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.

SENATE BILL NO. 418

INTRODUCED BY Ochsner 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,

mitigation, treatment, or prevention of disease in man;

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

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

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

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

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

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

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

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

(7) "Person" means any individual and any partnership, firm, corporation, association, or other business entity.

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

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

"37-7-101. Definitions. Unless the context requires otherwise, in parts 1 through 3 of this chapter the following definitions apply:

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

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

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

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

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

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

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

(5) "Department" means the department of professional

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

(6) (a) "Drug" means:

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

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

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

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

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

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

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

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

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

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

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

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

 SB 418

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

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

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

(2) The board shall:

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

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

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

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

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

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

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

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

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

(3) The department shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(4)~~(3) To be entitled to examination as a pharmacist, the applicant shall be a citizen of the United States, of good moral character, and a graduate of the school 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; but the applicant may not receive a registered pharmacist's license until he has complied with the internship requirements established by the board. ~~During this period, if the applicant has passed the examination, he shall be licensed as an intern only.~~

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

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

 SB 418

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

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

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

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

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

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

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

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

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

(3) has been convicted of a felony;

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

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

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

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

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

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

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

a store or pharmacy license:

(a) obtained by false representation or fraud;

(b) when the pharmacy for which the license is issued is kept open for the transaction of business without a pharmacist in charge;

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

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

(ii) a felony; or

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

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

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

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

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

"37-7-401. Restrictions upon sale or prescription of opiates -- coding prohibited -- refilling prescriptions. (1) It shall be unlawful for any physician to sell or give to or prescribe for any person any opium, morphine, alkaloid-cocaine, or alpha or beta eucaine or codeine or

SB 418

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

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

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

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

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

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

systemic circulation.

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

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

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

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

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

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

(8) "Prescriber" means a practitioner licensed under

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

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

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

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

Section 12. Coordination with ___Bill___ [LC 1288]. If ___Bill___ [LC 1298] introduced in the 47th Legislature is passed and approved that portion of Section 6, or any other section of this bill, that amends 37-7-302, MCA, to provide for a fee for registration by reciprocity is void and of no effect.

-End-

SENATE BILL NO. 418

INTRODUCED BY OCHSNER, 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,

SECOND READING

mitigation, treatment, or prevention of disease in man;

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

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

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

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

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

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

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

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

(7) "Person" means any individual and any partnership, firm, corporation, association, or other business entity.

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

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

"37-7-101. Definitions. Unless the context requires otherwise, in parts 1 through 3 of this chapter the following definitions apply:

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

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

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

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

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

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

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

(5) "Department" means the department of professional

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

(6) (a) "Drug" means:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) The board shall:

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

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

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

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

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

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

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

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

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

(3) The department shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(4)~~(3) To be entitled to examination as a pharmacist, the applicant shall be a citizen of the United States, of good moral character, and a graduate of the school 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; but the applicant may not receive a registered pharmacist's license until he has complied with the internship requirements established by the board. ~~During this period, if the applicant has passed the examination, he shall be licensed as an intern only.~~

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

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

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

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

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

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

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

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

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

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

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

(3) has been convicted of a felony;

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

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

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

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

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

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

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

a store or pharmacy license:

(a) obtained by false representation or fraud;

(b) when the pharmacy for which the license is issued is kept open for the transaction of business without a pharmacist in charge;

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

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

(ii) a felony; or

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

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

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

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

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

"37-7-401. Restrictions upon sale or prescription of opiates -- coding prohibited -- refilling prescriptions. (1) It shall be unlawful for any physician to sell or give to or prescribe for any person any opium, morphine, alkaloid-cocaine, or alpha or beta eucaine or codeine or

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

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

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

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

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

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

systemic circulation.

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

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

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

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

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

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

(8) "Prescriber" means a practitioner licensed under

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

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

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

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

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

-End-

SENATE BILL NO. 418

INTRODUCED BY OCHSNER, 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,

THIRD READING

mitigation, treatment, or prevention of disease in man;

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

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

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

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

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

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

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

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

(7) "Person" means any individual and any partnership, firm, corporation, association, or other business entity.

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

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

"37-7-101. Definitions. Unless the context requires otherwise, in parts 1 through 3 of this chapter the following definitions apply:

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

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

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

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

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

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

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

(5) "Department" means the department of professional

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

(6) (a) "Drug" means:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) The board shall:

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

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

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

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

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

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

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

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

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

(3) The department shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(4)~~(3) To be entitled to examination as a pharmacist, the applicant shall be a citizen of the United States, of good moral character, and a graduate of the school 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; but the applicant may not receive a registered pharmacist's license until he has complied with the internship requirements established by the board. ~~During this period, if the applicant has passed the examination, he shall be licensed as an intern only.~~

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

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

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

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

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

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

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

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

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

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

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

(3) has been convicted of a felony;

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

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

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

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

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

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

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

a store or pharmacy license:

(a) obtained by false representation or fraud;

(b) when the pharmacy for which the license is issued is kept open for the transaction of business without a pharmacist in charge;

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

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

(ii) a felony; or

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

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

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

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

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

"37-7-401. Restrictions upon sale or prescription of opiates -- coding prohibited -- refilling prescriptions. (1) It shall be unlawful for any physician to sell or give to or prescribe for any person any opium, morphine, alkaloid, cocaine, or alpha or beta eucaine or codeine or

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

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

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

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

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

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

systemic circulation.

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

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

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

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

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

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

(8) "Prescriber" means a practitioner licensed under

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

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

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

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

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

-End-

SENATE BILL NO. 418

INTRODUCED BY OCHSNER, 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, 50-32-101, 50-32-208, 50-32-209, AND 50-32-301, 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, mitigation, treatment, or prevention of disease in man;

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

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

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

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

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

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

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

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

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

firm, corporation, association, or other business entity.

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

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

"37-7-101. Definitions. Unless the context requires otherwise, in parts 1 through 3 of this chapter the following definitions apply:

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

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

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

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

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

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

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

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

(6) (a) "Drug" means:

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

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

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

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

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

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

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

diseases or which is used for this purpose.

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

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

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

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

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

both written and telephoned prescriptions.

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

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

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

(2) The board shall:

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

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

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

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

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

entering these places and making an inspection.

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

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

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

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

(3) The department shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(4)~~(3) To be entitled to examination as a pharmacist, the applicant shall be a citizen of the United States, of good moral character, and a graduate of the school 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; but the applicant may not receive a registered pharmacist's license until he has complied with the internship requirements established by the board. ~~During this period, if the applicant has passed the examination, he shall be licensed as an intern only.~~

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

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

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

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

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

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

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

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

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

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

(3) has been convicted of a felony;

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

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

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

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

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

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

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

(a) obtained by false representation or fraud;

(b) when the pharmacy for which the license is issued is kept open for the transaction of business without a pharmacist in charge;

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

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

(ii) a felony; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) a practitioner (or by his authorized agent); or

(b) the patient or research subject at the direction

and in the presence of the practitioner.

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

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

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

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

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

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

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

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

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

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

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

(13) (a) "Drug" means:

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

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

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

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

subsection.

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

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

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

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

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

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

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

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

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

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

(c) opium poppy and poppy straw; or

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

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

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

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

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

(22) "Practitioner" means:

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

(b) a pharmacy or other institution licensed,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 16. Coordination with SENATE Bill 412 [LC 1288]. If SENATE Bill 412 [LC 1288] introduced in the 47th Legislature is passed and approved that portion of Section 6, or any other section of this bill, that amends 37-7-302, MCA, to provide for a fee for registration by reciprocity is 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"

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

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

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

(a) a practitioner (or by his authorized agent); or

(b) the patient or research subject at the direction and in the presence of the practitioner.

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

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

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

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

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

SB 418

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

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

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

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

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

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

(13) (a) "Drug" means:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) opium poppy and poppy straw; or

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

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

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

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

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

(22) "Practitioner" means:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Renumber: subsequent section