

SENATE BILL NO. 418

INTRODUCED BY OCHSNER, ZABROCKI

BY REQUEST OF THE DEPARTMENT OF PROFESSIONAL AND OCCUPATIONAL LICENSING

IN THE SENATE

February 10, 1981	Introduced and referred to Committee on Public Health, Welfare and Safety.
February 20, 1981	Committee recommend bill do pass as amended. Report adopted.
February 21, 1981	Bill printed and placed on members' desks.
February 23, 1981	Second reading, do pass.
February 24, 1981	Correctly engrossed.
February 25, 1981	Third reading, passed. Ayes, 50; Noes, 0. Transmitted to House.

IN THE HOUSE

March 3, 1981	Introduced and referred to Committee on Human Services.
March 16, 1981	Committee recommend bill be concurred in as amended. Report adopted.
March 19, 1981	Motion pass consideration to the 65th legislative day.
March 26, 1981	Second reading, concurred in.
March 28, 1981	Third reading, concurred in as amended. Ayes, 90; Noes, 0.

IN THE SENATE

March 30, 1981

Returned from House with amendments.

April 3, 1981

Second reading, amendments concurred in.

April 6, 1981

Third reading, amendments concurred in. Ayes, 49; Noes, 0. Sent to enrolling.

Reported correctly enrolled.

1 *Sen* BILL NO. *418*
 2 INTRODUCED BY *Ochener Zorchi*
 3 BY REQUEST OF THE DEPARTMENT OF PROFESSIONAL AND
 4 OCCUPATIONAL LICENSING
 5

6 A BILL FOR AN ACT ENTITLED: "AN ACT TO REVISE AND CLARIFY
 7 THE LAW CREATING THE BOARD OF PHARMACISTS AND THE LAWS
 8 ADMINISTERED BY THE BOARD OF PHARMACISTS; AMENDING SECTIONS
 9 2-15-1609, 37-2-101, 37-7-101, 37-7-201, 37-7-301 THROUGH
 10 37-7-303, 37-7-311, 37-7-321, 37-7-401, AND 37-7-502, MCA."
 11

12 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

13 Section 1. Section 2-15-1609, MCA, is amended to read:
 14 "2-15-1609. Board of pharmacists. (1) There is a board
 15 of pharmacists.

16 (2) The board consists of three members appointed by
 17 the governor. The governor shall appoint the members from a
 18 list submitted annually by the Montana state pharmaceutical
 19 association. The list shall contain the names of five
 20 qualified persons for each appointment. Each member shall be
 21 a graduate of the college of pharmacy of the university of
 22 Montana or of a college or school of pharmacy ~~recognized and~~
 23 ~~approved~~ accredited by ~~or a member of~~ the American
 24 ~~association of colleges of pharmacy~~ COUNCIL ON
 25 pharmaceutical education. Each member shall have at least 5

1 consecutive years of practical experience as a pharmacist
 2 immediately before his appointment. ~~However, one member may~~
 3 ~~be a registered pharmacist of 15 years practical experience~~
 4 ~~and actually engaged in the practice of pharmacy.~~ A member
 5 who, during his term of office, ceases to be actively
 6 engaged in the practice of pharmacy in this state, shall be
 7 automatically disqualified from membership on the board.

8 (3) Each member shall serve for a term of 3 years. A
 9 member shall be removed from office by the governor on proof
 10 of malfeasance or misfeasance in office, after reasonable
 11 notice of charges against him and after a hearing.

12 (4) The board is allocated to the department for
 13 administrative purposes only as prescribed in 2-15-121."

14 Section 2. Section 37-2-101, MCA, is amended to read:
 15 "37-2-101. Definitions. As used in this part, the
 16 following definitions apply:

17 (1) "Medical practitioner" means any person licensed
 18 by the state of Montana to engage in the practice of
 19 medicine, dentistry, osteopathy, or chiropody (podiatry) and
 20 in such practice to administer or prescribe drugs.

21 (2) "Drug" means any article:
 22 (a) recognized in the official United States
 23 Pharmacopoeia, ~~the official~~ National Formulary, or in any
 24 supplement to such pharmacopoeia ~~or~~ formulary;
 25 (b) intended for use in the diagnosis, cure,

1 mitigation, treatment, or prevention of disease in man;
 2 (c) intended to affect the structure or any function
 3 of the body of man;
 4 (d) intended for use as a component of any article
 5 described in subsection (a), (b), or (c) of this subsection
 6 (2), but such term does not include any device or any
 7 components of a device.
 8 (3) "Device" means any instrument, apparatus, or
 9 contrivance intended:
 10 (a) for use in the diagnosis, cure, mitigation,
 11 treatment, or prevention of disease in man;
 12 (b) to affect the structure or any function of the
 13 body of man.
 14 (4) "Pharmacy" means an office, ~~pharmacy, drugstore,~~
 15 ~~or other~~ establishment which engages in the sale of drugs ~~at~~
 16 ~~retail requiring a prescription.~~
 17 (5) "Community pharmacy", when used in relation to a
 18 medical practitioner, means a pharmacy situated within 10
 19 miles of any place at which such medical practitioner
 20 maintains an office for professional practice.
 21 (6) "Drug company" means any person engaged in the
 22 manufacturing, processing, packaging, or distribution of
 23 drugs; but such term does not include a pharmacy.
 24 (7) "Person" means any individual and any partnership,
 25 firm, corporation, association, or other business entity.

1 (8) "State" means the state of Montana or any
 2 political subdivision thereof."
 3 Section 3. Section 37-7-101, MCA, is amended to read:
 4 "37-7-101. Definitions. Unless the context requires
 5 otherwise, in parts 1 through 3 of this chapter the
 6 following definitions apply:
 7 (1) "Board" means the board of pharmacists provided
 8 for in 2-15-1609.
 9 (2) "Chemical" means medicinal or industrial
 10 substances, whether simple, compound, or obtained through
 11 the process of the science and art of chemistry, whether of
 12 organic or inorganic origin.
 13 (3) "Commercial purposes" means the ordinary purposes
 14 of trade, agriculture, industry, and commerce, exclusive of
 15 the practices of medicine and pharmacy.
 16 (4) "Continuing education" means professional
 17 pharmaceutical postgraduate education in the following
 18 areas:
 19 (a) the socioeconomic and legal aspects of health
 20 care;
 21 (b) the properties and actions of drugs and dosage
 22 forms; and
 23 (c) the etiology, characteristics, and therapeutics of
 24 the disease state.
 25 (5) "Department" means the department of professional

1 and occupational licensing provided for in Title 2, chapter
2 15, part 16.

3 (6) (a) "Drug" means:

4 (i) articles recognized in the official United States
5 Pharmacopoeia~~y-official--Homeopathic--Pharmacopoeia--of--the~~
6 ~~United--States--or--official~~/ National Formulary or a
7 supplement to them;

8 (ii) articles intended for use in diagnosis, cure,
9 mitigation, treatment, or prevention of disease in man or
10 other animals;

11 (iii) articles (other than food) intended to affect the
12 structure or function of the body of man or other animals;
13 and

14 (iv) articles intended for use as a component of an
15 article specified in subsection (i), (ii), or (iii).

16 (b) "Drug" does not include devices or their
17 components, parts, or accessories.

18 (7) "Intern" means a natural person licensed by the
19 department to prepare, compound, dispense, and sell drugs,
20 medicines, chemicals, and poisons ~~in-a-pharmacy-having-a~~
21 ~~pharmacist-in-charge under the supervision of a registered~~
22 ~~and licensed pharmacist.~~

23 (8) "Medicine" means a remedial agent which has the
24 property of curing, preventing, treating, or mitigating
25 diseases or which is used for this purpose.

1 (9) "Person" includes an individual, partnership,
2 corporation, or association.

3 (10) "Pharmacist" means a natural person licensed by
4 the department to prepare, compound, dispense, and sell
5 drugs, medicines, chemicals, and poisons and who may affix
6 to his name the term "R.Ph."

7 (11) "Pharmacy" means ~~a--drugstore--or--other~~ an
8 established place registered by the department of
9 professional and occupational licensing, in which
10 prescriptions, drugs ~~requiring a prescription~~, medicines,
11 chemicals, and poisons are compounded, dispensed, vended, or
12 sold ~~at-retail~~.

13 (12) "Poison" means a substance which, when introduced
14 into the system, either directly or by absorption, produces
15 violent, morbid, or fatal changes or which destroys living
16 tissue with which it comes in contact.

17 (13) "Prescription" means an order given individually
18 for the person for whom prescribed, directly from the
19 prescriber to the furnisher or indirectly to the furnisher,
20 by means of an order signed by the prescriber and bearing
21 the name and address of the prescriber, his license
22 classification, the name of the patient, the name and the
23 quantity of the drug or drugs prescribed, the directions for
24 use and the date of its issue. These stipulations apply to
25 both written and telephoned prescriptions.

1 (14) "Wholesale" means a sale for the purpose of
2 resale."

3 Section 4. Section 37-7-201, MCA, is amended to read:

4 "37-7-201. Organization -- powers and duties. (1) The
5 board shall meet at least once a year to transact its
6 business. The board shall annually elect from its members a
7 president, vice-president, and secretary.

8 (2) The board shall:

9 (a) regulate the practice of pharmacy in this state
10 subject to this chapter;

11 (b) determine the minimum equipment necessary in and
12 for a pharmacy ~~and drug store~~;

13 (c) regulate, under therapeutic classification, the
14 sale of drugs, medicines, chemicals, and poisons and their
15 labeling;

16 (d) regulate the quality of drugs and medicines
17 dispensed in this state, using the United States
18 Pharmacopoeia ~~and--the~~ National Formulary or revisions
19 thereof as the standards;

20 (e) request the department to enter and inspect, at
21 reasonable times, places where drugs, medicines, chemicals,
22 or poisons are sold, vended, given away, compounded,
23 dispensed, or manufactured. It is a misdemeanor for a person
24 to refuse to permit or otherwise prevent the department from
25 entering these places and making an inspection.

1 (f) regulate the practice of interns under national
2 standards;

3 (g) make rules for the conduct of its business;

4 (h) perform other duties and exercise other powers as
5 this chapter requires;

6 (i) adopt and authorize the department to publish
7 rules for carrying out and enforcing parts 1 through 3 of
8 this chapter.

9 (3) The department shall:

10 (a) license, register, and examine, subject to
11 37-1-101, applicants whom the board considers qualified
12 under this chapter;

13 (b) license pharmacies and certain stores under this
14 chapter; and

15 (c) issue certificates of "certified pharmacy" under
16 this chapter."

17 Section 5. Section 37-7-301, MCA, is amended to read:

18 "37-7-301. Sale of drugs or medicines unlawful except
19 as provided. (1) It is unlawful for any person to compound,
20 dispense, vend, or sell at retail drugs, medicines,
21 chemicals, or poisons in any place other than a pharmacy,
22 except as hereinafter provided.

23 (2) It is unlawful for any proprietor, owner, or
24 manager of a pharmacy or any other person to permit the
25 compounding or dispensing of prescriptions or the vending or

1 selling at retail of drugs, medicines, chemicals, or poisons
 2 in any pharmacy except by a registered and licensed
 3 pharmacist or by an intern ~~in the temporary absence of such~~
 4 ~~pharmacist registered and licensed by the department, under~~
 5 ~~the supervision of a registered and licensed pharmacist.~~

6 (3) It is unlawful for any person to assume or pretend
 7 to the title of pharmacist or intern unless such person has
 8 a license as such, issued and in force pursuant to parts 1
 9 through 3 of this chapter.

10 (4) It is unlawful for any person other than a
 11 licensed and registered pharmacist or a licensed and
 12 registered intern ~~under the supervision of a licensed and~~
 13 ~~registered pharmacist~~ to compound, dispense, vend, or sell
 14 at retail drugs, medicines, chemicals, or poisons except as
 15 provided in parts 1 through 3."

16 Section 6. Section 37-7-302, MCA, is amended to read:

17 "37-7-302. Examination -- qualifications -- fees --
 18 reciprocity. (1) The department shall give reasonable notice
 19 of examinations by mail to known applicants. The department
 20 shall record the names of persons examined, together with
 21 the grounds on which the right of each to examination was
 22 claimed, and also the names of persons registered by
 23 examination or otherwise.

24 (2) The fee for an examination shall be set by the
 25 board at a figure commensurate with costs, which fee may in

1 the discretion of the board be returned to applicants not
 2 taking the examination. On again making payment of the fee,
 3 an applicant who fails is entitled to take the next
 4 succeeding examination free of charge.

5 ~~(3) -- The fee for registration by reciprocity is \$200.~~

6 ~~(4) (3)~~ To be entitled to examination as a pharmacist,
 7 the applicant shall be a citizen of the United States, of
 8 good moral character, and a graduate of the school of
 9 pharmacy of the university of Montana or of a college or
 10 school of pharmacy ~~recognized and approved accredited by or~~
 11 ~~a member of the American association of colleges of pharmacy~~
 12 council on pharmaceutical education; but the applicant may
 13 not receive a registered pharmacist's license until he has
 14 complied with the internship requirements established by the
 15 board. ~~During this period if the applicant has passed the~~
 16 ~~examination he shall be licensed as an intern only.~~

17 ~~(5) (4)~~ The board may in its discretion authorize the
 18 department to grant registration without examination to a
 19 pharmacist licensed by a board of pharmacy or a similar
 20 board of another state which accords similar recognition to
 21 licensees of this state if the requirements for registration
 22 in the other state are, in the opinion of the board,
 23 equivalent to the requirements of this chapter. The fee for
 24 registration by reciprocity is \$200.

25 ~~(6) (5)~~ Every person licensed and registered under this

1 chapter shall receive from the department an appropriate
 2 certificate attesting the fact, which shall be conspicuously
 3 displayed at all times in his place of business. ~~If the~~
 4 ~~holder is entitled to manage or conduct a pharmacy in this~~
 5 ~~state for himself or another, the fact shall be set forth in~~
 6 ~~the certificate.~~"

7 Section 7. Section 37-7-303, MCA, is amended to read:

8 "37-7-303. Annual renewal fee. (1) A person licensed
 9 and registered by the department shall annually pay to the
 10 department before June 30 a renewal of registration fee of
 11 \$15. A default in the payment of a renewal fee ~~for a period~~
 12 ~~of 30 days~~ after the date it is due increases the renewal
 13 fee to \$30. It is unlawful for a person who refuses or fails
 14 to pay the renewal fee to practice pharmacy in this state. A
 15 certificate and renewal expires at the time prescribed, not
 16 later than 1 year from its date. A defaulter in a renewal
 17 fee may be reinstated within 1 year of the default without
 18 examination on payment of the arrears and compliance with
 19 the continuing education provisions of this chapter.

20 (2) The board may charge an additional fee of up to
 21 \$10 for such license renewal to be used in administering the
 22 continuing education provisions of this chapter."

23 Section 8. Section 37-7-311, MCA, is amended to read:

24 "37-7-311. Revocation of license issued to pharmacist
 25 or intern. The board shall revoke, ~~temporarily~~ or

1 ~~permanently~~ licenses issued by the department to a
 2 pharmacist or intern whenever the holder of the license:

3 (1) has obtained it by false representations or fraud;

4 (2) is an habitual drunkard or addicted to the use of
 5 narcotic drugs;

6 (3) has been convicted of a felony;

7 (4) has been convicted of violating the pharmacy law;

8 or

9 (5) has been found by the board guilty of incompetency
 10 in the preparation of prescriptions or guilty of gross
 11 immorality affecting the discharge of his duties as a
 12 pharmacist or intern."

13 Section 9. Section 37-7-321, MCA, is amended to read:

14 "37-7-321. Store license -- certified pharmacy license
 15 -- suspension or revocation. (1) The department shall, on
 16 application on forms prescribed by the board and on the
 17 payment of an annual fee of \$10, license stores other than
 18 pharmacies in which are sold ordinary household or medicinal
 19 drugs prepared in sealed packages or bottles by a
 20 manufacturer qualified under the laws of the state in which
 21 the manufacturer resides. The name and address of the
 22 manufacturer shall appear conspicuously on each package sold
 23 by the licensee. It is unlawful for a store to sell,
 24 deliver, or give away household medicinal drugs without
 25 first having secured a license and thereafter keeping it in

1 force by proper renewal. ~~This subsection does not prevent a~~
 2 ~~vendor from setting a patent or proprietary medicine in the~~
 3 ~~original package when plainly labeled or nonmedical articles~~
 4 ~~usually sold by vendors.~~

5 (2) The board shall provide for the original
 6 certification and annual renewal by the department of every
 7 pharmacy doing business in this state. On presentation of
 8 evidence satisfactory to the board and on application on a
 9 form prescribed by the board and on the payment of an
 10 original certification fee of \$100, the department shall
 11 issue a license to a pharmacy as a certified pharmacy.
 12 However, the license may be granted only to pharmacies
 13 operated by registered pharmacists ~~or registered interns~~
 14 qualified under this chapter. The annual renewal fee for a
 15 pharmacy shall be set by the board in an amount not to
 16 exceed \$50. Any default in the payment of such renewal fee
 17 ~~for a period of 30 days~~ after the date the same is due shall
 18 increase the renewal fee to the sum of \$100. The license
 19 must be displayed in a conspicuous place in the pharmacy for
 20 which it is issued and expires on June 30 following the date
 21 of issue. It is unlawful for a person to conduct a pharmacy,
 22 use the word "pharmacy" to identify his business, or use the
 23 word "pharmacy" in advertising unless a license has been
 24 issued and is in effect.

25 (3) The board may suspend, revoke, or refuse to renew

1 a store or pharmacy license:

- 2 (a) obtained by false representation or fraud;
 3 (b) when the pharmacy for which the license is issued
 4 is kept open for the transaction of business without a
 5 pharmacist in charge;
 6 (c) when the person to whom the license is granted has
 7 been convicted of:
 8 (i) a violation of parts 1 through 3 of this chapter;
 9 (ii) a felony; or
 10 (iii) a violation of the Federal Food, Drug, and
 11 Cosmetic Act of ~~June 25, 1938, (52-Stats-1040 through 1059~~
 12 Title 21, chapter 9, United States Code);
 13 (d) when the person to whom the license is granted is
 14 a natural person whose pharmacist ~~or intern~~ license has been
 15 revoked; or
 16 (e) when the store or pharmacy is conducted in
 17 violation of parts 1 through 3 of this chapter.
 18 (4) Before a license can be revoked, the holder is
 19 entitled to a hearing by the board."

20 Section 10. Section 37-7-401, MCA, is amended to read:
 21 "37-7-401. Restrictions upon sale or prescription of
 22 opiates -- coding prohibited -- refilling prescriptions. (1)
 23 It shall be unlawful for any physician to sell or give to or
 24 prescribe for any person any opium, morphine,
 25 alkaloid-cocaine, or alpha or beta eucaine or codeine or

1 heroin or any derivative, mixture, or preparation of any of
2 them, except to a patient believed in good faith to require
3 the same for medical use and in quantities proportioned to
4 the needs of such patients.

5 (2) A prescription must be so written that it can be
6 compounded by any registered pharmacist. The coding of any
7 prescription is a violation of this section.

8 (3) A prescription marked "non repetatur", "non rep",
9 or "N.R." cannot be refilled. A prescription marked to be
10 refilled by a specified amount may be filled by any
11 registered pharmacist the number of times marked on the
12 prescription. A prescription not bearing any ~~limitation of~~
13 ~~refill instructions may not be refilled at will during the~~
14 ~~time specified without first obtaining permission from the~~
15 ~~prescriber. A prescription may not be refilled for more~~
16 ~~than 1 year from the date it was originally filled. A~~
17 ~~prescription may not be refilled when a refill is prohibited~~
18 ~~by federal or state law. No narcotic prescription may be~~
19 refilled."

20 Section 11. Section 37-7-502, MCA, is amended to read:

21 "37-7-502. Definitions. As used in this part, the
22 following definitions apply:

23 (1) "Bioavailability" means the extent and rate of
24 absorption from a dosage form as reflected by the
25 time-concentration curve of the administered drug in the

1 systemic circulation.

2 (2) "Bioequivalent" means a chemical equivalent which,
3 when administered to the same individual in the same dosage
4 regimen, will result in comparable bioavailability.

5 (3) "Brand name" means the proprietary or the
6 registered trademark name given to a drug product by its
7 manufacturer, labeler, or distributor and placed upon the
8 drug, its container, label, or wrapping at the time of
9 packaging.

10 (4) "Chemical equivalent" means drug products that
11 contain the same amounts of the same therapeutically active
12 ingredients in the same dosage forms and that meet present
13 compendium standards.

14 (5) "Drug product" means a dosage form containing one
15 or more active therapeutic ingredients along with other
16 substances included during the manufacturing process.

17 (6) "Generic name" means the chemical or established
18 name of a drug product or drug ingredient published in the
19 latest edition of the official United States Pharmacopoeia
20 ~~or official Homeopathic Pharmacopoeia of the United~~
21 ~~States/National Formulary.~~

22 (7) "Person" means an individual, firm, partnership,
23 association, corporation, or any other entity, whether
24 organized for profit or not.

25 (8) "Prescriber" means a practitioner licensed under

1 the professional laws of the state to administer medicine
2 and drugs.

3 (9) "Present compendium standard" means the official
4 standard for drug excipients and drug products listed in the
5 latest revision of the United States Pharmacopoeia and--the/
6 National Formulary.

7 (10) "Product selection" means to dispense without the
8 prescriber's express authorization a different drug product
9 in place of the drug product prescribed.

10 (11) "Therapeutically equivalent" means those chemical
11 equivalents which, when administered in the same dosage
12 regimen, will provide essentially the same therapeutic
13 effect as measured by the control of a symptom or a disease
14 and/or toxicity."

15 Section 12. Coordination with ___Bill___ [LC 1288]. If
16 ___Bill___ [LC 1288] introduced in the 47th Legislature is
17 passed and approved that portion of Section 6, or any other
18 section of this bill, that amends 37-7-302, MCA, to provide
19 for a fee for registration by reciprocity is void and of no
20 effect.

-End-

S B 418

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3 BY REQUEST OF THE DEPARTMENT OF PROFESSIONAL AND

4 OCCUPATIONAL LICENSING

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21 a graduate of the college of pharmacy of the university of
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24 ~~association of colleges of pharmacy~~ council on
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2 immediately before his appointment. ~~However, one member may~~
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5 who, during his term of office, ceases to be actively
6 engaged in the practice of pharmacy in this state, shall be
7 automatically disqualified from membership on the board.

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20 in such practice to administer or prescribe drugs.

21 (2) "Drug" means any article:

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23 Pharmacopoeia, ~~the official~~ National Formulary, or in any
24 supplement to such pharmacopoeia or formulary;

25 (b) intended for use in the diagnosis, cure,

1 mitigation, treatment, or prevention of disease in man;

2 (c) intended to affect the structure or any function

3 of the body of man;

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7 components of a device.

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11 treatment, or prevention of disease in man;

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19 miles of any place at which such medical practitioner

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22 manufacturing, processing, packaging, or distribution of

23 drugs; but such term does not include a pharmacy.

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21 ~~pharmacist in charge under the supervision of a registered~~
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2 corporation or association.

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4 the department to prepare, compound, dispense, and sell
5 drugs, medicines, chemicals, and poisons and who may affix
6 to his name the term "R.Ph."

7 (11) "Pharmacy" means ~~a drugstore or other~~ an
8 established place registered by the department of
9 professional and occupational licensing, in which
10 prescriptions, drugs requiring a prescription, medicines,
11 chemicals, and poisons are compounded, dispensed, vended, or
12 sold at retail.

13 (12) "Poison" means a substance which, when introduced
14 into the system, either directly or by absorption, produces
15 violent, morbid, or fatal changes or which destroys living
16 tissue with which it comes in contact.

17 (13) "Prescription" means an order given individually
18 for the person for whom prescribed, directly from the
19 prescriber to the furnisher or indirectly to the furnisher,
20 by means of an order signed by the prescriber and bearing
21 the name and address of the prescriber, his license
22 classification, the name of the patient, the name and the
23 quantity of the drug or drugs prescribed, the directions for
24 use and the date of its issue. These stipulations apply to
25 both written and telephoned prescriptions.

1 (15) "Wholesale" means a sale for the purpose of
2 resale."

3 Section 4. Section 37-7-201, MCA, is amended to read:

4 "37-7-201. Organization -- powers and duties. (1) The
5 board shall meet at least once a year to transact its
6 business. The board shall annually elect from its members a
7 president, vice-president, and secretary.

8 (2) The board shall:

9 (a) regulate the practice of pharmacy in this state
10 subject to this chapter;

11 (b) determine the minimum equipment necessary in and
12 for a pharmacy and drug stores;

13 (c) regulate, under therapeutic classification, the
14 sale of drugs, medicines, chemicals, and poisons and their
15 labeling;

16 (d) regulate the quality of drugs and medicines
17 dispensed in this state, using the United States
18 Pharmacopoeia and the National Formulary or revisions
19 thereof as the standards;

20 (e) request the department to enter and inspect, at
21 reasonable times, places where drugs, medicines, chemicals,
22 or poisons are sold, vended, given away, compounded,
23 dispensed, or manufactured. It is a misdemeanor for a person
24 to refuse to permit or otherwise prevent the department from
25 entering these places and making an inspection.

1 (f) regulate the practice of interns under national
2 standards;

3 (g) make rules for the conduct of its business;

4 (h) perform other duties and exercise other powers as
5 this chapter requires;

6 (i) adopt and authorize the department to publish
7 rules for carrying out and enforcing parts 1 through 3 of
8 this chapter.

9 (3) The department shall:

10 (a) license, register, and examine, subject to
11 37-1-101, applicants whom the board considers qualified
12 under this chapter;

13 (b) license pharmacies and certain stores under this
14 chapter; and

15 (c) issue certificates of "certified pharmacy" under
16 this chapter."

17 Section 5. Section 37-7-301, MCA, is amended to read:

18 "37-7-301. Sale of drugs or medicines unlawful except
19 as provided. (1) It is unlawful for any person to compound,
20 dispense, vend, or sell at retail drugs, medicines,
21 chemicals, or poisons in any place other than a pharmacy,
22 except as hereinafter provided.

23 (2) It is unlawful for any proprietor, owner, or
24 manager of a pharmacy or any other person to permit the
25 compounding or dispensing of prescriptions or the vending or

1 selling at retail of drugs, medicines, chemicals, or poisons
 2 in any pharmacy except by a registered and licensed
 3 pharmacist or by an intern in the temporary absence of such
 4 pharmacist ~~registered and licensed by the department, under~~
 5 ~~the supervision of a registered and licensed pharmacist.~~

6 (3) It is unlawful for any person to assume or pretend
 7 to the title of pharmacist or intern unless such person has
 8 a license as such, issued and in force pursuant to parts 1
 9 through 3 of this chapter.

10 (4) It is unlawful for any person other than a
 11 licensed and registered pharmacist or a licensed and
 12 registered intern ~~under the supervision of a licensed and~~
 13 ~~registered pharmacist~~ to compound, dispense, vend, or sell
 14 at retail drugs, medicines, chemicals, or poisons except as
 15 provided in parts 1 through 3."

16 Section 6. Section 37-7-302, MCA, is amended to read:

17 "37-7-302. Examination -- qualifications -- fees --
 18 reciprocity. (1) The department shall give reasonable notice
 19 of examinations by mail to known applicants. The department
 20 shall record the names of persons examined, together with
 21 the grounds on which the right of each to examination was
 22 claimed, and also the names of persons registered by
 23 examination or otherwise.

24 (2) The fee for an examination shall be set by the
 25 board at a figure commensurate with costs, which fee may in

1 the discretion of the board be returned to applicants not
 2 taking the examination. On again making payment of the fee,
 3 an applicant who fails is entitled to take the next
 4 succeeding examination free of charge.

5 ~~(3) The fee for registration by reciprocity is \$200.~~

6 ~~(4) (3)~~ To be entitled to examination as a pharmacist,
 7 the applicant shall be a citizen of the United States, of
 8 good moral character, and a graduate of the school of
 9 pharmacy of the university of Montana or of a college or
 10 school of pharmacy recognized and approved accredited by or
 11 ~~a member of the American association of colleges of pharmacy~~
 12 council on pharmaceutical education; but the applicant may
 13 not receive a registered pharmacist's license until he has
 14 complied with the internship requirements established by the
 15 board. ~~During this period, if the applicant has passed the~~
 16 ~~examination, he shall be licensed as an intern only.~~

17 ~~(5) (4)~~ The board may in its discretion authorize the
 18 department to grant registration without examination to a
 19 pharmacist licensed by a board of pharmacy or a similar
 20 board of another state which accords similar recognition to
 21 licensees of this state if the requirements for registration
 22 in the other state are, in the opinion of the board,
 23 equivalent to the requirements of this chapter. The fee for
 24 registration by reciprocity is \$200.

25 ~~(6) (5)~~ Every person licensed and registered under this

1 chapter shall receive from the department an appropriate
 2 certificate attesting the fact, which shall be conspicuously
 3 displayed at all times in his place of business. ~~If the~~
 4 ~~holder is entitled to engage or conduct a pharmacy in this~~
 5 ~~state for himself or another, the fact shall be set forth in~~
 6 ~~the certificate."~~

7 Section 7. Section 37-7-303, MCA, is amended to read:

8 "37-7-303. Annual renewal fee. (1) A person licensed
 9 and registered by the department shall annually pay to the
 10 department before June 30 a renewal of registration fee of
 11 \$15. A default in the payment of a renewal fee ~~for a period~~
 12 ~~of 30 days~~ after the date it is due increases the renewal
 13 fee to \$30. It is unlawful for a person who refuses or fails
 14 to pay the renewal fee to practice pharmacy in this state. A
 15 certificate and renewal expires at the time prescribed, not
 16 later than 1 year from its date. A defaulter in a renewal
 17 fee may be reinstated within 1 year of the default without
 18 examination on payment of the arrears and compliance with
 19 the continuing education provisions of this chapter.

20 (2) The board may charge an additional fee of up to
 21 \$10 ~~for such a license renewal~~ to be used in administering the
 22 continuing education provisions of this chapter."

23 Section 8. Section 37-7-311, MCA, is amended to read:

24 "37-7-311. Revocation of license issued to pharmacist
 25 or intern. The board shall revoke ~~temporarily~~ or

1 permanently licenses issued by the department to a
 2 pharmacist or intern whenever the holder of the license:

- 3 (1) has obtained it by false representations or fraud;
 4 (2) is an habitual drunkard or addicted to the use of
 5 narcotic drugs;
 6 (3) has been convicted of a felony;
 7 (4) has been convicted of violating the pharmacy law;
 8 or

9 (5) has been found by the board guilty of incompetency
 10 in the preparation of prescriptions or guilty of gross
 11 immorality affecting the discharge of his duties as a
 12 pharmacist or intern."

13 Section 9. Section 37-7-321, MCA, is amended to read:

14 "37-7-321. Store license -- certified pharmacy license
 15 -- suspension or revocation. (1) The department shall, on
 16 application on forms prescribed by the board and on the
 17 payment of an annual fee of \$10, license stores other than
 18 pharmacies in which are sold ordinary household or medicinal
 19 drugs prepared in sealed packages or bottles by a
 20 manufacturer qualified under the laws of the state in which
 21 the manufacturer resides. The name and address of the
 22 manufacturer shall appear conspicuously on each package sold
 23 by the licensee. It is unlawful for a store to sell,
 24 deliver, or give away household medicinal drugs without
 25 first having secured a license and thereafter keeping it in

1 force by proper renewal. ~~This subsection does not prevent a~~
 2 ~~vendor from selling a patent or proprietary medicine in the~~
 3 ~~original package when plainly labeled or nonmedical articles~~
 4 ~~usually sold by vendors.~~

5 (2) The board shall provide for the original
 6 certification and annual renewal by the department of every
 7 pharmacy doing business in this state. On presentation of
 8 evidence satisfactory to the board and on application on a
 9 form prescribed by the board and on the payment of an
 10 original certification fee of \$100, the department shall
 11 issue a license to a pharmacy as a certified pharmacy.
 12 However, the license may be granted only to pharmacies
 13 operated by registered pharmacists or ~~registered interns~~
 14 qualified under this chapter. The annual renewal fee for a
 15 pharmacy shall be set by the board in an amount not to
 16 exceed \$50. Any default in the payment of such renewal fee
 17 ~~for a period of 30 days after the date the same is due shall~~
 18 ~~increase the renewal fee to the sum of \$100.~~ The license
 19 must be displayed in a conspicuous place in the pharmacy for
 20 which it is issued and expires on June 30 following the date
 21 of issue. It is unlawful for a person to conduct a pharmacy,
 22 use the word "pharmacy" to identify his business, or use the
 23 word "pharmacy" in advertising unless a license has been
 24 issued and is in effect.

25 (3) The board may suspend, revoke, or refuse to renew

1 a store or pharmacy license:

- 2 (a) obtained by false representation or fraud;
- 3 (b) when the pharmacy for which the license is issued
- 4 is kept open for the transaction of business without a
- 5 pharmacist in charge;
- 6 (c) when the person to whom the license is granted has
- 7 been convicted of:
- 8 (i) a violation of parts 1 through 3 of this chapter;
- 9 (ii) a felony; or
- 10 (iii) a violation of the Federal Food, Drug, and
- 11 Cosmetic Act of June 25, 1938, (52 Stat. 1040 through 1052
- 12 Title 21, Chapter 9, United States Code);
- 13 (d) when the person to whom the license is granted is
- 14 a natural person whose pharmacist or ~~intern~~ license has been
- 15 revoked; or
- 16 (e) when the store or pharmacy is conducted in
- 17 violation of parts 1 through 3 of this chapter.
- 18 (4) Before a license can be revoked, the holder is
- 19 entitled to a hearing by the board."

20 Section 10. Section 37-7-401, MCA, is amended to read:

21 "37-7-401. Restrictions upon sale or prescription of

22 opiates -- coding prohibited -- refilling prescriptions. (1)

23 It shall be unlawful for any physician to sell or give to or

24 prescribe for any person any opium, morphine,

25 alkaloid-cocaine, or alpha or beta eucaine or codeine or

1 heroin or any derivative, mixture, or preparation of any of
2 them, except to a patient believed in good faith to require
3 the same for medical use and in quantities proportioned to
4 the needs of such patients.

5 (2) A prescription must be so written that it can be
6 compounded by any registered pharmacist. The coding of any
7 prescription is a violation of this section.

8 (3) A prescription marked "non repetatur", "non rep",
9 or "N.R." cannot be refilled. A prescription marked to be
10 refilled by a specified amount may be filled by any
11 registered pharmacist the number of times marked on the
12 prescription. A prescription not bearing any ~~indication of~~
13 ~~refill instructions~~ may ~~not~~ be refilled ~~at any time during the~~
14 ~~time specified without first obtaining permission from the~~
15 ~~prescriber. A prescription may not be refilled for more~~
16 ~~than 1/3 year from the date it was originally filled. A~~
17 ~~prescription may not be refilled when a refill is prohibited~~
18 ~~by federal or state law. No narcotic prescription may be~~
19 refilled."

20 Section 11. Section 37-7-502, MCA, is amended to read:
21 ~~37-7-502. Definitions. As used in this part, the~~
22 following definitions apply:

23 (1) "Bioavailability" means the extent and rate of
24 absorption from a dosage form as reflected by the
25 time-concentration curve of the administered drug in the

1 systemic circulation.

2 (2) "Bioequivalent" means a chemical equivalent which,
3 when administered to the same individual in the same dosage
4 regimen, will result in comparable bioavailability.

5 (3) "Brand name" means the proprietary or the
6 registered trademark name given to a drug product by its
7 manufacturer, labeler, or distributor and placed upon the
8 drug, its container, label, or wrapping at the time of
9 packaging.

10 (4) "Chemical equivalent" means drug products that
11 contain the same amounts of the same therapeutically active
12 ingredients in the same dosage forms and that meet present
13 compendium standards.

14 (5) "Drug product" means a dosage form containing one
15 or more active therapeutic ingredients along with other
16 substances included during the manufacturing process.

17 (6) "Generic name" means the chemical or established
18 name of a drug product or drug ingredient published in the
19 latest edition of the official United States Pharmacopoeia
20 ~~or official Homeopathic Pharmacopoeia of the United~~
21 ~~States/National Formulary.~~

22 (7) "Person" means an individual, firm, partnership,
23 association, corporation, or any other entity, whether
24 organized for profit or not.

25 (8) "Prescriber" means a practitioner licensed under

1 the professional laws of the state to administer medicine
2 and drugs.

3 (9) "Present compendium standard" means the official
4 standard for drug excipients and drug products listed in the
5 latest revision of the United States Pharmacopoeia and the
6 National Formulary.

7 (10) "Product selection" means to dispense without the
8 prescriber's express authorization a different drug product
9 in place of the drug product prescribed.

10 (11) "Therapeutically equivalent" means those chemical
11 equivalents which, when administered in the same dosage
12 regimen, will provide essentially the same therapeutic
13 effect as measured by the control of a symptom or a disease
14 and/or toxicity."

15 Section 12. Coordination with ___Bill___ [LC 1288]. If
16 ___Bill___ [LC 1288] introduced in the 47th Legislature is
17 passed and approved that portion of Section 6, or any other
18 section of this bill, that amends 37-7-302, MCA, to provide
19 for a fee for registration by reciprocity is void and of no
20 effect.

-End-

SENATE BILL NO. 418

INTRODUCED BY DCHSNER, ZABROCKI

BY REQUEST OF THE DEPARTMENT OF PROFESSIONAL AND OCCUPATIONAL LICENSING

A BILL FOR AN ACT ENTITLED: "AN ACT TO REVISE AND CLARIFY THE LAW CREATING THE BOARD OF PHARMACISTS AND THE LAWS ADMINISTERED BY THE BOARD OF PHARMACISTS; AMENDING SECTIONS 2-15-1609, 37-2-101, 37-7-101, 37-7-201, 37-7-301 THROUGH 37-7-303, 37-7-311, 37-7-321, 37-7-401, AND 37-7-502, MCA."

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

Section 1. Section 2-15-1609, MCA, is amended to read:

"2-15-1609. Board of pharmacists. (1) There is a board of pharmacists.

(2) The board consists of three members appointed by the governor. The governor shall appoint the members from a list submitted annually by the Montana state pharmaceutical association. The list shall contain the names of five qualified persons for each appointment. Each member shall be a graduate of the college of pharmacy of the university of Montana or of a college or school of pharmacy recognized and approved accredited by or a member of the American association of colleges of pharmacy council on pharmaceutical education. Each member shall have at least 5

consecutive years of practical experience as a pharmacist immediately before his appointment. However, one member may be a registered pharmacist of 15 years' practical experience and actually engaged in the practice of pharmacy. A member who, during his term of office, ceases to be actively engaged in the practice of pharmacy in this state, shall be automatically disqualified from membership on the board.

(3) Each member shall serve for a term of 3 years. A member shall be removed from office by the governor on proof of malfeasance or misfeasance in office, after reasonable notice of charges against him and after a hearing.

(4) The board is allocated to the department for administrative purposes only as prescribed in 2-15-121."

Section 2. Section 37-2-101, MCA, is amended to read:

"37-2-101. Definitions. As used in this part, the following definitions apply:

(1) "Medical practitioner" means any person licensed by the state of Montana to engage in the practice of medicine, dentistry, osteopathy, or chiropody (podiatry) and in such practice to administer or prescribe drugs.

(2) "Drug" means any article:

(a) recognized in the official United States Pharmacopoeia, the official National Formulary, or in any supplement to such pharmacopoeia or formulary;

(b) intended for use in the diagnosis, cure,

1 mitigation, treatment, or prevention of disease in man;

2 (c) intended to affect the structure or any function

3 of the body of man;

4 (d) intended for use as a component of any article

5 described in subsection (a), (b), or (c) of this subsection

6 (2), but such term does not include any device or any

7 components of a device.

8 (3) "Device" means any instrument, apparatus, or

9 contrivance intended:

10 (a) for use in the diagnosis, cure, mitigation,

11 treatment, or prevention of disease in man;

12 (b) to affect the structure or any function of the

13 body of man.

14 (4) "Pharmacy" means an office, ~~pharmacy, drugstore,~~

15 ~~or other establishment which engages in the sale of drugs at~~

16 ~~retail requiring a prescription.~~

17 (5) "Community pharmacy", when used in relation to a

18 medical practitioner, means a pharmacy situated within 10

19 miles of any place at which such medical practitioner

20 maintains an office for professional practice.

21 (6) "Drug company" means any person engaged in the

22 manufacturing, processing, packaging, or distribution of

23 drugs; but such term does not include a pharmacy.

24 (7) "Person" means any individual and any partnership,

25 firm, corporation, association, or other business entity.

1 (8) "State" means the state of Montana or any

2 political subdivision thereof."

3 Section 3. Section 37-7-101, MCA, is amended to read:

4 "37-7-101. Definitions. Unless the context requires

5 otherwise, in parts 1 through 3 of this chapter the

6 following definitions apply:

7 (1) "Board" means the board of pharmacists provided

8 for in 2-15-1609.

9 (2) "Chemical" means medicinal or industrial

10 substances, whether simple, compound, or obtained through

11 the process of the science and art of chemistry, whether of

12 organic or inorganic origin.

13 (3) "Commercial purposes" means the ordinary purposes

14 of trade, agriculture, industry, and commerce, exclusive of

15 the practices of medicine and pharmacy.

16 (4) "Continuing education" means professional

17 pharmaceutical postgraduate education in the following

18 areas:

19 (a) the socioeconomic and legal aspects of health

20 care;

21 (b) the properties and actions of drugs and dosage

22 forms; and

23 (c) the etiology, characteristics, and therapeutics of

24 the disease state.

25 (5) "Department" means the department of professional

1 and occupational licensing provided for in Title 2, chapter
2 15, part 16.

3 (6) (a) "Drug" means:

4 (i) articles recognized in the official United States
5 Pharmacopoeia, ~~official Homeopathic Pharmacopoeia of the~~
6 ~~United States, or official~~ National Formulary, or a
7 supplement to them;

8 (ii) articles intended for use in diagnosis, cure,
9 mitigation, treatment, or prevention of disease in man or
10 other animals;

11 (iii) articles (other than food) intended to affect the
12 structure or function of the body of man or other animals;
13 and

14 (iv) articles intended for use as a component of an
15 article specified in subsection (i), (ii), or (iii).

16 (b) "Drug" does not include devices or their
17 components, parts, or accessories.

18 (7) "Intern" means a natural person licensed by the
19 department to prepare, compound, dispense, and sell drugs,
20 medicines, chemicals, and poisons ~~in a pharmacy having a~~
21 ~~pharmacist in charge~~ under the supervision of a registered
22 and licensed pharmacist.

23 (8) "Medicine" means a remedial agent which has the
24 property of curing, preventing, treating, or mitigating
25 diseases or which is used for this purpose.

1 (9) "Person" includes an individual, partnership,
2 corporation, or association.

3 (10) "Pharmacist" means a natural person licensed by
4 the department to prepare, compound, dispense, and sell
5 drugs, medicines, chemicals, and poisons and who may affix
6 to his name the term "R.Ph."

7 (11) "Pharmacy" means ~~a drugstore or other~~ an
8 established place registered by the department of
9 professional and occupational licensing, in which
10 prescriptions, drugs requiring a prescription, medicines,
11 chemicals, and poisons are compounded, dispensed, vended, or
12 sold at retail.

13 (12) "Poison" means a substance which, when introduced
14 into the system, either directly or by absorption, produces
15 violent, morbid, or fatal changes or which destroys living
16 tissue with which it comes in contact.

17 (13) "Prescription" means an order given individually
18 for the person for whom prescribed, directly from the
19 prescriber to the furnisher or indirectly to the furnisher,
20 by means of an order signed by the prescriber and bearing
21 the name and address of the prescriber, his license
22 classification, the name of the patient, the name and the
23 quantity of the drug or drugs prescribed, the directions for
24 use and the date of its issue. These stipulations apply to
25 both written and telephoned prescriptions.

1 (14) "Wholesale" means a sale for the purpose of
2 resale."

3 Section 4. Section 37-7-201, MCA, is amended to read:

4 "37-7-201. Organization -- powers and duties. (1) The
5 board shall meet at least once a year to transact its
6 business. The board shall annually elect from its members a
7 president, vice-president, and secretary.

8 (2) The board shall:

9 (a) regulate the practice of pharmacy in this state
10 subject to this chapter;

11 (b) determine the minimum equipment necessary in and
12 for a pharmacy and drug store;

13 (c) regulate, under therapeutic classification, the
14 sale of drugs, medicines, chemicals, and poisons and their
15 labeling;

16 (d) regulate the quality of drugs and medicines
17 dispensed in this state, using the United States
18 Pharmacopoeia and the National Formulary or revisions
19 thereof as the standards;

20 (e) request the department to enter and inspect, at
21 reasonable times, places where drugs, medicines, chemicals,
22 or poisons are sold, vended, given away, compounded,
23 dispensed, or manufactured. It is a misdemeanor for a person
24 to refuse to permit or otherwise prevent the department from
25 entering these places and making an inspection.

1 (f) regulate the practice of interns under national
2 standards;

3 (g) make rules for the conduct of its business;

4 (h) perform other duties and exercise other powers as
5 this chapter requires;

6 (i) adopt and authorize the department to publish
7 rules for carrying out and enforcing parts 1 through 3 of
8 this chapter.

9 (3) The department shall:

10 (a) license, register, and examine, subject to
11 37-1-101, applicants whom the board considers qualified
12 under this chapter;

13 (b) license pharmacies and certain stores under this
14 chapter; and

15 (c) issue certificates of "certified pharmacy" under
16 this chapter."

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19 as provided. (1) It is unlawful for any person to compound,
20 dispense, vend, or sell at retail drugs, medicines,
21 chemicals, or poisons in any place other than a pharmacy,
22 except as hereinafter provided.

23 (2) It is unlawful for any proprietor, owner, or
24 manager of a pharmacy or any other person to permit the
25 compounding or dispensing of prescriptions or the vending or

1 selling at retail of drugs, medicines, chemicals, or poisons
 2 in any pharmacy except by a registered and licensed
 3 pharmacist or by an intern ~~in the temporary absence of such~~
 4 pharmacist registered and licensed by the department, under
 5 the supervision of a registered and licensed pharmacist.

6 (3) It is unlawful for any person to assume or pretend
 7 to the title of pharmacist or intern unless such person has
 8 a license as such, issued and in force pursuant to parts 1
 9 through 3 of this chapter.

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 11 licensed and registered pharmacist or a licensed and
 12 registered intern under the supervision of a licensed and
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 14 at retail drugs, medicines, chemicals, or poisons except as
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 20 shall record the names of persons examined, together with
 21 the grounds on which the right of each to examination was
 22 claimed, and also the names of persons registered by
 23 examination or otherwise.

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 25 board at a figure commensurate with costs, which fee may in

1 the discretion of the board be returned to applicants not
 2 taking the examination. On again making payment of the fee,
 3 an applicant who fails is entitled to take the next
 4 succeeding examination free of charge.

5 ~~(3) The fee for registration by reciprocity is \$200.~~

6 ~~(4)~~ (3) To be entitled to examination as a pharmacist,
 7 the applicant shall be a citizen of the United States, of
 8 good moral character, and a graduate of the school of
 9 pharmacy of the university of Montana or of a college or
 10 school of pharmacy recognized and approved accredited by or
 11 ~~a member of the American association of colleges of pharmacy~~
 12 council on pharmaceutical education; but the applicant may
 13 not receive a registered pharmacist's license until he has
 14 complied with the internship requirements established by the
 15 board. ~~During this period, if the applicant has passed the~~
 16 ~~examination, he shall be licensed as an intern only.~~

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 18 department to grant registration without examination to a
 19 pharmacist licensed by a board of pharmacy or a similar
 20 board of another state which accords similar recognition to
 21 licensees of this state if the requirements for registration
 22 in the other state are, in the opinion of the board,
 23 equivalent to the requirements of this chapter. The fee for
 24 registration by reciprocity is \$200.

25 ~~(6)~~ (5) Every person licensed and registered under this

1 chapter shall receive from the department an appropriate
 2 certificate attesting the fact, which shall be conspicuously
 3 displayed at all times in his place of business. ~~if the~~
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 12 ~~of 30 days~~ after the date it is due increases the renewal
 13 fee to \$30. It is unlawful for a person who refuses or fails
 14 to pay the renewal fee to practice pharmacy in this state. A
 15 certificate and renewal expires at the time prescribed, not
 16 later than 1 year from its date. A defaulter in a renewal
 17 fee may be reinstated within 1 year of the default without
 18 examination on payment of the arrears and compliance with
 19 the continuing education provisions of this chapter.

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 21 \$10 for such license renewal to be used in administering the
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 25 or intern. The board shall revoke ~~temporarily or~~

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 2 pharmacist or intern whenever the holder of the license:

3 (1) has obtained it by false representations or fraud;

4 (2) is an habitual drunkard or addicted to the use of
 5 narcotic drugs;

6 (3) has been convicted of a felony;

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8 or

9 (5) has been found by the board guilty of incompetency
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 18 pharmacies in which are sold ordinary household or medicinal
 19 drugs prepared in sealed packages or bottles by a
 20 manufacturer qualified under the laws of the state in which
 21 the manufacturer resides. The name and address of the
 22 manufacturer shall appear conspicuously on each package sold
 23 by the licensee. It is unlawful for a store to sell,
 24 deliver or give away household medicinal drugs without
 25 first having secured a license and thereafter keeping it in

1 force by proper renewal. ~~This subsection does not prevent a~~
 2 ~~vendor from selling a patent or proprietary medicine in the~~
 3 ~~original package when plainly labeled or nonmedical articles~~
 4 ~~usually sold by vendors.~~

5 (2) The board shall provide for the original
 6 certification and annual renewal by the department of every
 7 pharmacy doing business in this state. On presentation of
 8 evidence satisfactory to the board and on application on a
 9 form prescribed by the board and on the payment of an
 10 original certification fee of \$100, the department shall
 11 issue a license to a pharmacy as a certified pharmacy.
 12 However, the license may be granted only to pharmacies
 13 operated by registered pharmacists or ~~registered interns~~
 14 qualified under this chapter. The annual renewal fee for a
 15 pharmacy shall be set by the board in an amount not to
 16 exceed \$50. Any default in the payment of such renewal fee
 17 ~~for a period of 30 days~~ after the date the same is due shall
 18 increase the renewal fee to the sum of \$100. The license
 19 must be displayed in a conspicuous place in the pharmacy for
 20 which it is issued and expires on June 30 following the date
 21 of issue. It is unlawful for a person to conduct a pharmacy,
 22 use the word "pharmacy" to identify his business, or use the
 23 word "pharmacy" in advertising unless a license has been
 24 issued and is in effect.

25 (3) The board may suspend, revoke, or refuse to renew

1 a store or pharmacy license:

- 2 (a) obtained by false representation or fraud;
- 3 (b) when the pharmacy for which the license is issued
- 4 is kept open for the transaction of business without a
- 5 pharmacist in charge;
- 6 (c) when the person to whom the license is granted has
- 7 been convicted of:
- 8 (i) a violation of parts 1 through 3 of this chapter;
- 9 (ii) a felony; or
- 10 (iii) a violation of the Federal Food, Drug, and
- 11 Cosmetic Act of ~~June 25, 1938, (52 Stat. 1040 through 1059)~~
- 12 Title 21, Chapter 9, United States Code;
- 13 (d) when the person to whom the license is granted is
- 14 a natural person whose pharmacist or ~~intern~~ license has been
- 15 revoked; or
- 16 (e) when the store or pharmacy is conducted in
- 17 violation of parts 1 through 3 of this chapter.
- 18 (4) Before a license can be revoked, the holder is
- 19 entitled to a hearing by the board."

20 Section 10. Section 37-7-401, MCA, is amended to read:

21 "37-7-401. Restrictions upon sale or prescription of

22 opiates -- coding prohibited -- refilling prescriptions. (1)

23 It shall be unlawful for any physician to sell or give to or

24 prescribe for any person any opium, morphine,

25 alkaloid-cocaine, or alpha or beta eucaine or codeine or

1 heroin or any derivative, mixture, or preparation of any of
2 them, except to a patient believed in good faith to require
3 the same for medical use and in quantities proportioned to
4 the needs of such patients.

5 (2) A prescription must be so written that it can be
6 compounded by any registered pharmacist. The coding of any
7 prescription is a violation of this section.

8 (3) A prescription marked "non repetatur", "non rep",
9 or "N.R." cannot be refilled. A prescription marked to be
10 refilled by a specified amount may be filled by any
11 registered pharmacist the number of times marked on the
12 prescription. A prescription not bearing any ~~instruction of~~
13 refill instructions may not be refilled ~~at will during the~~
14 time specified without first obtaining permission from the
15 prescriber. A prescription may not be refilled for more
16 than 3 year from the date it was originally filled. A
17 prescription may not be refilled when a refill is prohibited
18 by federal or state law. No narcotic prescription may be
19 refilled."

20 Section 11. Section 37-7-502, MCA, is amended to read:
21 "37-7-502. Definitions. As used in this part, the
22 following definitions apply:

23 (1) "Bioavailability" means the extent and rate of
24 absorption from a dosage form as reflected by the
25 time-concentration curve of the administered drug in the

1 systemic circulation.

2 (2) "Bioequivalent" means a chemical equivalent which,
3 when administered to the same individual in the same dosage
4 regimen, will result in comparable bioavailability.

5 (3) "Brand name" means the proprietary or the
6 registered trademark name given to a drug product by its
7 manufacturer, labeler, or distributor and placed upon the
8 drug, its container, label, or wrapping at the time of
9 packaging.

10 (4) "Chemical equivalent" means drug products that
11 contain the same amounts of the same therapeutically active
12 ingredients in the same dosage forms and that meet present
13 compendium standards.

14 (5) "Drug product" means a dosage form containing one
15 or more active therapeutic ingredients along with other
16 substances included during the manufacturing process.

17 (6) "Generic name" means the chemical or established
18 name of a drug product or drug ingredient published in the
19 latest edition of the official United States Pharmacopoeia
20 ~~or official Homeopathic Pharmacopoeia of the United~~
21 States/National Formulary.

22 (7) "Person" means an individual, firm, partnership,
23 association, corporation, or any other entity, whether
24 organized for profit or not.

25 (8) "Prescriber" means a practitioner licensed under

1 the professional laws of the state to administer medicine
2 and drugs.

3 (9) "Present compendium standard" means the official
4 standard for drug excipients and drug products listed in the
5 latest revision of the United States Pharmacopoeia and the
6 National Formulary.

7 (10) "Product selection" means to dispense without the
8 prescriber's express authorization a different drug product
9 in place of the drug product prescribed.

10 (11) "Therapeutically equivalent" means those chemical
11 equivalents which, when administered in the same dosage
12 regimen, will provide essentially the same therapeutic
13 effect as measured by the control of a symptom or a disease
14 and/or toxicity."

15 Section 12. Coordination with ___Bill___ [LC 1288]. If
16 ___Bill___ [LC 1288] introduced in the 47th Legislature is
17 passed and approved that portion of Section 6, or any other
18 section of this bill, that amends 37-7-302, MCA, to provide
19 for a fee for registration by reciprocity is void and of no
20 effect.

-End-

1 SENATE BILL NO. 418

2 INTRODUCED BY OCHSNER, ZABROCKI

3 BY REQUEST OF THE DEPARTMENT OF PROFESSIONAL AND

4 OCCUPATIONAL LICENSING

5
6 A BILL FOR AN ACT ENTITLED: "AN ACT TO REVISE AND CLARIFY
7 THE LAW CREATING THE BOARD OF PHARMACISTS AND THE LAWS
8 ADMINISTERED BY THE BOARD OF PHARMACISTS; AMENDING SECTIONS
9 2-15-1609, 37-2-101, 37-7-101, 37-7-201, 37-7-301 THROUGH
10 37-7-303, 37-7-311, 37-7-321, 37-7-401, AND 37-7-502,
11 50-32-101, 50-32-208, 50-32-209, AND 50-32-301, MCA."

12
13 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

14 Section 1. Section 2-15-1609, MCA, is amended to read:

15 "2-15-1609. Board of pharmacists. (1) There is a board
16 of pharmacists.

17 (2) The board consists of three members appointed by
18 the governor. The governor shall appoint the members from a
19 list submitted annually by the Montana state pharmaceutical
20 association. The list shall contain the names of five
21 qualified persons for each appointment. Each member shall be
22 a graduate of the college of pharmacy of the university of
23 Montana or of a college or school of pharmacy recognized and
24 approved accredited by ~~or--a--member--of~~ the American
25 ~~association--of--colleges--of--pharmacy~~ council on

1 pharmaceutical education. Each member shall have at least 5
2 consecutive years of practical experience as a pharmacist
3 immediately before his appointment. ~~However, one member may~~
4 ~~be a registered pharmacist of 15 years' practical experience~~
5 ~~and actually engaged in the practice of pharmacy.~~ A member
6 who, during his term of office, ceases to be actively
7 engaged in the practice of pharmacy in this state, shall be
8 automatically disqualified from membership on the board.

9 (3) Each member shall serve for a term of 3 years. A
10 member shall be removed from office by the governor on proof
11 of malfeasance or misfeasance in office, after reasonable
12 notice of charges against him and after a hearing.

13 (4) The board is allocated to the department for
14 administrative purposes only as prescribed in 2-15-121."

15 Section 2. Section 37-2-101, MCA, is amended to read:

16 "37-2-101. Definitions. As used in this part, the
17 following definitions apply:

18 (1) "Medical practitioner" means any person licensed
19 by the state of Montana to engage in the practice of
20 medicine, dentistry, osteopathy, or chiropody (podiatry) and
21 in such practice to administer or prescribe drugs.

22 (2) "Drug" means any article:

23 (a) recognized in the official United States
24 Pharmacopoeia ~~or the official~~ National Formulary or in any
25 supplement to such pharmacopoeia ~~or~~ formulary;

1 (b) intended for use in the diagnosis, cure,
2 mitigation, treatment, or prevention of disease in man;

3 (c) intended to affect the structure or any function
4 of the body of man;

5 (d) intended for use as a component of any article
6 described in subsection (a), (b), or (c) of this subsection
7 (2), but such term does not include any device or any
8 components of a device.

9 (3) "Device" means any instrument, apparatus, or
10 contrivance intended:

11 (a) for use in the diagnosis, cure, mitigation,
12 treatment, or prevention of disease in man;

13 (b) to affect the structure or any function of the
14 body of man.

15 (4) "Pharmacy" means an ~~office--pharmacy--drugstore~~
16 ~~or other~~ establishment which engages in the sale of drugs at
17 ~~retail requiring a prescription.~~

18 (5) "Community pharmacy", when used in relation to a
19 medical practitioner, means a pharmacy situated within 10
20 miles of any place at which such medical practitioner
21 maintains an ~~office~~ for professional practice.

22 (6) "Drug company" means any person engaged in the
23 manufacturing, processing, packaging, or distribution of
24 drugs; but such term does not include a pharmacy.

25 (7) "Person" means any individual and any partnership,

1 firm, corporation, association, or other business entity.

2 (8) "State" means the state of Montana or any
3 political subdivision thereof."

4 Section 3. Section 37-7-101, MCA, is amended to read:
5 *37-7-101. Definitions. Unless the context requires
6 otherwise, in parts 1 through 3 of this chapter the
7 following definitions apply:

8 (1) "Board" means the board of pharmacists provided
9 for in 2-15-1609.

10 (2) "Chemical" means medicinal or industrial
11 substances, whether simple, compound, or obtained through
12 the process of the science and art of chemistry, whether of
13 organic or inorganic origin.

14 (3) "Commercial purposes" means the ordinary purposes
15 of trade, agriculture, industry, and commerce, exclusive of
16 the practices of medicine and pharmacy.

17 (4) "Continuing education" means professional
18 pharmaceutical postgraduate education in the following
19 areas:

20 (a) the socioeconomic and legal aspects of health
21 care;

22 (b) the properties and actions of drugs and dosage
23 forms; and

24 (c) the etiology, characteristics, and therapeutics of
25 the disease state.

1 (5) "Department" means the department of professional
2 and occupational licensing provided for in Title 2, chapter
3 15, part 16.

4 (6) (a) "Drug" means:

5 (i) articles recognized in the official United States
6 Pharmacopoeia~~ia~~~~---official~~~~---Homeopathic~~~~---Pharmacopoeia~~~~---of~~~~---the~~
7 ~~United~~~~---States~~~~---~~~~or~~~~---official~~ National Formulary, or a
8 supplement to them;

9 (ii) articles intended for use in diagnosis, cure,
10 mitigation, treatment, or prevention of disease in man or
11 other animals;

12 (iii) articles (other than food) intended to affect the
13 structure or function of the body of man or other animals;
14 and

15 (iv) articles intended for use as a component of an
16 article specified in subsection (i), (ii), or (iii).

17 (b) "Drug" does not include devices or their
18 components, parts, or accessories.

19 (7) "Intern" means a natural person licensed by the
20 department to prepare, compound, dispense, and sell drugs,
21 medicines, chemicals, and poisons ~~in~~~~---a~~~~---pharmacy~~~~---having~~~~---a~~
22 ~~pharmacist~~~~---in~~~~---charge~~ under the supervision of a registered
23 and licensed pharmacist.

24 (8) "Medicine" means a remedial agent which has the
25 property of curing, preventing, treating, or mitigating

1 diseases or which is used for this purpose.

2 (9) "Person" includes an individual, partnership,
3 corporation, or association.

4 (10) "Pharmacist" means a natural person licensed by
5 the department to prepare, compound, dispense, and sell
6 drugs, medicines, chemicals, and poisons and who may affix
7 to his name the term "R.Ph."

8 (11) "Pharmacy" means ~~a~~~~---drugstore~~~~---or~~~~---other~~ an
9 established place registered by the department of
10 professional and occupational licensing, in which
11 prescriptions, drugs requiring a prescription, medicines,
12 chemicals, and poisons are compounded, dispensed, vended, or
13 sold ~~at~~~~---retail~~.

14 (12) "Poison" means a substance which, when introduced
15 into the system, either directly or by absorption, produces
16 violent, morbid, or fatal changes or which destroys living
17 tissue with which it comes in contact.

18 (13) "Prescription" means an order given individually
19 for the person for whom prescribed, directly from the
20 prescriber to the furnisher or indirectly ~~to~~ the furnisher,
21 by means of an order signed by the prescriber and bearing
22 the name and address of the prescriber, his license
23 classification, the name of the patient, the name ~~and~~ the
24 quantity of the drug or drugs prescribed, the ~~directions~~ for
25 use and the date of its issue. These stipulations apply to

1 both written and telephoned prescriptions.

2 (14) "Wholesale" means a sale for the purpose of
3 resale."

4 Section 4. Section 37-7-201, MCA, is amended to read:
5 "37-7-201. Organization -- powers and duties. (1) The
6 board shall meet at least once a year to transact its
7 business. The board shall annually elect from its members a
8 president, vice-president, and secretary.

9 (2) The board shall:

10 (a) regulate the practice of pharmacy in this state
11 subject to this chapter;

12 (b) determine the minimum equipment necessary in and
13 for a pharmacy ~~and drug store~~;

14 (c) regulate, under therapeutic classification, the
15 sale of drugs, medicines, chemicals, and poisons and their
16 labeling;

17 (d) regulate the quality of drugs and medicines
18 dispensed in this state, using the United States
19 Pharmacopoeia ~~and the~~ National Formulary or revisions
20 thereof as the standards;

21 (e) request the department to enter and inspect, at
22 reasonable times, ~~in~~ places where drugs, medicines, chemicals,
23 or poisons are sold, vended, given away, compounded,
24 dispensed, or manufactured. It is a misdemeanor for a person
25 to refuse to permit or otherwise prevent the department from

1 entering these places and making an inspection.

2 (f) regulate the practice of interns under national
3 standards;

4 (g) make rules for the conduct of its business;

5 (h) perform other duties and exercise other powers as
6 this chapter requires;

7 (i) adopt and authorize the department to publish
8 rules for carrying out and enforcing parts 1 through 3 of
9 this chapter.

10 (3) The department shall:

11 (a) license, register, and examine, subject to
12 37-1-101, applicants whom the board considers qualified
13 under this chapter;

14 (b) license pharmacies and certain stores under this
15 chapter; and

16 (c) issue certificates of "certified pharmacy" under
17 this chapter."

18 Section 5. Section 37-7-301, MCA, is amended to read:
19 "37-7-301. Sale of drugs or medicines unlawful except
20 as provided. (1) It is unlawful for any person to compound,
21 dispense, vend, or sell at retail drugs, medicines,
22 chemicals, or poisons in any place other than a pharmacy,
23 except as hereinafter provided.

24 (2) It is unlawful for any proprietor, owner, or
25 manager of a pharmacy or any other person to permit the

1 compounding or dispensing of prescriptions or the vending or
 2 selling at retail of drugs, medicines, chemicals, or poisons
 3 in any pharmacy except by a registered and licensed
 4 pharmacist or by an intern ~~in the temporary absence of such~~
 5 pharmacist registered and licensed by the department, under
 6 the supervision of a registered and licensed pharmacist.

7 (3) It is unlawful for any person to assume or pretend
 8 to the title of pharmacist or intern unless such person has
 9 a license as such, issued and in force pursuant to parts 1
 10 through 3 of this chapter.

11 (4) It is unlawful for any person other than a
 12 licensed and registered pharmacist or a licensed and
 13 registered intern under the supervision of a licensed and
 14 registered pharmacist to compound, dispense, vend, or sell
 15 at retail drugs, medicines, chemicals, or poisons except as
 16 provided in parts 1 through 3."

17 Section 6. Section 37-7-302, MCA, is amended to read:

18 "37-7-302. Examination -- qualifications -- fees --
 19 reciprocity. (1) The department shall give reasonable notice
 20 of examinations by mail to known applicants. The department
 21 shall record the names of persons examined, together with
 22 the grounds on which the right of each to examination was
 23 claimed, and also the names of persons registered by
 24 examination or otherwise.

25 (2) The fee for an examination shall be set by the

1 board at a figure commensurate with costs, which fee may in
 2 the discretion of the board be returned to applicants not
 3 taking the examination. On again making payment of the fee,
 4 an applicant who fails is entitled to take the next
 5 succeeding examination free of charge.

6 ~~(3) -- The fee for registration by reciprocity is \$200.~~

7 ~~(4)(3)~~ To be entitled to examination as a pharmacist,
 8 the applicant shall be a citizen of the United States, of
 9 good moral character, and a graduate of the school of
 10 pharmacy of the university of Montana or of a college or
 11 school of pharmacy ~~recognized and approved~~ accredited by or
 12 a member of the American ~~association of colleges of pharmacy~~
 13 council on pharmaceutical education; but the applicant may
 14 not receive a registered pharmacist's license until he has
 15 complied with the internship requirements established by the
 16 board. ~~During this period, if the applicant has passed the~~
 17 ~~examination, he shall be licensed as an intern only.~~

18 ~~(5)(4)~~ The board may in its discretion authorize the
 19 department to grant registration without examination to a
 20 pharmacist licensed by a board of pharmacy or a similar
 21 board of another state which accords similar recognition to
 22 licensees of this state if the requirements for registration
 23 in the other state are, in the opinion of the board,
 24 equivalent to the requirements of this chapter. The fee for
 25 registration by reciprocity is \$200.

1 ~~(6)~~(5) Every person licensed and registered under this
 2 chapter shall receive from the department an appropriate
 3 certificate attesting the fact, which shall be conspicuously
 4 displayed at all times in his place of business. ~~if--the~~
 5 ~~holder--is--entitled-to-manage-or-conduct-a-pharmacy-in-this~~
 6 ~~state-for-himself-or-another--the-fact-shall-be-set-forth-in~~
 7 ~~the-certificate"~~

8 Section 7. Section 37-7-303, MCA, is amended to read:

9 "37-7-303. Annual renewal fee. (1) A person licensed
 10 and registered by the department shall annually pay to the
 11 department before June 30 a renewal of registration fee of
 12 \$15. A default in the payment of a renewal fee ~~for-a--period~~
 13 ~~of--30--days~~ after the date it is due increases the renewal
 14 fee to \$30. It is unlawful for a person who refuses or fails
 15 to pay the renewal fee to practice pharmacy in this state. A
 16 certificate and renewal expires at the time prescribed, not
 17 later than 1 year from its date. A defaulter in a renewal
 18 fee may be reinstated within 1 year of the default without
 19 examination on payment of the arrears and compliance with
 20 the continuing education provisions of this chapter.

21 (2) The board may charge an additional fee of up to
 22 \$10 for such license renewal to be used in administering the
 23 continuing education provisions of this chapter."

24 Section 8. Section 37-7-311, MCA, is amended to read:

25 "37-7-311. Revocation of license issued to pharmacist

1 or intern. The board shall ~~revoke--temporarily--or~~
 2 ~~permanently~~ licenses issued by the department to a
 3 pharmacist or intern whenever the holder of the license:

- 4 (1) has obtained it by false representations or fraud;
- 5 (2) is an habitual drunkard or addicted to the use of
- 6 narcotic drugs;
- 7 (3) has been convicted of a felony;
- 8 (4) has been convicted of violating the pharmacy law;
- 9 or
- 10 (5) has been found by the board guilty of incompetency

11 in the preparation of prescriptions or guilty of gross
 12 immorality affecting the discharge of his duties as a
 13 pharmacist or intern."

14 Section 9. Section 37-7-321, MCA, is amended to read:

15 "37-7-321. Store license -- certified pharmacy license
 16 -- suspension or revocation. (1) The department shall, on
 17 application on forms prescribed by the board and on the
 18 payment of an annual fee of \$10, license stores other than
 19 pharmacies in which are sold ordinary household or medicinal
 20 drugs prepared in sealed packages or bottles by a
 21 manufacturer qualified under the laws of the state in which
 22 the manufacturer resides. The name and address of the
 23 manufacturer shall appear conspicuously on each package sold
 24 by the licensee. It is unlawful for a store to sell,
 25 deliver, or give away household medicinal drugs without

1 first having secured a license and thereafter keeping it in
 2 force by proper renewal. ~~This subsection does not prevent a~~
 3 ~~vendor from selling a patent or proprietary medicine in the~~
 4 ~~original package when plainly labeled or nonmedical articles~~
 5 ~~usually sold by vendors.~~

6 (2) The board shall provide for the original
 7 certification and annual renewal by the department of every
 8 pharmacy doing business in this state. On presentation of
 9 evidence satisfactory to the board and on application on a
 10 form prescribed by the board and on the payment of an
 11 original certification fee of \$100, the department shall
 12 issue a license to a pharmacy as a certified pharmacy.
 13 However, the license may be granted only to pharmacies
 14 operated by registered pharmacists ~~or registered interns~~
 15 qualified under this chapter. The annual renewal fee for a
 16 pharmacy shall be set by the board in an amount not to
 17 exceed \$50. Any default in the payment of such renewal fee
 18 ~~for a period of 30 days~~ after the date the same is due shall
 19 increase the renewal fee to the sum of \$100. The license
 20 must be displayed in a conspicuous place in the pharmacy for
 21 which it is issued and expires on June 30 following the date
 22 of issue. It is unlawful for a person to conduct a pharmacy,
 23 use the word "pharmacy" to identify his business, or use the
 24 word "pharmacy" in advertising unless a license has been
 25 issued and is in effect.

1 (3) The board may suspend, revoke, or refuse to renew
 2 a store or pharmacy license:

3 (a) obtained by false representation or fraud;
 4 (b) when the pharmacy for which the license is issued
 5 is kept open for the transaction of business without a
 6 pharmacist in charge;

7 (c) when the person to whom the license is granted has
 8 been convicted of:

9 (i) a violation of parts 1 through 3 of this chapter;

10 (ii) a felony; or

11 (iii) a violation of the Federal Food, Drug, and
 12 Cosmetic Act of June 25, 1938, (52 Stat. 1040 through 1059
 13 Title 21, chapter 9, United States Code);

14 (d) when the person to whom the license is granted is
 15 a natural person whose pharmacist ~~or intern~~ license has been
 16 revoked; or

17 (e) when the store or pharmacy is conducted in
 18 violation of parts 1 through 3 of this chapter.

19 (4) Before a license can be revoked, the holder is
 20 entitled to a hearing by the board."

21 Section 10. Section 37-7-401, MCA, is amended to read:

22 "37-7-401. Restrictions upon sale or prescription of
 23 opiates -- coding prohibited -- refilling prescriptions. (1)
 24 It shall be unlawful for any physician to sell or give to or
 25 prescribe for any person any opium, morphine,

1 alkaloid-cocaine, or alpha or beta eucaine or codeine or
 2 heroin or any derivative, mixture, or preparation of any of
 3 them, except to a patient believed in good faith to require
 4 the same for medical use and in quantities proportioned to
 5 the needs of such patients.

6 (2) A prescription must be so written that it can be
 7 compounded by any registered pharmacist. The coding of any
 8 prescription is a violation of this section.

9 (3) A prescription marked "non repetatur", "non rep",
 10 or "N.R." cannot be refilled. A prescription marked to be
 11 refilled by a specified amount may be filled by any
 12 registered pharmacist the number of times marked on the
 13 prescription. A prescription not bearing any ~~limitation--of~~
 14 ~~refill instructions~~ may ~~not~~ be refilled ~~at-will-during-the~~
 15 ~~time-specified without first obtaining permission from the~~
 16 ~~prescriber. A prescription may not be refilled for more~~
 17 ~~than 3 year YEARS from the date it was originally filled.~~
 18 ~~A--prescription--may--not--be--refilled--when--a--refill--is~~
 19 ~~prohibited-by-federal-or-state-law~~ No narcotic prescription
 20 may be refilled."

21 Section 11. Section 37-7-502, MCA, is amended to read:
 22 "37-7-502. Definitions. As used in this part, the
 23 following definitions apply:

24 (1) "Bioavailability" means the extent and rate of
 25 absorption from a dosage form as reflected by the

1 time-concentration curve of the administered drug in the
 2 systemic circulation.

3 (2) "Bioequivalent" means a chemical equivalent which,
 4 when administered to the same individual in the same dosage
 5 regimen, will result in comparable bioavailability.

6 (3) "Brand name" means the proprietary or the
 7 registered trademark name given to a drug product by its
 8 manufacturer, labeler, or distributor and placed upon the
 9 drug, its container, label, or wrapping at the time of
 10 packaging.

11 (4) "Chemical equivalent" means drug products that
 12 contain the same amounts of the same therapeutically active
 13 ingredients in the same dosage forms and that meet present
 14 compendium standards.

15 (5) "Drug product" means a dosage form containing one
 16 or more active therapeutic ingredients along with other
 17 substances included during the manufacturing process.

18 (6) "Generic name" means the chemical or established
 19 name of a drug product or drug ingredient published in the
 20 latest edition of the official United States Pharmacopoeia
 21 ~~or---official---Homeopathic---Pharmacopoeia--of--the--United~~
 22 States/National Formulary.

23 (7) "Person" means an individual, firm, partnership,
 24 association, corporation, or any other entity, whether
 25 organized for profit or not.

1 (8) "Prescriber" means a practitioner licensed under
2 the professional laws of the state to administer medicine
3 and drugs.

4 (9) "Present compendium standard" means the official
5 standard for drug excipients and drug products listed in the
6 latest revision of the United States Pharmacopoeia and the/
7 National Formulary.

8 (10) "Product selection" means to dispense without the
9 prescriber's express authorization a different drug product
10 in place of the drug product prescribed.

11 (11) "Therapeutically equivalent" means those chemical
12 equivalents which, when administered in the same dosage
13 regimen, will provide essentially the same therapeutic
14 effect as measured by the control of a symptom or a disease
15 and/or toxicity."

16 SECTION 12. SECTION 50-32-101, MCA, IS AMENDED TO

17 READ:

18 "50-32-101. Definitions. As used in this chapter, the
19 following definitions apply:

20 (1) "Administer" means the direct application of a
21 dangerous drug, whether by injection, inhalation, ingestion,
22 or any other means, to the body of a patient or research
23 subject by:

- 24 (a) a practitioner (or by his authorized agent); or
25 (b) the patient or research subject at the direction

1 and in the presence of the practitioner.

2 (2) "Agent" means an authorized person who acts on
3 behalf of or at the direction of a manufacturer,
4 distributor, or dispenser. It does not include a common or
5 contract carrier, public warehouseman, or employee of the
6 carrier or warehouseman.

7 (3) "Board" means the board of pharmacists provided
8 for in 2-15-1609.

9 (4) "Bureau" means the ~~bureau of narcotics~~ and
10 ~~dangerous drugs~~ drug enforcement administration, United
11 States department of justice, or its successor agency.

12 (5) "Counterfeit substance" means a dangerous drug
13 which or the container or labeling of which without
14 authorization bears the trademark, trade name, or other
15 identifying mark, imprint, number, or device or any likeness
16 thereof of a manufacturer, distributor, or dispenser other
17 than the person who in fact manufactured, distributed, or
18 dispensed the drug.

19 (6) "Dangerous drug" means a drug, substance, or
20 immediate precursor in Schedules I through V hereinafter set
21 forth.

22 (7) "Deliver" or "delivery" means the actual,
23 constructive, or attempted transfer from one person to
24 another of a dangerous drug, whether or not there is an
25 agency relationship.

1 (8) "Department" means the department of professional
2 and occupational licensing provided for in Title 2, chapter
3 15, part 16.

4 (9) "Dispense" means to deliver a dangerous drug to an
5 ultimate user or research subject by or pursuant to the
6 lawful order of a practitioner, including the prescribing,
7 administering, packaging, labeling, or compounding necessary
8 to prepare the drug for that delivery.

9 (10) "Dispenser" means a practitioner who dispenses.

10 (11) "Distribute" means to deliver other than by
11 administering or dispensing a dangerous drug.

12 (12) "Distributor" means a person who distributes.

13 (13) (a) "Drug" means:

14 (i) a substance recognized as a drug in the official
15 United States Pharmacopoeia~~----official--~~ Homeopathic
16 Pharmacopoeia~~of-the-United-States--or--official~~ National
17 Formulary or any supplement to ~~any-of-them~~ it;

18 (ii) a substance intended for use in the diagnosis,
19 cure, mitigation, treatment, or prevention of disease in man
20 or animals;

21 (iii) a substance (other than food) intended to affect
22 the structure or any function of the body of man or animals;
23 and

24 (iv) a substance intended for use as a component of any
25 article specified in (a)(i), (a)(ii), or (a)(iii) of this

1 subsection.

2 (b) "Drug" does not include a device or its
3 components, parts, or accessories.

4 (14) "Immediate precursor" means a substance which the
5 board of pharmacists finds and by rule designates as being
6 the principal compound commonly used or produced primarily
7 for use and which is an immediate chemical intermediary used
8 or likely to be used in the manufacture of a dangerous drug,
9 the control of which is necessary to prevent, curtail, or
10 limit manufacture.

11 (15) (a) "Manufacture" means the production,
12 preparation, propagation, compounding, conversion, or
13 processing of a dangerous drug either directly or indirectly
14 by extraction from substances of natural origin,
15 independently by means of chemical synthesis, or by a
16 combination of extraction and chemical synthesis and
17 includes any packaging or repackaging of the drug or
18 labeling or relabeling of its container.

19 (b) "Manufacture" does not include the preparation or
20 compounding of a dangerous drug by an individual for his own
21 use or the preparation, compounding, packaging, or labeling
22 of a dangerous drug:

23 (i) by a practitioner as an incident to his
24 administering or dispensing of a dangerous drug in the
25 course of his professional practice; or

1 (ii) by a practitioner or his authorized agent under
2 his supervision for the purpose of or as an incident to
3 research, teaching, or chemical analysis and not for sale.

4 (16) "Marijuana (marihuana)" means all plant material
5 from the genus cannabis containing tetrahydrocannabinol
6 (THC) or seeds of the genus capable of germination.

7 (17) "Narcotic drug" means any of the following,
8 whether produced directly or indirectly by extraction from
9 substances of vegetable origin, independently by means of
10 chemical synthesis, or by a combination of extraction and
11 chemical synthesis:

12 (a) opium and opiate and any salt, compound,
13 derivative, or preparation of opium or opiate;

14 (b) any salt, compound, isomer, derivative, or
15 preparation thereof which is chemically equivalent or
16 identical with any of the drugs referred to in (17)(a) of
17 this section, but not including the isoquinoline alkaloids
18 of opium;

19 (c) opium poppy and poppy straw; or

20 (d) coca leaves and any salt, compound, derivative, or
21 preparation of coca leaves and any salt, compound, isomer,
22 derivative, or preparation thereof which is chemically
23 equivalent or identical with any of these drugs, but not
24 including decocainized coca leaves or extractions of coca
25 leaves which do not contain cocaine or ecgonine.

1 (18) "Opiate" means any drug having an
2 addiction-forming or addiction-sustaining liability similar
3 to morphine or being capable of conversion into a drug
4 having addiction-forming or addiction-sustaining liability.
5 It does not include, unless specifically designated as a
6 dangerous drug under 50-32-202, the dextrorotatory isomer of
7 3-methoxy-n-methylmorphinan and its salts
8 (dextromethorphan). It does include its racemic and
9 levorotatory forms.

10 (19) "Opium poppy" means the plant of the species
11 papaver somniferum L., except its seeds.

12 (20) "Person" means an individual, corporation,
13 government or governmental subdivision or agency, business
14 trust, estate, trust, partnership, association, or any other
15 legal entity.

16 (21) "Poppy straw" means all parts, except the seeds,
17 of the opium poppy after mowing.

18 (22) "Practitioner" means:

19 (a) a physician, dentist, veterinarian, scientific
20 investigator, or other person licensed, registered, or
21 otherwise permitted to distribute, dispense, or conduct
22 research with respect to or to administer a dangerous drug
23 in the course of professional practice or research in this
24 state; and

25 (b) a pharmacy or other institution licensed,

1 registered, or otherwise permitted to distribute, dispense,
2 or conduct research with respect to or to administer a
3 dangerous drug in the course of professional practice or
4 research in this state.

5 (23) The term "prescription" is given the meaning it
6 has in 37-7-101.

7 (24) "Production" includes the manufacture, planting,
8 cultivation, growing, or harvesting of a substance or drug
9 regulated under the provisions of this chapter.

10 (25) "State", when applied to a part of the United
11 States, includes any state, district, commonwealth,
12 territory, insular possession thereof, and any area subject
13 to the legal authority of the United States of America.

14 (26) "Ultimate user" means a person who lawfully
15 possesses a dangerous drug for his own use or for the use of
16 a member of his household or for administering to an animal
17 owned by him or by a member of his household."

18 SECTION 13. SECTION 50-32-208, MCA, IS AMENDED TO

19 READ:

20 "50-32-208. Prescription and medical requirements for
21 scheduled drugs: -- penalty. (1) No dangerous drug in
22 Schedule II may be dispensed without the written
23 prescription of a practitioner.

24 (2) In emergency situations, as defined by rule of the
25 board, Schedule II drugs may be dispensed upon a

1 practitioner's oral prescription reduced promptly to writing
2 and filed by the pharmacy. Prescriptions shall be retained
3 in conformity with the requirements of 50-32-309. No
4 prescription for a Schedule II drug may be refilled.

5 (3) A dangerous drug included in Schedule III or IV,
6 which is a prescription drug as determined under the federal
7 or Montana food, drug, and cosmetic acts, shall not be
8 dispensed without a written or oral prescription of a
9 practitioner. The prescription shall not be filled or
10 refilled more than 6 months after the date thereof or be
11 refilled more than five times unless renewed by the
12 practitioner.

13 (4) A dangerous drug included in Schedule V shall not
14 be distributed or dispensed other than for a medical
15 purpose.

16 (5) Any person who violates the provisions of this
17 section is guilty of a misdemeanor and upon conviction may
18 be fined not to exceed \$1,000 or be imprisoned in county
19 jail for a term not to exceed 1 year, or both fined and
20 imprisoned."

21 SECTION 14. SECTION 50-32-209, MCA, IS AMENDED TO

22 READ:

23 "50-32-209. Annual republication of schedules. The
24 board shall revise and the department shall republish the
25 schedules of dangerous drugs annually. For the purposes of

1 this section the mandate to republish may be satisfied by
2 publication in the administrative rules of Montana pursuant
3 to Title 2, chapter 4."

4 SECTION 15. SECTION 50-32-301, MCA, IS AMENDED TO
5 READ:

6 "50-32-301. Annual registration required for
7 manufacturer, distributor, or dispenser. (1) Every person
8 who manufactures, distributes, or dispenses any dangerous
9 drug within this state must, ~~on and after January 1, 1974,~~
10 obtain annually a registration issued by the department in
11 accordance with board rules.

12 (2) Persons registered by the board under this chapter
13 to manufacture, distribute, dispense, or conduct research
14 with dangerous drugs may possess, manufacture, distribute,
15 dispense, or conduct research with those drugs to the extent
16 authorized by their registration and in conformity with the
17 other provisions of this chapter."

18 Section 16. Coordination with SENATE Bill 412 [LC
19 1288]. If SENATE Bill 412 [LC 1288] introduced in the 47th
20 Legislature is passed and approved that portion of Section
21 6, or any other section of this bill, that amends 37-7-302,
22 MCA, to provide for a fee for registration by reciprocity is
23 void and of no effect.

-End-

HOUSE AMENDMENTS TO SENATE BILL 418
HUMAN SERVICES COMMITTEE OF THE HOUSE
MARCH 13, 1981

CORRECTED PRINTING

Third reading copy be amended as follows:

1. Title, line 10.
Following: "37-7-401,"
Strike: "AND"
Following: "37-7-502,"
Insert: "50-32-101, 50-32-208, 50-32-209, AND 50-32-301,"
2. Page 15, line 16.
Following: "3"
Strike: "year"
Insert: "years"
3. Page 17.
Following: line 14
Insert: attached
4. Page 17, line 15.
Following: "Coordination with"
Insert: "Senate"
Following: "Bill"
Insert: "412"
5. Page 17, line 16.
Following: line 15
Insert: "Senate"
Following: "Bill"
Insert: "412"

1 "Section 2. Section 50-32-101, MCA, is amended to read:

2 "50-32-101. Definitions. As used in this chapter, the
3 following definitions apply:

4 (1) "Administer" means the direct application of a
5 dangerous drug, whether by injection, inhalation, ingestion,
6 or any other means, to the body of a patient or research
7 subject by:

- 8 (a) a practitioner (or by his authorized agent); or
- 9 (b) the patient or research subject at the direction
10 and in the presence of the practitioner.

11 (2) "Agent" means an authorized person who acts on
12 behalf of or at the direction of a manufacturer,
13 distributor, or dispenser. It does not include a common or
14 contract carrier, public warehouseman, or employee of the
15 carrier or warehouseman.

16 (3) "Board" means the board of pharmacists provided
17 for in 2-15-1609.

18 (4) "Bureau" means the ~~bureau of narcotics and~~
19 ~~dangerous drugs~~ drug enforcement administration, United
20 States department of justice, or its successor agency.

21 (5) "Counterfeit substance" means a dangerous drug
22 which or the container or labeling of which without
23 authorization bears the trademark, trade name, or other
24 identifying mark, imprint, number, or device or any likeness
25 thereof of a manufacturer, distributor, or dispenser other
26 than the person who in fact manufactured, distributed, or
27 dispensed the drug.

28 (6) "Dangerous drug" means a drug, substance, or
29 immediate precursor in Schedules I through V hereinafter set
30 forth.

1 (7) "Deliver" or "delivery" means the actual,
2 constructive, or attempted transfer from one person to
3 another of a dangerous drug, whether or not there is an
4 agency relationship.

5 (8) "Department" means the department of professional
6 and occupational licensing provided for in Title 2, chapter
7 15, part 16.

8 (9) "Dispense" means to deliver a dangerous drug to an
9 ultimate user or research subject by or pursuant to the
10 lawful order of a practitioner, including the prescribing,
11 administering, packaging, labeling, or compounding necessary
12 to prepare the drug for that delivery.

13 (10) "Dispenser" means a practitioner who dispenses.

14 (11) "Distribute" means to deliver other than by
15 administering or dispensing a dangerous drug.

16 (12) "Distributor" means a person who distributes.

17 (13) (a) "Drug" means:

18 (i) a substance recognized as a drug in the official
19 United States Pharmacopoeia ~~or official Homeopathic~~
20 ~~Pharmacopoeia of the United States~~ or official National
21 Formulary or any supplement to ~~any of them~~ it;

22 (ii) a substance intended for use in the diagnosis,
23 cure, mitigation, treatment, or prevention of disease in man
24 or animals;

25 (iii) a substance (other than food) intended to affect
26 the structure or any function of the body of man or animals;
27 and

28 (iv) a substance intended for use as a component of any
29 article specified in (a)(i), (a)(ii), or (a)(iii) of this
30 subsection.

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1 (b) "Drug" does not include a device or its
2 components, parts, or accessories.

3 (14) "Immediate precursor" means a substance which the
4 board of pharmacists finds and by rule designates as being
5 the principal compound commonly used or produced primarily
6 for use and which is an immediate chemical intermediary used
7 or likely to be used in the manufacture of a dangerous drug,
8 the control of which is necessary to prevent, curtail, or
9 limit manufacture.

10 (15) (a) "Manufacture" means the production,
11 preparation, propagation, compounding, conversion, or
12 processing of a dangerous drug either directly or indirectly
13 by extraction from substances of natural origin,
14 independently by means of chemical synthesis, or by a
15 combination of extraction and chemical synthesis and
16 includes any packaging or repackaging of the drug or
17 labeling or relabeling of its container.

18 (b) "Manufacture" does not include the preparation or
19 compounding of a dangerous drug by an individual for his own
20 use or the preparation, compounding, packaging, or labeling
21 of a dangerous drug:

22 (i) by a practitioner as an incident to his
23 administering or dispensing of a dangerous drug in the
24 course of his professional practice; or

25 (ii) by a practitioner or his authorized agent under
26 his supervision for the purpose of or as an incident to
27 research, teaching, or chemical analysis and not for sale.

28 (16) "Marijuana (marihuana)" means all plant material
29 from the genus cannabis containing tetrahydrocannabinol
30 (THC) or seeds of the genus capable of germination.

1 (17) "Narcotic drug" means any of the following,
2 whether produced directly or indirectly by extraction from
3 substances of vegetable origin, independently by means of
4 chemical synthesis, or by a combination of extraction and
5 chemical synthesis:

6 (a) opium and opiate and any salt, compound,
7 derivative, or preparation of opium or opiate;

8 (b) any salt, compound, isomer, derivative, or
9 preparation thereof which is chemically equivalent or
10 identical with any of the drugs referred to in (17)(a) of
11 this section, but not including the isoquinoline alkaloids
12 of opium;

13 (c) opium poppy and poppy straw; or

14 (d) coca leaves and any salt, compound, derivative, or
15 preparation of coca leaves and any salt, compound, isomer,
16 derivative, or preparation thereof which is chemically
17 equivalent or identical with any of these drugs, but not
18 including decocainized coca leaves or extractions of coca
19 leaves which do not contain cocaine or ecgonine.

20 (18) "Opiate" means any drug having an
21 addiction-forming or addiction-sustaining liability similar
22 to morphine or being capable of conversion into a drug
23 having addiction-forming or addiction-sustaining liability.
24 It does not include, unless specifically designated as a
25 dangerous drug under 50-32-202, the dextrorotatory isomer of
26 3-methoxy-n-methylmorphinan and its salts
27 (dextromethorphan). It does include its racemic and
28 levorotatory forms.

29 (19) "Opium poppy" means the plant of the species
30 papaver somniferum L., except its seeds.

1 (20) "Person" means an individual, corporation,
2 government or governmental subdivision or agency, business
3 trust, estate, trust, partnership, association, or any other
4 legal entity.

5 (21) "Poppy straw" means all parts, except the seeds,
6 of the opium poppy after mowing.

7 (22) "Practitioner" means:

8 (a) a physician, dentist, veterinarian, scientific
9 investigator, or other person licensed, registered, or
10 otherwise permitted to distribute, dispense, or conduct
11 research with respect to or to administer a dangerous drug
12 in the course of professional practice or research in this
13 state; and

14 (b) a pharmacy or other institution licensed,
15 registered, or otherwise permitted to distribute, dispense,
16 or conduct research with respect to or to administer a
17 dangerous drug in the course of professional practice or
18 research in this state.

19 (23) The term "prescription" is given the meaning it
20 has in 37-7-101.

21 (24) "Production" includes the manufacture, planting,
22 cultivation, growing, or harvesting of a substance or drug
23 regulated under the provisions of this chapter.

24 (25) "State", when applied to a part of the United
25 States, includes any state, district, commonwealth,
26 territory, insular possession thereof, and any area subject
27 to the legal authority of the United States of America.

28 (26) "Ultimate user" means a person who lawfully
29 possesses a dangerous drug for his own use or for the use of
30 a member of his household or for administering to an animal

1 owned by him or by a member of his household."

2 Section 13. Section 50-32-208, MCA, is amended to read:

3 "50-32-208. Prescription and medical requirements for
4 scheduled drugs -- penalty. (1) No dangerous drug in
5 Schedule II may be dispensed without the written
6 prescription of a practitioner.

7 (2) In emergency situations, as defined by rule of the
8 board, Schedule II drugs may be dispensed upon a
9 practitioner's oral prescription reduced promptly to writing
10 and filed by the pharmacy. Prescriptions shall be retained
11 in conformity with the requirements of 50-32-309. No
12 prescription for a Schedule II drug may be refilled.

13 (3) A dangerous drug included in Schedule III or IV,
14 which is a prescription drug as determined under the federal
15 or Montana food, drug, and cosmetic acts, shall not be
16 dispensed without a written or oral prescription of a
17 practitioner. The prescription shall not be filled or
18 refilled more than 6 months after the date thereof or be
19 refilled more than five times unless renewed by the
20 practitioner.

21 (4) A dangerous drug included in Schedule V shall not
22 be distributed or dispensed other than for a medical
23 purpose.

24 (5) Any person who violates the provisions of this
25 section is guilty of a misdemeanor and upon conviction may
26 be fined not to exceed \$1,000 or be imprisoned in county
27 jail for a term not to exceed 1 year, or both fined and
28 imprisoned."

29 Section 14. Section 50-32-209, MCA, is amended to read:

30 "50-32-209. Annual republication of schedules. The

1 board shall revise and the department shall republish the
2 schedules of dangerous drugs annually. For the purposes of
3 this section the mandate to republish may be satisfied by
4 publication in the administrative rules of Montana pursuant
5 to Title 2, chapter 4."

6 Section 5. Section 50-32-301, MCA, is amended to read:

7 "50-32-301. Annual registration required for
8 manufacturer, distributor, or dispenser. (1) Every person
9 who manufactures, distributes, or dispenses any dangerous
10 drug within this state ~~must on and after January 1, 1974~~
11 obtain annually a registration issued by the department in
12 accordance with board rules.

13 (2) Persons registered by the board under this chapter
14 to manufacture, distribute, dispense, or conduct research
15 with dangerous drugs may possess, manufacture, distribute,
16 dispense, or conduct research with those drugs to the extent
17 authorized by their registration and in conformity with the
18 other provisions of this chapter." "

Renumber: subsequent section