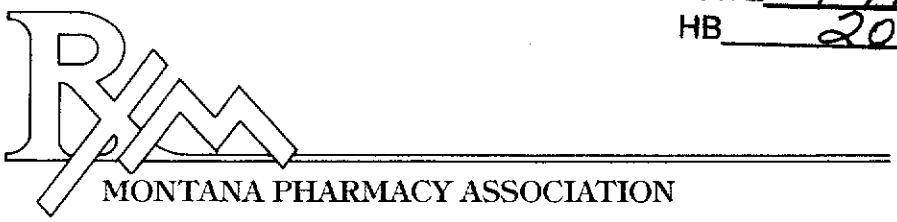
EXHIBIT 6
DATE 1-17-05
HB 203



MONTANA PHARMACY ASSOCIATION
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January 17, 2005
Testimony on House Bill 203

The Montana Pharmacy Association has one problem with HB 203--repealing the requirement that the person hired by the Department to assist the Board of Pharmacy be a registered pharmacist with five years of experience (Page one, line 28 repeals 37-7-104, MCA).

Ours, however, is a serious problem. Pharmacy is a complex profession. It is in a period of rapid human and technological change.

The Montana Board of Pharmacy is meeting the needs of the Montana public and its own licensees.

Consider the following challenges facing the profession. Consider these in light of the Board's duty to protect the public health of the citizens of Montana:

• The US Food and Drug Administration is approving approximately 4000 new drugs per year.

• The increasingly complicated drug regimens of senior citizens, persons with mental illnesses, developmental disabilities; or those with serious physical limitations arising from illness or injury.

• The proliferation of unlicensed and unregulated mail order and internet operations offering controlled substances (legend drugs) without a doctor's prescription.

• The need to develop rules, policies and procedures for electronic prescribing, the faxing of prescriptions.

• The number of over-the-counter drugs now available; as well nutritional suppplements, vitamins and herbal remedies.

• Opening of Canadian storefronts, offering to 'broker' prescriptions in Billings, Great Falls and other Montana cities in 2004. The Montana Board of Pharmacy acted quickly and decisively to make these operations cease and desist the unlicensed practice of pharmacy in the state of Montana.

• Responsibility to maintain the licensure and registration records of pharmacists, pharmacy technicians, wholesale drug companies. Responsibility to inspect and monitor over 200 retail pharmacies, over 50 hospital pharmacies.

January 17, 2005

Amendment to House Bill 203
Requested by the Montana Pharmacy Association.

Page One, Line 28.
Strike: Section~~s~~
Strike: ~~AND 37-7-104~~

Montana Code Annotated 2003

37-7-104. Qualifications of employee hired to assist board. A person hired by the department to enter and inspect an establishment under this chapter; to examine the books of a manufacturer, druggist, storekeeper, wholesaler, pharmacist, or intern; to assist in a prosecution under this chapter; and to assist the board in supervising internships, reciprocity agreements, professional correspondence, and examinations shall be:

(1) a citizen of the United States and a resident of this state; and

(2) a pharmacist registered under this chapter, with at least 5 years of practical experience.

History: En. 66-1521.1 by Sec. 158, Ch. 350, L. 1974; R.C.M. 1947, 66-1521.1; amd. Sec. 8, Ch. 22, L. 1979.

Provided by Montana Legislative Services

Montana Code Annotated 2003

37-7-101. Definitions. As used in parts 1 through 7 of this chapter, the following definitions apply:

(1) (a) "Administer" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or any other means.

(b) The term does not include immunization by injection for children under 18 years of age.

(2) "Board" means the board of pharmacy provided for in 2-15-1733.

(3) "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.

(4) "Collaborative pharmacy practice" means the practice of pharmacy by a pharmacist who has agreed to work in conjunction with one or more prescribers, on a voluntary basis and under protocol, and who may perform certain patient care functions under certain specified conditions or limitations authorized by the prescriber.

(5) "Collaborative pharmacy practice agreement" means a written and signed agreement between one or more pharmacists and one or more prescribers that provides for collaborative pharmacy practice for the purpose of drug therapy management of patients.

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

(7) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device based on:

(a) a practitioner's prescription drug order;

(b) a professional practice relationship between a practitioner, pharmacist, and patient;

(c) research, instruction, or chemical analysis, but not for sale or dispensing; or

(d) the preparation of drugs or devices based on routine, regularly observed prescribing patterns.

(8) "Confidential patient information" means privileged information accessed by, maintained by, or transmitted to a pharmacist in patient records or that is communicated to the patient as part of patient counseling.

(9) "Department" means the department of labor and industry provided for in Title 2, chapter 15, part 17.

(10) "Device" has the same meaning as defined in 37-2-101.

(11) "Dispense" or "dispensing" means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for administration to or use by a patient.

(12) "Distribute" means the delivery of a drug or device by means other than administering or dispensing.

(13) "Drug" means a substance:

(a) recognized as a drug in any official compendium or supplement;

(b) intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(c) other than food, intended to affect the structure or function of the body of humans or animals; and

(d) intended for use as a component of a substance specified in subsection (13)(a), (13)(b), or (13)(c).

(14) "Drug utilization review" means an evaluation of a prescription drug order and patient records for duplication of therapy, interactions, proper utilization, and optimum therapeutic outcomes. The term includes but is not limited to the following evaluations:

(a) known allergies;

(b) rational therapy contraindications;

(c) reasonable dose and route administration;

(d) reasonable directions for use;

(e) drug-drug interactions;

(f) drug-food interactions;

(g) drug-disease interactions; and

(h) adverse drug reactions.

(15) "Equivalent drug product" means a drug product that has the same established name, active ingredient or ingredients, strength or concentration, dosage form, and route of administration and meets the same standards as another drug product as determined by any official compendium or supplement. Equivalent drug products may differ in shape, scoring, configuration, packaging, excipients, and expiration time.

(16) "Intern" means:

(a) a person who is licensed by the state to engage in the practice of pharmacy while under the personal supervision of a preceptor and who is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;

(b) a graduate of an accredited college of pharmacy who is licensed by the state for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

(c) a qualified applicant awaiting examination for licensure; or

(d) a person participating in a residency or fellowship program.

(17) (a) "Manufacturing" means the production, preparation, propogation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis.

(b) Manufacturing includes:

(i) any packaging or repackaging;

(ii) labeling or relabeling;

(iii) promoting or marketing; and

(iv) preparing and promoting commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.

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

(19) "Patient counseling" means the communication by the pharmacist of information, as defined by the rules of the board, to the patient or caregiver in order to ensure the proper use of drugs or devices.

(20) "Person" includes an individual, partnership, corporation, association, or other legal entity.

(21) "Pharmaceutical care" means the provision of drug therapy and other patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of disease process.

(22) "Pharmacist" means a person licensed by the state to engage in the practice of pharmacy and who may affix to the person's name the term "R.Ph.".

(23) "Pharmacy" means an established location, either physical or electronic, registered by the board where drugs or devices are dispensed with pharmaceutical care or where pharmaceutical care is provided.

(24) "Pharmacy technician" means an individual who assists a pharmacist in the practice of pharmacy.

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

(26) "Practice of pharmacy" means:

(a) interpreting, evaluating, and implementing prescriber orders;

(b) administering drugs and devices pursuant to a collaborative practice agreement and compounding, labeling, dispensing, and distributing drugs and devices, including patient counseling;

(c) properly and safely procuring, storing, distributing, and disposing of drugs and devices and maintaining proper records;

(d) monitoring drug therapy and use;

(e) initiating or modifying drug therapy in accordance with collaborative pharmacy practice agreements established and approved by health care facilities or voluntary agreements with prescribers;

(f) participating in quality assurance and performance improvement activities;

(g) providing information on drugs, dietary supplements, and devices to patients, the public, and other health care providers; and

(h) participating in scientific or clinical research as an investigator or in collaboration with other investigators.

(27) "Practice telepharmacy" means to provide pharmaceutical care through the use of information technology to patients at a distance.

(28) "Preceptor" means an individual who is registered by the board and participates in the instructional training of a pharmacy intern.

(29) "Prescriber" has the same meaning as provided in 37-7-502.

(30) "Prescription drug" means any drug that is required by federal law or regulation to be dispensed only by a prescription subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353).

(31) "Prescription drug order" means an order from a prescriber for a drug or device that is communicated directly or indirectly by the prescriber to the furnisher by means of a signed order, by electronic transmission, in person, or by telephone. The order must include the name and address of the prescriber, the prescriber's license classification, the name and address of the patient, the name, strength, and quantity of the drug, drugs, or device prescribed, the directions for use, and the date of its issue. These stipulations apply to written, oral, electronically transmitted, and telephoned prescriptions and orders derived from collaborative pharmacy practice.

(32) "Utilization plan" means a plan under which a pharmacist may use the services of a pharmacy technician in the practice of pharmacy to perform tasks that:

(a) do not require the exercise of the pharmacist's independent professional judgment; and

(b) are verified by the pharmacist.

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

History: En. Sec. 2, Ch. 175, L. 1939; amd. Sec. 1, Ch. 33, L. 1951; amd. Sec. 2, Ch. 241, L. 1971; amd. Sec. 148, Ch. 350, L. 1974; amd. Sec. 1, Ch. 439, L. 1977; R.C.M. 1947, 66-1502; amd. Sec. 7, Ch. 22, L. 1979; amd. Sec. 3, Ch. 379, L. 1981; amd. Sec. 1, Ch. 247, L. 1983; amd. Sec. 1, Ch. 219, L. 1991; amd. Sec. 36, Ch. 429, L. 1995; amd. Sec. 3, Ch. 388, L. 2001; amd. Sec. 116, Ch. 483, L. 2001.