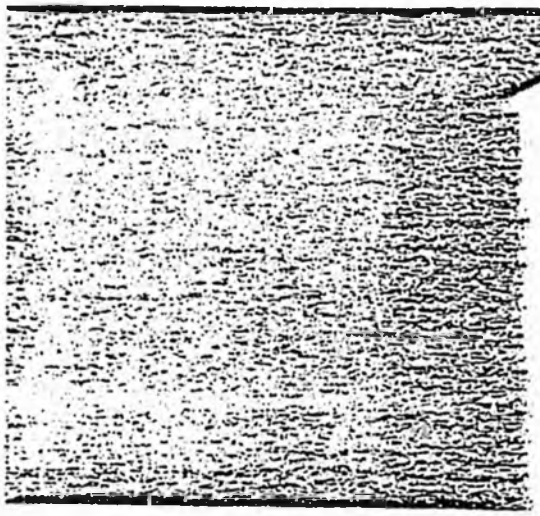
This bill would have authorized the Board of Pharmacy to hire its own executive secretary. This would have been an undesirable departure from the consolidation and uniformity of the occupational licensing system under AS 08.01. It would have set a disturbing precedent for other boards in securing autonomous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

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

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

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

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



CSHB 715(LSC)

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

Sincerely,

/s/

Bill Sheffield
Governor

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

July 20, 1983

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

Dear Commissioner Lyon:

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

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

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

Sincerely,

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

Ketchikan Medical Clinic, Inc.

2612 TONGASS
KETCHIKAN, ALASKA 99901

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

Phone 225-5144
Phone 225-5145

July 26, 1993

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

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

Gentlemen:

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

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

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

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

Sincerely,

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

TLC:dg

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

Ketchikan Medical Clinic, Inc.

3612 TONGASS
KETCHIKAN, ALASKA 99901

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

Phone 225-5144
Phone 225-5145

December 19, 1983

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

Gentlemen:

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

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

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

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

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

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

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

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

Sincerely,

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

TLC:dp

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

Interior Alaska Veterinary Medical Association

800 College Road

FAIRBANKS, ALASKA
99701

September 27, 1983

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

To Whom It May Concern:

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

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

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

Sincerely,

Kate Klause, D.V.M

Kate Klause, D.V.M
President IVMA

KK/mj

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

July 28, 1983

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

Dear Sir:

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

I would appreciate your letting me know what this means.

Yours sincerely,

Harriet J. Schirmer, M.D.

HJS:kaw

Susitna Valley Veterinary Clinic

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

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

August 12, 1983

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

Dear Sirs,

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

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

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

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

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

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

Valerie Shepard DVM
Board of Veterinary Examiners

Fairbanks Alternative
Placement Center

Detention
Furlough
Re-Entry

KILA, Inc.

Locally Controlled
Integrated and Coordinated
Human Services

Fairbanks Substance
Abuse Center

Education
Outreach
Prevention
Training
Treatment

3099 Airport Way
Fairbanks, Alaska 99701 5599
(907) 452 6972

December 16, 1993

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

Dear Mr. Miller,

I just recently came into possession of the proposed regulations promulgated by the Board of Pharmacy (as required by AS 17.30.010 as passed under SB 130).

I have no overwhelming opposition to the proposed regulations developing, but I do need to ask why it only costs $5/year to get registered with the feds and $10/year to get registered with the State of Alaska? Why is registration with the State deemed desirable? Why not just get a listing of those registered with the feds from the feds? I am concerned only because the need for such registration evades my reading of the proposed regulations. Section 11 AAC 02.415 (6) is already covered under federal law and regulations; why does the state need to engage in such realms?

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

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

Sincerely yours,

Frank J. Gold, EdD
Executive Director & Staff Psychologist

FJG:ss

cc: SCADA
Fairbanks Delegation

Article 1. Regulation of Manufacture, Distribution, Prescription, and Dispensing of Controlled Substances.

Section
10. Regulations
20. Registration requirements
30. Registration
40. Denial, revocation, and suspension of registration
50. Order to show cause
60. Records of registrants
70. Order forms; prescriptions
80. Unlawful administration, prescription and dispensation of controlled substances

Collateral references. — 25 Am. Jur. 2d, Drugs, Narcotics, and Poisons, §§ 7 et seq., 28 et seq.

Sec. 17.30.010. Regulations. (a) The Board of Pharmacy shall adopt regulations under the Administrative Procedure Act (AS 44.62) which are necessary for the administration of this chapter, and may charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances as authorized by federal law in the state.

(b) 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. (§ 4 ch 45 SLA 1982)

Cross references. — For penalty for furnishing false or fraudulent information in or omitting material information from any application, report, record, or other document required to be kept or filed under this chapter, see AS 11.71.040(a)(8). For penalty for failure to make, keep, or furnish any record, notification, order form, statement, invoice, or information required under this chapter, see AS 11.71.050(a)(4).

Editor's notes. — Section 24, ch. 45, SLA 1982 provides: "Orders issued and regulations adopted under a law amended or repealed by this Act and in effect on January 1, 1983, and not in conflict with this Act continue until amended or repealed."

Sec. 17.30.020. Registration requirements. (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.

(b) A person registered under this chapter to manufacture, distribute, dispense, or conduct research with controlled substances 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.

(c) The following persons may lawfully possess controlled substances under this chapter without registration:

(1) an agent or employee of a registered manufacturer, distributor, dispenser, or researcher of a controlled substance so long as the possession is incidental to the usual course of the agent's or employee's business or employment;

(2) a common or contract carrier or warehouseman, or the carrier's or warehouseman's employee, whose possession of a controlled substance is in the usual course of the carrier's, warehouseman's, or employee's business or employment;

(3) an ultimate user or a person in possession of a controlled substance under a lawful order of a registered practitioner or in lawful possession of a schedule VA controlled substance.

(d) The board may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if it finds it consistent with public health and safety.

(e) A separate registration is required for each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

(f) The board may inspect the establishment of a registrant or application for registration in accordance with regulations adopted by the board. (§ 4 ch 45 SLA 1982)

Cross references. — For penalty for refusal of entry into a premises for an inspection authorized under this chapter, see AS 11.71.060(a)(5); for schedule VA substance, see AS 11.71.180.

Sec. 17.30.030. Registration. (a) The board shall register an applicant to manufacture, distribute, or dispense controlled substances listed in the schedules established under federal law unless it finds that the registration would be inconsistent with the public interest. In determining the public interest, the board shall consider the following factors:

(1) maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable state and local law;

(3) a conviction of the applicant under federal or state laws relating to controlled substances;

(4) past experience in the manufacture, distribution, or dispensing of controlled substances and the existence in the applicant's establishment of effective controls against diversion of controlled substances

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(5) furnishing by the applicant of false information in an application filed under this chapter;

(6) suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and

(7) any other factors relevant to and consistent with the public health and safety.

(b) A practitioner registered under federal law to conduct research with controlled substances shall be issued a registration to conduct research with these substances in the state if the practitioner furnishes the board with evidence of the federal registration.

(c) A manufacturer, distributor, or dispenser who complies with federal law pertaining to registration requirements other than fees is entitled to be registered under this chapter. (§ 4 ch 45 SLA 1982)

Sec. 17.30.040. Denial, revocation, and suspension of registration. (a) A registration applied for or issued under AS 17.30.030 to manufacture, distribute, dispense, or conduct research with a controlled substance may be denied, suspended, or revoked by the board upon a finding that

(1) the registrant has furnished false or fraudulent material information in an application filed under this chapter;

(2) the registrant has been convicted of a felony offense under state or federal law; or

(3) the registrant's federal registration to manufacture, distribute, dispense, or conduct research with controlled substances has been denied, suspended, or revoked.

(b) The board may limit the denial, revocation, or suspension of a registration to a particular controlled substance with respect to which grounds for denial, revocation, or suspension exist.

(c) If the board denies, suspends, or revokes a registration, all controlled substances owned or possessed by the registrant at the time of the denial or suspension or the effective date of the revocation order may be placed under seal by the board or the Department of Public Safety and remain in the custody of the department, subject only to the orders and decrees of a court having jurisdiction over the property. A disposition may not be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. After a revocation order is final, all controlled substances held by the registrant are forfeited to the state.

(d) The board shall promptly notify the Drug Enforcement Administration of the United States Department of Justice of all orders denying, suspending, or revoking registrations and of all forfeitures of controlled substances. (§ 4 ch 45 SLA 1982)

Cross references. — For penalty for furnishing false or fraudulent information in or omitting material information from application, see AS 11.71.040(a)(8).

Sec. 17.30.050. Order to show cause. (a) Before denying, suspending, or revoking a registration, or refusing a renewal of a registration, the board shall serve upon the applicant or registrant an order to show cause why a registration should not be denied, revoked, or suspended, or why a renewal should not be refused. The order to show cause shall contain a statement of the basis for issuance of the order and shall require the applicant or registrant to appear before the board at a time and place not less than 30 days after the date of service of the order. For a refusal of renewal of registration the show cause order must be served not later than 30 days before the expiration of the registration. These proceedings must be conducted in accordance with procedures for administrative adjudication under AS 44.62.330 — 44.62.630 without regard to criminal prosecution or other proceeding. Proceedings to refuse renewal of registration do not make the existing registration void. The existing registration remains in effect pending the outcome of the administrative hearing.

(b) The board may, without an order to show cause, suspend a registration simultaneously with the institution of proceedings under AS 17.30.040 if it finds that there is an imminent danger to the public health or safety which warrants this action. The suspension continues in effect until the conclusion of the proceedings, including judicial review of the proceedings, unless withdrawn by the board or dissolved by a court of competent jurisdiction. (§ 4 ch 45 SLA 1982)

Sec. 17.30.060. Records of registrants. A person registered to manufacture, distribute, dispense, or conduct research with controlled substances 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. (§ 4 ch 45 SLA 1982)

Cross references. — For penalty for furnishing false or fraudulent information in or omitting material information from records required to be kept under this chapter, see AS 11.71.040(a)(8); for penalty for failure to make, keep, or furnish records required by this chapter, see AS 11.71.050(a)(4).

Sec. 17.30.070. Order forms; prescriptions. (a) A controlled substance may be distributed by one registrant to another registrant only if the distribution is in accordance with federal requirements for order forms.

(b) A controlled substance may not be dispensed by a practitioner other than in accordance with federal requirements regarding prescriptions for controlled substances.

(c) If the classification of a controlled substance in a schedule set out in AS 11.71.140 — 11.71.190, or by a regulation adopted in accordance

with AS 11.71.120(a), is different from its corresponding classification under federal law, the requirements of (a) and (b) of this section are determined by the classification of the substance under federal law. (§ 4 ch 45 SLA 1982)

Cross references. — For penalty for failure to make, keep, or furnish order forms required under this chapter, see AS 11.71.050(a)(4).

Editor's notes. — AS 11.71.120(a), referred to in subsection (c), does not authorize adoption of regulations classifying controlled substances. AS 11.71.120(a) does, however, authorize recommendations for legislation to classify controlled substances.

Sec. 17.30.080. Unlawful administration, prescription and dispensation of controlled substances. A controlled substance classified under federal law or in a schedule set out in AS 11.71.140 — 11.71.190 or by regulations adopted in accordance with AS 11.71.120(a) may not be administered, prescribed, dispensed, or distributed other than for a medical purpose. (§ 4 ch 45 SLA 1982)

Editor's notes. — See editor's note to AS 17.30.070.

Article 2. Enforcement Forfeiture and Review Provisions.

Section	Section
100. Cooperative arrangements	120. Petition for sale of seized item
110. Items subject to forfeiture	122. State disposal of forfeited property
112. Proceedings resulting in forfeiture	124. Remittance to claimant
114. Seizure and custody of property	126. Forfeiture of controlled substances
116. Procedure for forfeiture action	130. Judicial review
118. Petition for release of seized items	

Collateral references. — 25 Am. Jur. 2d, Drugs, Narcotics, and Poisons, §§ 27, 40 et seq.

Sec. 17.30.100. Cooperative arrangements. (a) The commissioner of public safety 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.

(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. (§ 4 ch 45 SLA 1982)

Sec. 17.30.110. Items subject to forfeiture. The following may be forfeited to the state:

(1) a controlled substance which has been manufactured, distributed, dispensed, acquired, or possessed in violation of this chapter or AS 11.71;

(2) raw materials, products, and equipment which are used or intended for use in manufacturing, distributing, compounding, processing, delivering, importing, or exporting a controlled substance which is a felony under this chapter or AS 11.71;

(3) property which is used or intended for use as a container for property described in (1) or (2) of this section;

(4) a conveyance, including but not limited to aircraft, vehicles or vessels, which has been used or is intended for use in transporting or in any manner in facilitating the transportation, sale, receipt, possession, or concealment of property described in (1) or (2) of this section in violation of a felony offense under this chapter or AS 11.71; however,

(A) a conveyance may not be forfeited under this paragraph if the owner of the conveyance establishes, by a preponderance of the evidence, at a hearing before the court as the trier of fact, that use of the conveyance in violation of this chapter or AS 11.71 was committed by another person and that the owner was neither a consenting party nor privy to the violation;

(B) a forfeiture of a conveyance encumbered by a valid security interest at the time of seizure is subject to the interest of the secured party if the secured party establishes, by a preponderance of the evidence, at a hearing before the court as the trier of fact, that use of the conveyance in violation of this chapter or AS 11.71 was committed by another person and that the secured party was neither a consenting party nor privy to the violation;

(5) books, records, and research products and materials, including formulas, microfilm, tapes, and data, which are used in violation of this chapter or AS 11.71;

(6) money, securities, negotiable instruments, or other things of value used in financial transactions derived from activity prohibited by this chapter or AS 11.71; and

(7) a firearm which is visible, carried during, or used in furtherance of a violation of this chapter or AS 11.71. (§ 4 ch 45 SLA 1982)

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Revisor's notes. — Formerly AS 17.30.110(p) and (q). Renumbered in 1983.

Sec. 17.30.130. Judicial review. A final determination, finding, or conclusion of the board under this chapter or a regulation adopted under it is a final decision of the matter involved. A person aggrieved by a decision may obtain review of the decision in the superior court in accordance with AS 44.62.560 — 44.62.570. However, a person is not entitled to a hearing de novo in the superior court. (§ 4 ch 45 SLA 1982)

Article 3. Education and Research.

Section
140. Education and research

Sec. 17.30.140. Education and research. (a) The commissioner of health and social services shall provide for educational programs designed to prevent and deter the abuse of controlled substances. In connection with these programs, the commissioner may

(1) assist the regulated industry and interested groups and organizations in contributing to the reduction of abuse of controlled substances;

(2) promote better recognition of the problems surrounding abuse of controlled substances within the regulated industry and among interested groups and organizations;

(3) consult with interested groups and organizations to aid them in solving administrative and organizational problems;

(4) evaluate procedures, projects and techniques conducted or proposed as part of educational programs on abuse of controlled substances;

(5) disseminate the results of research on abuse of controlled substances to promote a better public understanding of the problems which exist and their solutions; and

(6) with the cooperation of the Department of Law, assist in the education and training of state and local law enforcement officials in their efforts to prevent illicit traffic in and abuse of controlled substances.

(b) The commissioner of health and social services shall encourage research on controlled substances and may

(1) establish methods to assess the effects of controlled substances and identify and characterize those with potential for abuse;

(2) make studies and undertake research to

(A) develop new or improved approaches, techniques, systems, equipment, and devices to strengthen the enforcement of this chapter;

(B) determine patterns of abuse of controlled substances and their social effects; and

(C) improve methods for preventing, predicting, and understanding the abuse of controlled substances;

(3) enter into contracts with public agencies, institutions of higher education, and private organizations or individuals for conducting research, demonstrations, or special projects which bear directly on abuse of controlled substances and for related research and educational activities. (§ 4 ch 45 SLA 1982)

Article 4. General Provisions.

Section

150. Reliance on drug enforcement administration
155. Confidentiality of certain information
900. Definitions

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 regulatory functions of this chapter, including results of inspections conducted by it, may be relied on and acted on by the board in the exercise of its regulatory functions under this chapter. (§ 4 ch 45 SLA 1982)

Revisor's notes. — As enacted, this section contained a subsection (b), but the provisions of that subsection were renumbered as AS 17.30.155.

Sec. 17.30.155. Confidentiality of certain information. A practitioner engaged in medical practice or research may not 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. (§ 4 ch 45 SLA 1982)

Revisor's notes. — Enacted as AS 17.30.150(b). Renumbered in 1982.

Sec. 17.30.900. Definitions. (a) Unless the context clearly requires otherwise, the definitions set out in AS 11.71.900 apply to this chapter.

(b) In this chapter, "board" means the Board of Pharmacy provided for in AS 08.80.010. (§ 4 ch 45 SLA 1982)

Revisor's notes. — Enacted as AS 17.30.160. Renumbered in 1982.

Collateral references. — Marijuana, psilocybin, peyote or similar drugs of vegetable origin as narcotics for purposes of drug prosecution. 50 ALR3d 1164.

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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;

(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.

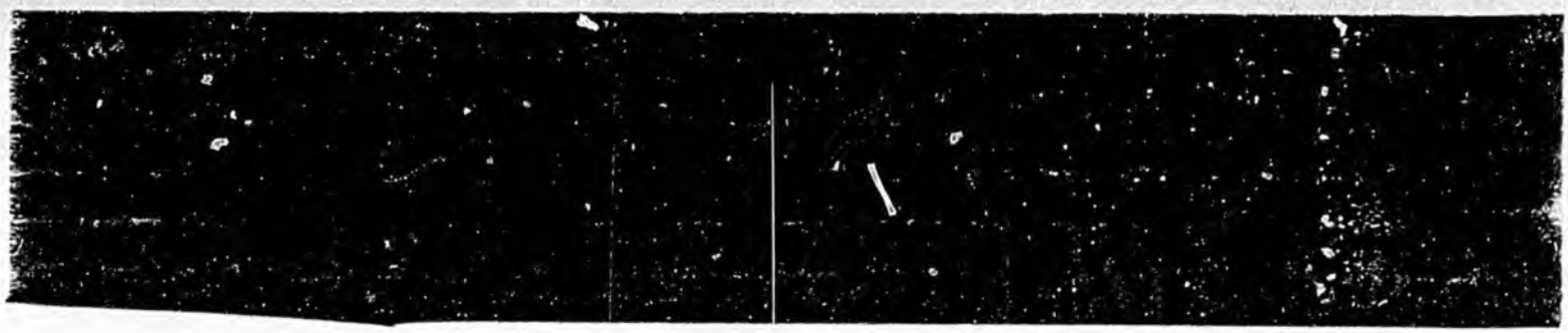
(d) The Patient Qualification Review Committee and the board shall protect the privacy of individuals who participate in the therapeutic research program by withholding the names and other identifying characteristics of those individuals from all persons who are not connected with the research. Persons 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)



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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.

ROBERT J. GLORIOSO
PRESIDENT
RAYMOND F. LEE
SECRETARY-TREASURER
MANO FREY
BUSINESS MANAGER

CONSTRUCTION AND GENERAL LABORERS UNION LOCAL 341

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FIELD REPRESENTATIVES:
ANDREW PIEKARSKI
LARRY VAN SKY
WILLIAM MCPHETERS
ROBERT J. GLORIOSO

March 7, 1986

Representative Max F. Gruenberg
Alaska State Legislature
Pouch V (MS 3100)
Juneau, Alaska 99811

Dear Representative Gruenberg:

As Chairman of the House Committee on Health, Education and Social Services of our Fourteenth Alaska Legislature, and a statesman with a sincere interest in health care issues, we would appreciate your support of legislation requiring effective training and certification of Pharmacy Assistants within the State of Alaska. First and foremost, such legislation would better assure safe dispensation of pharmaceutical products to the public while also providing peace of mind to pharmacists, assistants, and employers that their consumers are well served.

I have enclosed similar legislation (and regulations) now in effect in the State of Washington which may serve as a model.

I would, again, like to thank you and your staff for your efforts on this issue.

Sincerely,

Mano Frey

Mano Frey
Business Manager

MF/dsr

Enclosures 2

cc: Don Rouleau
Legislative Representative

Chapter 18.64A RCW
PHARMACY ASSISTANTS

Sections

18.64A.005 Regulation of health care professions——Criteria.
18.64A.010 Definitions.
18.64A.020 Regulations fixing classification, qualifications, educational requirements, training programs, supervision, etc.
18.64A.030 Regulations governing services which may be performed by pharmacy assistants——Certification to levels of classification.
18.64A.040 Limitations on practice by pharmacy assistants.
18.64A.050 Grounds for refusal, suspension or revocation of pharmacy assistant's certificate——Hearing——Appeal.
18.64A.060 Pharmacy's application for pharmacy assistant——Fee——Approval or rejection by board——Hearing——Appeal.
18.64A.070 Persons presently acting as pharmacy assistants——Pharmacies presently employing persons acting as pharmacy assistants.
18.64A.080 Pharmacy's or pharmacist's liability, responsibility.
18.64A.900 Severability——1977 ex.s. c 101.

Health professions account——Fees credited——Requirements for biennial budget request: RCW 43.24.072.

RCW 18.64A.005 Regulation of health care professions——Criteria. See chapter 18.120 RCW.

RCW 18.64A.010 Definitions. Terms used in this chapter shall have the meaning set forth in this section unless the context clearly indicates otherwise:

(1) "Board" means the state board of pharmacy;

(2) "Pharmacist" means a person duly licensed by the state board of pharmacy to engage in the practice of pharmacy;

(3) "Pharmacy" means every place properly licensed by the board of pharmacy where the practice of pharmacy is conducted;

(4) "Pharmacy assistant level A" means:

(a) A person who is enrolled in, or who has satisfactorily completed, a board approved training program designed to prepare persons to perform nondiscretionary functions associated with the practice of pharmacy; or

(b) A person who is a graduate with a degree in pharmacy or medicine of a foreign school, university, or college recognized by the board;

(5) "Pharmacy assistant level B" means a person certified by the board to perform limited functions in the pharmacy;

(6) "Practice of pharmacy" means the definition given in RCW 18.64.011, as now or hereafter amended. [1977 ex.s. c 101 § 1.]

RCW 18.64A.020 Regulations fixing classification, qualifications, educational requirements, training programs, supervision, etc. (1) The board shall adopt, in accordance with chapter 34.04 RCW, rules and regulations fixing the classification and qualifications and the educational and training requirements for persons who may be employed as pharmacy assistants or who may be enrolled in any pharmacy assistant training program. Such regulations shall provide that:

(a) Licensed pharmacists shall supervise the training of pharmacy assistants; and

(b) Training programs shall assure the competence of pharmacy assistants to aid and assist pharmacy operations. Training programs shall consist of instruction and/or practical training.

(2) The board may disapprove or revoke approval of any training program for failure to conform to board rules and regulations. In the case of the disapproval or revocation of approval of a training program by the board, a hearing shall be conducted in accordance with RCW 18.64.160 as now or hereafter amended, and appeal may be taken in accordance with the Administrative Procedure Act, chapter 34.04 RCW. [1977 ex.s. c 101 § 2.]

RCW 18.64A.030 Regulations governing services which may be performed by pharmacy assistants——Certification to levels of classification. The board shall adopt, in accordance with chapter 34.04 RCW, rules and regulations governing the extent to which pharmacy assistants may perform services associated with the practice of pharmacy during training and after successful completion of a training course. Such regulations shall provide for the certification of pharmacy assistants at a uniform annual fee to be determined by the board according to the following levels of classification:

(1) "Level A pharmacy assistants" may assist in performing, under the immediate supervision and control of a licensed pharmacist, manipulative, nondiscretionary functions associated with the practice of pharmacy.

(2) "Level B pharmacy assistants" may perform, under the general supervision of a licensed pharmacist, duties including but not limited to, typing of prescription labels, filing, refiling, bookkeeping, pricing, stocking, delivery, nonprofessional phone inquiries, and documentation of third party reimbursements. [1977 ex.s. c 101 § 3.]

RCW 18.64A.040 Limitations on practice by pharmacy assistants. (1) A pharmacy assistant shall practice pharmacy in this state only after authorization by the board and only to the extent permitted by the board in accordance with this chapter.

(2) A pharmacist shall be assisted by a pharmacy assistant in the practice of pharmacy in this state only after authorization by the board and only to the extent permitted by the board in accordance with this chapter: *Provided*, That no pharmacist may supervise more than one person performing level A pharmacy assistant duties and functions: *Provided further*, That in pharmacies operating in connection with facilities licensed pursuant

to chapters 70.41 or 71.12 RCW, whether or not situated within the said facility, the ratio of pharmacists to persons performing level A pharmacy assistant duties and functions shall be as follows: in the preparation of medicine or other materials used by patients within the facility, one pharmacist supervising no more than three persons performing level A pharmacy assistant duties and functions; in the preparation of medicine or other materials dispensed to persons not patients within the facility, one pharmacist supervising not more than one person performing level A pharmacy assistant duties and functions. [1977 ex.s. c 101 § 4.]

RCW 18.64A.050 Grounds for refusal, suspension or revocation of pharmacy assistant's certificate——Hearing——Appeal. The board of pharmacy shall have the power to refuse, suspend, or revoke the certificate of any pharmacy assistant upon proof that:

(1) His or her certificate was procured through fraud, misrepresentation or deceit;

(2) He or she has been found guilty of any offense in violation of the laws of this state relating to drugs, poisons, cosmetics or drug sundries by any court of competent jurisdiction: *Provided*, That nothing herein shall be construed to affect or alter the provisions of RCW 9.96A.020;

(3) He or she is unfit to perform his or her duties because of habitual intoxication or abuse of controlled substances;

(4) He or she has exhibited gross incompetency in the performance of his or her duties;

(5) He or she has wilfully or repeatedly violated any of the rules and regulations of the board of pharmacy;

(6) He or she has wilfully or repeatedly performed duties beyond the scope of his or her certificate in violation of the provisions of this chapter; or

(7) He or she has impersonated a licensed pharmacist.

In any case of the refusal, suspension or revocation of a certificate by the board, a hearing shall be conducted in accordance with RCW 18.64.160, as now or hereafter amended, and appeal may be taken in accordance with the Administrative Procedure Act, chapter 34.04 RCW. [1977 ex.s. c 101 § 5.]

RCW 18.64A.060 Pharmacy's application for pharmacy assistant——Fee——Approval or rejection by board——Hearing——Appeal. No pharmacy licensed in this state shall utilize the services of pharmacy assistants without approval of the board.

Any pharmacy licensed in this state may apply to the board for permission to use the services of pharmacy assistants. The application shall be accompanied by a uniform fee to be determined by the board, shall detail the manner and extent to which the pharmacy assistants would be used and supervised, and shall provide other information in such form as the board may require.

The board may approve or reject such applications. In addition, the board may modify the proposed utilization of pharmacy assistants and approve the application as modified. No such approval shall extend for more than one year, but approval once granted may be renewed annually upon payment of a uniform fee as determined by the board. Whenever it appears to the board that a pharmacy assistant is being utilized in a manner inconsistent with the approval granted, the board may withdraw such approval. In the event a hearing is requested upon the rejection of an application, or upon the withdrawal of approval, a hearing shall be conducted in accordance with chapter 18.64 RCW, as now or hereafter amended, and appeal may be taken in accordance with the Administrative Procedure Act, chapter 34.04 RCW. [1977 ex.s. c 101 § 6.]

RCW 18.64A.070 Persons presently acting as pharmacy assistants——Pharmacies presently employing persons acting as pharmacy assistants. (1) Persons presently assisting a pharmacist by performing the functions of a pharmacy assistant may continue to do so under the supervision of a licensed pharmacist: *Provided*, That within eighteen months after May 28, 1977, such persons shall be in compliance with the provisions of this chapter.

(2) Pharmacies presently employing persons to perform the functions of a pharmacy assistant may continue to do so while obtaining board approval for the use of certified pharmacy assistants: *Provided*, That within eighteen months after May 28, 1977, such pharmacies shall be in compliance with the provisions of this chapter. [1977 ex.s. c 101 § 7.]

RCW 18.64A.080 Pharmacy's or pharmacist's liability, responsibility. No pharmacy or pharmacist which utilizes the services of a pharmacy assistant with approval by the board, shall be considered as aiding and abetting an unlicensed person to practice pharmacy within the meaning of chapter 18.64 RCW, as now or hereafter amended: *Provided, however*, That the pharmacy or pharmacist shall retain responsibility for any act performed by a pharmacy assistant in the course of his or her employment. [1977 ex.s. c 101 § 8.]

RCW 18.64A.900 Severability——1977 ex.s. c 101. If any provision of this act, or its application to any person or circumstance is held invalid, the remainder of the act, or the application of the provision to other persons or circumstances is not affected. [1977 ex.s. c 101 § 10.]

Chapter 360-52 WAC
PHARMACY ASSISTANT

WAC

360-52-010	Level A pharmacy assistants utilization.
360-52-020	Level A education and training.
360-52-030	Limitations, trainees.
360-52-040	Level A program approval.
360-52-050	Level A certification.
360-52-060	Level B pharmacy assistants utilization.
360-52-070	Level B certification programs.
360-52-080	Identification.
360-52-090	Board approval of pharmacies utilizing pharmacy assistants.
360-52-100	Level A experience equivalency.

WAC 360-52-010 Level A pharmacy assistants utilization. (1) Level A pharmacy assistants may assist in performing, under the immediate supervision and control of a licensed pharmacist, manipulative, nondiscretionary functions associated with the practice of pharmacy.

(2) Immediate supervision shall include visual and/or physical proximity that will insure adequate safety controls, except that the board of pharmacy may apply the standards of the joint commission on accreditation of hospitals for facilities licensed pursuant to chapters 70-.41 or 71.12 RCW.

(3) The following shall not be considered to be manipulative and nondiscretionary functions associated with the practice of pharmacy:

(a) Consultation with the prescriber regarding the patient and his prescription.

(b) Receipt of a verbal prescription other than refill approval or denial from a prescriber.

(c) Consultation with the patient regarding the prescription, both prior to and after the prescription filling and/or regarding any information contained in a patient medication record system.

(d) Interpretation and identification of the contents of the prescription document.

(e) Determination of the product required for the prescription.

(f) Extemporaneous compounding of the prescription, except in accordance with written policies and procedures in accordance with WAC 360-52-090(2), whereby the accuracy, correct procedure and preparation, and safety of pharmaceutical constituents can be verified by the pharmacist.

(g) Interpretation of data in a patient medication record system.

(h) Final check on all aspects of the completed prescription and assumption of the responsibility for the filled prescription, including but not limited to accuracy of drug, strength, labeling, and proper container.

(i) Dispense prescriptions to patient with proper patient information as required by WAC 360-16-250.

(j) Any duty required by law, rule or regulation to be performed only by a registered pharmacist. [Order 141, § 360-52-010, filed 12/9/77.]

WAC 360-52-020 Level A education and training. (1) The education and/or training of level A pharmacy assistants shall be obtained in one of the following manners:

(a) Formal academic program for pharmacy assistant training approved by the board.

(b) On-the-job training program following guidelines approved by the board.

(2) The minimum educational requirement shall be high school graduation or G.E.D. [Order 141, § 360-52-020, filed 12/9/77.]

WAC 360-52-030 Limitations, trainees. An individual enrolled in a training program for level A pharmacy assistants will perform level A functions only under the immediate supervision of a pharmacist preceptor or a delegated alternate pharmacist. [Order 141, § 360-52-030, filed 12/9/77.]

WAC 360-52-040 Level A program approval. (1) Program standards. The board will establish standards by which programs designed to train level A pharmacy assistants shall be judged.

(2) Approval. In order for a program for training pharmacy assistants to be considered for approval by the board, the director of the program, who shall be a pharmacist, shall submit to the board a description of the course of training offered, including subjects taught, method of teaching, and practical experience provided. The director of the program shall also advise the board concerning the skills and knowledge which are obtained in such course, and the method by which the proficiency of the pharmacy assistant in those skills and knowledge was tested or ascertained. The board may require such additional information from program sponsors as it desires.

(3) Program change. The board shall be informed and shall grant approval before any significant change in program can be implemented.

(4) Reapproval. Each approved program will be reexamined at intervals to be determined by the board. Approval will be continued or withdrawn following each reexamination.

(5) Registry. A registry of approved programs shall be maintained by the board which shall be available upon request to interested persons. [Order 141, § 360-52-040, filed 12/9/77.]

WAC 360-52-050 Level A certification. Any person completing an approved pharmacy assistant training program and who wishes to perform in that capacity shall apply to the board for certification as a level A pharmacy assistant, on forms to be supplied by the board, which shall include a verification of program

competency by a notarized statement of the program director and a declaration by the applicant that he has never been found guilty by any court of competent jurisdiction of any violation of any laws relating to drugs or the practice of pharmacy.

The fee for annual certification shall be ten dollars. [Order 141, § 360-52-050, filed 12/9/77.]

WAC 360-52-060 Level B pharmacy assistants utilization. Level B pharmacy assistants may perform, under the general supervision of a licensed pharmacist, duties including but not limited to typing of prescription labels, filing, refiling, bookkeeping, pricing or determination of cost or charge, stocking, delivery, nonprofessional phone inquiries, and documentation of third party reimbursements. [Statutory Authority: RCW 18.64.005(11) and 18.64A.030. 80-02-113 (Order 153, Resolution 1/80), § 360-52-060, filed 1/28/80. Statutory Authority: RCW 69.50.201. 79-04-048 (Order 147, Resolution 3-79), § 360-52-060, filed 3/27/79; Order 141, § 360-52-060, filed 12/9/77.]

WAC 360-52-070 Level B certification programs. (1) Training. No formal training or educational program will be required by the board, and there will be no age or educational restrictions. The supervising pharmacist shall thoroughly instruct the level B pharmacy assistant in the limitations of the functions he may perform.

(2) Record of certifications. All pharmacies employing level B pharmacy assistants shall complete a certification application on a form approved by the board, such form to include a declaration by the applicant that he or she has never been found guilty by any court of competent jurisdiction of any violation of any laws relating to drugs or the practice of pharmacy, for each level B pharmacy assistant employed. The completed form will be witnessed by the responsible pharmacist for the pharmacy and will be produced for inspection on the request of the board or its agents. The fee for certification will be included in the fee for authorization to utilize services of pharmacy assistants. [Order 141, § 360-52-070, filed 12/9/77.]

WAC 360-52-080 Identification. All level A pharmacy assistants must wear badges or tags clearly identifying them as level A pharmacy assistants while on duty. Those pharmacy assistants working within the pharmacy and having contact with patients or the general public shall wear badges or tags clearly identifying their status. [Order 141, § 360-52-080, filed 12/9/77.]

WAC 360-52-090 Board approval of pharmacies utilizing pharmacy assistants. (1) Application. All licensed pharmacies may apply on a form supplied by the board for permission to utilize the services of pharmacy assistants. The fee for such application or annual renewal shall be twenty-five dollars.

(2) Utilization plan for level A pharmacy assistants. The application for approval must describe the manner in which the pharmacy assistants will be utilized and supervised, including job descriptions, task analysis or similar type documents that define the duties performed and the conditions under which they are performed, number of positions in each category, as well as other information as may be required by the board. The board will be notified of all changes to the utilization plan. A copy of the utilization plan must be maintained in the pharmacy.

(3) Utilization plan for level B pharmacy assistants. The application for approval shall list the job title or function of the pharmacy assistant.

(4) The board may give conditional approval for pilot or demonstration projects for innovative applications in the utilization of pharmacy assistants. [Order 141, § 360-52-090, filed 12/9/77.]

WAC 360-52-100 Level A experience equivalency. Individuals who are employed in a pharmacy and who were performing as level A pharmacy assistants prior to May 28, 1977 and have been continuously employed as level A assistants since that date, or who have 1,040 hours employment performing level A pharmacy assistant functions within the last eighteen months, shall be considered to have met the educational and/or training requirements upon verification to the board, in a notarized statement by the appropriate supervising or director pharmacist(s), as to the skill and knowledge of the individual, taking into consideration the approved guidelines. The level A assistant may, under these conditions apply for certification to the board. [Order 141, § 360-52-100, filed 12/9/77.]

BILL SHEFFIELD, GOVERNOR

REPLY TO:

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DEPARTMENT OF LAW

OFFICE OF THE ATTORNEY GENERAL

March 6, 1986

M E M O R A N D U M

TO: Nancy Bennett, Legislative Aide
House HESS Committee

FROM: Peter B. Froehlich
Assistant Attorney General

RE: Attached proposed amendment to HB 641 re controlled substances

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

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

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

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

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

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

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

HMB:PBF:pjg

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

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

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