

PHARMACY BOARD LAWS
AS OF THE 2019 LEGISLATIVE SESSION

TITLE 37, CHAPTER 7
PHARMACY

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CHAPTER 7 PHARMACY

Chapter Cross-References

Montana prescription drug take-back day, 1-1-232.
Professional service corporations, Title 35, ch. 4.
General provisions relating to health care practitioners, Title 37, ch. 2.
Use of diagnostic drugs by optometrist not prohibited, 37-10-103.
Dangerous drugs, Title 45, ch. 9.
Controlled substances, Title 50, ch. 32.

Chapter Administrative Rules

Title 24, chapter 174, ARM Board of Pharmacy.

Part 1 General

Part Law Review Articles

Pharmacy, Facsimile, and Cyberspace: An Examination of Legal Frameworks for Electronic Prescribing, Ridgely & Greenberg, 13 Alb. L.J. Sci. & Tech. 1 (2002).
Pharmacy Malpractice, Postel, 147 Chi. Daily L. Bull. 1 (2001).
Drug, Device and Biotech Information, Kohn, 65 Def. Couns. J. 425 (1998).

37-7-101. Definitions. As used in 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) Except as provided in 37-7-105, 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) "Cancer drug" means a prescription drug used to treat:
 - (a) cancer or its side effects; or
 - (b) the side effects of a prescription drug used to treat cancer or its side effects.
- (4) "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.
- (5) "Clinical pharmacist practitioner" means a licensed pharmacist in good standing who meets the requirements specified in 37-7-306.
- (6) "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.
- (7) "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.
- (8) "Commercial purposes" means the ordinary purposes of trade, agriculture, industry, and commerce, exclusive of the practices of medicine and pharmacy.
- (9) "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.

(10) "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.

(11) "Controlled substance" means a substance designated in Schedules II through V of Title 50, chapter 32, part 2.

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

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

(14) "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.

(15) "Distribute" or "distribution" means the sale, purchase, trade, delivery, handling, storage, or receipt of a drug or device and does not include administering or dispensing a prescription drug, pursuant to section 353(b)(1), or a new animal drug, pursuant to section 360b(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, et seq.

(16) "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 (16)(a), (16)(b), or (16)(c).

(17) "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.

(18) "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.

(19) "FDA" means the United States food and drug administration.

(20) "Health care facility" has the meaning provided in 50-5-101.

(21) (a) "Health clinic" means a facility in which advice, counseling, diagnosis, treatment, surgery, care, or services relating to preserving or maintaining health are provided on an outpatient basis for a period of less than 24 consecutive hours to a person not residing at or confined to the facility.

(b) The term includes an outpatient center for primary care and an outpatient center for surgical services, as those terms are defined in 50-5-101, and a local public health agency as defined in 50-1-101.

(c) The term does not include a facility that provides routine health screenings, health education, or immunizations.

(22) "Health information system" means one of the following systems used to compile and manage patient health care information:

(a) an electronic health record system;

(b) a health information exchange approved by the board;

(c) a pharmacy dispensing system; or

(d) a system defined by the board by rule.

(23) "Hospital" has the meaning provided in 50-5-101.

(24) "Immunization-certified pharmacist" means a pharmacist who:

(a) has successfully completed an immunization delivery course of training that is approved by the accreditation council for pharmacy education or by an authority approved by the board and that, at a minimum, includes instruction in hands-on injection technique, clinical evaluation of indications and contraindications of immunizations, storage and handling of immunizations, and documentation and reporting; and

(b) holds a current basic cardiopulmonary resuscitation certification issued by the American heart association, the American red cross, or another recognized provider.

(25) "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.

(26) "Long-term care facility" has the meaning provided in 50-5-101.

(27) "Manufacturing" means the production, preparation, propagation, 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.

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

(29) "Outsourcing facility" means a facility at one geographic location or address that:

(a) engages in compounding of sterile drugs;

(b) has elected to register as an outsourcing facility with FDA; and

(c) complies with all the requirements of section 353b of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq.

(30) "Participant" means a physician's office, pharmacy, hospital, or health clinic that has elected to voluntarily participate in the cancer drug repository program provided for in 37-7-1403 and that accepts donated cancer drugs or devices under rules adopted by the board.

(31) "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.

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

(33) "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 a disease process.

(34) "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.".

(35) "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.

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

(37) "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.

(38) "Practice of pharmacy" means:

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

(b) administering drugs and devices pursuant to a collaborative practice agreement, except as provided in 37-7-105, 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.

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

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

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

(42) "Prescription drug" means any drug that is required by federal law or regulation to be dispensed only by a prescription subject to section 353(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq.

(43) "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.

(44) "Provisional community pharmacy" means a pharmacy that has been approved by the board, including but not limited to federally qualified health centers, as defined in 42 CFR 405.2401, where prescription drugs are dispensed to appropriately screened, qualified patients.

(45) "Qualified patient" means a person who is uninsured, indigent, or has insufficient funds to obtain needed prescription drugs or cancer drugs.

(46) "Registry" means the prescription drug registry provided for in 37-7-1502.

(47) "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.

(48) "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; amd. Sec. 1, Ch. 293, L. 2009; amd. Sec. 4, Ch. 299, L. 2009; amd. Sec. 1, Ch. 119, L. 2011; amd. Sec. 2, Ch. 241, L. 2011; amd. Sec. 1, Ch. 220, L. 2013; amd. Sec. 1, Ch. 33, L. 2017; amd. Sec. 1, Ch. 130, L. 2019; amd. Sec. 1, Ch. 463, L. 2019.

Compiler's Comments

2019 Amendments — Composite Section: Chapter 130 inserted definition of health information system; and made minor changes in style. Amendment effective October 1, 2019.

Chapter 463 inserted definition of immunization-certified pharmacist; and made minor changes in style. Amendment effective July 1, 2019.

2017 Amendment: Chapter 33 inserted definitions of FDA and outsourcing facility; in definition of distribute or distribution substituted current definition for former definition that read: "'Distribute' means the delivery of a drug or device by means other than administering or dispensing "; in definition of manufacturing deleted (b) that read: "(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"; in definition of prescription drug substituted "section 353(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq." for "section 503(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 353"; and made minor changes in style. Amendment effective October 1, 2017.

Severability: Section 14, Ch. 33, L. 2017, was a severability clause.

2013 Amendment: Chapter 220 in definition of practice of pharmacy in (b) inserted "except as provided in 37-7-105". Amendment effective October 1, 2013.

2011 Amendments — Composite Section: Chapter 119 in definition of administer in (b) inserted exception clause; and made minor changes in style. Amendment effective October 1, 2011.

Chapter 241 inserted definitions of controlled substance and registry; and made minor changes in style. Amendment effective July 1, 2011.

Severability: Section 18, Ch. 241, L. 2011, was a severability clause.

2009 Amendments — Composite Section: Chapter 293 inserted definition of clinical pharmacist practitioner; and made minor changes in style. Amendment effective October 1, 2009.

Chapter 299 in introductory clause before "this chapter" deleted "parts 1 through 7 of"; inserted definitions of cancer drug, health care facility, health clinic, hospital, long-term care facility, participant, provisional community pharmacy, and qualified patient; and made minor changes in style. Amendment effective October 1, 2009.

Preamble: The preamble attached to Ch. 293, L. 2009, provided: "WHEREAS, the Medicare Payment Advisory Commission has recommended that the Centers for Medicare and Medicaid Services recognize pharmacists engaging in medication therapy management as practitioners under Medicare, thus permitting those professionals to bill the program independently for their patient care services; and

WHEREAS, the introduction of this federal legislation would require each state to define and articulate requirements necessary for a pharmacist to become clinically certified; and

WHEREAS, the Montana Pharmacy Association hopes to be proactive in having this state legislation ready in anticipation of the federal law; and

WHEREAS, advancing pharmacy practitioners within the state of Montana achieves better patient care and advances national goals for health care reform; and

WHEREAS, pharmacists have demonstrated a large role in producing favorable outcomes with medication therapy management because of their drug knowledge, clinical skills, and access to patients; and

WHEREAS, well-trained, credentialed pharmacists are needed to work with physicians in managing patients with chronic medical conditions requiring a large number of medications; and

WHEREAS, pharmacists play a critical role in health care access to patients, especially in rural Montana."

2001 Amendments — Composite Section: Chapter 388 in introductory clause substituted "As used in parts 1 through 7 of this chapter" for "Unless the context requires otherwise, in parts 1 through 3 of this chapter"; inserted definitions of administer, collaborative pharmacy practice, collaborative pharmacy practice agreement, compounding, confidential patient information, device, dispense or dispensing, distribute, drug utilization review, equivalent drug product, manufacturing, patient counseling, pharmaceutical care, practice of pharmacy, practice telepharmacy, preceptor, prescriber, and prescription drug; throughout definition of drug substituted reference to substance for reference to article, in (a) substituted "recognized as a drug in any official compendium or supplement" for "recognized in the official United States Pharmacopoeia/National Formulary or a supplement", and deleted former (b) that read: "(b) Drug does not include devices or their components, parts, or accessories"; substituted definition of intern for former language that read: "'Intern' means a natural person licensed by the department to prepare, compound, dispense, and sell drugs, medicines, chemicals, and poisons under the supervision of a registered and licensed pharmacist"; in definition of pharmacist after "'Pharmacist' means" substituted "a person licensed by the state to engage in the practice of pharmacy" for "a natural person licensed by the department to prepare, compound, dispense, and sell drugs, medicines, chemicals, and poisons"; in definition of pharmacy after "'Pharmacy' means" substituted "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" for "an established place registered by the department of commerce in which prescriptions, drugs requiring a prescription, medicines, chemicals, and poisons are compounded, dispensed, vended, or sold"; in definition of pharmacy technician after "technician" deleted "or auxiliary" and at end deleted "pursuant to an approved utilization plan"; substituted prescription drug order for prescription as defined term, in first sentence after "means an order" substituted "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" for "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", in second sentence after "classification" substituted "the name and address of the patient, the name, strength, and quantity of the drug, drugs, or device prescribed" for "the name of the patient, the

name and the quantity of the drug or drugs prescribed", and in third sentence after "apply to" substituted "written, oral, electronically transmitted, and telephoned prescriptions and orders derived from collaborative pharmacy practice" for "both written and telephoned prescriptions"; in definition of utilization plan in introductory clause after "technician" deleted "or auxiliary"; and made minor changes in style. Amendment effective October 1, 2001.

Chapter 483 in definition of department substituted reference to department of labor and industry for reference to department of commerce and substituted "part 17" for "part 18"; in definition of pharmacy after "department" deleted "of commerce"; (amendment in definition of pharmacy by Ch. 388 rendered amendment by Ch. 483 void) and made minor changes in style. Amendment effective July 1, 2001.

1995 Amendment: Chapter 429 deleted definition of continuing education that read: "'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"; and made minor changes

in style.

Severability: Section 131, Ch. 429, L. 1995, was a severability clause.

Saving Clause: Section 132, Ch. 429, L. 1995, was a saving clause.

Applicability: Section 133, Ch. 429, L. 1995, provided: "[This act] applies to licenses applied for, complaints submitted, and proceedings begun after [the effective date of this section]." Effective October 1, 1995.

1991 Amendment: Inserted definition of pharmacy technician or auxiliary and definition of utilization plan. Amendment effective January 1, 1992.

1983 Amendment: In (1), substituted "board of pharmacy" for "board of pharmacists".

1981 Amendments: Chapter 274 substituted "department of commerce" for "department of professional and occupational licensing" in (5) and (11); changed internal references to the department and the board.

Chapter 379 deleted a reference to the official Homeopathic Pharmacopoeia of the United States from (6)(a)(i); substituted "under the supervision of a registered and licensed pharmacist" for "in a pharmacy having a pharmacist in charge" at the end of (7); deleted the reference to drugstore in the definition of pharmacy in (11); inserted "requiring a prescription" after "drugs" in (11); deleted "at retail" from the end of (11).

Administrative Rules

ARM 24.174.301 Definitions.

ARM 24.174.834 Copy of prescription.

Law Review Articles

Communications Strategies in Product Liability Crises, Pines, 48 Food Drug L.J. 153 (1993).

Placebos: A Misbranding Dilemma, Stachowski, 40 Med. Trial Tech. Q. 102 (1993).

37-7-102. Practice subject to regulation. The practice of pharmacy is a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest.

History: En. Sec. 647, Pol. C. 1895; re-en. Sec. 1629, Rev. C. 1907; re-en. Sec. 8, Ch. 134, L. 1915; re-en. Sec. 3177, R.C.M. 1921; re-en. Sec. 3177, R.C.M. 1935; amd. Sec. 7, Ch. 175, L. 1939; amd. Sec. 1, Ch. 70, L. 1957; amd. Sec. 5, Ch. 241, L. 1971; amd. Sec. 153, Ch. 350, L. 1974; amd. Sec. 2, Ch. 439, L. 1977; R.C.M. 1947, 66-1507(part).

Administrative Rules

ARM 24.174.301 Definitions.

ARM 24.174.837 Prescription required for Schedule V.

ARM 24.174.840 Transmission of prescriptions by electronic means.

Title 24, chapter 174, subchapter 21, ARM Renewals and continuing education.

37-7-103. Exemptions. Subject only to 37-7-401 and 37-7-402, this chapter does not:

(1) subject a person who is licensed in this state to practice medicine, dentistry, or veterinary medicine to inspection by the board, prevent the person from compounding or using drugs, medicines,

chemicals, or poisons in the person's practice, or prevent a person who is licensed to practice medicine from furnishing to a patient drugs, medicines, chemicals, or poisons that the person considers proper in the treatment of the patient;

(2) prevent the sale of drugs, medicines, chemicals, or poisons at wholesale;

(3) prevent the sale of drugs, chemicals, or poisons at either wholesale or retail for use for commercial purposes or in the arts;

(4) change any of the provisions of this code relating to the sale of insecticides and fungicides;

(5) prevent the sale of common household preparations and other drugs if the stores selling them are licensed under the terms of this chapter;

(6) apply to or interfere with manufacture, wholesaling, vending, or retailing of flavoring extracts, toilet articles, cosmetics, perfumes, spices, and other commonly used household articles of a chemical nature for use for nonmedicinal purposes;

(7) prevent a registered nurse employed by a family planning clinic under contract with the department of public health and human services from dispensing factory prepackaged contraceptives, other than mifepristone, if the dispensing is in accordance with a physician's written protocol specifying the circumstances under which dispensing is appropriate and is in accordance with the board's requirements for labeling, storage, and recordkeeping of drugs; or

(8) prevent a certified agency from possessing, or a certified euthanasia technician or support personnel under the supervision of the employing veterinarian from administering, any controlled substance authorized by the board of veterinary medicine for the purpose of euthanasia pursuant to Title 37, chapter 18, part 6.

History: En. Sec. 14, Ch. 175, L. 1939; amd. Sec. 10, Ch. 101, L. 1977; R.C.M. 1947, 66-1525; amd. Sec. 2, Ch. 472, L. 1989; amd. Sec. 59, Ch. 418, L. 1995; amd. Sec. 88, Ch. 546, L. 1995; amd. Sec. 7, Ch. 60, L. 2003; amd. Sec. 2, Ch. 125, L. 2007.

Compiler's Comments

2007 Amendment: Chapter 125 in (7) near middle substituted "contraceptives, other than mifepristone" for "oral contraceptives"; and made minor changes in style. Amendment effective October 1, 2007.

Termination Provision Repealed: Section 1, Ch. 153, L. 2007, repealed sec. 11, Ch. 60, L. 2003, which terminated the 2003 amendments to this section January 1, 2008.

2003 Amendment: Chapter 60 inserted (8) providing that nothing in Title 37, chapter 7, prevents a certified agency from possessing, or a certified euthanasia technician or support personnel under the supervision of the employing veterinarian from administering, any controlled substance authorized by the board of veterinary medicine for the purpose of euthanasia; and made minor changes in style. Amendment effective January 1, 2004, and terminates January 1, 2008.

1995 Amendments: Chapter 418 in (5) substituted "department of public health" for "department of health and environmental sciences"; and made minor changes in style. Amendment effective July 1, 1995.

Chapter 546 in (5) substituted "department of public health and human services" for "department of health and environmental sciences"; and made minor changes in style. Amendment effective July 1, 1995.

Transition: Section 499, Ch. 418, L. 1995, provided: "The provisions of 2-15-131 through 2-15-137 apply to [this act]."

Saving Clauses: Section 503, Ch. 418, L. 1995, was a saving clause.

Section 571, Ch. 546, L. 1995, was a saving clause.

1989 Amendment: Inserted (5) allowing dispensing of oral contraceptives under certain circumstances; and made minor changes in phraseology. Amendment effective April 8, 1989.

Cross-References

Licensing of physicians, Title 37, ch. 3, part 3.

Licensing of dentists, Title 37, ch. 4, part 3.

Licensing — veterinary medicine, Title 37, ch. 18, part 3.

Pesticides, Title 80, ch. 8.

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 must be:

- (1) a citizen of the United States and a resident of this state; and
- (2) a pharmacist registered under this chapter.

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; amd. Sec. 37, Ch. 467, L. 2005.

Compiler's Comments

2005 Amendment: Chapter 467 in introductory clause near end after "chapter" substituted "must" for "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"; in (2) at end after "chapter" deleted "with at least 5 years of practical experience"; and made minor changes in style. Amendment effective July 1, 2005.

Cross-References

Duties of Department, 37-1-101.

37-7-105. Administration of immunizations. (1) An immunization-certified pharmacist may:

(a) prescribe and administer the following immunizations without a collaborative practice agreement in place:

- (i) influenza to individuals who are 12 years of age or older;
- (ii) pneumococcal, tetanus, diphtheria, and pertussis to individuals who are 18 years of age or older; and

(iii) herpes zoster to those individuals identified in the guidelines published by the United States centers for disease control and prevention's advisory committee on immunization practices; and

(b) administer immunizations to individuals 7 years of age or older as provided by the most recent guidelines by vaccine and age group published by the United States centers for disease control and prevention and as determined within a collaborative practice agreement.

(2) In the event of an adverse reaction, a pharmacist may administer epinephrine or diphenhydramine to:

(a) an individual who is 12 years of age or older; and

(b) a child who is 7 years of age or older and under 12 years of age within a collaborative practice agreement.

(3) If a pharmacist provides an immunization that is part of a series requiring multiple doses over time, the pharmacist shall notify the individual or the individual's legal representative at the time the next immunization in the series is due to be administered by sending a notice to the individual or representative that the followup immunization is needed to fulfill the series requirement.

(4) A pharmacist who administers an immunization pursuant to this section shall:

(a) ensure that the individual who is being immunized is assessed for contraindications to immunization;

(b) ensure that the individual who is being immunized or the individual's legal representative receives a copy of the appropriate vaccine information statement;

(c) if the pharmacist is notified of an adverse reaction, report the reaction to:

(i) the patient's primary health care provider, if the patient identifies one;

(ii) the medical provider or providers with whom the pharmacist has a collaborative practice agreement; and

(iii) the vaccine adverse event reporting system established under the United States department of health and human services;

(d) provide a signed certificate of immunization to the primary health care provider, if known, of each individual who is immunized and to the individual who is immunized that includes the individual's name, date of immunization, address of immunization, administering pharmacist, immunization agent, manufacturer, and lot number;

(e) create a record for each immunization, in which the individual's name, date, address of immunization, administering pharmacist, immunization agent, manufacturer, and lot number are included, and maintain the record for 7 years from the date the immunization was administered or until 7 years after the individual reaches 18 years of age, whichever is later; and

(f) offer the patient the opportunity to have the immunization information reported to the state immunization information system.

(5) For the purposes of this section, "vaccine information statement" means an information sheet that is produced by the United States centers for disease control and prevention that explains the benefits and risks associated with a vaccine to a vaccine recipient or the legal representative of the vaccine recipient.

History: En. Sec. 2, Ch. 119, L. 2011; amd. Sec. 2, Ch. 220, L. 2013; amd. Sec. 1, Ch. 58, L. 2017; amd. Sec. 2, Ch. 463, L. 2019.

Compiler's Comments

2019 Amendment: Chapter 463 in (1)(a)(ii) added pertussis to list of vaccines; inserted (1)(b) permitting immunizations to individuals 7 years of age and older; inserted (2)(b) concerning adverse reaction protocol for a child between 7 and 12; inserted (3) concerning procedure when immunization requires multiple doses over time; inserted (4)(c)(i), (4)(c)(ii), and (4)(c)(iii) concerning requirements for reporting adverse reactions; in (4)(d) near beginning after "care provider"; inserted "if known"; in (4)(e) at the end inserted "or until 7 years after the individual reaches 18 years of age, whichever is later"; inserted (4)(f) concerning reporting immunization data; in (5) deleted definition of immunization-certified pharmacist (see 2019 Session Law for former text); and made minor changes in style. Amendment effective July 1, 2019.

2017 Amendment: Chapter 58 in (1)(b) substituted "pneumococcal, tetanus, and diphtheria" for "pneumococcal polysaccharide vaccine and tetanus and diphtheria"; and made minor changes in style. Amendment effective March 1, 2017.

2013 Amendment: Chapter 220 substituted current language regarding immunization by pharmacists for former text that read: "A pharmacist may administer immunization against the influenza virus by injection or inhalation for individuals who are 12 years of age or older". Amendment effective October 1, 2013.

Effective Date: This section is effective October 1, 2011.

Part 2 Board of Pharmacy

Part Cross-References

Right to know, Art. II, sec. 9, Mont. Const.

Open meetings, Title 2, ch. 3, part 2.

Meeting defined, 2-3-202.

Allocation of boards for administrative purposes, 2-15-121.

Quasi-judicial boards, 2-15-124.

Board established, 2-15-1733.

Duties of Department, Director, and boards, Title 37, ch. 1, part 1.

Disrupting meeting as disorderly conduct, 45-8-101.

Part Administrative Rules

Title 24, chapter 174, subchapter 1, ARM Organizational rules.

Title 24, chapter 174, subchapter 2, ARM Procedural rules.

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 regulate the practice of pharmacy in this state, including but not limited to:

(a) establishing minimum standards for:

(i) equipment necessary in and for a pharmacy;

(ii) the purity and quality of drugs, devices, and other materials dispensed within the state through the practice of pharmacy, using an official compendium recognized by the board or current practical standards;

(iii) specifications for the facilities, including outsourcing facilities, as well as for the environment, supplies, technical equipment, personnel, and procedures for the storage, compounding, or dispensing of drugs and devices;

(iv) monitoring drug therapy; and

(v) maintaining the integrity and confidentiality of prescription information and other confidential patient information;

(b) requesting the department to inspect, at reasonable times:

(i) places where drugs, medicines, chemicals, or poisons are sold, vended, given away, compounded, dispensed, or manufactured; and

(ii) the appropriate records and the license of any person engaged in the practice of pharmacy for the purpose of determining whether any laws governing the legal distribution of drugs or devices or the practice of pharmacy are being violated. The board shall cooperate with all agencies charged with the enforcement of the laws of the United States, other states, or this state relating to drugs, devices, and the practice of pharmacy. It is a misdemeanor for a person to refuse to permit or otherwise prevent the department from entering these places and making an inspection.

(c) regulating:

(i) the training, qualifications, employment, licensure, and practice of interns;

(ii) the training, qualifications, employment, and registration of pharmacy technicians; and

(iii) under therapeutic classification, the sale and labeling of drugs, devices, medicines, chemicals, and poisons;

(d) examining applicants and issuing and renewing licenses of:

(i) applicants whom the board considers qualified under this chapter to practice pharmacy;

(ii) pharmacies and certain stores under this chapter;

(iii) wholesale distributors;

(iv) third-party logistics providers as defined in 37-7-602; and

(v) persons engaged in the manufacture and distribution of drugs or devices;

(e) in concurrence with the board of medical examiners, defining the additional education, experience, or certification required of a licensed pharmacist to become a certified clinical pharmacist practitioner;

(f) issuing certificates of "certified pharmacy" under this chapter;

(g) establishing and collecting license and registration fees;

(h) approving pharmacy practice initiatives that improve the quality of, or access to, pharmaceutical care but that fall outside the scope of this chapter. This subsection (2)(h) may not be construed to expand on the definition of the practice of pharmacy.

(i) establishing a medical assistance program to assist and rehabilitate licensees who are subject to the jurisdiction of the board and who are found to be physically or mentally impaired by habitual intemperance or the excessive use of addictive drugs, alcohol, or any other drug or substance or by mental illness or chronic physical illness. The board shall ensure that a licensee who is required or volunteers to participate in the medical assistance program as a condition of continued licensure or reinstatement of licensure must be allowed to enroll in a qualified medical assistance program within this state and may not require a licensee to enroll in a qualified treatment program outside the state unless the board finds that there is no qualified treatment program in this state.

(j) making rules for the conduct of its business;

(k) performing other duties and exercising other powers as this chapter requires; and

(l) adopting and authorizing the department to publish rules for carrying out and enforcing parts 1 through 7 of this chapter, including but not limited to:

(i) requirements and qualifications for the transfer of board-issued licenses;

(ii) minimum standards for pharmacy internship programs and qualifications for licensing pharmacy interns;

(iii) qualifications and procedures for registering pharmacy technicians; and

(iv) requirements and procedures necessary to allow a pharmacy licensed in another jurisdiction to be registered to practice telepharmacy across state lines.

(3) The board may:

(a) join professional organizations and associations organized exclusively to promote the improvement of standards of the practice of pharmacy for the protection of the health and welfare of the public and whose activities assist and facilitate the work of the board; and

(b) establish standards of care for patients concerning health care services that a patient may expect with regard to pharmaceutical care.

History: Ap. p. Sec. 644, Pol. C. 1895; re-en. Sec. 1626, Rev. C. 1907; re-en. Sec. 5, Ch. 134, L. 1915; re-en. Sec. 3174, R.C.M. 1921; re-en. Sec. 3174, R.C.M. 1935; amd. Sec. 4, Ch. 175, L. 1939; amd. Sec. 25, Ch. 93, L. 1969; amd. Sec. 3, Ch. 241, L. 1971; amd. Sec. 150, Ch. 350, L. 1974; Sec. 66-1504, R.C.M. 1947; Ap. p. Sec. 646, Pol. C. 1895; re-en. Sec. 1628, Rev. C. 1907; re-en. Sec. 7, Ch. 134, L. 1915; re-en. Sec. 3176, R.C.M. 1921; re-en. Sec. 3176, R.C.M. 1935; amd. Sec. 6, Ch. 175, L. 1939; amd. Sec. 1, Ch. 81, L. 1969; amd. Sec. 4, Ch. 168, L. 1971; amd. Sec. 4, Ch. 241, L. 1971; amd. Sec. 1, Ch. 71, L. 1974; amd. Sec. 152, Ch. 350, L. 1974; amd. Sec. 7, Ch. 533, L. 1977; Sec. 66-1506, R.C.M. 1947; R.C.M. 1947, 66-1504(1), (2)(a) thru (2)(f), (2)(h) thru (2)(j), (3), 66-1506(part); amd. Sec. 4, Ch. 379, L. 1981; amd. Sec. 1, Ch. 134, L. 1991; amd. Sec. 4, Ch. 388, L. 2001; amd. Sec. 3, Ch. 293, L. 2009; amd. Sec. 7, Ch. 122, L. 2011; amd. Sec. 2, Ch. 33, L. 2017.

Compiler's Comments

2017 Amendment: Chapter 33 in (2)(a)(iii) before "environment" inserted "including outsourcing facilities, as well as for the"; in (2)(d)(iii) substituted "wholesale distributors" for "wholesale drug distributors"; inserted (2)(d)(iv) concerning third-party logistics providers; and made minor changes in style. Amendment effective October 1, 2017.

Severability: Section 14, Ch. 33, L. 2017, was a severability clause.

2011 Amendment: Chapter 122 inserted (2)(i) requiring the establishment of a medical assistance program; and made minor changes in style. Amendment effective October 1, 2011.

2009 Amendment: Chapter 293 inserted (2)(e) providing that board establish requirements for becoming certified clinical pharmacist practitioner; and made minor changes in style. Amendment effective October 1, 2009.

Preamble: The preamble attached to Ch. 293, L. 2009, provided: "WHEREAS, the Medicare Payment Advisory Commission has recommended that the Centers for Medicare and Medicaid Services recognize pharmacists engaging in medication therapy management as practitioners under Medicare, thus permitting those professionals to bill the program independently for their patient care services; and

WHEREAS, the introduction of this federal legislation would require each state to define and articulate requirements necessary for a pharmacist to become clinically certified; and

WHEREAS, the Montana Pharmacy Association hopes to be proactive in having this state legislation ready in anticipation of the federal law; and

WHEREAS, advancing pharmacy practitioners within the state of Montana achieves better patient care and advances national goals for health care reform; and

WHEREAS, pharmacists have demonstrated a large role in producing favorable outcomes with medication therapy management because of their drug knowledge, clinical skills, and access to patients; and

WHEREAS, well-trained, credentialed pharmacists are needed to work with physicians in managing patients with chronic medical conditions requiring a large number of medications; and

WHEREAS, pharmacists play a critical role in health care access to patients, especially in rural Montana."

2001 Amendment: Chapter 388 in (2) in introductory clause after "state" substituted "including but not limited to" for "subject to this chapter"; in (2)(a) substituted "establishing minimum standards for" for "determine the minimum"; inserted (2)(a)(ii) through (2)(a)(v) regarding minimum standards for drug purity and quality, specifications for facilities, environment, supplies, technical equipment, personnel, and procedures, monitoring drug therapy, and prescription information; deleted former (2)(c) and (2)(d) that read: "(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/National Formulary or revisions thereof as the standards"; in (2)(b) before "inspect" deleted "enter and"; in (2)(b)(ii) inserted first two sentences regarding inspection of appropriate records and pharmacy licenses; substituted (2)(c) through (2)(g) regarding regulation of interns, pharmacy technicians, and applicants, issuing certificates, and establishing and collecting fees for former (2)(f) that read: "(f) regulate the practice of interns under national standards"; in (2)(j) after "enforcing" substituted "parts 1 through 7 of this chapter, including but not limited to:

(i) requirements and qualifications for the transfer of board-issued licenses;

(ii) minimum standards for pharmacy internship programs and qualifications for licensing pharmacy interns;

(iii) qualifications and procedures for registering pharmacy technicians; and

(iv) requirements and procedures necessary to allow a pharmacy licensed in another jurisdiction to be registered to practice telepharmacy across state lines" for "parts 1 through 3 of this chapter"; substituted (3) allowing the board to join professional organizations and associations and establish standards of care for patients for former (3) that read: "(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;

(c) license wholesale drug distributors;

(d) issue certificates of "certified pharmacy" under this chapter; and

(e) establish and collect license fees"; and made minor changes in style. Amendment effective October 1, 2001.

1991 Amendment: Inserted (3)(c) requiring Department to license wholesale drug distributors; inserted (3)(e) requiring Department to establish and collect license fees; and made minor changes in style. Amendment effective July 1, 1991.

1991 Statement of Intent: The statement of intent attached to Ch. 134, L. 1991, provided: "A statement of intent is required for this bill because it is anticipated that promulgation of administrative rules will be necessary to implement this bill. This bill is proposed solely to bring Montana standards on licensing wholesale drug distributors into compliance with rules of the federal food and drug administration (FDA). Unless state law complies with FDA requirements by September 1992, federal law would prohibit the distribution of drugs by manufacturers and wholesalers in Montana. In adopting administrative rules, the department of commerce [now department of labor and industry] shall implement the federal Prescription Drug Marketing Act of 1987 as well as guidelines developed by the FDA."

Applicability: Section 13, Ch. 134, L. 1991, provided: "(1) The provisions of [sections 1 through 11] [37-7-201 and Title 37, ch. 7, part 6] are applicable to activities that occur on or after April 1, 1992.

(2) Rulemaking by the board may commence on July 1, 1991, to be applicable on April 1, 1992."

1981 Amendment: Deleted "and drugstore" from the end of (2)(b); and made minor changes in phraseology.

1979 Statement of Intent: The statement of intent adopted with Ch. 291, L. 1979, codified as 45-9-108, provided: "A statement of intent is required for this bill in that in section 3 it delegates authority to the Board of Pharmacy to adopt rules.

House Bill 422 defines the offense of criminal possession of precursors to certain dangerous drugs. The bill provides that its provisions do not apply to those persons or businesses which have a legitimate reason for possessing the precursors. It is possible that certain persons, businesses or research facilities may now or at a later date have a legitimate need for these precursors. The purpose for giving rulemaking authority to the Board of Pharmacy is that it can best determine whether a person, business or research facility has a legitimate need for the precursors. It will also alleviate having to amend the statute in future sessions if it appears that someone is entitled to be exempted from the criminal provisions of the statute."

Administrative Rules

Title 24, chapter 174, ARM Board of Pharmacy.

Case Notes

Person Engaged in Acts Constituting Practice of Pharmacy Subject to Board Regulation and Injunctive Order: The defendant argued that he was not subject to regulation by the board of pharmacy with respect to his business, which was engaged in obtaining out-of-state drugs from unlicensed drug companies for individuals in Montana. The Supreme Court denied the defendant's motion for summary judgment and upheld the lower court's summary judgment in favor of the board, stating that engaging in acts that constitute the practice of pharmacy makes one subject to the board's regulatory powers and subject to injunctive orders. *Bd. of Pharmacy v. Kennedy*, 2010 MT 227, 358 Mont. 57, 243 P.3d 415.

37-7-202. Salaries and expenses of board members. Each member of the board shall receive compensation and travel expenses as provided for in 37-1-133.

History: En. Sec. 645, Pol. C. 1895; re-en. Sec. 1627, Rev. C. 1907; re-en. Sec. 6, Ch. 134, L. 1915; re-en. Sec. 3175, R.C.M. 1921; re-en. Sec. 3175, R.C.M. 1935; amd. Sec. 5, Ch. 175, L. 1939; amd. Sec. 26, Ch. 177, L. 1965; amd. Sec. 1, Ch. 82, L. 1969; amd. Sec. 1, Ch. 72, L. 1974; amd. Sec. 151, Ch. 350, L. 1974; amd. Sec. 34, Ch. 439, L. 1975; R.C.M. 1947, 66-1505; amd. Sec. 12, Ch. 474, L. 1981.

Compiler's Comments

1981 Amendment: Deleted "\$25 a day as" after "receive"; deleted "for the performance of his services as a board member" after "compensation"; deleted "shall be compensated in addition thereto for" before "travel expenses"; substituted "37-1-103" for "2-18-501 through 2-18-503, in attending meetings"; and made minor changes in punctuation.

Board Compensation and Travel Expenses — Preamble: The preamble of SB 463 (Ch. 474, L. 1981), which provided for uniform compensation and travel expenses for board members, is located in the compiler's comments under 37-1-133.

37-7-203. Repealed. Sec. 128, Ch. 429, L. 1995.

History: En. Sec. 4, Ch. 104, L. 1931; re-en. Sec. 3202.10, R.C.M. 1935; amd. Sec. 10, Ch. 175, L. 1939; amd. Sec. 8, Ch. 241, L. 1971; amd. Sec. 157, Ch. 350, L. 1974; R.C.M. 1947, 66-1521.

37-7-204. Repealed. Sec. 24, Ch. 100, L. 2011.

History: En. Sec. 1, Ch. 307, L. 1993.

Part 3 Licensing

Part Cross-References

- Licensing to follow contested case procedure, 2-4-631.
- Recognition of out-of-state licenses during disaster or emergency, 10-3-204.
- Unfair trade practices and consumer protection, Title 30, ch. 14.
- Duty of Department to administer and grade examinations and to investigate unprofessional conduct, 37-1-101.
- Reporting disciplinary actions against licensees, 37-1-105.
- Duties of Director in investigation of unethical conduct, 37-1-121.
- Duty of Board to adopt and enforce licensing and certification rules, 37-1-131.
- Licensing boards to establish fees commensurate with costs, 37-1-134.
- Licensing investigation and review — record access, 37-1-135.
- Disciplinary authority of Boards — injunctions, 37-1-136.
- Grounds for disciplinary action as grounds for license denial conditions to new licenses, 37-1-137.
- Licensure of criminal offenders, Title 37, ch. 1, part 2.
- Nondiscrimination in licensing, 49-3-204.
- License not required for sale of pesticides, 80-8-207.

37-7-301. Unlawful practice. Except as provided in 37-7-307 through 37-7-309, it is unlawful for a person to:

- (1) engage in the practice of pharmacy unless licensed by the board; or
- (2) assist in the practice of pharmacy unless registered by the board as a pharmacy technician.

History: En. Sec. 640, Pol. C. 1895; re-en. Sec. 1622, Rev. C. 1907; re-en. Sec. 1, Ch. 134, L. 1915; re-en. Sec. 3170, R.C.M. 1921; re-en. Sec. 3170, R.C.M. 1935; amd. Sec. 1, Ch. 175, L. 1939; amd. Sec. 1, Ch. 241, L. 1971; R.C.M. 1947, 66-1501; amd. Sec. 9, Ch. 22, L. 1979; amd. Sec. 5, Ch. 379, L. 1981; amd. Sec. 2, Ch. 219, L. 1991; amd. Sec. 5, Ch. 388, L. 2001.

Compiler's Comments

2001 Amendment: Chapter 388 substituted (1) and (2) stating unlawful practices for former (1) through (4) that read: "(1) 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) 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 registered and licensed by the department and under the supervision of a registered and licensed pharmacist;

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

(4) 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." Amendment effective October 1, 2001.

1991 Amendment: At beginning inserted exception clause; and made minor changes in style. Amendment effective January 1, 1992.

1981 Amendment: Substituted "registered and licensed by the department, under the supervision of a registered and licensed pharmacist" for "in the temporary absence of such pharmacist" at the end of (2); inserted "under the supervision of a licensed and registered pharmacist" after "registered intern" in (4).

Administrative Rules

ARM 24.174.301 Definitions.

Case Notes

Constitutionality: In prosecution of grocer for selling aspirin without a license, this section was held unconstitutional insofar as it limited to pharmacists the right to sell drugs in manufacturers' original packages. Since the law absolved pharmacists from all responsibility as to purity, strength, and quality of such drugs, restriction of sales to pharmacists did not tend to protect or preserve the public health and hence the act was not a valid exercise of police power. *St. v. Stephens*, 102 M 414, 59 P2d 54 (1936).

Practice of Pharmacy Proper Subject of Regulation: The practice of pharmacy is a proper subject for police regulation. *Johnson v. Great Falls*, 38 M 369, 99 P 1059 (1909).

37-7-302. Qualifications — display of license. (1) To be entitled to examination as a pharmacist, the applicant must be of good moral character and must have graduated and received the first professional undergraduate degree from the school of pharmacy of the university of Montana-Missoula or have received an accredited pharmacy degree that has been approved by the board. However, an applicant may not receive a registered pharmacist's license until the applicant has complied with the internship requirements established by the board.

(2) Each person licensed and registered under this chapter must receive from the department an appropriate license. The license must be conspicuously displayed at all times in the place of business.

History: En. Sec. 646, Pol. C. 1895; re-en. Sec. 1628, Rev. C. 1907; re-en. Sec. 7, Ch. 134, L. 1915; re-en. Sec. 3176, R.C.M. 1921; re-en. Sec. 3176, R.C.M. 1935; amd. Sec. 6, Ch. 175, L. 1939; amd. Sec. 1, Ch. 81, L. 1969; amd. Sec. 4, Ch. 168, L. 1971; amd. Sec. 4, Ch. 241, L. 1971; amd. Sec. 1, Ch. 71, L. 1974; amd. Sec. 152, Ch. 350, L. 1974; amd. Sec. 7, Ch. 533, L. 1977; R.C.M. 1947, 66-1506(part); amd. Sec. 2, Ch. 341, L. 1981; amd. Sec. 15, Ch. 345, L. 1981; amd. Sec. 6, Ch. 379, L. 1981; amd. Sec. 3, Ch. 247, L. 1983; amd. Sec. 37, Ch. 429, L. 1995; amd. sec. 36, Ch. 308, L. 1995; amd. Sec. 38, Ch. 467, L. 2005.

Compiler's Comments

2005 Amendment: Chapter 467 deleted former (1) and (2) that read: "(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 must be set by the board at a figure commensurate with costs. The fee may in the discretion of the board be returned to applicants not taking the examination"; in (1) near middle of first sentence after "Montana-Missoula or" substituted "have received" for "from" and after "degree" deleted "program"; in (2) at end of first sentence after "appropriate" substituted "license" for "certificate attesting the fact"; and made minor changes in style. Amendment effective July 1, 2005.

1995 Amendment: Chapter 429 deleted former (4) that read: "(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 registration are, in the opinion of the board, equivalent to the requirements of this chapter. The fee for registration by reciprocity shall be prescribed by the board"; and made minor changes in style.

Name Change — Directions to Code Commissioner: Pursuant to sec. 36, Ch. 308, L. 1995, in this section the Code Commissioner changed "university of Montana" to "university of Montana-Missoula".

Severability: Section 131, Ch. 429, L. 1995, was a severability clause.

Saving Clause: Section 132, Ch. 429, L. 1995, was a saving clause.

Applicability: Section 133, Ch. 429, L. 1995, provided: "[This act] applies to licenses applied for, complaints submitted, and proceedings begun after [the effective date of this section]." Effective October 1, 1995.

1983 Amendment: In (2), deleted last sentence, which read: "On again making payment of the fee, an applicant who fails is entitled to take the next succeeding examination free of charge."; and in first sentence of (3), substituted present language for "To be entitled to examination as a pharmacist, the applicant shall be 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 accredited by the American council on pharmaceutical education".

1983 Statement of Intent: The statement of intent attached to Ch. 247, L. 1983, provided: "A Statement of Intent is required on House Bill 337 because sections 2 and 3 [amending 2-15-1843 (renumbered 2-15-1733) and 37-7-302] delegate to the Board of Pharmacists power to approve accredited pharmacy degree programs for qualifications for appointment for licensed members on the Board and for qualifications to be entitled for examination as a pharmacist. It is intended that the Board will approve those standards which are at least equivalent to the minimum standards required by the American Council on Pharmaceutical Education. The American Council on Pharmaceutical Education operates as an independent organization, but is recognized by the United States Commissioner of Education, the Department of Health and Human Services, and the Council on Postsecondary Accreditation."

1981 Amendments: Chapter 341 deleted "a citizen of the United States" after "applicant shall be" near the beginning of (3).

Chapter 345 substituted "The fee for registration by reciprocity shall be prescribed by the board" for "The fee for registration by reciprocity is \$200" at the end of (4).

Chapter 379 moved the language in former (3), which provided a fee for registration by reciprocity to the end of (4); substituted requirement that applicants be graduates of schools accredited by the council on pharmaceutical education for the requirement that the schools be recognized and approved or a member of the association of colleges of pharmacy in (3); deleted "During this period, if the applicant has passed the examination, he shall be licensed as an intern only." from the end of (3); deleted "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." from the end of (5).

Coordination With Senate Bill 412: Section 16, Ch. 379, L. 1981, provided: "If Senate Bill 412 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, to provide for a fee for registration by reciprocity is void and of no effect." SB 412 was approved April 15, 1981. As required by this instruction, "The fee for registration by reciprocity shall be prescribed by the board." was substituted in codification for the sentence "The fee for registration by reciprocity is \$200." as amended into 37-7-302(4). (Note that such replacement sentence was taken from the amendment to former subsection (3) of 37-7-302 by sec. 15, Ch. 345, L. 1981 (SB 412).)

Fees Prescribed by Board — 1981 Statement of Intent and Preamble: Chapter 345, L. 1981 (SB 412), that amended this section relating to the Board prescribing fees, contained a statement of intent and a preamble. For the texts see compiler's comments at 37-1-134.

Citizenship Qualifications — Preamble: The preamble to Ch. 341, L. 1981, provided: "WHEREAS, the Legislative Audit Committee in its sunset reviews determined that a few professions and occupations require citizenship as a qualification for licensure; and

WHEREAS, a number of courts, including the United States Supreme Court, have found citizenship qualifications for licensure unconstitutional.

THEREFORE, it is the intent of this act to delete citizenship requirements as a qualification for licensure by those boards presently having a citizenship requirement."

Administrative Rules

ARM 24.174.401 Fee schedule.

ARM 24.174.501 Examination for licensure as a registered pharmacist.

ARM 24.174.806 License to be posted.

37-7-303. Repealed. Sec. 127, Ch. 467, L. 2005.

History: En. Sec. 647, Pol. C. 1895; re-en. Sec. 1629, Rev. C. 1907; re-en. Sec. 8, Ch. 134, L. 1915; re-en. Sec. 3177, R.C.M. 1921; re-en. Sec. 3177, R.C.M. 1935; amd. Sec. 7, Ch. 175, L. 1939; amd. Sec. 1, Ch. 70, L. 1957; amd. Sec. 5, Ch. 241, L. 1971; amd. Sec. 153, Ch. 350, L. 1974; amd. Sec. 2, Ch. 439, L. 1977; R.C.M. 1947, 66-1507(part); amd. Sec. 16, Ch. 345, L. 1981; amd. Sec. 7, Ch. 379, L. 1981; amd. Sec. 38, Ch. 429, L. 1995; amd. Sec. 10, Ch. 492, L. 1997; amd. Sec. 6, Ch. 388, L. 2001; amd. Sec. 13, Ch. 271, L. 2003.

37-7-304. Repealed. Sec. 128, Ch. 429, L. 1995.

History: En. 66-1507.1 by Sec. 3, Ch. 439, L. 1977; R.C.M. 1947, 66-1507.1.

37-7-305. Repealed. Sec. 128, Ch. 429, L. 1995.

History: En. 66-1507.2 by Sec. 4, Ch. 439, L. 1977; R.C.M. 1947, 66-1507.2.

37-7-306. Clinical pharmacist practitioner qualifications. (1) A clinical pharmacist practitioner is a licensed pharmacist in good standing who:

(a) is certified by the board, in concurrence with the board of medical examiners, to provide drug therapy management, including initiating, modifying, or discontinuing therapies, identifying and managing drug-related problems, or ordering tests under the direction or supervision of a prescriber;

(b) has additional education, experience, or certification as required by the board in concurrence with the board of medical examiners; and

(c) has in place a collaborative pharmacy practice agreement.

(2) Only a pharmacist certified by the board may legally be identified as a clinical pharmacist practitioner.

History: En. Sec. 2, Ch. 293, L. 2009.

Compiler's Comments

Preamble: The preamble attached to Ch. 293, L. 2009, provided: "WHEREAS, the Medicare Payment Advisory Commission has recommended that the Centers for Medicare and Medicaid Services recognize pharmacists engaging in medication therapy management as practitioners under Medicare, thus permitting those professionals to bill the program independently for their patient care services; and

WHEREAS, the introduction of this federal legislation would require each state to define and articulate requirements necessary for a pharmacist to become clinically certified; and

WHEREAS, the Montana Pharmacy Association hopes to be proactive in having this state legislation ready in anticipation of the federal law; and

WHEREAS, advancing pharmacy practitioners within the state of Montana achieves better patient care and advances national goals for health care reform; and

WHEREAS, pharmacists have demonstrated a large role in producing favorable outcomes with medication therapy management because of their drug knowledge, clinical skills, and access to patients; and

WHEREAS, well-trained, credentialed pharmacists are needed to work with physicians in managing patients with chronic medical conditions requiring a large number of medications; and

WHEREAS, pharmacists play a critical role in health care access to patients, especially in rural Montana."

Effective Date: This section is effective October 1, 2009.

37-7-307. Utilization plan — contents — responsibility of pharmacist. (1) A utilization plan must set forth:

(a) the name and qualifications of the supervising pharmacist or pharmacists;

(b) the nature and location of the supervising pharmacist's pharmacy practice;

(c) a summary of the tasks delegated by the pharmacist and the methods by which a supervising pharmacist may verify and document the tasks. "Verify" means the personal confirmation by a supervising pharmacist of the correctness of the tasks undertaken by the pharmacy technician.

(d) any other information the board considers relevant.

(2) The board shall approve a utilization plan if it determines that the duties to be delegated are:

(a) assigned, verified, and documented by the supervising pharmacist; and

(b) within the scope of the training and competence of the person to whom the authority is delegated.

(3) A supervising pharmacist is responsible for the actions of a pharmacy technician or auxiliary who performs services for the pharmacist under the terms of a utilization plan.

History: En. Sec. 3, Ch. 219, L. 1991.

Compiler's Comments

1991 Statement of Intent: The statement of intent attached to Ch. 219, L. 1991, provided: "It is the intent of the legislature that the board of pharmacy, to implement [sections 3 through 5] [37-7-307 through 37-7-309], adopt rules that, among other issues, describe the functions that a pharmacist is permitted to delegate to a pharmacy technician or auxiliary, including but not limited to:

(1) removing a stock bottle from the shelf and counting and pouring the contents into a suitable container under direct supervision of a pharmacist;

(2) typing a prescription label and affixing it to a prescription bottle, with a final check and any patient counseling performed by the pharmacist;

(3) entering prescription information into a data processing system under supervision of a pharmacist who must be able to check all entries;

(4) maintaining prescription records, including prescription numbers, refill data, and other information on the patient profile system;

(5) prepackaging unit dose drugs for internal distribution. These prepackage unit dose drugs must be quarantined together with bulk containers until a pharmacist performs a final check and maintains appropriate records.

(6) selling nonprescription drugs in their original containers without engaging in patient counseling;

(7) receiving and checking in pharmaceuticals, including controlled substances, if the pharmacy technician or auxiliary initials and dates all invoices with the actual date the drugs were received;

(8) participating in the biennial inventory of controlled substances, provided a pharmacist supervises the process. The supervising pharmacist must cosign the inventory list with the participating pharmacist and pharmacy technician or auxiliary.

(9) compounding intravenous solutions if a mechanism for verification exists that includes checking of the original order, solutions, additives, dosages, and clarity.

The legislature further intends that the board's rules allow a supervising pharmacist to use the services of only one technician or auxiliary at a time, except that the pharmacist may use two at a time if both are performing any of the following procedures:

(1) intravenous admixture and other sterile product preparation;

(2) filling of unit dose cassettes;

(3) prepackaging; and

(4) bulk compounding."

Effective Date: Section 8(2), Ch. 219, L. 1991, provided: "[Sections 1 through 6] [37-7-101, 37-7-301, 37-7-307 through 37-7-309, and 37-7-323] are effective January 1, 1992."

37-7-308. Preparation and approval of utilization plan — revocation of or refusal to renew plan — contested case hearing. (1) A supervising pharmacist shall:

(a) prepare the utilization plan and submit a summary of the plan to the board for approval;

(b) keep on file in the pharmacy a copy of the utilization plan for inspection by the board; and

(c) annually review the utilization plan and provide documentation to the board that the plan accurately reflects the current use of the services of a pharmacy technician or auxiliary.

(2) The board shall refuse to approve or shall revoke or fail to renew approval of a utilization plan if it does not conform to the provisions of 37-7-307 through 37-7-309 and rules adopted under those sections.

(3) One year after the board revokes approval of a utilization plan, the supervising pharmacist may reapply for approval by complying with the requirements of 37-7-307 through 37-7-309 and with rules adopted under those sections.

(4) Before refusing to approve or before revoking or failing to renew approval of a utilization plan, the board shall provide the supervising pharmacist a reasonable time in which to supply additional

information demonstrating compliance with the requirements of 37-7-307 through 37-7-309 and with rules adopted under those sections and the opportunity to request a hearing.

(5) If a supervising pharmacist requests a hearing, the board shall conduct the hearing in accordance with the contested case procedures in Title 2, chapter 4, part 6.

History: En. Sec. 4, Ch. 219, L. 1991.

Compiler's Comments

1991 Statement of Intent: The statement of intent attached to Ch. 219, L. 1991, provided: "It is the intent of the legislature that the board of pharmacy, to implement [sections 3 through 5] [37-7-307 through 37-7-309], adopt rules that, among other issues, describe the functions that a pharmacist is permitted to delegate to a pharmacy technician or auxiliary, including but not limited to:

(1) removing a stock bottle from the shelf and counting and pouring the contents into a suitable container under direct supervision of a pharmacist;

(2) typing a prescription label and affixing it to a prescription bottle, with a final check and any patient counseling performed by the pharmacist;

(3) entering prescription information into a data processing system under supervision of a pharmacist who must be able to check all entries;

(4) maintaining prescription records, including prescription numbers, refill data, and other information on the patient profile system;

(5) prepackaging unit dose drugs for internal distribution. These prepackage unit dose drugs must be quarantined together with bulk containers until a pharmacist performs a final check and maintains appropriate records.

(6) selling nonprescription drugs in their original containers without engaging in patient counseling;

(7) receiving and checking in pharmaceuticals, including controlled substances, if the pharmacy technician or auxiliary initials and dates all invoices with the actual date the drugs were received;

(8) participating in the biennial inventory of controlled substances, provided a pharmacist supervises the process. The supervising pharmacist must cosign the inventory list with the participating pharmacist and pharmacy technician or auxiliary.

(9) compounding intravenous solutions if a mechanism for verification exists that includes checking of the original order, solutions, additives, dosages, and clarity.

The legislature further intends that the board's rules allow a supervising pharmacist to use the services of only one technician or auxiliary at a time, except that the pharmacist may use two at a time if both are performing any of the following procedures:

(1) intravenous admixture and other sterile product preparation;

(2) filling of unit dose cassettes;

(3) prepackaging; and

(4) bulk compounding."

Effective Date: Section 8(2), Ch. 219, L. 1991, provided: "[Sections 1 through 6] [37-7-101, 37-7-301, 37-7-307 through 37-7-309, and 37-7-323] are effective January 1, 1992."

Administrative Rules

ARM 24.174.712 Application for approval of utilization plan.

ARM 24.174.714 Inspection of utilization plan and training record.

37-7-309. Utilization plan approval fee — renewal of approval — renewal fee. (1) A pharmacy in which a pharmacist uses the services of a pharmacy technician or auxiliary under an approved utilization plan shall pay to the board a utilization plan approval fee in an amount set by the board as provided in 37-1-134. Payment must be made when the utilization plan is submitted and is not refundable.

(2) Approval of a utilization plan expires 1 year from the date of approval. The board shall grant renewal of approval upon payment of a renewal fee in an amount set by the board and documentation as required by 37-7-308(1)(c).

(3) The board may adopt fees, as provided in 37-1-134, for other costs associated with implementation of 37-7-307 through 37-7-309, including the costs of onsite inspection of the utilization plan at the participating pharmacy.

(4) The board shall deposit fees received in the state special revenue fund for use by the board in administration of 37-7-307 through 37-7-309, subject to 37-1-101(6).

History: En. Sec. 5, Ch. 219, L. 1991.

Compiler's Comments

1991 Statement of Intent: The statement of intent attached to Ch. 219, L. 1991, provided: "It is the intent of the legislature that the board of pharmacy, to implement [sections 3 through 5] [37-7-307 through 37-7-309], adopt rules that, among other issues, describe the functions that a pharmacist is permitted to delegate to a pharmacy technician or auxiliary, including but not limited to:

(1) removing a stock bottle from the shelf and counting and pouring the contents into a suitable container under direct supervision of a pharmacist;

(2) typing a prescription label and affixing it to a prescription bottle, with a final check and any patient counseling performed by the pharmacist;

(3) entering prescription information into a data processing system under supervision of a pharmacist who must be able to check all entries;

(4) maintaining prescription records, including prescription numbers, refill data, and other information on the patient profile system;

(5) prepackaging unit dose drugs for internal distribution. These prepackage unit dose drugs must be quarantined together with bulk containers until a pharmacist performs a final check and maintains appropriate records.

(6) selling nonprescription drugs in their original containers without engaging in patient counseling;

(7) receiving and checking in pharmaceuticals, including controlled substances, if the pharmacy technician or auxiliary initials and dates all invoices with the actual date the drugs were received;

(8) participating in the biennial inventory of controlled substances, provided a pharmacist supervises the process. The supervising pharmacist must cosign the inventory list with the participating pharmacist and pharmacy technician or auxiliary.

(9) compounding intravenous solutions if a mechanism for verification exists that includes checking of the original order, solutions, additives, dosages, and clarity.

The legislature further intends that the board's rules allow a supervising pharmacist to use the services of only one technician or auxiliary at a time, except that the pharmacist may use two at a time if both are performing any of the following procedures:

(1) intravenous admixture and other sterile product preparation;

(2) filling of unit dose cassettes;

(3) prepackaging; and

(4) bulk compounding."

Effective Date: Section 8(2), Ch. 219, L. 1991, provided: "[Sections 1 through 6] [37-7-101, 37-7-301, 37-7-307 through 37-7-309, and 37-7-323] are effective January 1, 1992."

37-7-310 reserved.

37-7-311. Repealed. Sec. 128, Ch. 429, L. 1995.

History: En. Sec. 644, Pol. C. 1895; re-en. Sec. 1626, Rev. C. 1907; re-en. Sec. 5, Ch. 134, L. 1915; re-en. Sec. 3174, R.C.M. 1921; re-en. Sec. 3174, R.C.M. 1935; amd. Sec. 4, Ch. 175, L. 1939; amd. Sec. 25, Ch. 93, L. 1969; amd. Sec. 3, Ch. 241, L. 1971; amd. Sec. 150, Ch. 350, L. 1974; R.C.M. 1947, 66-1504(2)(g); amd. Sec. 10, Ch. 22, L. 1979; amd. Sec. 4, Ch. 362, L. 1981; amd. Sec. 8, Ch. 379, L. 1981; amd. Sec. 4, Ch. 247, L. 1983.

37-7-312 through 37-7-320 reserved.

37-7-321. Certified pharmacy license — display. The board shall provide for the original certification and renewal by the board of every pharmacy doing business in this state. On presentation of evidence satisfactory to the board, on application on a prescribed form, and on the payment of an original certification fee prescribed by the board, the board shall issue a license to a pharmacy as a certified pharmacy. However, the license may be granted only to pharmacies operated by registered pharmacists qualified under this chapter. The license must be displayed in a conspicuous place in the pharmacy for which it is issued. A person may not operate a pharmacy, use the word "pharmacy" to identify the business, or use the word "pharmacy" in advertising unless a license has been issued and is in effect.

History: En. Sec. 8, Ch. 175, L. 1939; amd. Sec. 1, Ch. 76, L. 1959; amd. Sec. 1, Ch. 9, L. 1967; amd. Sec. 1, Ch. 80, L. 1969; amd. Sec. 6, Ch. 241, L. 1971; amd. Sec. 1, Ch. 308, L. 1974; amd. Sec. 154, Ch. 350, L. 1974; amd. Sec. 8, Ch. 533, L. 1977; R.C.M. 1947, 66-1508; amd. Sec. 17, Ch. 345, L. 1981; amd. Sec. 5, Ch. 362, L. 1981; amd. Sec. 9, Ch. 379, L. 1981; amd. Sec. 5, Ch. 247, L. 1983; amd. Sec. 39, Ch. 429, L. 1995; amd. Sec. 11, Ch. 492, L. 1997; amd. Sec. 7, Ch. 388, L. 2001; amd. Sec. 39, Ch. 467, L. 2005.

Compiler's Comments

2005 Amendment: Chapter 467 in second sentence near beginning substituted "prescribed form" for "form prescribed by the board"; deleted former fourth and fifth sentences that read: "The renewal fee for a pharmacy must be set by the board. Any default in the payment of the renewal fee after the date the fee is due increases the renewal fee as prescribed by the board", at end of fourth sentence after "issued" deleted "and expires on the date set by board rule", and at beginning of fifth sentence substituted "A person may not operate" for "It is unlawful for a person to conduct"; deleted former (2) that read: "(2) The board may impose discipline or deny or refuse to renew a pharmacy license for reasons specified in and subject to conditions specified in Title 37, chapter 1"; and made minor changes in style. Amendment effective July 1, 2005.

2001 Amendment: Chapter 388 throughout section in three places substituted "board" for "department". Amendment effective October 1, 2001.

1997 Amendment: Chapter 492 in (1), in first sentence near middle, and in fourth sentence, near beginning, before "renewal", deleted "annual"; and made minor changes in style. Amendment effective July 1, 1997.

Preamble: The preamble attached to Ch. 492, L. 1997, provided: "WHEREAS, the Legislature finds that delays in licensing board responses to complaints of misconduct by licensees and unlicensed practice that result in frustration on behalf of the public, licensees, and boards is caused by a lack of personnel to assist with compliance issues; and

WHEREAS, licensing boards collect and accumulate sufficient funds from the fees charged to licensees to meet the cost of compliance and enforcement personnel, but these same boards often lack the authority to expend the funds that they collect; and

WHEREAS, the delayed processing and the accumulating complaint backlog have a deleterious effect on the productivity and reputation of the licensees; and

WHEREAS, the Legislature finds that certain licensing boards need to be granted temporary spending authority to address the delayed processing and accumulated complaint backlog; and

WHEREAS, a uniformly flexible approach to license renewal scheduling would also reduce frustration on the part of licensees and the public that they serve; and

WHEREAS, inflexible examination dates for license applicants in the plumbing and electrical fields have caused undue hardship with no discernable [sic] public benefit; and

WHEREAS, the Committee on Business and Labor desires to alleviate these and other related problems by appropriating funds for certain professional and occupational boards that need additional compliance specialists, by allowing the Department of Commerce [now Department of Labor and Industry] to establish license renewal dates by rule, and by allowing electrical and plumbing apprentices to take the examination required for licensure before the apprenticeships expire."

1995 Amendment: Chapter 429 at end of sixth sentence in (1) substituted "expires on the date set by department rule" for "expires on June 30 following the date of issue"; in (2) substituted "The board may impose discipline or deny or refuse to renew a pharmacy for reasons specified in and subject to conditions specified in Title 37, chapter 1" for (2) and (3) that read: "The board may suspend, revoke, or refuse to renew a 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; or
 - (ii) a violation of the Federal Food, Drug, and Cosmetic Act (Title 21, chapter 9, U.S.C.); chapter 2 or 7 of Title 37, chapter 9 or 10 of Title 45, or chapter 31 or 32 of Title 50, MCA; or rules adopted under such act or chapters;
 - (d) when the person to whom the license is granted is a natural person whose pharmacist license has been revoked; or
 - (e) when the pharmacy is conducted in violation of parts 1 through 3 of this chapter.
- (3) Before a license can be revoked, the holder is entitled to a hearing by the board"; and made minor changes in style.

Severability: Section 131, Ch. 429, L. 1995, was a severability clause.

Saving Clause: Section 132, Ch. 429, L. 1995, was a saving clause.

Applicability: Section 133, Ch. 429, L. 1995, provided: "[This act] applies to licenses applied for, complaints submitted, and proceedings begun after [the effective date of this section]." Effective October 1, 1995.

1983 Amendment: In (2)(c)(ii), inserted last clause referring to state statutes and to rules adopted under federal or state statutes.

1981 Amendments: Chapter 345 substituted "an annual fee prescribed by the board" for "an annual fee of \$10" near the beginning of former subsection (1); substituted "fee prescribed by the board" for "fee of \$100" in the second sentence of (1); deleted "in an amount not to exceed \$50" after "board" in the fourth sentence of (1); and substituted "increase the renewal fee as prescribed by the board" for "increase the renewal fee to the sum of \$100" in the fifth sentence of (1).

Chapter 362 deleted former subsection (1) relating to the licensing of stores other than pharmacies; deleted "store or" before "pharmacy" in (2) and (2)(e); deleted "(ii) a felony; or" from (2)(c); made minor changes in phraseology.

Chapter 379 deleted the last sentence of former subsection (1) relating to sale of patent or proprietary medicine in original package; deleted "or registered interns" after "registered pharmacists" near the middle of (1); deleted "for a period of 30 days" after "payment of such renewal fee" in the fifth sentence of (1); substituted a citation to the U.S. Code for a citation to the U.S. Statutes at Large in (2)(c)(ii); and deleted "or intern" after "pharmacist" in (2)(d).

Fees Prescribed by Board — Statement of Intent and Preamble: Chapter 345, L. 1981 (SB 412), which amended this section relating to the Board prescribing fees, contained a statement of intent and a preamble. For the texts see compiler's comments at 37-1-134.

Administrative Rules

ARM 24.174.401 Fee schedule.

ARM 24.174.501 and 24.174.801 General license requirements.

Title 24, chapter 174, subchapter 11, ARM Institutional pharmacies.

Case Notes

Denial of License — Interest of Physicians in Pharmacy: Where Board of Pharmacists (now Board of Pharmacy) refused to grant license to operate pharmacy on sole ground that building corporation owned by physicians owned 97% of capital stock of applicant, Board was acting beyond its authority as provided by Title 37, ch. 7, since nowhere in the statutes is there any indication, express or implied, of legislative policy to exclude physicians from ownership of pharmacies. Because there is neither grant of power to Board to deny license on basis of ownership by physicians nor a legislative policy to exclude them from ownership, the Board has no authority to do so; furthermore, 37-7-103 indicates an express legislative policy contrary to Board's action in denying license. *Missoula Clinic Pharmacy v. Zimmerman*, 153 M 103, 454 P2d 619 (1969).

Sale of Unlabeled Drugs — Suspension for Sale: A pharmacy license may be suspended for a single sale of unlabeled drugs in violation of 37-7-504. *W. Drug of Great Falls v. Gosman*, 141 M 8, 374 P2d 507 (1962).

37-7-322. Use of words pharmacy, apothecary, drug store, or chemist shop for advertising. It is unlawful for a person to carry on, conduct, or transact a retail business under a name which contains as a part of the business the words "pharmacy", "apothecary", "drug store", or "chemist shop" or any abbreviation, translation, extension, or variation of those terms or in any manner by advertisement circular or poster, sign, or otherwise to describe or refer to the place of business conducted by that person by the term, abbreviation, translation, extension, or variation unless the business conducted is a pharmacy within the meaning of this chapter and licensed and in the charge of a licensed pharmacist.

History: En. Sec. 11, Ch. 175, L. 1939; amd. Sec. 9, Ch. 101, L. 1977; R.C.M. 1947, 66-1522; amd. Sec. 8, Ch. 388, L. 2001.

Compiler's Comments

2001 Amendment: Chapter 388 near middle after ""apothecary"" inserted ""drug store"" and at end substituted "licensed pharmacist" for "registered pharmacist"; and made minor changes in style. Amendment effective October 1, 2001.

Cross-References

Assumed business names, Title 30, ch. 13, part 2.

Case Notes

Section Unconstitutional: Since a store can sell ordinary household or medicinal drugs under 37-7-103 and 37-7-321, it cannot be deprived of use of word "drug" in advertisement under this section (prior to 1977 amendment) since the law makes no requirement that the registered pharmacist who may use the name "drug" and sell the drugs make any analysis, inspection, or examination of the drug to be passed on by him to the purchasing public. *Pike v. Porter*, 126 M 482, 253 P2d 1055 (1952).

Unreasonable Classification as Unconstitutional: The provision excluding those who are not registered pharmacists from use of word "drug" (prior to 1977 amendment) in advertising household drugs bears no reasonable relationship to protection of human life, health, or safety but merely discriminates in favor of a certain class and is unconstitutional. *Pike v. Porter*, 126 M 482, 253 P2d 1055 (1952).

37-7-323. Penalty — enforcement. (1) A person, firm, partnership, or corporation violating any of the provisions of parts 1 through 3 of this chapter is guilty of a misdemeanor and upon conviction for each violation shall automatically lose any license issued by the board.

(2) In addition to the penalty provided in subsection (1), the board may withdraw its approval of a utilization plan previously approved for a supervising pharmacist who:

- (a) violates any provision of 37-7-307 through 37-7-309 or rules adopted under those sections;
- (b) obtained the approval of the utilization plan through fraud; or
- (c) acts in a manner contrary to the terms of the utilization plan.

(3) The board may seek an injunction to enforce the provisions of subsection (2).

History: En. Sec. 5, Ch. 104, L. 1931; re-en. Sec. 3202.11, R.C.M. 1935; amd. Sec. 15, Ch. 175, L. 1939; R.C.M. 1947, 66-1526; amd. Sec. 6, Ch. 219, L. 1991; amd. Sec. 9, Ch. 388, L. 2001.

Compiler's Comments

2001 Amendment: Chapter 388 in (1) near end after "shall" deleted "be punished accordingly and shall". Amendment effective October 1, 2001.

1991 Amendment: Inserted (2) allowing withdrawal of utilization plan approval under certain circumstances; inserted (3) allowing Board to seek an injunction; and made minor changes in style. Amendment effective January 1, 1992.

Cross-References

Disciplinary authority of boards — injunctions, 37-1-136.

Criminal responsibility and accountability of corporations, 45-2-311, 45-2-312.

Misdemeanor penalty when none specified, 46-18-212.

Fines in felony and misdemeanor cases, 46-18-231.

37-7-324. Deposit of fees and fines. Fines paid under this chapter, except those paid to a justice's court, and fees collected by the department for registration and licenses issued under this chapter shall be deposited in the state special revenue fund for the use of the board, subject to 37-1-101(6).

History: En. Sec. 6, Ch. 104, L. 1931; re-en. Sec. 3202.12, R.C.M. 1935; amd. Sec. 16, Ch. 175, L. 1939; amd. Sec. 134, Ch. 147, L. 1963; amd. Sec. 159, Ch. 350, L. 1974; R.C.M. 1947, 66-1527; amd. Sec. 1, Ch. 277, L. 1983; amd. Sec. 23, Ch. 557, L. 1987.

Compiler's Comments

1987 Amendment: Near beginning, after "chapter", inserted "except those paid to a justice's court".

1983 Amendment: Substituted reference to state special revenue fund for reference to earmarked revenue fund.

Cross-References

Collection and disposition of fines, penalties, forfeitures, and fees, 3-10-601.

Part 4

Prescriptions Regulated — Review — Counseling — Identification

Part Cross-References

Dispensing of drugs, Title 37, ch. 2, part 1.

Dangerous drugs, Title 45, ch. 9.

Controlled substances, Title 50, ch. 32.

37-7-401. Restrictions on prescriptions. (1) An authorized prescriber may not sell, give to, or prescribe for any person any opium, morphine, alkaloid-cocaine, alpha or beta eucaine, codeine, heroin, or any derivative, mixture, or preparation of any of them, except to a patient believed in good faith to require opium, morphine, alkaloid-cocaine, alpha or beta eucaine, codeine, heroin, or any derivative, mixture, or preparation of the enumerated substances for medical use and in quantities proportioned to the needs of the patient.

(2) A prescription must be written so that the prescription 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 may be filled by any registered pharmacist the number of times marked on the prescription. A prescription not bearing any refill instructions may not be refilled without first obtaining permission from the prescriber. A prescription may not be refilled for more than 1 year from the date the prescription was originally written. A Schedule II prescription may not be refilled.

History: En. Sec. 2, Ch. 11, L. 1911; re-en. Sec. 3187, R.C.M. 1921; re-en. Sec. 3187, R.C.M. 1935; amd. Sec. 2, Ch. 33, L. 1951; R.C.M. 1947, 66-1514; amd. Sec. 10, Ch. 379, L. 1981; amd. Sec. 17, Ch. 97, L. 1989; amd. Sec. 2, Ch. 444, L. 1989; amd. Sec. 10, Ch. 388, L. 2001; amd. Sec. 27, Ch. 126, L. 2005.

Compiler's Comments

2005 Amendment: Chapter 126 in (3) in second sentence after "refilled" deleted "by a specified amount" and at end of fourth sentence after "originally" substituted "written" for "filled"; and made minor changes in style. Amendment effective July 1, 2005.

2001 Amendment: Chapter 388 in (1) near beginning after "unlawful for any" substituted "authorized prescriber" for "physician, physician assistant-certified, or nurse specialist"; in (3) in fourth sentence after "refilled for more than" substituted "1 year" for "3 years" and in fifth sentence substituted "Schedule II prescription" for "narcotic prescription"; and made minor changes in style. Amendment effective October 1, 2001.

1989 Amendments: Chapter 97 near beginning of (1), after "physician", inserted reference to physician assistant-certified.

Chapter 444, in (1), after "physician", inserted "or nurse specialist"; and made minor changes in phraseology and style. Amendment effective July 1, 1989.

Severability: Section 22, Ch. 97, L. 1989, was a severability clause.

1981 Amendment: Substituted prohibitory language on refills of prescriptions not having refill instructions for permissive language in subsection (3). Restricted refills to 3 years from the date originally filled.

37-7-402. Penalty for violation of provisions on sale or prescription of opiates, coding, refilling.

Any person found guilty of the violation of 37-7-401 shall be punished for each separate offense (and each and every individual case shall constitute a separate offense) by a fine of not less than \$50 or more than \$500 or by imprisonment in the county jail for a period of not less than 60 days or more than 100 days or by both such fine and imprisonment.

History: En. Sec. 3, Ch. 11, L. 1911; re-en. Sec. 3188, R.C.M. 1921; re-en. Sec. 3188, R.C.M. 1935; R.C.M. 1947, 66-1515.

Cross-References

Criminal responsibility and accountability of corporations, 45-2-311, 45-2-312.

Fines in felony and misdemeanor cases, 46-18-231.

37-7-403. Repealed. Sec. 8, Ch. 247, L. 1983.

History: En. Sec. 1, Ch. 11, L. 1935; re-en. Sec. 3185.1, R.C.M. 1935; amd. Sec. 155, Ch. 350, L. 1974; R.C.M. 1947, 66-1511.

37-7-404. Repealed. Sec. 8, Ch. 247, L. 1983.

History: En. Sec. 2, Ch. 11, L. 1935; re-en. Sec. 3185.2, R.C.M. 1935; amd. Sec. 156, Ch. 350, L. 1974; R.C.M. 1947, 66-1512.

37-7-405. Repealed. Sec. 8, Ch. 247, L. 1983.

History: En. Sec. 3, Ch. 11, L. 1935; re-en. Sec. 3185.3, R.C.M. 1935; R.C.M. 1947, 66-1513.

37-7-406. Standards for prospective drug utilization review and patient counseling. (1) The board may by rule set standards for the provision of prospective drug utilization review information from a pharmacist to a patient before a prescription is dispensed to the patient or the patient's representative. The review may include, when applicable, an appropriate level of screening for potential drug therapy problems due to therapeutic duplication, drug disease contraindications, drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse.

(2) Under the standards provided for in this section, the pharmacist should offer to discuss those matters that, in the pharmacist's professional judgment, the pharmacist considers significant to the patient's safe and proper use of the prescribed drug. The patient counseling should encompass the topics set forth in 42 U.S.C. 1396r-8 of the Social Security Act and administrative rules established by the board.

(3) Communications between a pharmacist and a patient pursuant to the standards provided for in this section constitute health care information for the purposes of Title 50, chapter 16, part 5.

(4) Standards established by the board under this section apply to all patients seen by a pharmacist or to categories of patients as the board may designate. However, standards provided for in this section may not apply to inpatients of a health care facility in which a nurse or other licensed health care professional is authorized to administer the prescribed drug.

History: En. Sec. 1, Ch. 664, L. 1991; amd. Sec. 11, Ch. 388, L. 2001.

Compiler's Comments

2001 Amendment: Chapter 388 in (1) deleted third sentence that read: "The sources for the standards must be nationally recognized compendia as the board may designate"; in (2) in second sentence after "Social Security Act" inserted "and administrative rules established by the board"; and made minor changes in style. Amendment effective October 1, 2001.

Preamble: The preamble attached to Ch. 664, L. 1991, provided: "WHEREAS, the United States Congress has enacted a requirement in 42 U.S.C. 1396r-8 of the Social Security Act that states participating in Medicaid institute programs of drug utilization review and patient counseling by pharmacists; and

WHEREAS, similar changes in pharmacy practice could benefit the health and welfare of all Montanans and not just Medicaid recipients, and to that end the Board of Pharmacy should have the authority to set standards for pharmacists concerning drug utilization review and patient counseling, including standards for pharmacists who fill prescriptions by mail order from outside this state."

1991 Statement of Intent: The statement of intent attached to Ch. 664, L. 1991, provided: "A statement of intent is needed for this bill because it grants the board of pharmacy additional regulatory and rulemaking authority. In order to benefit all patient-consumers, the board may adopt rules similar to medicaid regulations governing drug utilization review and patient counseling. The board is also required to adopt rules to regulate the activities of out-of-state mail service pharmacies, including their licensing, reporting requirements, drug utilization review and patient counseling, and site inspections."

Severability: Section 10, Ch. 664, L. 1991, was a severability clause.

Administrative Rules

ARM 24.174.901 Patient records.

ARM 24.174.902 Prospective drug review.

ARM 24.174.903 Patient counseling.

37-7-407. Penalty. In addition to all other penalties provided by law, a person violating 37-7-406 shall be fined not more than \$250 for each violation.

History: En. Sec. 8, Ch. 664, L. 1991.

37-7-408 and 37-7-409 reserved.

37-7-410. Positive identification required. (1) (a) Except as provided in subsection (2), a pharmacy may not dispense a controlled substance to a potential recipient without first positively identifying the recipient by means of a valid driver's license, a school district or postsecondary education photo identification, a tribal photo identification, or other identification allowed by the board by rule.

(b) Documentation of the recipient's identification must be permanently linked to the record of the dispensed controlled substance and must include:

(i) a copy of the identification presented; or

(ii) a record that includes:

(A) the recipient's name;

(B) the type of identification presented and the unique identification number; and

(C) the government entity that issued the identification.

(2) Positive identification is not required if:

(a) the controlled substance is dispensed directly to the patient and:

(i) the filled prescription is delivered to the patient or the patient's health care provider; or

(ii) the patient is being treated at a health care facility or is housed in a correctional facility; or

(b) the potential recipient of the controlled substance is personally and positively known by a pharmacist or an employee of the pharmacy who is present and identifies the recipient and the personal identification is documented by recording:

(i) the recipient's name;

(ii) a notation indicating that the recipient was known to a pharmacist or an employee of the pharmacy; and

(iii) the identity of the individual making the personal identification.

History: En. Sec. 1, Ch. 89, L. 2019.

Compiler's Comments

Effective Date: Section 7(1), Ch. 89, L. 2019, provided that this section is effective October 1, 2019.

Part 5 Drug Product Selection

Part Compiler's Comments

Severability Clause: Section 12, Ch. 403, L. 1977, was a severability clause.

37-7-501. Short title. This part may be cited as the "Montana Drug Product Selection Act".

History: En. 66-1528 by Sec. 1, Ch. 403, L. 1977; R.C.M. 1947, 66-1528.

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 that, when administered to the same individual in the same dosage regimen, will result in comparable bioavailability.

(3) "Biological product" has the meaning provided in 42 U.S.C. 262.

(4) "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.

(5) "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.

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

(7) "Generic name" means the chemical or established name of a drug product or drug ingredient published in the latest edition of an official compendium recognized by the board.

(8) "Interchangeable biological product" means a biological product that the federal food and drug administration has:

(a) licensed; and

(b) (i) determined meets the standards for interchangeability pursuant to 42 U.S.C. 262(k)(4); or

(ii) determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal food and drug administration's approved drug products with therapeutic equivalence evaluations.

(9) "Person" has the meaning provided in 37-7-101.

(10) "Prescriber" means a medical practitioner, as defined in 37-2-101, licensed under the professional laws of the state to administer and prescribe medicine and drugs.

(11) "Present compendium standard" means the official standard for drug excipients and drug products listed in the latest revision of an official compendium recognized by the board.

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

(13) "Therapeutically equivalent" means those chemical equivalents that, 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.

History: En. 66-1529 by Sec. 2, Ch. 403, L. 1977; R.C.M. 1947, 66-1529; amd. Sec. 11, Ch. 379, L. 1981; amd. Sec. 12, Ch. 388, L. 2001; amd. Sec. 1, Ch. 42, L. 2017.

Compiler's Comments

2017 Amendment: Chapter 42 inserted definitions of biological product and interchangeable biological product; and made minor changes in style. Amendment effective October 1, 2017.

2001 Amendment: Chapter 388 in definition of generic name at end substituted "an official compendium recognized by the board" for "the official United States Pharmacopoeia/National Formulary"; in definition of person substituted "has the same meaning as provided in 37-7-101" for "means an individual, firm, partnership, association, corporation, or any other entity, whether organized for profit or not"; in definition of prescriber after "means a" substituted "medical practitioner, as defined in 37-2-101" for "practitioner" and after "administer" inserted "and prescribe"; in definition of present compendium standard at end substituted "an official compendium recognized by the board" for "the United States Pharmacopoeia/National Formulary"; and made minor changes in style. Amendment effective October 1, 2001.

1981 Amendment: Substituted a reference to the National Formulary for the Homeopathic Pharmacopoeia in (6); and made minor changes in phraseology.

37-7-503. Rulemaking. The board of pharmacy may adopt, amend, or repeal rules necessary for the implementation, continuation, and enforcement of this part in accordance with the Montana Administrative Procedure Act.

History: En. 66-1535 by Sec. 8, Ch. 403, L. 1977; R.C.M. 1947, 66-1535; amd. Sec. 1, Ch. 247, L. 1983.

Compiler's Comments

1983 Amendment: Substituted "board of pharmacy" for "board of pharmacists".

Cross-References

Montana Administrative Procedure Act, Title 2, ch. 4.

37-7-504. General prohibition of drug product substitution. No person may substitute a drug product different from the one ordered or deviate in any manner from the requirements of an order or prescription, except as provided in this part.

History: En. 66-1523(2) by Sec. 10, Ch. 403, L. 1977; R.C.M. 1947, 66-1523; amd. Sec. 2, Ch. 42, L. 2017.

Compiler's Comments

2017 Amendment: Chapter 42 in (1) after "substitute a drug" inserted "product". Amendment effective October 1, 2017.

Cross-References

Unfair trade practices and consumer protection, Title 30, ch. 14.

37-7-505. Product selection permitted — limitation. (1) Except as limited by subsection (2) and unless instructed otherwise by the purchaser:

(a) a pharmacist who receives a prescription for a specific drug product by brand or proprietary name may select a less expensive drug product with the same generic name, strength, quantity, dose, and dosage form as the prescribed drug that is, in the pharmacist's professional opinion, therapeutically equivalent, bioequivalent, and bioavailable; and

(b) a pharmacist who receives a prescription for a specific biological product may select a less expensive interchangeable biological product.

(2) If, in the professional opinion of the prescriber, it is medically necessary that an equivalent drug product or interchangeable biological product not be selected, the prescriber may so indicate by certifying that the specific brand-name drug product prescribed or the specific brand-name biological product prescribed is medically necessary for that particular patient. In the case of a prescription transmitted orally, the prescriber must expressly indicate to the pharmacist that the specific brand-name drug product prescribed or the specific biological product prescribed is medically necessary.

(3) (a) Within 5 business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate the specific product provided to the patient, including the name of the product and the manufacturer, to the prescriber through any of the following electronic records systems:

- (i) an interoperable electronic medical records system;
- (ii) an electronic prescribing technology;
- (iii) a pharmacy benefit management system; or
- (iv) a pharmacy record.

(b) Communication through an electronic records system as described in subsection (3)(a) is presumed to provide notice to the prescriber.

(c) If the pharmacist is unable to communicate pursuant to an electronic records system as provided in subsection (3)(a), the pharmacist shall communicate to the prescriber which biological product was dispensed to the patient using facsimile, telephone, electronic transmission, or other prevailing means.

(d) Communication is not required under this subsection (3) when:

(i) there is no federal food and drug administration approved interchangeable biological product for the product prescribed; or

(ii) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(4) The pharmacist shall maintain a record of the biological product dispensed for at least 2 years.

History: En. 66-1530 by Sec. 3, Ch. 403, L. 1977; R.C.M. 1947, 66-1530; amd. Sec. 13, Ch. 388, L. 2001; amd. Sec. 3, Ch. 42, L. 2017.

Compiler's Comments

2017 Amendment: Chapter 42 inserted (1)(b) regarding substitution of an interchangeable biological product; in (2) after "equivalent drug product" inserted "or interchangeable biological product", after "the specific brand-name drug product" inserted "prescribed or the specific brand-name biological product prescribed", after "indicate to the pharmacists that the" inserted "specific", and near end after "drug product prescribed" inserted "or the specific biological product prescribed"; inserted (3) regarding communication from the pharmacist to the patient; inserted (4) regarding maintaining a record for at least 2 years; and made minor changes in style. Amendment effective October 1, 2017.

2001 Amendment: Chapter 388 in (1) near beginning before "prescription" deleted "written or oral"; in (2) near middle of first sentence after "certifying that" deleted "in his professional judgment"; and made minor changes in style. Amendment effective October 1, 2001.

37-7-506. Notice to purchaser. (1) A pharmacist who selects a drug product, as provided in 37-7-505, shall notify the person presenting the prescription that the person may refuse the product selection as provided in 37-7-505.

(2) Each pharmacy shall display in a prominent place that is in clear and unobstructed public view, at or near the place where prescriptions are dispensed, a sign stating: "This pharmacy may be able to select a less expensive drug product that is equivalent to the one prescribed by your physician unless you or your physician request otherwise." The printing on the sign must be in block letters not less than 1 inch in height.

History: En. 66-1531 by Sec. 4, Ch. 403, L. 1977; R.C.M. 1947, 66-1531; amd. Sec. 1368, Ch. 56, L. 2009.

Compiler's Comments

2009 Amendment: Chapter 56 made section gender neutral; and made minor changes in style. Amendment effective October 1, 2009.

37-7-507. Savings passed on. (1) A pharmacist selecting a less expensive drug product must pass on to the purchaser the full amount of the savings realized by the product selection. In no event may the pharmacist charge a different professional fee for dispensing a different drug product than the drug product originally prescribed.

(2) If the prescriber prescribes a drug product by its generic name, the pharmacist must, consistent with reasonable judgment, dispense the lowest retail priced, therapeutically equivalent brand which is in stock.

History: En. 66-1532 by Sec. 5, Ch. 403, L. 1977; R.C.M. 1947, 66-1532.

37-7-508. Product selection not practice of medicine. The selection of a drug product by a registered pharmacist under the provisions of this part does not constitute the practice of medicine.

History: En. 66-1533 by Sec. 6, Ch. 403, L. 1977; R.C.M. 1947, 66-1533.

Cross-References

Exemptions from physician's licensing requirements, 37-3-103.

37-7-509. Limitations on liability. (1) A pharmacist making a product selection under the provisions of this part assumes no greater responsibility for selecting the dispensed drug product than the pharmacist would incur in filling a prescription for a drug product prescribed by a generic name.

(2) When a pharmacist selects a drug product, the prescriber may not be held liable in an action for loss, damage, injury, or death to a person caused by the use of the selected drug product, except that if the original drug product was incorrectly prescribed, the prescriber is not relieved of liability.

History: En. 66-1534 by Sec. 7, Ch. 403, L. 1977; R.C.M. 1947, 66-1534; amd. Sec. 1369, Ch. 56, L. 2009.

Compiler's Comments

2009 Amendment: Chapter 56 made section gender neutral. Amendment effective October 1, 2009.

Cross-References

Availability of remedies — liability, Title 27, ch. 1.
Montana Medical Legal Panel Act, Title 27, ch. 6.

37-7-510. Penalty. (1) In addition to all other penalties provided by law, a person who violates the provisions of 37-7-505, 37-7-506, or 37-7-507 or any rule promulgated as provided in 37-7-503 shall be fined no more than \$250 for each violation.

(2) The penalty imposed under this part may be remitted or mitigated upon such terms and conditions as the board of pharmacy considers proper and consistent with the public health and safety.

(3) A civil penalty imposed under this part becomes due and payable when the person incurring the penalty receives a notice in writing from the board of pharmacy. The notice shall be sent by registered or certified mail and must include:

- (a) reference to the particular sections of the statute or rule;
- (b) a short and plain statement of the matters asserted as charged;
- (c) a statement of the amount of the penalty or penalties imposed; and
- (d) a statement of the person's right to request a hearing.

(4) The person to whom the notice is addressed has 20 days from the date of the notice in which to make written application for a hearing before the board of pharmacy.

History: En. 66-1536 by Sec. 11, Ch. 403, L. 1977; R.C.M. 1947, 66-1536; amd. Sec. 1, Ch. 247, L. 1983.

Compiler's Comments

1983 Amendment: Substituted "board of pharmacy" for "board of pharmacists" in three places.

Cross-References

Contested case as including licensing, 2-4-102, 2-4-631.
Contested case procedure, Title 2, ch. 4, part 6.
Criminal responsibility and accountability of corporations, 45-2-311, 45-2-312.

Part 6

Wholesale Distributors — Licensing

Part Compiler's Comments

1991 Statement of Intent: The statement of intent attached to Ch. 134, L. 1991, provided: "A statement of intent is required for this bill because it is anticipated that promulgation of administrative rules will be necessary to implement this bill. This bill is proposed solely to bring Montana standards on licensing wholesale drug distributors into compliance with rules of the federal food and drug administration (FDA). Unless state law complies with FDA requirements by September 1992, federal law would prohibit the distribution of drugs by manufacturers and wholesalers in Montana. In adopting administrative rules, the department of commerce [now department of labor and industry] shall implement the federal Prescription Drug Marketing Act of 1987 as well as guidelines developed by the FDA."

Applicability: Section 13, Ch. 134, L. 1991, provided: "(1) The provisions of [sections 1 through 11] [37-7-201 and Title 37, ch. 7, part 6] are applicable to activities that occur on or after April 1, 1992.

(2) Rulemaking by the board may commence on July 1, 1991, to be applicable on April 1, 1992."

Effective Date: Section 14, Ch. 134, L. 1991, provided: "[This act] is effective July 1, 1991."

Part Administrative Rules

Title 24, chapter 174, subchapter 12, ARM Wholesale drug distributors licensing.

Part Law Review Articles

A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals, Stoll, 45 Food Drug Cosm. L.J. 279 (1990).

37-7-601. Scope and purpose. This part applies to the wholesale distribution, third-party logistics, manufacturing, or repackaging of prescription drugs in this state. The purpose of this part is to implement the federal Prescription Drug Marketing Act of 1987 and the Drug Quality and Security Act of 2013, which includes but is not limited to the Drug Supply Chain Security Act, by providing minimum standards, terms, and conditions for licensing by the department of persons or entities engaged in the wholesale distribution, third-party logistics, manufacturing, or repackaging of prescription drugs.

History: En. Sec. 2, Ch. 134, L. 1991; amd. Sec. 3, Ch. 33, L. 2017.

Compiler's Comments

2017 Amendment: Chapter 33 in first sentence after "applies to" deleted "a person or entity engaged in" and after "distribution" inserted "third-party logistics, manufacturing, or repackaging"; in last sentence after "1987" inserted "and the Drug Quality and Security Act of 2013, which includes but is not limited to the Drug Supply Chain Security Act" and after "wholesale" deleted "distributions" and inserted "distribution, third-party logistics, manufacturing, or repackaging"; and made minor changes in style. Amendment effective October 1, 2017.

Severability: Section 14, Ch. 33, L. 2017, was a severability clause.

37-7-602. Definitions. As used in this part, the following definitions apply:

(1) (a) "Dispenser" means a retail pharmacy, a hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of the entities listed in this subsection (1)(a), if they are under common ownership and control and do not act as a wholesale distributor.

(b) The term does not include a person who dispenses only products used in animals in accordance with FDA laws and regulations.

(2) "Manufacturer" means:

(a) a person approved by application to the FDA to manufacture a product as defined in section 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., or a biologic pursuant to 42 U.S.C. 262;

(b) a person who manufactures a product as defined in section 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., or a biologic pursuant to 42 U.S.C. 262 that is not the subject of an approved application or license by the FDA;

(c) a colicensed partner of a person described in subsection (2)(a) or (2)(b) that obtains the product directly from a person described in subsection (2)(a), (2)(b), or (2)(d); or

(d) an affiliate of a person described in subsection (2)(a), (2)(b), or (2)(c) that receives the product directly from a person described in subsection (2)(a), (2)(b), or (2)(c).

(3) "Prescription drug" has the same meaning as provided in 37-7-101.

(4) "Repackager" means a person who owns or operates an establishment that repacks and relabels a product or a package for:

(a) further sale; or

(b) distribution without a further transaction.

(5) "Third-party logistics provider" or "3PL" means an entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product but does not take ownership of the product or have responsibility to direct the sale or disposition of the product.

(6) "Transaction" has the same meaning as provided in section 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq.

(7) (a) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient.

(b) The term does not include the exclusions listed in section 353(e)(4) of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq.

(8) "Wholesale distributor" means a person or entity, other than a manufacturer, a manufacturer's colicensed partner, a third-party logistics provider, or a repackager, who is engaged in wholesale distribution of prescription drugs.

History: En. Sec. 3, Ch. 134, L. 1991; amd. Sec. 14, Ch. 388, L. 2001; amd. Sec. 73, Ch. 114, L. 2003; amd. Sec. 4, Ch. 33, L. 2017.

Compiler's Comments

2017 Amendment: Chapter 33 inserted definitions of dispenser, repackager, third-party logistics provider, and transaction; deleted definitions that read: "'Blood' means whole blood collected from a single donor and processed either for transfusion or for further manufacturing", "'Blood component' means that part of blood separated by physical or mechanical means", and "'Drug sample' means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug"; in definition of manufacturer substituted current text for former text that read: "'Manufacturer' means a person or entity engaged in the manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug or device"; in definition of wholesale distribution substituted "wholesale distribution" for "wholesale drug distribution" and in (b) substituted "The term does not include the exclusions listed in section 353(e)(4) of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq." for "The term does not include:

(i) intracompany sales;

(ii) the purchase or other acquisition, by a hospital or other health care entity that is a member of a group purchasing organization, of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of group purchasing organizations;

(iii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code, 26 U.S.C. 501(c)(3), as amended, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(iv) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control. For purposes of this subsection (6)(b)(iv), "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise.

(v) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For the purposes of this subsection (6)(b)(v), "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

(vi) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(vii) the distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(viii) the sale, purchase, or trade of blood and blood components intended for transfusion"; in definition of wholesale distributor substituted "wholesale distributor" for "wholesale drug distributor", after "entity" inserted "other than a manufacturer, a manufacturer's colicensed partner, a third-party logistics provider, or a repackager, who is" and after "drugs" deleted "including but not limited to manufacturers, repackers, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail pharmacies that conduct wholesale distributions"; and made minor changes in style. Amendment effective October 1, 2017.

Severability: Section 14, Ch. 33, L. 2017, was a severability clause.

2003 Amendment: Chapter 114 in (6)(b)(iii) after "Code" substituted "26 U.S.C. 501(c)(3), as amended" for "of 1954". Amendment effective October 1, 2003.

2001 Amendment: Chapter 388 in definition of prescription drug substituted "has the same meaning as provided in 37-7-101" for "means any drug for humans that is required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.S. 353)"; and made minor changes in style. Amendment effective October 1, 2001.

37-7-603. Prohibited purchase or receipt of drugs — dispensing and distribution restrictions — penalty. (1) Except as otherwise provided, it is unlawful for a person to knowingly purchase or receive a prescription drug from a source other than a person or entity licensed under this part.

(2) Licensed wholesale distributors, third-party logistics providers, manufacturers, and repackagers may not dispense or distribute prescription drugs directly to patients, except when the licensed wholesale distributor is also a licensed pharmacy.

(3) A person who violates the provisions of this section is guilty of a misdemeanor.

History: En. Sec. 4, Ch. 134, L. 1991; amd. Sec. 5, Ch. 33, L. 2017.

Compiler's Comments

2017 Amendment: Chapter 33 in (2) substituted "wholesale distributors, third-party logistics providers, manufacturers, and repackagers" for "wholesale drug distributors other than pharmacies" and at end inserted exception clause; and made minor changes in style. Amendment effective October 1, 2017.

Severability: Section 14, Ch. 33, L. 2017, was a severability clause.

37-7-604. Wholesale distributor, third-party logistics provider, manufacturer, and repackager licensing requirements — fee — federal compliance. (1) A person or distribution outlet may not act as a wholesale distributor, third-party logistics provider, manufacturer, or repackager without first obtaining a license from the board and paying the license fee.

(2) A license may not be issued or renewed for a wholesale distributor, third-party logistics provider, manufacturer, or repackager to operate in this state unless the applicant:

(a) agrees to abide by federal and state law and to comply with the rules adopted by the FDA and the board; and

(b) pays the license fee set by the board.

(3) The board in its discretion may require that a separate license be obtained for:

(a) each facility directly or indirectly owned or operated by the same business entity within the state; or

(b) a parent entity with divisions, subsidiaries, or affiliates within the state if operations are conducted at more than one location and joint ownership and control exists among all entities.

(4) An applicant for a license under this section or for a license renewal shall provide written documentation to the board attesting that the applicant has maintained and will continue to maintain:

(a) adequate storage conditions and facilities;

(b) minimum liability and other insurance that may be required by applicable federal or state law;

(c) a functioning security system that includes:

(i) an after hours central alarm or comparable entry detection system;

(ii) restricted access to the premises;

(iii) comprehensive employee applicant screening; and

(iv) safeguards against employee theft;

(d) a system of records setting forth all activities of wholesale distribution, third-party logistics, manufacturing, or repackaging for at least a period of the 2 previous years. The system of records must be accessible, as defined by board regulations, for inspections authorized by the board.

(e) a list of active entity principals, including officers, directors, primary shareholders, and management executives, who shall at all times demonstrate and maintain their responsibility for conducting the business in conformity with sound financial practices as well as state and federal law;

(f) complete, updated information, to be provided to the board as a condition for obtaining and renewing a license, pertaining to each wholesale distributor, third-party logistics provider, manufacturer, or repackager to be licensed, including but not limited to:

(i) all pertinent corporate license information, if applicable; and

(ii) other information regarding ownership, principals, key personnel, and facilities;

(g) a written protocol of procedures and policies that ensures preparation by the applicant or licensee under this section for the handling of security or operational problems, including but not limited to those caused by:

(i) natural disaster or government emergency;

(ii) inventory inaccuracies or product shipping and receiving;

(iii) insufficient inspections for all incoming and outgoing product shipments;
(iv) lack of control of outdated or other unauthorized products;
(v) inappropriate disposition of returned goods; and
(vi) failure to promptly comply with product recalls; and
(h) operations in compliance with all federal requirements applicable to a wholesale distributor, third-party logistics provider, manufacturer, or repackager.

(5) An agent or employee of a licensed wholesale distributor, third-party logistics provider, manufacturer, or repackager need not be licensed as a wholesale distributor, third-party logistics provider, manufacturer, or repackager.

(6) For purposes of this section, all rules and regulations promulgated by the board must conform to the wholesale distributor, third-party logistics provider, manufacturer, and repackager licensing guidelines and rules formally adopted by the FDA. If a conflict arises between an FDA guideline or rule and a rule or regulation of the board, the former controls.

(7) Wholesale distributors, third-party logistics providers, manufacturers, and repackagers licensed by the board shall comply with the tracing requirements defined in sections 353 and 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., and all corresponding guidelines and rules.

History: En. Sec. 5, Ch. 134, L. 1991; amd. Sec. 6, Ch. 33, L. 2017.

Compiler's Comments

2017 Amendment: Chapter 33 throughout section in eight places substituted references to wholesale distributor, third-party logistics provider, manufacturer, or repackager for references to wholesale drug distributor; in (2)(a) after "adopted by" inserted "FDA and"; in (4) substituted "An applicant for a license under this section or for a license renewal" for "In order to obtain and maintain a wholesale drug distributorship in this state, an applicant"; in (4)(d) in first sentence before "for at least" deleted "as defined in 37-7-602"; in (4)(e) at beginning inserted "a list of active entity"; in (4)(f) substituted "renewing a license" for "retaining a license"; in (4)(g) substituted "applicant or licensee under this section" for "wholesale drug distributor"; in (6) in first sentence after "guidelines" inserted "and rules" and at end substituted "FDA" for "United States food and drug administration" and in last sentence substituted "an FDA guideline or rule" for "a food and drug administration guideline"; inserted (7) requiring compliance with tracing requirements; and made minor changes in style. Amendment effective October 1, 2017.

Severability: Section 14, Ch. 33, L. 2017, was a severability clause.

37-7-605. Out-of-state licensing requirements. (1) An out-of-state wholesale distributor, third-party logistics provider, manufacturer, or repackager may not conduct business in this state without first obtaining a license from the board and paying the license fee established by the board.

(2) Application for a license under this section must be made on an approved form.

(3) The issuance of a license may not affect tax liability imposed by the department of revenue on any out-of-state licensee.

(4) A person acting as principal or agent for an out-of-state licensee may not sell or distribute prescription drugs in this state unless the wholesale distributor, third-party logistics provider, manufacturer, or repackager has obtained a license.

History: En. Sec. 6, Ch. 134, L. 1991; amd. Sec. 40, Ch. 467, L. 2005; amd. Sec. 7, Ch. 33, L. 2017; amd. Sec. 23, Ch. 3, L. 2019.

Compiler's Comments

2019 Amendment: Chapter 3 in (3) substituted "out-of-state licensee" for "out-of-state license". Amendment effective October 1, 2019.

2017 Amendment: Chapter 33 in (1) substituted "wholesale distributor, third-party logistics provider, manufacturer, or repackager" for "wholesale drug distributor"; in (3) at end substituted "license" for "wholesale drug distributor"; and in (4) after "out-of-state" substituted "licensee" for "wholesale drug distributor", after "distribute" inserted "prescription", and after "unless the" substituted "wholesale distributor, third-party logistics provider, manufacturer, or repackager" for "distributor". Amendment effective October 1, 2017.

Severability: Section 14, Ch. 33, L. 2017, was a severability clause.

2005 Amendment: Chapter 467 in (2) after "made on" substituted "an approved form" for "a form furnished by the board"; and made minor changes in style. Amendment effective July 1, 2005.

37-7-606. Licenses. A license for a wholesale distributor, third-party logistics provider, manufacturer, or repackager is effective during the period specified by department rule.

History: En. Sec. 7, Ch. 134, L. 1991; amd. Sec. 40, Ch. 429, L. 1995; amd. Sec. 12, Ch. 492, L. 1997; amd. Sec. 41, Ch. 467, L. 2005; amd. Sec. 8, Ch. 33, L. 2017.

Compiler's Comments

2017 Amendment: Chapter 33 substituted "A license for a wholesale distributor, third-party logistics provider, manufacturer, or repackager" for "The license for wholesale drug distributors". Amendment effective October 1, 2017.

Severability: Section 14, Ch. 33, L. 2017, was a severability clause.

2005 Amendment: Chapter 467 deleted former second sentence that read: "An application for renewal of a license must be mailed to each licensee at least 30 days prior to the renewal date, and if the renewal application and the fee are not mailed by the renewal date, the license is void upon its expiration date." Amendment effective July 1, 2005.

1997 Amendment: Chapter 492 in first sentence, after "effective during the", deleted "12-month". Amendment effective July 1, 1997.

Preamble: The preamble attached to Ch. 492, L. 1997, provided: "WHEREAS, the Legislature finds that delays in licensing board responses to complaints of misconduct by licensees and unlicensed practice that result in frustration on behalf of the public, licensees, and boards is caused by a lack of personnel to assist with compliance issues; and

WHEREAS, licensing boards collect and accumulate sufficient funds from the fees charged to licensees to meet the cost of compliance and enforcement personnel, but these same boards often lack the authority to expend the funds that they collect; and

WHEREAS, the delayed processing and the accumulating complaint backlog have a deleterious effect on the productivity and reputation of the licensees; and

WHEREAS, the Legislature finds that certain licensing boards need to be granted temporary spending authority to address the delayed processing and accumulated complaint backlog; and

WHEREAS, a uniformly flexible approach to license renewal scheduling would also reduce frustration on the part of licensees and the public that they serve; and

WHEREAS, inflexible examination dates for license applicants in the plumbing and electrical fields have caused undue hardship with no discernable [sic] public benefit; and

WHEREAS, the Committee on Business and Labor desires to alleviate these and other related problems by appropriating funds for certain professional and occupational boards that need additional compliance specialists, by allowing the Department of Commerce [now Department of Labor and Industry] to establish license renewal dates by rule, and by allowing electrical and plumbing apprentices to take the examination required for licensure before the apprenticeships expire."

1995 Amendment: Chapter 429 in first sentence, after "effective", substituted "during the 12-month period specified by department rule" for "from April 1 to March 31 of the following year"; and in second sentence, after "licensee", substituted "at least 30 days prior to the renewal date" for "on or before March 1" and after "mailed" substituted "by the renewal date" for "by March 31".

Severability: Section 131, Ch. 429, L. 1995, was a severability clause.

Saving Clause: Section 132, Ch. 429, L. 1995, was a saving clause.

Applicability: Section 133, Ch. 429, L. 1995, provided: "[This act] applies to licenses applied for, complaints submitted, and proceedings begun after [the effective date of this section]." Effective October 1, 1995.

37-7-607. Repealed. Sec. 128, Ch. 429, L. 1995.

History: En. Sec. 8, Ch. 134, L. 1991.

37-7-608. Repealed. Sec. 128, Ch. 429, L. 1995.

History: En. Sec. 9, Ch. 134, L. 1991.

37-7-609. Board access to records. Wholesale distributors, third-party logistics providers, manufacturers, and repackagers may keep records at a central location apart from the principal office of the wholesale distributor, third-party logistics provider, manufacturer, and repackager or the location where the drugs are stored and from where they are shipped, if the records are available for inspection within 2 working days of a request by the board. The records may be kept in any form permissible under federal law applicable to prescription drug recordkeeping.

History: En. Sec. 10, Ch. 134, L. 1991; amd. Sec. 9, Ch. 33, L. 2017.

Compiler's Comments

2017 Amendment: Chapter 33 in two places substituted references to wholesale distributors, third-party logistics providers, manufacturers, and repackagers for references to wholesale drug distributors; and made minor changes in style. Amendment effective October 1, 2017.

Severability: Section 14, Ch. 33, L. 2017, was a severability clause.

37-7-610. Rulemaking authority. (1) The board shall adopt rules and regulations necessary to carry out the purpose and enforce the provisions of this part, including FDA guidelines and rules pursuant to the Drug Quality and Security Act of 2013, which includes the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., to implement:

(a) product tracing, reporting, and other requirements compliant with FDA uniform national policy; or

(b) national standards for the licensing of wholesale distributors, third-party logistics providers, manufacturers, and repackagers.

(2) If the rules and regulations conflict with the wholesale distributor, third-party logistics provider, manufacturer, or repackager guidelines or rules promulgated by the FDA, the latter control.

History: En. Sec. 11, Ch. 134, L. 1991; amd. Sec. 10, Ch. 33, L. 2017.

Compiler's Comments

2017 Amendment: Chapter 33 in (1) after "part" inserted "including FDA guidelines and rules pursuant to the Drug Quality and Security Act of 2013, which includes the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., to implement"; inserted (1)(a) concerning requirements compliant with FDA uniform national policy; inserted (1)(b) concerning national standards for licensure; in (2) substituted "wholesale distributor, third-party logistics provider, manufacturer, or repackager guidelines or rules" for "wholesale drug distribution guidelines" and substituted "FDA" for "United States food and drug administration"; and made minor changes in style. Amendment effective October 1, 2017.

Severability: Section 14, Ch. 33, L. 2017, was a severability clause.

Cross-References

Adoption and publication of rules, Title 2, ch. 4, part 3.

Administrative Rules

Title 24, chapter 174, subchapter 12, ARM Wholesale drug distributors licensing.

37-7-611. Criminal background check for wholesale distributors and third-party logistics providers. (1) Each applicant for licensure as a wholesale distributor or a third-party logistics provider shall submit a full set of the applicant's fingerprints to the board for the purpose of obtaining a state and federal criminal history background check.

(2) Each license applicant is responsible to pay all fees charged in relation to obtaining the state and federal criminal history background check.

(3) The board may require a licensee renewing a license to submit a full set of the licensee's fingerprints to the board for the purpose of obtaining a state and federal criminal history background check.

(4) The Montana department of justice may share the fingerprint data obtained under subsection (1) or (3) with the federal bureau of investigation.

History: En. Sec. 11, Ch. 33, L. 2017.

Compiler's Comments

Effective Date: This section is effective October 1, 2017.

Severability: Section 14, Ch. 33, L. 2017, was a severability clause.

37-7-612. Bond requirements for wholesale distributors. An applicant for licensure as a wholesale distributor and all wholesale distributors renewing licenses shall comply with the surety bond requirements as provided in rule.

History: En. Sec. 12, Ch. 33, L. 2017.

Compiler's Comments

Effective Date: This section is effective October 1, 2017.

Severability: Section 14, Ch. 33, L. 2017, was a severability clause.

Part 7 Out-of-State Mail Service Pharmacies

Part Compiler's Comments

Preamble: The preamble attached to Ch. 664, L. 1991, provided: "WHEREAS, the United States Congress has enacted a requirement in 42 U.S.C. 1396r-8 of the Social Security Act that states participating in Medicaid institute programs of drug utilization review and patient counseling by pharmacists; and

WHEREAS, similar changes in pharmacy practice could benefit the health and welfare of all Montanans and not just Medicaid recipients, and to that end the Board of Pharmacy should have the authority to set standards for pharmacists concerning drug utilization review and patient counseling, including standards for pharmacists who fill prescriptions by mail order from outside this state."

1991 Statement of Intent: The statement of intent attached to Ch. 664, L. 1991, provided: "A statement of intent is needed for this bill because it grants the board of pharmacy additional regulatory and rulemaking authority. In order to benefit all patient-consumers, the board may adopt rules similar to Medicaid regulations governing drug utilization review and patient counseling. The board is also required to adopt rules to regulate the activities of out-of-state mail service pharmacies, including their licensing, reporting requirements, drug utilization review and patient counseling, and site inspections."

Severability: Section 10, Ch. 664, L. 1991, was a severability clause.

Part Administrative Rules

Title 24, chapter 174, subchapter 10, ARM Out-of-state mail service pharmacies.

Part Law Review Articles

Prescribing a Cure for Online Pharmacies, Ayers, 72 Tenn. L. Rev. 949 (2005).

Nailing Jell-O to a Wall: Regulating Internet Pharmacies, Hochberg, 37 J. Health 445 (2004).

Regulation of Mail-Order Pharmacy, Munro, 12 J. Legal Med. 1 (1991).

A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals, Stoll, 45 Food Drug Cosm. L.J. 279 (1990).

37-7-701. Legislative declaration. The legislature recognizes that with the proliferation of alternate methods of health care delivery, there has arisen among third-party payors and insurance companies the desire to control the cost and use of pharmacy services through a variety of mechanisms, including the use of mail service pharmacies located outside this state. As a result, the legislature finds and declares that to continue to protect the consumer-patients of this state, all out-of-state mail service pharmacies that provide services to this state's residents must be registered with the board, shall disclose specific information about their services, shall meet the same standards for utilization of technicians as an in-state pharmacy, and shall provide pharmacy services at a high level of competence.

History: En. Sec. 2, Ch. 664, L. 1991; amd. Sec. 2, Ch. 300, L. 1993; amd. Sec. 2, Ch. 274, L. 1995.

Compiler's Comments

1995 Amendment: Chapter 274 near middle of second sentence substituted "registered" for "licensed"; and made minor changes in style. Amendment effective March 28, 1995.

1995 Statement of Intent: The statement of intent attached to Ch. 274, L. 1995, provided: "A statement of intent is required for this bill because the bill gives the board of pharmacy authority to adopt administrative rules for the registration of out-of-state mail service pharmacies."

It is the intent of the legislature to correct a deficiency in Title 37, chapter 7, part 7 (Chapter 664, Laws of 1991), that arose from a defective attempt to grant rulemaking authority to the board of pharmacy to carry out the provisions regarding out-of-state mail service pharmacies. [Section 4] [37-7-712] is specifically intended to grant rulemaking authority to the board of pharmacy to carry out the purpose and to enforce the provisions of Title 37, chapter 7, part 7. Sections 37-7-701 and 37-7-703 are intended to provide for regulation of out-of-state pharmacies and pharmacists through recognition of the licenses issued by their states of domicile through registration, rather than licensure, by the state of Montana."

Severability: Section 6, Ch. 274, L. 1995, was a severability clause.

1993 Amendment: Chapter 300 near end of second sentence inserted "shall meet the same standards for utilization of technicians as an in-state pharmacy"; and made minor changes in style. Amendment effective July 1, 1993.

Severability: Section 6, Ch. 300, L. 1993, was a severability clause.

37-7-702. Out-of-state mail service pharmacy defined. "Out-of-state mail service pharmacy" means a pharmacy located outside this state that:

(1) ships, mails, or delivers by any lawful means a dispensed legend drug to a resident in this state pursuant to a legally issued prescription;

(2) provides to a resident of this state information on drugs or devices that may include but is not limited to advice relating to therapeutic values, potential hazards, and uses; or

(3) counsels pharmacy patients residing in this state concerning adverse and therapeutic effects of drugs.

History: En. Sec. 3, Ch. 664, L. 1991.

37-7-703. Registration requirements. Each out-of-state mail service pharmacy must be registered with the board of pharmacy. In order to be registered with the board to do business in this state and for the renewal of its registration, an out-of-state mail service pharmacy:

(1) (a) shall submit a certificate from the appropriate licensing authority with which it is currently licensed and in good standing in the state in which its dispensing facilities are located; and

(b) shall comply with all applicable laws, regulations, and standards of that state and the United States and, if requested by the board, provide evidence that it has complied;

(2) shall register with the board and provide information on ownership and location, including the names and titles of the corporate officers, of the out-of-state mail service pharmacy and the identity of a pharmacist licensed in the state in which the pharmacy is located who is in charge of dispensing prescriptions for shipment to Montana from the out-of-state mail service pharmacy;

(3) shall submit a utilization plan for the employment of pharmacy technicians if allowed by the state where the mail service pharmacy is located. If the state in which the pharmacy is located does not establish a ratio of technicians to pharmacists for determining the number of pharmacy technicians or otherwise define the role of the pharmacist in compounding or dispensing drugs at the pharmacy, then the out-of-state mail service pharmacy may not allow a pharmacist to supervise more than one supportive person at any one time in the compounding or dispensing of prescription drugs, unless approved by the board as provided in 37-7-307 through 37-7-309.

(4) shall submit to the board proof of the pharmacist's good standing with the licensing authority in the state where the pharmacist is employed and the pharmacist's written commitment to comply with the utilization plan, if any, for each pharmacist identified under subsection (2) and shall provide to the board the same toll-free telephone service referenced in 37-7-706 in order to comply with all information requests by the board; and

(5) shall pay an initial registration fee and a periodic renewal fee in an amount to be determined by the board and at a time established by the department by rule.

History: En. Sec. 4, Ch. 664, L. 1991; amd. Sec. 3, Ch. 300, L. 1993; amd. Sec. 3, Ch. 274, L. 1995; amd. Sec. 13, Ch. 492, L. 1997.

Compiler's Comments

1997 Amendment: Chapter 492 in introductory clause, near middle after "in this state and for", substituted "the renewal" for "annual renewal"; and in (5) substituted "a periodic renewal" for "annual

renewal" and at end inserted "and at a time established by the department by rule". Amendment effective July 1, 1997.

Preamble: The preamble attached to Ch. 492, L. 1997, provided: "WHEREAS, the Legislature finds that delays in licensing board responses to complaints of misconduct by licensees and unlicensed practice that result in frustration on behalf of the public, licensees, and boards is caused by a lack of personnel to assist with compliance issues; and

WHEREAS, licensing boards collect and accumulate sufficient funds from the fees charged to licensees to meet the cost of compliance and enforcement personnel, but these same boards often lack the authority to expend the funds that they collect; and

WHEREAS, the delayed processing and the accumulating complaint backlog have a deleterious effect on the productivity and reputation of the licensees; and

WHEREAS, the Legislature finds that certain licensing boards need to be granted temporary spending authority to address the delayed processing and accumulated complaint backlog; and

WHEREAS, a uniformly flexible approach to license renewal scheduling would also reduce frustration on the part of licensees and the public that they serve; and

WHEREAS, inflexible examination dates for license applicants in the plumbing and electrical fields have caused undue hardship with no discernable [sic] public benefit; and

WHEREAS, the Committee on Business and Labor desires to alleviate these and other related problems by appropriating funds for certain professional and occupational boards that need additional compliance specialists, by allowing the Department of Commerce [now Department of Labor and Industry] to establish license renewal dates by rule, and by allowing electrical and plumbing apprentices to take the examination required for licensure before the apprenticeships expire."

1995 Amendment: Chapter 274 in introductory clause, in three places, substituted reference to registration for reference to licensure; at beginning of (1)(a) substituted "shall submit a certificate from the appropriate licensing authority with which it is currently" for "must be"; at beginning of (2), after "shall", substituted "register with" for "submit an application in form and content as determined by", after "location" inserted "including the names and titles of the corporate officers", and after "pharmacist" inserted "licensed in the state in which the pharmacy is located who is"; in (3) substituted second sentence regarding supervision of supportive persons for former language that read: "Any plan that has a ratio of technicians to pharmacists greater than the maximum ratio allowed for an in-state retail pharmacy under the board's rules must be approved by the board as provided in 37-7-307 through 37-7-309"; in (4) at beginning after "shall", substituted "submit to" for "register each pharmacist identified under subsection (2) with" and near middle, after "if any", inserted "for each pharmacist identified under subsection (2) and shall provide to the board the same toll-free telephone service referenced in 37-7-706 in order to comply with all information requests by the board"; in (5) substituted "registration" for "license"; and made minor changes in style. Amendment effective March 28, 1995.

1995 Statement of Intent: The statement of intent attached to Ch. 274, L. 1995, provided: "A statement of intent is required for this bill because the bill gives the board of pharmacy authority to adopt administrative rules for the registration of out-of-state mail service pharmacies.

It is the intent of the legislature to correct a deficiency in Title 37, chapter 7, part 7 (Chapter 664, Laws of 1991), that arose from a defective attempt to grant rulemaking authority to the board of pharmacy to carry out the provisions regarding out-of-state mail service pharmacies. [Section 4] [37-7-712] is specifically intended to grant rulemaking authority to the board of pharmacy to carry out the purpose and to enforce the provisions of Title 37, chapter 7, part 7. Sections 37-7-701 and 37-7-703 are intended to provide for regulation of out-of-state pharmacies and pharmacists through recognition of the licenses issued by their states of domicile through registration, rather than licensure, by the state of Montana."

Severability: Section 6, Ch. 274, L. 1995, was a severability clause.

1993 Amendment: Chapter 300 an end of first sentence inserted "of pharmacy"; in (2), after "location", inserted "of the out-of-state mail service pharmacy", before "pharmacist" deleted "licensed", and after "in charge of" inserted "dispensing prescriptions for shipment to Montana"; inserted (3) requiring submission of a utilization plan; inserted (4) requiring registration of pharmacists; and made minor changes in style. Amendment effective July 1, 1993.

Severability: Section 6, Ch. 300, L. 1993, was a severability clause.

Administrative Rules

ARM 24.174.1001 Registration of out-of-state mail service pharmacies.

ARM 24.174.1002 Conditions of registration.

37-7-704. Inspections. If the licensing or regulatory agency of the state in which an out-of-state mail service pharmacy is domiciled fails or refuses to inspect the out-of-state mail service pharmacy after receiving a request for an inspection from the board of this state, the board may cancel the out-of-state pharmacy's right to do business in this state unless the out-of-state pharmacy agrees to an onsite inspection by the board of this state.

History: En. Sec. 5, Ch. 664, L. 1991.

37-7-705. Product selection of prescribed drugs — notification. (1) An out-of-state mail service pharmacy may not substitute a prescription drug unless the substitution is made in compliance with the laws of this state and the rules and regulations of the board.

(2) An out-of-state mail service pharmacy may not dispense a substitute drug product to a resident of this state without notifying the patient of the substitution either by telephone or in writing.

History: En. Sec. 6, Ch. 664, L. 1991.

37-7-706. Patient communication — telephone service. Every out-of-state mail service pharmacy shall provide a toll-free telephone service, available at least 6 days a week and for 40 hours a week, to facilitate communication as may be required under this part, between patients in this state and a pharmacist who has access to the patients' records at the out-of-state mail service pharmacy. The toll-free telephone number must be affixed to all drug product containers dispensed to patients in this state.

History: En. Sec. 7, Ch. 664, L. 1991.

37-7-707 through 37-7-709 reserved.

37-7-710. Repealed. Sec. 128, Ch. 429, L. 1995.

History: En. Sec. 4, Ch. 300, L. 1993.

37-7-711. Penalty. In addition to all other penalties provided by law, a person violating 37-7-703 through 37-7-706 shall be fined not more than \$250 for each violation.

History: En. Sec. 8, Ch. 664, L. 1991.

37-7-712. Rulemaking authority. The board of pharmacy may adopt rules to implement this part.

History: En. Sec. 4, Ch. 274, L. 1995.

Compiler's Comments

1995 Statement of Intent: The statement of intent attached to Ch. 274, L. 1995, provided: "A statement of intent is required for this bill because the bill gives the board of pharmacy authority to adopt administrative rules for the registration of out-of-state mail service pharmacies.

It is the intent of the legislature to correct a deficiency in Title 37, chapter 7, part 7 (Chapter 664, Laws of 1991), that arose from a defective attempt to grant rulemaking authority to the board of pharmacy to carry out the provisions regarding out-of-state mail service pharmacies. [Section 4] [37-7-712] is specifically intended to grant rulemaking authority to the board of pharmacy to carry out the purpose and to enforce the provisions of Title 37, chapter 7, part 7. Sections 37-7-701 and 37-7-703 are intended to provide for regulation of out-of-state pharmacies and pharmacists through recognition of the licenses issued by their states of domicile through registration, rather than licensure, by the state of Montana."

Severability: Section 6, Ch. 274, L. 1995, was a severability clause.

Effective Date: Section 7, Ch. 274, L. 1995, provided: "[This act] is effective on passage and approval." Approved March 28, 1995.

Cross-References

Adoption and publication of rules, Title 2, ch. 4, part 3.

Administrative Rules

Title 24, chapter 174, subchapter 10, ARM Out-of-state mail service pharmacies.

Parts 8 through 10 reserved

Part 11 Peer Review

Part Cross-References

Licensing investigation and review — record access, 37-1-135.

Health care practitioners — nonliability for peer review, Title 37, ch. 2, part 2.

Part Law Review Articles

The Peer Review Privilege: A Law in Search of a Valid Policy, Goldberg, 10 Am. J.L. & Med. 151 (1984).

37-7-1101. Nonliability for peer review. No member, employee, or volunteer intervenor of the Montana pharmaceutical association in its peer review program is liable in damages to any person for any action taken or recommendation made within the scope of the program if the member, employee, or volunteer acts in good faith in accordance with the rules of the association.

History: En. Sec. 1, Ch. 235, L. 1987.

Parts 12 and 13 reserved

Part 14 Donated Drugs and Devices Program

37-7-1401. Programs for donation of unused prescription drugs, cancer drugs, and devices — rulemaking required. (1) The board of pharmacy shall, in consultation and cooperation with the department of public health and human services, create a program for the donation of prescription drugs collected from long-term care facilities to qualified patients.

(2) For the purposes of the program created pursuant to subsection (1), prescription drugs, except those drugs defined as a dangerous drug in 50-32-101 or a drug designated as a precursor to a controlled substance in 50-32-401, unneeded by a resident or former resident of a long-term care facility may be donated by the long-term care facility to a provisional community pharmacy that provides or may provide prescription drugs to individuals who are qualified patients for transfer free of charge or at a reduced charge to those individuals.

(3) This section does not amend or otherwise change the law applicable to the prescribing of prescription drugs, the sale of those drugs, or the licensing of long-term care facilities or pharmacies.

(4) The board of pharmacy shall adopt rules to implement this part. The rules must address:

(a) the collection, receipt, and storage of donated drugs and devices;

(b) the transfer of prescription drugs donated by a long-term care facility to provisional community pharmacies;

(c) which pharmacies may be considered provisional community pharmacies that may sell or give the prescription drugs donated by long-term care facilities to others;

- (d) eligibility criteria and other standards and procedures for participants that accept and distribute or dispense donated cancer drugs or devices;
 - (e) the forms needed for the administration of the donated drug programs;
 - (f) categories of cancer drugs and devices that the cancer drug repository program will accept for dispensing and categories it will not accept, including the reason that a cancer drug or device will not be accepted;
 - (g) the price for which the prescription drugs donated by a long-term care facility may be sold;
- and
- (h) the maximum handling fee that may be charged by participants that accept and distribute or dispense a cancer drug or device.
- (5) In adopting the rules, the board of pharmacy shall consider the ability of persons to pay for the drugs and the existence and operation of similar programs in other states.

History: En. Sec. 1, Ch. 362, L. 2001; amd. Sec. 5, Ch. 299, L. 2009.

Compiler's Comments

2009 Amendment: Chapter 299 in (4)(a) substituted "the collection, receipt, and storage of donated drugs and devices" for "collection and receipt of donated prescription drugs from residents of long-term care facilities, keeping of those drugs within the long-term care facility"; in (4)(b) substituted "transfer of prescription drugs donated by a long-term care facility" for "transfer of the drugs"; in (4)(c) at end substituted "prescription drugs donated by long-term care facilities" for "drugs"; inserted (4)(d), (4)(e), and (4)(f) requiring rules to address eligibility criteria for participants, administrative forms, and acceptable categories of cancer drugs and devices; in (4)(g) substituted "prescription drugs donated by a long-term care facility" for "drugs"; inserted (4)(h) requiring rules to address maximum handling fees; deleted former (5) that read: "(5) As used in this part, the following definitions apply:

(a) "Long-term care facility" has the meaning provided in 50-5-101.

(b) "Provisional community pharmacy" means the practice of pharmacy at a site that has been approved by the board, including but not limited to federally qualified health centers as defined in 42 CFR 405.2401, where prescription drugs are dispensed to appropriately screened, qualified patients.

(c) "Qualified patients" mean persons who are uninsured, indigent, or have insufficient funds to obtain needed prescription drugs"; and made minor changes in style. Amendment effective October 1, 2009.

Effective Dates: Section 5, Ch. 362, L. 2001, provided that subsection (4) of this section is effective on passage and approval. Approved April 23, 2001. The remainder of this section is effective October 1, 2001.

37-7-1402. Identifying information to be deleted from donated drugs or devices. A person or entity donating a prescription drug, a cancer drug, or a device pursuant to the programs created under this part shall delete from the container in which the drug or device is held any information by which the person for whom the drug or device was prescribed may be identified.

History: En. Sec. 2, Ch. 362, L. 2001; amd. Sec. 6, Ch. 299, L. 2009.

Compiler's Comments

2009 Amendment: Chapter 299 at beginning substituted "A person or entity donating a prescription drug, a cancer drug, or a device" for "A long-term care facility donating a prescription drug", near middle after "drug" inserted "or device", and after "by which" substituted "the person for whom the drug or device was prescribed" for "the long-term care facility resident or former resident for whom the drugs were prescribed"; and made minor changes in style. Amendment effective October 1, 2009.

Effective Date: This section is effective October 1, 2001.

37-7-1403. Cancer drug repository program — donations — registry. (1) The board shall establish a cancer drug repository program for accepting donated cancer drugs and devices and dispensing the drugs and devices to qualified patients. Participation in the program is voluntary.

(2) Any person or entity, including but not limited to a health care facility or the manufacturer of a cancer drug or device, may donate cancer drugs or devices to a participant pursuant to the provisions of 37-7-1403 through 37-7-1405.

(3) The board shall establish and maintain a registry of participants in the cancer drug repository program. The participant registry must:

- (a) include the participant's name, address, and telephone number; and
- (b) identify whether the participant is a physician's office, pharmacy, hospital, or health clinic.

(4) The board shall make the participant registry available to a person or entity wishing to donate a cancer drug or device to the cancer drug repository program.

History: En. Sec. 1, Ch. 299, L. 2009.

Compiler's Comments

Effective Date: This section is effective October 1, 2009.

37-7-1404. Cancer drugs or devices accepted or dispensed — conditions. (1) (a) Unless otherwise prohibited by law, a cancer drug or device may be accepted or dispensed under the cancer drug repository program established under 37-7-1403 if the drug or device is in its original, unopened, sealed, and tamper-evident unit dose packaging.

(b) A cancer drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit dose packaging is unopened.

(2) A cancer drug may not be accepted or dispensed under this section if the drug:

- (a) bears an expiration date that is earlier than 6 months after the date the drug was donated;
- (b) is considered adulterated or misbranded under the provisions of Title 50, chapter 31, part 3; or
- (c) is subject to restricted distribution pursuant to 21 CFR 314.520.

(3) Subject to the limitations provided in this section, an unused cancer drug or device dispensed under the medicaid program provided for in Title 53, chapter 6, may be accepted and dispensed under the cancer drug repository program.

(4) A cancer drug or device donated under this program must be stored:

- (a) separately from other prescription drugs or stock;
- (b) according to the manufacturer's recommended storage conditions; and
- (c) in the compounding or dispensing area if stored in a pharmacy.

(5) In dispensing a donated cancer drug or device, a participant shall give first priority to a qualified patient in the participant's service area. Other cancer patients may receive donated cancer drugs or devices if a qualified patient is not available.

(6) A participant shall notify a patient if the patient is receiving a cancer drug or device that has been donated.

History: En. Sec. 2, Ch. 299, L. 2009.

Compiler's Comments

Effective Date: This section is effective October 1, 2009.

37-7-1405. Participants — duties — fee authorized. (1) A participant shall comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of a donated cancer drug or device and shall inspect all donated drugs and devices before dispensing them to determine if they are adulterated or misbranded.

(2) A cancer drug or device may be:

(a) dispensed only pursuant to a prescription issued by a prescriber authorized to prescribe cancer drugs or devices; or

(b) distributed to another participant for dispensing.

(3) A cancer drug or device donated to the cancer drug repository program may not be resold.

(4) A participant may charge a handling fee for distributing or dispensing a cancer drug or device.

(5) A participant shall maintain records of donated drugs and devices and the distribution of the drugs and devices.

(6) (a) For cancer drugs or devices that are donated to the participant, records maintained pursuant to subsection (5) must include but are not limited to the following information:

- (i) the date the participant received the cancer drug or device;
- (ii) the drug name, strength, and amount;
- (iii) the prescription number;
- (iv) the expiration date of the drug;

- (v) the manufacturer's name and lot number; and
- (vi) the name and address of the person or entity donating the drug.
- (b) For cancer drugs or devices that are distributed or dispensed by the participant, records maintained pursuant to subsection (5) must include but are not limited to the following information:
 - (i) the name and address of the receiving person or entity;
 - (ii) the name, strength, and quantity of the drug;
 - (iii) the dosage form, if applicable;
 - (iv) the name and address of the participant who distributed or dispensed the drug or device;
 - (v) the date the participant distributed or dispensed the drug or device;
 - (vi) the manufacturer's name and lot number; and
 - (vii) the expiration date of the drug.

History: En. Sec. 3, Ch. 299, L. 2009.

Compiler's Comments

Effective Date: This section is effective October 1, 2009.

37-7-1406 and 37-7-1407 reserved.

37-7-1408. Donated drugs and devices — immunity. (1) A resident or former resident of a long-term care facility and the long-term care facility donating a prescription drug, a cancer drug, or a device as part of the programs created pursuant to this part are not liable for simple negligence in the donation of a drug or device if the requirements of this part and the rules implementing this part have been complied with.

(2) Except as provided in subsection (3):

(a) a person or entity, including the manufacturer of a cancer drug or device that exercises reasonable care in donating, accepting, distributing, or dispensing a cancer drug or device under the provisions of 37-7-1403 through 37-7-1405 and rules adopted by the board, is immune from civil or criminal liability or professional disciplinary action of any kind for an injury, death, or loss to a person or property relating to the accepting, distributing, or dispensing of the cancer drug or device;

(b) a person or entity, unless directly negligent, is not liable for the negligence or lack of care of other persons or entities and is entitled to the immunity of this part.

(3) (a) The donation of a cancer drug or device by the manufacturer of the drug or device does not absolve the manufacturer from criminal or civil liability or increase a liability that would have existed had the drug or device not been donated.

(b) The civil immunity provisions of subsection (2) do not apply to a person employed by or an entity operated by the state or a political subdivision of the state.

History: En. Sec. 3, Ch. 362, L. 2001; amd. Sec. 7, Ch. 299, L. 2009.

Compiler's Comments

2009 Amendment: Chapter 299 in (1) after "prescription drug" inserted "a cancer drug, or a device" and after "drug" inserted "or device"; inserted (2) and (3) creating civil and criminal immunity for certain persons or entities who donate, accept, distribute, or dispense cancer drugs or devices and establishing limits on immunity granted under section; and made minor changes in style. Amendment effective October 1, 2009.

Effective Date: This section is effective October 1, 2001.

Part 15

Prescription Drug Registry

Part Compiler's Comments

Severability: Section 18, Ch. 241, L. 2011, was a severability clause.

Effective Date: Section 19, Ch. 241, L. 2011, provided that this part is effective July 1, 2011.

37-7-1501. Short title. This part may be cited as the "Montana Patient Safety Act".

History: En. Sec. 1, Ch. 241, L. 2011.

37-7-1502. Prescription drug registry — purpose. (1) The board shall establish and maintain a prescription drug registry for the purpose of improving patient safety by:

(a) making a list of controlled substances prescribed to a patient available to the patient or to the patient's health care provider; and

(b) allowing authorized staff of the board who have signed appropriate confidentiality agreements to review the registry for possible misuse and diversion of controlled substances.

(2) The board shall electronically collect information on prescription drug orders involving controlled substances pursuant to 37-7-1503 and shall disseminate information as provided in 37-7-1504 through 37-7-1506.

History: En. Sec. 3, Ch. 241, L. 2011.

37-7-1503. Prescription drug registry — registration and reporting requirements. (1) Each person licensed under Title 37 to prescribe or dispense prescription drugs shall register to use the prescription drug registry at the time of initial licensure or renewal of licensure.

(2) (a) Except as provided in subsection (2)(b), each entity licensed by the board as a certified pharmacy or as an out-of-state mail order pharmacy that dispenses drugs to patients in Montana shall provide prescription drug order information for controlled substances to the registry by:

(i) electronically transmitting the information in a format established by the board unless the board has granted a waiver allowing the information to be submitted in a nonelectronic manner; and

(ii) submitting the information in accordance with time limits set by the board unless the board grants an extension because:

(A) the pharmacy has suffered a mechanical or electronic failure or cannot meet the deadline for other reasons beyond its control; or

(B) the board is unable to receive electronic submissions.

(b) This subsection (2) does not apply to:

(i) a prescriber who dispenses or administers drugs to the prescriber's patients; or

(ii) a prescription drug order for a controlled substance dispensed to a person who is hospitalized.

History: En. Sec. 4, Ch. 241, L. 2011; amd. Sec. 5, Ch. 89, L. 2019; amd. Sec. 2, Ch. 130, L. 2019.

Compiler's Comments

2019 Amendments — Composite Section: Chapters 89 and 130 inserted (1) requiring certain persons licensed under Title 37 to register to use the prescription drug registry at the time of initial licensure or renewal of licensure; and made minor changes in style. Amendments effective October 1, 2019.

Style changes were slightly different in the chapters. In each case, the codifier chose appropriate text.

37-7-1504. Prescription drug registry review. The board may review the information in the registry for possible misuse and diversion of controlled substances prescribed and dispensed to a patient. The board may provide information about possible misuse or diversion to prescribers and dispensers as allowed by rule.

History: En. Sec. 5, Ch. 241, L. 2011.

37-7-1505. Confidentiality. Patient information that is collected, recorded, transmitted, and stored for the registry is protected and may not be disclosed except as allowed in 37-7-1506. The board shall adopt rules to protect the confidentiality of the registry and to ensure that only authorized individuals have access to the registry.

History: En. Sec. 6, Ch. 241, L. 2011.

37-7-1506. Providing prescription drug registry information. (1) Registry information is health care information as defined in 50-16-504 and is confidential. Except as provided in 37-7-1504, the board is authorized to provide data from the registry, upon request, only to the following:

(a) a person authorized to prescribe or dispense prescription drugs if the person certifies that the information is needed to provide medical or pharmaceutical treatment to a patient who is the subject of the request and who is under the person's care or has been referred to the person for care;

(b) a prescriber who requests information relating to the prescriber's own prescribing information if the prescriber certifies that the requested information is for a purpose in accordance with board rule;

(c) an individual requesting the individual's registry information if the individual provides evidence satisfactory to the board that the individual requesting the information is the person about whom the data entry was made;

(d) a designated representative of a government agency responsible for licensing, regulating, or disciplining licensed health care professionals who are authorized to prescribe, administer, or dispense drugs, in order to conduct investigations related to a health care professional who is the subject of an active investigation for drug misuse or diversion;

(e) a county coroner or a peace officer employed by a federal, state, tribal, or local law enforcement agency if the county coroner or peace officer has obtained an investigative subpoena;

(f) an authorized individual under the direction of the department of public health and human services for the purpose of reviewing and enforcing that department's responsibilities under the public health, medicare, or medicaid laws; or

(g) a prescription drug registry in another state if the data is subject to limitations and restrictions similar to those provided in 37-7-1502 through 37-7-1513.

(2) The board shall maintain a record of each individual or entity that requests information from the registry and whether the request was granted pursuant to this section.

(3) The board may release information in summary, statistical, or aggregate form for educational, research, or public information purposes. The information may not identify a person or entity.

(4) Information collected by or obtained from the registry may not be used:

(a) for commercial purposes; or

(b) as evidence in any civil or administrative action, except in an investigation and disciplinary proceeding by the department or the agency responsible for licensing, regulating, or disciplining licensed health care professionals who are authorized to prescribe, administer, or dispense prescription drugs.

(5) Information obtained from the registry in accordance with the requirements of this section may be used in the course of a criminal investigation and subsequent criminal proceedings.

(6) (a) Registry information may be integrated into a health information system if the system:

(i) limits access to the information to those individuals authorized under subsection (1) to receive registry information;

(ii) meets the privacy and security requirements of the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d, et seq.; and

(iii) meets other criteria established by the board by rule.

(b) Information integrated into a health information system remains subject to the confidentiality requirements of 37-7-1505.

(7) The board shall adopt rules to ensure that only authorized individuals have access to the registry and only to appropriate information from the registry. The rules must be consistent with:

(a) the privacy provisions of the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d, et seq.;

(b) administrative rules adopted in connection with that act;

(c) Article II, section 10, of the Montana constitution; and

(d) the privacy provisions of Title 50, chapter 16.

(8) The procedures established by the board under this section may not impede patient access to prescription drugs for legitimate medical purposes.

History: En. Sec. 7, Ch. 241, L. 2011; amd. Sec. 3, Ch. 130, L. 2019.

Compiler's Comments

2019 Amendment: Chapter 130 inserted (6) regarding requirements for registry information to be integrated into a health information system; and made minor changes in style. Amendment effective October 1, 2019.

37-7-1507. Prescription drug registry — immunity. (1) A person or entity that complies with the reporting requirements of 37-7-1503 is not subject to civil liability or other legal or equitable relief for reporting the information to the board.

(2) Unless a court of competent jurisdiction finds that a person or entity committed an unlawful act pursuant to 37-7-1513, a person or entity in proper possession of information pursuant to this part is not subject to civil liability or other legal or equitable relief for any of the following acts or omissions:

(a) furnishing information pursuant to 37-7-1502 through 37-7-1506;

(b) receiving, using or relying on, or not using or relying on information received pursuant to 37-7-1502 through 37-7-1506; or

(c) relying on information that was entered into the registry in error, was factually incorrect, or was released by the board to the wrong person or entity.

(3) The immunity provisions of this section do not apply to the board, a state agency, or any political subdivision of the state.

History: En. Sec. 8, Ch. 241, L. 2011.

37-7-1508. Registry information retention — destruction. The board shall retain the information collected for the registry for up to 3 years, as established by rule. After 3 years, the board shall destroy the information unless it is being used as part of an active investigation.

History: En. Sec. 9, Ch. 241, L. 2011.

37-7-1509. Administration of prescription drug registry. The board may hire or contract for other professional, technical, or clerical staff as necessary to operate the registry. A contractor shall comply with the provisions regarding confidentiality of prescription information in 37-7-1505 and 37-7-1506 and is subject to the penalties specified in 37-7-1513 for unlawful acts.

History: En. Sec. 10, Ch. 241, L. 2011.

37-7-1510. Prescription drug registry — advisory group. (1) The board shall establish an advisory group to provide information and advice about the development and operation of the registry, including but not limited to information on:

(a) the criteria for reporting information from the registry to prescribers and pharmacists;

(b) the design and implementation of educational courses about the registry;

(c) standards for evaluating the effectiveness of the registry; and

(d) administrative rules for establishing and maintaining the registry.

(2) The advisory group consists of but is not limited to representatives of:

(a) health care licensing boards that oversee health care providers who have authority to prescribe or dispense drugs;

(b) associations that represent health care professionals who have authority to prescribe or dispense drugs;

(c) associations that advocate for patients;

(d) entities involved in tribal health services or issues; and

(e) the department of justice provided for in 2-15-2001.

(3) The advisory group may identify other individuals for appointment to the group.

(4) The board shall establish rules for the conduct of advisory group business.

(5) The advisory group may not receive or access confidential health care information contained in the registry.

History: En. Sec. 11, Ch. 241, L. 2011.

37-7-1511. Prescription drug registry — funding. (1) Each person licensed under Title 37 to prescribe or dispense prescription drugs shall pay to the board an annual, nonrefundable fee that is set by rule commensurate with costs.

(2) The board may apply for any available grants and may accept gifts, grants, or donations to assist in establishing and maintaining the registry.

(3) Funds collected pursuant to this part must be deposited into a state special revenue account to the credit of the department. The money must be used to defray the expenses of the board in establishing and maintaining the registry and in discharging its administrative and regulatory duties under this part.

History: En. Sec. 12, Ch. 241, L. 2011; amd. Sec. 1, Ch. 357, L. 2015; amd. Sec. 4, Ch. 130, L. 2019.

Compiler's Comments

2019 Amendment: Chapter 130 in (1) substituted current text for former text that read: "Each person licensed under Title 37 who is authorized to prescribe, dispense, or distribute controlled substances shall pay to the board a nonrefundable fee that is set by rule commensurate with costs, not to exceed \$30." Amendment effective October 1, 2019.

Termination Provision Repealed — Code Commissioner Explanation: Section 5, Ch. 130, L. 2019, repealed secs. 1 and 2, Ch. 13, L. 2017, which terminated subsection (1) of this section June 30, 2019. Effective October 1, 2019.

Because Ch. 130 did not include an effective date, it takes effect on October 1, 2019, which is after the June 30, 2019, termination date, so the 2017 provisions could potentially be construed to have terminated subsection (1). Because the sole purpose of section 5 of Ch. 130, L. 2019, was to make subsection (1) of this section permanent, the code commissioner has not terminated subsection (1).

Extension of Termination Date: Sections 1 and 2, Ch. 13, L. 2017, amended sec. 20, Ch. 241, L. 2011, and sec. 2, Ch. 357, L. 2015, by extending the termination date of subsection (1) of this section imposed by those sections to June 30, 2019. Effective February 13, 2017.

2015 Amendment: Chapter 357 in (1) substituted "is authorized to prescribe, dispense, or distribute" for "prescribes, dispenses, or distributes" and substituted "commensurate with costs, not to exceed \$30" for "and that may not exceed \$15". Amendment effective July 1, 2015.

Extension of Termination Date: Section 2, Ch. 357, L. 2015, amended sec. 20, Ch. 241, L. 2011, by extending the termination date of subsection (1) of this section imposed by Ch. 241 to June 30, 2017. Effective July 1, 2015.

Termination: Section 20, Ch. 241, L. 2011, provided that subsection (1) of this section terminates July 1, 2015.

37-7-1512. Rulemaking authority. The board shall adopt rules to carry out and enforce this part, including but not limited to rules that:

(1) specify the type of information to be reported on prescription drug orders involving controlled substances;

(2) establish the requirements for transmitting from a pharmacy to the board prescription drug order information involving controlled substances;

(3) define the electronic format for submission of information;

(4) define the circumstances under which a pharmacy may receive a waiver from the requirement to submit information electronically;

(5) specify the procedure through which a pharmacy may request an extension of the time limit for submitting information;

(6) establish how a person or entity authorized to receive information from the registry may submit a request for the information;

(7) specify the ways in which the board may use records involving requests for registry information to document and report on statistics involving the registry;

(8) set the fees to be charged for establishing and maintaining the registry; and

(9) establish confidentiality provisions to ensure that the privacy of patient information is maintained.

History: En. Sec. 13, Ch. 241, L. 2011.

37-7-1513. Unlawful acts — sanctions — civil penalties. (1) A pharmacist who fails to submit prescription drug order information to the board as required by 37-7-1503 or who willfully submits incorrect prescription drug order information must be referred to the board for consideration of administrative sanctions.

(2) A person or entity authorized to possess registry information pursuant to 37-7-1504 through 37-7-1506 who willfully discloses or uses the registry information in violation of 37-7-1504 through 37-7-1506 or a rule adopted pursuant to this part must be referred to the appropriate licensing board or regulatory agency for consideration of administrative sanctions.

(3) In addition to the administrative sanction provided in subsection (2), a person or entity who willfully discloses or uses information from the registry in violation of 37-7-1504 through 37-7-1506 or a rule adopted pursuant to this part is liable for a civil penalty of up to \$10,000 for each violation.

(4) The board may institute and maintain in the name of the state any enforcement proceedings under this section. Upon request of the department, the attorney general shall petition the district court to impose, assess, and recover the civil penalty.

(5) An action under subsection (3) or to enforce this part or a rule adopted under this part may be brought in the district court of any county where a violation occurs or, if mutually agreed on by the parties in the action, in the district court of the first judicial district.

(6) Civil penalties collected pursuant to this part must be deposited into the state special revenue account created pursuant to 37-7-1511 and must be used to defray the expenses of the board in establishing and maintaining the registry and in discharging its administrative and regulatory duties in relation to this part.

History: En. Sec. 14, Ch. 241, L. 2011.

37-7-1514. Report to legislature. The board shall provide a report to the appropriate interim committees of the legislature each interim, including but not limited to information on:

- (1) the cost of establishing and maintaining the registry;
- (2) any grants, gifts, or donations received to assist in establishing and maintaining the registry;
- (3) how registry information was used; and
- (4) how quickly the board was able to answer requests for information from the registry.

History: En. Sec. 15, Ch. 241, L. 2011.

37-7-1515. (Effective July 1, 2021) Mandatory use of prescription drug registry. A prescriber or an agent of the prescriber shall review a patient's records under the prescription drug registry before the prescriber issues a prescription for an opioid or a benzodiazepine for the patient, unless:

- (1) the patient is receiving hospice care;
- (2) the prescription is for a number of doses that is intended to last the patient 7 days or less and cannot be refilled;
- (3) the prescription drug is lawfully administered to the patient in a health care facility;
- (4) due to an emergency, it is not possible to review the patient's records under the registry before the prescriber issues a prescription for the patient;
- (5) the patient is being treated for chronic pain and the prescriber reviews the patient's records under the prescription drug registry every 3 months; or
- (6) it is not possible to review the patient's records under the registry because the registry is not operational or because of other technological failure if the failure is reported to the board.

History: En. Sec. 3, Ch. 89, L. 2019.

Compiler's Comments

Effective Date: Section 7(2), Ch. 89, L. 2019, provided that this section is effective July 1, 2021.