MONTANA BOARD OF PHARMACY RULES

AS OF SEPTEMBER 30, 2024

This version of the Administrative Rules of Montana is provided as a tool for board members and department staff. In case of inconsistencies, the rule text in the Montana Administrative Register is the official rule text and will prevail.

DEPARTMENT OF LABOR AND INDUSTRY

CHAPTER 174
BOARD OF PHARMACY

Subchapter 1
Organizational Rules

Subchapter 2
Procedural Rules

Subchapter 3
Definitions

Subchapter 4
General Provisions

Subchapter 5
Licensing

Subchapter 8
Pharmacies

Subchapter 12
Wholesale Distributor and Supply Chain Licensing

Rules 24.174.1413 through 24.174.1419 reserved

24.174.1420 Schedule I Dangerous Drugs (REPEALED)

24.174.1421 Schedule II Dangerous Drugs (REPEALED)

24.174.1422 Schedule III Dangerous Drugs (REPEALED)

24.174.1423 Schedule IV Dangerous Drugs (REPEALED)

Rule 24.174.1424 Schedule V Dangerous Drugs (REPEALED)

Subchapter 15
Cancer Drug Repository

Rule 24.174.1501 Participation

24.174.1502 Donation of Cancer Drugs (REPEALED)

24.174.1503 Acceptable Cancer Drugs

24.174.1504 Nonacceptable Cancer Drugs (REPEALED)

24.174.1505 Dispensing and Distribution of Cancer Drugs

24.174.1506 Storage Requirements

24.174.1507 Record-Keeping Requirements (REPEALED)

24.174.1508 Handling Fee (REPEALED)

24.174.1509 Pharmacy or Facility Registry (REPEALED)

24.174.1510 Inspections and Termination From Program (REPEALED)

Subchapter 16
Professional Assistance Program

Rule 24.174.1601 Medical Assistance Program Purpose (REPEALED)

24.174.1602 Reporting of Suspected Impairment (REPEALED)

Subchapter 22 reserved

Subchapter 23
Unprofessional Conduct

Rule 24.174.2301 Unprofessional Conduct

Subchapter 24
Disciplinary/Complaint Procedures

Rule 24.174.2401 Screening Panel (REPEALED)

Rule 24.174.2402 Complaint Procedure (REPEALED)

24.174.2403 Legal Suspension or Revocation (REPEALED)

24.174.101 BOARD ORGANIZATION

(1) The Board of Pharmacy adopts and incorporates the organizational rules of the Department of Labor and Industry as listed in chapter 1 of this title.

Authorizing statute(s): 2-4-201, MCA

Implementing statute(s): 2-4-201, MCA

History: Eff. 12/31/72; TRANS, from Dept. of Prof. & Occup. Lic. , Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2023 MAR p. 300, Eff. 3/25/23.

24.174.201 PROCEDURAL RULES

(1) The Board of Pharmacy adopts and incorporates the procedural rules of the Department of Labor and Industry as listed in chapter 2 of this title.

Authorizing statute(s): 2-4-201, MCA

Implementing statute(s): 2-4-201, MCA

History: Eff. 12/31/72; AMD, Eff. 11/4/76; TRANS, from Dept. of Prof & Occup. Lic. , Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2023 MAR p. 300, Eff. 3/25/23.

24.174.202 PUBLIC PARTICIPATION

(1) The Board of Pharmacy adopts and incorporates the public participation rules of the Department of Labor and Industry as listed in chapter 2 of this title.

Authorizing statute(s): 2-3-103, MCA

Implementing statute(s): 2-3-103, MCA

History: Eff. 12/31/72; AMD, Eff. 11/4/76; TRANS, from Dept. of Prof & Occup. Lic. , Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2023 MAR p. 300, Eff. 3/25/23.

24.174.301 DEFINITIONS

(1) "Airborne particulate cleanliness classification" means the level of cleanliness defined by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) "Classification of Air Cleanliness" (ISO 14644-1) for Class 5, Class 7, and Class 8.

(a) ISO Class 5 is an atmospheric environment that contains less than 3,520 particles 0.5 microns in diameter per cubic meter of air;

(b) ISO Class 7 is an atmospheric environment that contains less than 352,000 particles 0.5 microns in diameter per cubic meter of air; and

(c) ISO Class 8 is an atmospheric environment that contains less than 3,520,000 particles 0.5 microns in diameter per cubic meter of air.

(2) "Beyond use date" (BUD) means the date after which the preparation may not be dispensed or administered to a patient. BUD also means expiration date.

(3) "Biological safety cabinet" means a ventilated cabinet with an inward airflow for personnel protection; a downward, High Efficiency Particulate Arresting (HEPA) filtered, laminar airflow for product protection; and HEPA filtered exhaust system for environmental protection.

(4) "Board of Pharmaceutical Specialties" (BPS) means an independent nongovernmental certification body that provides recognition of persons involved in the advanced practice of pharmacy specialties through development and administration and a certification process that is consistent with public policy regarding the credentialing of healthcare professionals.

(5) "Chart order" means a lawful order entered on the chart or a medical record of a patient or resident of a facility by a practitioner, or his or her designated agent, for a drug or device and shall be considered a prescription.

(6) "Class 100 environment" means an atmospheric environment which contains fewer than 100 particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209E.

(7) "Clean room" means an environment in which the concentration of airborne particles is controlled and monitored with parameters including high efficiency particulate air (HEPA) filtered airflow, pressurization, temperature, and humidity.

(8) "Clinical practice experience," for purposes of issuing a clinical pharmacist practitioner endorsement, means working in a pharmacy practice setting which includes at least 50 percent of time spent in:

(a) communication with healthcare professionals and patients regarding drug therapy, wellness, and health promotion;

(b) designing, implementing, monitoring, evaluating, and modifying or recommending modifications in drug therapy to optimize patient care;

(c) identifying, assessing, and solving medication-related problems and providing a clinical judgment as to the continuing effectiveness of the therapeutic plan;

(d) conducting physical assessment applicable to the area of practice, evaluating patient problems, and ordering and monitoring medications, and/or laboratory tests in accordance with established standards of practice;

(e) referring patients to other healthcare professionals as appropriate;

(f) integrating relevant diet, exercise, and other non-drug therapy with pharmaceutical care;

(g) retrieving, evaluating, utilizing, and managing data and professional resources;

(h) documenting interventions and evaluating outcomes; and

(i) integrating national standards for the quality of healthcare.

(9) "Collaborative practice agreement" is defined as set forth in ARM 24.174.524.

(10) "Compounded sterile preparation" (CSP) means:

(a) a preparation prepared according to the manufacturer's labeled instructions and other manipulations when preparing sterile products that expose the original contents to potential contamination, and includes all preparations compounded in a sterile environment; or

(b) a preparation containing nonsterile ingredients or employing nonsterile components and devices that must be sterilized before administration.

(11) "Cytotoxic" means a pharmaceutical agent capable of killing living cells.

(12) "DEA" means the Drug Enforcement Administration of the United States Department of Justice.

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

(14) "Device" is defined in 37-2-101, MCA, and is required under federal law to bear the label "Caution: Federal law requires dispensing by or on the order of a physician" or "Rx only."

(15) "Drug kit" means a secured kit stored outside of a pharmacy containing those drugs which may be required to meet the short-term therapeutic need of patients within an institution not having an in-house pharmacy or 24-hour access to dispensing services, and which would not be available from any other authorized source in sufficient time, and without which would compromise the quality of care of the patient.

(16) "Drug order" means a written or electronic order issued by an authorized practitioner, or a verbal order promptly transcribed, for the compounding and dispensing of a drug or device to be administered to patients within a facility and shall be considered a prescription.

(17) "Drug room" means a secure, lockable temperature-controlled location within a facility that does not have an institutional pharmacy and which contains drugs and devices for administration to patients within the facility pursuant to a valid drug order.

(18) "Electronic prescription" means a prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file. Controlled substance prescriptions for Schedules II through V shall be transmitted in accordance with DEA requirements as outlined in 21 CFR Part 1300.

(19) "Electronic signature" means a confidential personalized method of affixing a signature to an electronic document that will guarantee the identity of the prescriber.

(20) "Emergency drug cart" or "crash cart" means a secure lockable cart or container in an inpatient setting that stores drugs and devices necessary to meet the immediate therapeutic needs of a patient and which cannot be obtained from any other authorized source in sufficient time to prevent harm.

(21) "Facility" means an outpatient center for surgical services, a hospital and/or long-term care facility, or a home infusion facility.

(22) "Floor stock" means prescription drugs not labeled for a specific patient, which are maintained at a nursing station or other hospital department other than the pharmacy, and which are administered to patients within the facility pursuant to a valid drug order. Floor stock shall be maintained in a secure manner pursuant to written policies and procedures, which shall include, but not be limited to, automated dispensing devices.

(23) "Formulary" means a current compilation of pharmaceuticals authorized for use within the institution by representatives of the medical staff and pharmacy department.

(24) "Home infusion facility" means a facility where parenteral solutions are compounded and distributed to outpatients for home infusion pursuant to a valid prescription or drug order.

(25) "Immediate use" means a preparation compounded pursuant to the conditions in ARM 24.174.1121 and whose administration must begin within one hour of preparation.

(26) "Institutional pharmacy" means that physical portion of an institutional facility where drugs, devices, and other material used in the diagnosis and treatment of injury, illness, and disease are dispensed, compounded, and distributed to other healthcare professionals for administration to patients within or outside the facility, and pharmaceutical care is provided.

(27) "Internship" means the practical experiences required to provide an intern, as defined in 37-7-101, MCA, with the knowledge and practical experience necessary for professional licensure as a pharmacist.

(28) "Internship period" means 300 Introductory Pharmacy Practice Experience (IPPE) hours, and 1,440 Advanced Pharmacy Practice Experience (APPE) hours of practical experience in an approved pharmacy, hospital, or other facility or location relevant to the pharmacy profession. The intern may acquire the internship hours concurrently with school attendance in approved courses, introductory pharmacy practice experience, and advanced pharmacy practice experience, or demonstration projects

in the Pharm.D. program. The intern may acquire a maximum of 48 hours experience per calendar week.

(29) "Labeling" means the process of preparing and affixing a label to any drug container exclusive, however, of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and Montana law or rule.

(30) "Laminar airflow hood" (LAF) means a workspace where the work surface is subjected to a constant HEPA filtered airflow that is directed towards the user.

(31) "Long-term care facility" has the same meaning as provided in 50-5-101, MCA, and means a facility or part of a facility that provides skilled nursing care, residential care, intermediate nursing care, or intermediate developmental disability care to a total of two or more individuals, or that provides personal care.

(32) "Medical gas" means any gaseous substance that meets medical purity standards and has application in a medical environment. Examples of medical gases include, but are not limited to, oxygen, carbon dioxide, nitrous oxide, cyclopropane, helium, nitrogen, and air.

(33) "Medical gas distributor" is a person engaged in the manufacture, processing, packaging, labeling, or distribution of a medical gas to a person other than a consumer or patient.

(34) "Medical gas supplier" is a person engaged in selling, transferring, or delivering to a patient or a patient's agent one or more doses of medical gas in the manufacturer's or distributor's original container for subsequent use by the patient.

(35) "Multi-dose vial" means a vial of liquid medication intended for parenteral administration, whether by injection or infusion, that contains more than one dose of medication; is labeled as containing more than one dose of medication by the manufacturer; and typically contains an antimicrobial preservative to help prevent the growth of bacteria.

(36) "Night cabinet" means a secure locked cabinet or other enclosure located outside the pharmacy, containing drugs which authorized personnel may access in the absence of a pharmacist.

(37) "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for consumer use in accordance with the requirements of the laws and rules of Montana and the federal government.

(38) "Outpatient center for surgical services" is as defined at 50-5-101, MCA.

(39) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of skin.

(40) "Pharmacist-in-charge" means a pharmacist licensed in Montana who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy, who assures that the pharmacy and all pharmacy personnel working in the pharmacy have current and appropriate licensure and certification, and who is personally in full and actual charge of such pharmacy. The pharmacist-in-charge at an out-of-state mail service pharmacy does not have to be licensed in Montana.

(41) "Preceptor" means a pharmacist or other approved individual who meets those requirements for the supervision and training of an intern. A preceptor shall have overall responsibility for the required training of the intern.

(42) "Provisional pharmacy" means a pharmacy licensed by the Montana Board of Pharmacy and includes, but is not limited to, federally qualified health centers as defined in 42 CFR 405.2401, where prescription drugs are dispensed to appropriately screened, qualified patients.

(43) "Qualified patients" mean patients who are uninsured, indigent, or have insufficient funds to obtain needed prescription drugs.

(44) "Remote pharmacy" means a licensed pharmacy at which prescriptions may be filled or transmitted to a central hub pharmacy for filling and subsequent delivery to the remote site or the patient's home. Patient counseling by a pharmacist may occur at this site.

(45) "Remote telepharmacy dispensing machine site" means a licensed site containing prescription inventory which is secured in an automated dispensing device and which has access to its parent pharmacy and registered pharmacists via computer, video, and audio link at all times during business hours.

(46) "Remote telepharmacy site" means a licensed site staffed by a registered pharmacy technician with access to its parent pharmacy and registered pharmacists via computer, video, and audio link at all times during business hours.

(47) "Risk levels for sterile preparations" means the three risk levels of CSP recognized by the United States Pharmacopeia (USP) in USP Chapter 797 "Pharmaceutical Compounding - Sterile Preparations" that are based on the probability of contamination by microbial, chemical, or physical agents. Pursuant to the conditions set forth in ARM 24.174.1121, the three risk levels are low-risk, medium-risk, and high-risk.

(48) "Same-day use" means that the administration of the preparation shall commence within 24 hours from the time of preparation.

(49) "Satellite pharmacy" means a specialized inpatient pharmacy staffed by a pharmacist which is adjacent to or near the department served and is connected via computer to the central institutional pharmacy.

(50) "Security" or "secure system" means a system to maintain the confidentiality and integrity of patient records, which are being sent electronically.

(51) "Single-dose vial" means a sterile medication in a vial without preservatives.

(52) "Sterile pharmaceutical" means any dosage form containing no viable microorganisms including, but not limited to, parenterals and ophthalmics.

(53) "Supervising pharmacist" means the registered pharmacist who is serving as the pharmacist on duty and is in charge of the day-to-day supervision of the pharmacy personnel.

(54) "Supervision" means that all drug distribution or dispensing activities, immunizations, or other activities performed by pharmacy personnel are under the direction of a registered pharmacist.

(55) "Verification audit" means a comparison and verification of written patient orders with medications removed for that patient.

Authorizing statute(s): 37-7-201, 50-32-314, MCA

Implementing statute(s): 37-7-102, 37-7-201, 37-7-301, 37-7-306, 37-7-321, 37-7-406, 37-7-603, 37-7-604, 37-7-605, 50-32-314, MCA

History: Eff. 6/9/61; AMD, Eff. 2/27/72; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1993 MAR p. 293, Eff. 2/26/93; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2008 MAR p. 1151, Eff. 6/13/08; AMD, 2010 MAR p. 74, Eff. 1/15/10; AMD, 2012 MAR p. 506, Eff. 3/9/12; AMD, 2012 MAR p. 896, Eff. 4/27/12; AMD, 2015 MAR p. 302, Eff. 3/27/15; AMD, 2021 MAR p. 1671, Eff. 11/20/21; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.302 HOSPITAL/HEALTH CARE FACILITY DEFINITIONS

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-321, MCA

History: NEW, Eff. 3/21/71; AMD, Eff. 8/4/76; AMD, Eff. 1/3/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic. , Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2000 MAR p. 460, Eff. 2/11/00; AMD, 2001 MAR p. 783, Eff. 5/11/01; TRANS, from Commerce, 2002 MAR p. 904; REP, 2002 MAR p. 3605, Eff. 12/27/02.

24.174.303 INTERNSHIP PROGRAM DEFINITIONS (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, Eff. 5/20/72; AMD, 1977 MAR p. 106, Eff. 9/23/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; AMD, 1997 MAR p. 163, Eff. 11/18/97; AMD, 2001 MAR p. 783, Eff. 5/11/01; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2011 MAR p. 1148, Eff. 6/24/11; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.401 FEE SCHEDULE

(1) Application for pharmacist licensure transfer $180

(2) Pharmacist initial license 70

(3) Pharmacist annual renewal fee 65

(4) Clinical pharmacist practitioner initial endorsement/registration and annual renewal fee 25

(5) Community and institutional pharmacy initial license (includes initial license, change in location, and change in ownership) 240

(6) Community and institutional pharmacy annual renewal fee 150

(7) Limited pharmacy facility, (initial license and annual renewal) 45

(8) Intern registration 50

(9) Montana NAPLEX examination processing fee (a separate exam fee is paid directly to NABP) 35

(10) Montana multistate pharmacy jurisprudence examination (MPJE) exam fee (a separate exam fee is paid directly to NABP) 25

(11) Utilization plan initial endorsement and annual renewal fee 75

(12) Pharmacy technician registration fee 35

(13) Pharmacy technician renewal fee 30

(14) Wholesale distributor initial license and annual renewal fee 240

(15) Out-of-state mail service pharmacy initial license and annual renewal fee 240

(16) Certification of grades/transfer of internship hours 20

(17) Outpatient center for surgical services (initial or renewal) 45

(18) Drugs dispensed by a medical practitioner initial registration 240

(19) Drugs dispensed by a medical practitioner annual renewal fee 150

(20) Third-party logistics provider (3PL) initial license and annual renewal fee 240

(21) Repackager initial license and annual renewal fee 240

(22) Manufacturer initial license and annual renewal fee 240

(23) Veterinary retail facility initial license and annual renewal fee 150

(24) Additional standardized fees are specified in ARM 24.101.403.

(25) The fees to be assessed for registration to manufacture, distribute, dispense, conduct research on, or analyze a dangerous drug shall be assessed the following fees upon application and annual renewal:

(a) manufacture 100

(b) distribute 100

(c) dispense – pharmacy 75

(d) dispense – outpatient centers for surgical services 75

(26) The fees for registration to manufacture, distribute, or supply medical gases shall be assessed according to the following annual fee:

(a) medical gas distributor 75

(b) medical gas supplier 75

Authorizing statute(s): 37-1-134, 37-2-104, 37-7-201, 37-7-604, 37-7-610, 37-18-803, 50-32-314, MCA

Implementing statute(s): 37-1-134, 37-2-104, 37-7-201, 37-7-306, 37-7-321, 37-7-604, 37-7-605, 37-7-703, 37-18-803, 50-32-314, MCA

History: NEW, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 1279, Eff. 4/25/80; AMD, 1981 MAR p. 625, Eff. 6/26/81; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; AMD, 1984 MAR p. 1567, Eff. 10/26/84; AMD, 1987 MAR p. 478, Eff. 5/1/87; AMD, 1988 MAR p. 271, Eff. 2/12/88; AMD, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 1992 MAR p. 1754, Eff. 8/14/92; AMD, 1994 MAR p. 571, Eff. 3/18/94; AMD, 1995 MAR p. 2689, Eff. 12/8/95; AMD, 1997 MAR p. 2060, Eff. 11/18/97; AMD, 1998 MAR p. 3103, Eff. 11/20/98; RESCIND, (CI-75), 1998 MAR p. 3200, Eff. 12/4/98; AMD, 1999 MAR p. 1124, Eff. 5/21/99; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2006 MAR p. 1583, Eff. 7/1/06; AMD, 2006 MAR p. 2134, Eff. 9/22/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2008 MAR p. 631, Eff. 4/11/08; AMD, 2008 MAR p. 1151, Eff. 6/13/08; AMD, 2010 MAR p. 2968, Eff. 12/24/10; AMD, 2017 MAR p. 1653, Eff. 9/23/17; AMD, 2019 MAR p.

1633, Eff. 9/21/19; AMD, 2021 MAR p. 1673, Eff. 11/20/21; AMD, 2022 MAR p. 1842, Eff. 9/24/22; AMD, 2024 MAR p. 84, Eff. 1/13/24; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.402 DANGEROUS DRUG FEE SCHEDULE (REPEALED)

(REPEALED)

Authorizing statute(s): 37-1-134, 37-7-201, 50-32-103, 50-32-314, MCA

Implementing statute(s): 37-1-134, 37-7-201, 37-7-321, 50-32-103, 50-32-314, MCA

History: NEW, Eff. 8/4/74; AMD, Eff. 2/4/75; AMD, Eff. 12/5/75; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; AMD, 1987 MAR p. 478, Eff. 5/1/87; AMD, 1998 MAR p. 3103, Eff. 11/20/98; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 2134, Eff. 9/22/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2012 MAR p. 896, Eff. 4/27/12; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.403 CHANGE IN ADDRESS AND/OR EMPLOYMENT

(1) All licensees shall notify the board in writing within 30 days of any change in employment and/or any change of business or personal address.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2010 MAR p. 2968, Eff. 12/24/10.

24.174.404 FEE ABATEMENT

(1) The Board of Pharmacy adopts and incorporates by reference the fee abatement rule of the Department of Labor and Industry found at ARM 24.101.301.

Authorizing statute(s): 37-1-131, MCA

Implementing statute(s): 17-2-302, 17-2-303, 37-1-134, MCA

History: NEW, 2006 MAR p. 1615, Eff. 6/23/06.

24.174.407 QUALITY ASSURANCE PROGRAM REQUIREMENTS

(1) Each pharmacy or other facility licensed by the board shall have in place a quality assurance program to detect, identify, and prevent errors, for improving public safety, or both. The quality assurance program shall include necessary documentation, internal reporting, and assessment of errors to determine the root cause and contributing factors, such as system or process failures, provide an appropriate response, and communicate the findings to all pharmacy personnel.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2015 MAR p. 302, Eff. 3/27/15; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.411 PHARMACIST MEAL/REST BREAKS

(1) In any pharmacy staffed by a single pharmacist, the pharmacist shall take a meal/rest break for a period of up to 30 minutes per shift without closing the pharmacy and removing support personnel, provided the pharmacist reasonably believes that the security of prescription drugs will be maintained in the pharmacist's absence.

(2) The time of the meal/rest break will be conspicuously posted in clear view of patients approaching the prescription area.

(3) In the pharmacist's absence a sign indicating that no pharmacist is on duty will be conspicuously displayed in clear view of patients approaching the prescription area.

(4) The pharmacist will remain on the premises if the prescription area is to remain open, and be available for emergencies.

(5) When authorized by the pharmacist, only registered technicians and interns directly involved in the process of filling prescriptions may remain in the prescription department to perform nondiscretionary duties as delineated by the pharmacist.

(6) Upon returning, the pharmacist shall review any work performed in the pharmacist's absence.

(7) In the pharmacist's absence there may be no dispensing of new prescriptions that the pharmacist has checked and that are waiting to be picked up, nor may counseling be provided.

(8) At the discretion of the pharmacist, previously checked medication refills may be handed to patients or their agents by registered technicians in the pharmacist's absence, and the technicians must offer the patient counseling by the pharmacist. If the patient desires counseling, the patient may wait for the pharmacist to return or may leave a telephone number for the pharmacist to call upon return.

(9) Telephoned new prescriptions must not be accepted by support personnel in the pharmacist's absence.

(10) New hardcopy prescriptions may be accepted and processed by registered technicians in the pharmacist's absence. These prescriptions may not be dispensed until the pharmacist has performed prospective drug review and completed the final check.

(11) If two or more pharmacists are on duty, the pharmacists shall stagger their breaks so that the prescription department is not left without a pharmacist on duty.

(12) The pharmacist-in-charge shall develop written policies and procedures for operation of the prescription department in the temporary absence of the pharmacist.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2015 MAR p. 302, Eff. 3/27/15.

24.174.501 EXAMINATION FOR LICENSURE AS A REGISTERED PHARMACIST

(1) The board has selected the National Association of Boards of Pharmacy (NABP) licensure examination (NAPLEX) to be administered to candidates for licensure in Montana. The examination shall be prepared to measure the competence of the applicant to engage in the practice of pharmacy. A score of 75 shall be a passing score for this examination. A candidate who does not attain this score may retake the examination pursuant to NABP requirements.

(2) In addition, the NABP shall administer a multistate pharmacy jurisprudence examination (MPJE). This examination shall be prepared to measure the competence of the applicant regarding the statutes and rules governing the practice of pharmacy. A score of not less than 75 shall be a passing score for this examination. A candidate who does not attain this score may retake the examination after a 30-day waiting period from the date of the exam.

(3) Pharmacy graduates from outside the 50 states, the District of Columbia, or Puerto Rico, who seek certification of educational equivalency in order to sit for the North American pharmacist licensure examination must also complete the following:

(a) an interview before the Board of Pharmacy or its designee;

(b) 1500 hours of internship in the United States;

(c) receive a Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification from NABP, which includes the following:

(i) Foreign Pharmacy Graduate Equivalency Examination (FPGEE);

(ii) Test of Spoken English (TSE); and

(iii) Test of English as a Foreign Language (TOEFL).

(4) NABP minimum passing scores must be achieved on all tests and examinations.

Authorizing statute(s): 37-1-131, 37-7-201, MCA

Implementing statute(s): 37-1-131, 37-7-201, 37-7-302, MCA

History: NEW, Eff. 11/25/77; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; AMD, 1986 MAR p. 945, Eff. 5/30/86; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2011 MAR p. 1148, Eff. 6/24/11; AMD, 2016 MAR p. 1696, Eff. 9/24/16; AMD, 2018 MAR p. 1825, Eff. 9/8/18.

24.174.502 TRANSFER OF LICENSE FROM ANOTHER STATE

(1) Applicants seeking a license on the basis of having taken the NAPLEX examination and then issued a license by another state shall submit the following information to the board:

(a) NABP transfer of licensure application;

(b) proof of passing examination score on the NAPLEX examination;

(c) verification of current licensure in good standing from all other states where licensed; and

(d) appropriate fees.

(2) An applicant who has been registered as a pharmacist by examination in another state but who has not taken the NAPLEX examination shall appear before the board for consideration of transfer of licensure and submit the following information to the board:

(a) transfer of licensure application;

(b) proof of passing examination score;

(c) verification of current licensure in good standing from all other states where licensed; and

(d) appropriate fees.

(3) In addition to the requirements in (1) and (2), the applicant will be required to pass the MPJE, to measure the competence of the applicant regarding the statutes and rules governing the practice of pharmacy. A score of not less than 75 shall be a passing score for this examination.

(4) The applicant has one year from the date of the NABP application in which to complete the licensure process. An applicant who does not obtain a license in one year will be required to file a new application and pay the appropriate fees.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-1-304, MCA

History: NEW, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2007 MAR p. 1936, Eff. 11/22/07.

24.174.503 ADMINISTRATION OF VACCINES BY PHARMACISTS, INTERNS, AND PHARMACY TECHNICIANS

(1) An immunization-certified pharmacist may prescribe and administer those immunizations listed in 37-7-105, MCA, without a collaborative practice agreement in place, as required by the statute.

(2) An immunization-certified pharmacist must have a collaborative practice agreement with a practitioner authorized to prescribe drugs to administer immunizations not listed in 37-7-105, MCA, to persons seven years of age or older, as provided in the most recent guidelines by vaccine and age group published by the U.S. Centers for Disease Control and Prevention (CDC) and as determined within a collaborative practice agreement; or, in the case of a public health emergency, a directive from the State Medical Officer of the Montana Department of Public Health and Human Services.

(3) An immunization-certified pharmacist, as defined in 37-7-101, MCA, shall:

(a) provide a copy of the immunization certificate and current basic cardiopulmonary resuscitation (CPR) certification to the board for initial endorsement on license; and

(b) maintain documentation of immunization endorsement and current CPR certification on file at the practice site.

(4) In order to administer immunizations, with or without a collaborative practice agreement, an immunization-certified pharmacist must meet the requirements of 37-7-105, MCA, and:

(a) administer vaccinations in accordance with established protocol that includes site-specific emergency measures;

(b) have access to a current edition of the CDC reference "Epidemiology and Prevention of Vaccine-Preventable Diseases";

(c) maintain the following:

(i) written policies and procedures for the types of immunizations administered;

(ii) specific description of the procedures, methods, and decision criteria to follow for administering the immunization;

(iii) a detailed description of the procedures and patient activities to follow in the course of administering immunizations;

(iv) training for staff procedures and record keeping requirements; and

(v) disposal of used or contaminated supplies; and

(d) maintain the following information in the patient's medical records as required by 37-7-105, MCA, which shall be considered confidential information:

(i) the patient's name, address, allergies, and date of birth;

(ii) the product's name, dose, manufacturer, lot number, and expiration date;

(iii) the date of administration;

(iv) the site and route of administration; and

(v) the administering pharmacist's name or identifiable initials and the pharmacy's address.

(5) An immunization-certified pharmacist may delegate the administration of immunizations to a pharmacy intern or a pharmacy technician under the direct supervision of the pharmacist upon meeting the immunization certification requirements listed in 37-7-105, MCA, and this rule. The board shall issue an immunization endorsement on the license of an intern or pharmacy technician upon receipt of qualifications being met.

(6) The board shall randomly select renewal notice forms of immunization-certified pharmacists and pharmacy technicians for audit and verification of the requirements listed in this rule.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, 37-7-105, 37-7-201, MCA

History: NEW, 2002 MAR p. 794, Eff. 2/1/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2010 MAR p. 74, Eff. 1/15/10; AMD, 2011 MAR p. 1148, Eff. 6/24/11; AMD, 2012 MAR p. 896, Eff. 4/27/12; AMD, 2015 MAR p. 1491, Eff. 9/25/15; AMD, 2019 MAR p. 2240, Eff. 12/7/19; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.504 INACTIVE LICENSE (REPEALED)

(REPEALED)

Authorizing statute(s): 37-1-319, 37-7-201, MCA

Implementing statute(s): 37-1-319, 37-7-201, MCA

History: NEW, 2006 MAR p. 1615, Eff. 6/23/06; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.505 PHARMACIST PRESCRIBING: GENERAL REQUIREMENTS

(1) Pursuant to 37-7-106, MCA, and these rules, any pharmacist may independently prescribe.

(2) The pharmacist prescribing under this rule must obtain adequate information about the patient's health status to make appropriate decisions based on the applicable standard of care and the best available evidence. For each drug or device the pharmacist intends to prescribe, the pharmacist must maintain a patient assessment based on current clinical guidelines, best practice standards, or evidence-based research findings, as applicable.

(3) The pharmacist must document an appropriate follow-up care plan, including any monitoring parameters, as indicated by the patient assessment.

(4) The pharmacist must inquire about the identity of the patient's primary care provider or provider of record. If a provider is identified, the pharmacist must document the information and notify the provider at the earliest reasonable time following the prescribing of a drug or device.

(5) The pharmacist must maintain documentation adequate to justify the care provided, including, but not limited to the information collected as part of the patient assessment, the prescription record, any notification provided as required under this rule, and the follow-up care plan. Records must be made available for inspection by the board.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-106, MCA

History: NEW, 2023 MAR p. 1865, Eff. 12/23/23.

24.174.507 MILITARY TRAINING OR EXPERIENCE (REPEALED)

(REPEALED)

Authorizing statute(s): 37-1-145, MCA

Implementing statute(s): 37-1-145, MCA

History: NEW, 2014 MAR p. 1261, Eff. 6/13/14; AMD, 2019 MAR p. 1633, Eff. 9/21/19; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.508 NONROUTINE APPLICATIONS

(1) For the purpose of processing nonroutine applications, the board incorporates the definitions of routine and nonroutine at ARM 24.101.402 by reference.

(2) Nonroutine applications must be reviewed and approved by the board before a license may be issued.

(3) A new application submitted by a business entity is nonroutine when the specific business or facility location applying for licensure, not the entire corporation or parent company, meets any of the nonroutine criteria established by ARM 24.101.402.

(a) A change of ownership application is nonroutine when the new owner listed on the application meets any of the nonroutine criteria established ARM 24.101.402.

(b) A change of location application is routine, provided the applicant meets the requirements in ARM 24.174.803, ARM 24.174.1004, or ARM 24.174.1207.

Authorizing statute(s): 37-1-131, MCA

Implementing statute(s): 37-1-101, 37-1-131, MCA

History: NEW, 2021 MAR p. 556, Eff. 5/15/21.

24.174.509 APPLICANTS WITH CRIMINAL CONVICTIONS

(1) The board incorporates ARM 24.101.406 by reference with no modifications.

Authorizing statute(s): 37-1-131, MCA

Implementing statute(s): 37-1-101, 37-1-131, MCA

History: NEW, 2021 MAR p. 556, Eff. 5/15/21.

24.174.510 PRESCRIPTION REQUIREMENTS

(TRANSFERRED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-505, MCA

History: NEW, 1985 MAR p. 1017, Eff. 7/26/85; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2010 MAR p. 74, Eff. 1/15/10; AMD, 2011 MAR p. 1148, Eff. 6/24/11; AMD and TRANS, to ARM 24.174.831, 2015 MAR p. 302, Eff. 3/27/15.

24.174.511 LABELING FOR PRESCRIPTIONS

(TRANSFERRED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, Eff. 7/19/68; AMD, 1978 MAR p. 393, Eff. 3/25/78; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2001 MAR p. 783, Eff. 5/11/01; TRANS, from Commerce, 2002 MAR p. 904; TRANS, to ARM 24.174.832, 2015 MAR p. 302, Eff. 3/27/15.

24.174.512 RECORDS OF DISPENSING

(TRANSFERRED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 1985 MAR p. 1017, Eff. 7/26/85; TRANS, from Commerce, 2002 MAR p. 904; TRANS, to ARM 24.174.833, 2015 MAR p. 302, Eff. 3/27/15.

24.174.513 COPY OF PRESCRIPTION

(TRANSFERRED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, MCA

History: NEW, Eff. 6/7/66; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; TRANS, to ARM 24.174.834, 2015 MAR p. 302, Eff. 3/27/15.

24.174.514 TRANSFER OF PRESCRIPTIONS

(TRANSFERRED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 1985 MAR p. 1017, Eff. 7/26/85; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD and TRANS, to ARM 24.174.835, 2015 MAR p. 302, Eff. 3/27/15.

24.174.515 EMERGENCY PRESCRIPTION REFILLS

(TRANSFERRED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; TRANS, to ARM 24.174.836, 2015 MAR p. 302, Eff. 3/27/15.

24.174.520 PRESCRIPTION REQUIRED FOR SCHEDULE V

(TRANSFERRED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-102, 37-7-201, MCA

History: NEW, Eff. 9/16/71; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904; TRANS, to ARM 24.174.837, 2015 MAR p. 302, Eff. 3/27/15.

24.174.521 RETURNED PRESCRIPTION

(TRANSFERRED)

Authorizing statute(s): 37-7-201, 37-7-1401, MCA

Implementing statute(s): 37-7-201, 37-7-1401, MCA

History: NEW, Eff. 6/12/57; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; TRANS, to ARM 24.174.838, 2015 MAR p. 302, Eff. 3/27/15.

24.174.522 ALTERNATE DELIVERY OF PRESCRIPTIONS

(TRANSFERRED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-301, MCA

History: NEW, Eff. 9/24/61; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; TRANS, to ARM 24.174.839, 2015 MAR p. 302, Eff. 3/27/15.

24.174.523 TRANSMISSION OF PRESCRIPTIONS BY ELECTRONIC MEANS

(TRANSFERRED)

Authorizing statute(s): 37-7-201, 50-32-103, MCA

Implementing statute(s): 37-7-102, 37-7-201, 50-32-208, MCA

History: NEW, 1995 MAR p. 2689, Eff. 12/8/95; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2010 MAR p. 74, Eff. 1/15/10; AMD, 2012 MAR p. 896, Eff. 4/27/12; AMD and TRANS, to ARM 24.174.840, 2015 MAR p. 302, Eff. 3/27/15.

24.174.524 COLLABORATIVE PRACTICE AGREEMENT REQUIREMENTS

(1) A pharmacist engaged in collaborative practice must:

(a) maintain an executed written copy of the collaborative practice agreement at the pharmacy and any other location in which the practice is occurring; and

(b) make the agreement available for inspection by the board.

(2) The collaborative practice agreement must include:

(a) identification of the practitioner(s) and pharmacist(s) who are parties to the agreement;

(i) the practitioner as defined in 37-2-101, MCA, must be licensed in good standing in Montana;

(b) the types of decisions that the pharmacist is allowed to make;

(c) a method for the practitioner to monitor compliance with the agreement and clinical outcomes and to intercede where necessary;

(d) a provision that allows the practitioner to override a collaborative practice decision made by the pharmacist whenever the practitioner deems it necessary or appropriate;

(e) a provision that allows either party to cancel the agreement by written notification;

(f) an effective date;

(g) signatures of collaborating pharmacists and practitioners, or a representative from the medical practice or clinic that is authorized to represent its practitioners, who are party to the agreement, as well as dates of signing; and

(h) a procedure for periodic review and renewal within a time frame that is clinically appropriate.

(3) Documentation of allowed pharmacist activities must be kept as part of the patient's permanent record and be readily available to other health care professionals providing care to the patient and who are authorized to receive it. Documentation of allowed activities shall be considered protected health information.

(4) Collaborative practice agreements approved by an institutional committee such as the pharmacy and therapeutics committee and that will be used solely for patients while they are receiving care in the institution are exempt.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, 37-7-201, MCA

History: NEW, 2002 MAR p. 794, Eff. 2/1/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2019 MAR p. 1633, Eff. 9/21/19; AMD, 2021 MAR p. 1671, Eff. 11/20/21.

24.174.525 DEFINITIONS (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-306, MCA

History: NEW, 2010 MAR p. 2968, Eff. 12/24/10; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.526 CLINICAL PHARMACIST PRACTITIONER QUALIFICATIONS AND REQUIREMENTS

(1) An applicant for a clinical pharmacist practitioner registration shall:

(a) submit an application on a form prescribed by the board;

(b) pay a required registration fee and annual renewal fee;

(c) hold an active, unrestricted Montana pharmacist license;

(d) have completed the years of clinical practice experience that meet the requirements for Board of Pharmacy Specialties (BPS) certification or other equivalent national certification, and hold one of the following active certifications:

(i) BPS certification; or

(ii) nationally recognized certification equivalent to BPS certification standards in an area of practice as approved by the board and the Board of Medical Examiners (BME).

(e) submit a signed collaborative practice agreement to the board that includes a description of the type of supervision the collaborating practitioner will exercise over the clinical pharmacist practitioner;

(f) following approval of the board, submit the application and collaborative practice agreement to the BME for approval; and

(g) appear before the board and/or BME if requested.

(2) Within ten days of discontinuing work under an approved collaborative drug therapy agreement, the pharmacist shall notify the board and the clinical pharmacist practitioner's registration shall be inactive, until such time as a new application is approved.

(3) A clinical pharmacist practitioner shall complete an annual renewal of a pharmacist's license and pay the clinical pharmacist practitioner endorsement renewal fee.

(4) The board shall audit clinical pharmacist practitioners for compliance with continued registration.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-306, MCA

History: NEW, 2010 MAR p. 2968, Eff. 12/24/10; AMD, 2018 MAR p. 1825, Eff. 9/8/18; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.527 REQUIREMENTS TO MAINTAIN CLINICAL PHARMACIST PRACTITIONER REGISTRATION (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-306, MCA

History: NEW, 2010 MAR p. 2968, Eff. 12/24/10; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.528 UNPROFESSIONAL CONDUCT (REPEALED)

(REPEALED)

Authorizing statute(s): 37-1-319, 37-7-201, MCA

Implementing statute(s): 37-1-316, 37-7-306, MCA

History: NEW, 2010 MAR p. 2968, Eff. 12/24/10; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.601 SUMMARY OF OBJECTIVES (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, Eff. 5/20/72; AMD, 1977 MAR p. 106, Eff. 9/23/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1997 MAR p. 2060, Eff. 11/18/97; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2010 MAR p. 74, Eff. 1/15/10; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.602 INTERNSHIP REQUIREMENTS

(1) The experience required to obtain licensure as a pharmacist shall be that instruction period composed of computed time obtained under the supervision of the preceptor in a site approved by the school in which the intern is enrolled.

(2) An intern may practice only under the supervision of a supervising pharmacist.

(3) An intern registration may be issued to an individual who:

(a) is currently enrolled in an accredited pharmacy program;

(b) is a graduate of an accredited pharmacy program serving an internship; or

(c) is a graduate of a pharmacy program located outside the United States of America which is not accredited and who is licensed pursuant to (14).

(4) All intern applicants must:

(a) submit a completed application to the board;

(b) pay the required fee; and

(c) complete at least one day of the accredited pharmacy program.

(5) The intern is responsible for the knowledge and observation of the extent of the intern's legal liability and legal restrictions applicable under the federal, state, and municipal laws and rules.

(6) Intern and internship documentation, hours, and forms shall be furnished by the school of pharmacy and filed directly to the school of pharmacy.

(a) An intern must be licensed by the board before computed time is credited.

(7) An out-of-state intern must register with the board and comply with rules related to internship and this chapter.

(8) Employment and the intern training periods are not to be interpreted as being the same. An intern may work in excess of the computed time.

(9) Intern registration based on enrollment in or graduation from an accredited pharmacy program shall expire not later than 12 months after the date of graduation or at the time of professional licensure,

whichever comes first. Intern registration based on graduation from a pharmacy program located outside of the United States of America which is not accredited shall expire not later than 12 months after the date of issuance of the registration or at the time of professional licensure, whichever comes first.

(10) The intern shall notify the board of any change of permanent address within 30 days.

(11) Intern certificate of registration shall be displayed at any experiential or employment location.

(12) An intern registration may be extended, subject to approval by the board, upon application by the intern, if extenuating circumstances are present.

(13) Suspension of an intern from university or college attendance concurrently suspends an intern's certificate of registration.

(14) A graduate of a foreign school of pharmacy seeking licensure to practice as a pharmacy intern in the state of Montana shall:

(a) submit proof of a Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification from the National Association of Boards of Pharmacy (NABP), which includes the following:

(i) Test of Spoken English (TSE);

(ii) Test of English as a Foreign Language (TOEFL); and

(iii) Foreign Pharmacy Graduate Equivalency Exam (FPGEE);

(b) achieve NABP minimum passing scores on all tests and examinations;

(c) have an internship practice site identified and that practice site must be a licensed pharmacy in good standing with the board;

(d) have an internship preceptor identified and that preceptor must:

(i) be a licensed pharmacist in good standing with the board; and

(ii) be a registered preceptor in good standing with the board;

(e) appear before the board with their preceptor; and

(f) complete 1,740 hours of internship in the United States in order to be eligible for pharmacist licensure in Montana.

Authorizing statute(s): 37-7-131, 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, Eff. 5/20/72; AMD, 1977 MAR p. 106, Eff. 9/23/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1997 MAR p. 2060, Eff. 11/18/97;

AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2010 MAR p. 74, Eff. 1/15/10; AMD, 2011 MAR p. 1148, Eff. 6/24/11; AMD, 2015 MAR p. 302, Eff. 3/27/15; AMD, 2017 MAR p. 1653, Eff. 9/23/17; AMD, 2019 MAR p. 1633, Eff. 9/21/19; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.603 OUT-OF-STATE INTERNSHIP REQUIREMENTS (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, Eff. 5/20/72; AMD, 1977 MAR p. 106, Eff. 9/23/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic. , Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.604 PRECEPTOR REQUIREMENTS

(1) Each preceptor shall:

(a) apply for board approval to be a preceptor when the preceptor is a pharmacist. For pharmacists, the board shall issue an endorsement on the pharmacist's license when requirements are met;

(b) have been actively engaged in:

(i) the practice of pharmacy for one year, unless otherwise approved by the board; or

(ii) other approved disciplines;

(c) be actively engaged in the pharmacy profession or other approved discipline or healthcare profession while acting as preceptor;

(d) not have been convicted of violation of any statutes or rules relating to pharmacy within three years prior to application;

(e) be acutely aware of the responsibilities governing professional conduct in this state;

(f) have current knowledge of developments in the profession by exhibiting such attendances, readings, and actions, which conform to the best traditions of pharmacy;

(g) make reports and certifications as required by a school of pharmacy;

(h) not be permitted to leave an intern to work alone or unsupervised to assume the responsibility of a pharmacist; and

(i) complete a training course as approved by the ACPE or the school of pharmacy prior to applying for a pharmacist preceptor endorsement.

(2) The repackaging, labeling, counseling, dispensing, or distribution of drugs shall be under the supervision of a supervising pharmacist.

(3) A supervising pharmacist or preceptor may precept more than one intern at a time.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, Eff. 5/20/72; AMD, 1977 MAR p. 106, Eff. 9/23/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1997 MAR p. 2060, Eff. 11/18/97; AMD, 2001 MAR p. 783, Eff. 5/11/01; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2011 MAR p. 1148, Eff. 6/24/11; AMD, 2019 MAR p. 1633, Eff. 9/21/19; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.605 FOREIGN INTERN REQUIREMENTS (REPEALED)

(REPEALED)

Authorizing statute(s): 37-1-131, 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2017 MAR p. 1653, Eff. 9/23/17; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.611 APPROVED TRAINING AREAS (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, Eff. 5/20/72; AMD, 1977 MAR p. 106, Eff. 9/23/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.612 INTERNSHIP REQUIRED FORMS AND REPORTS (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, Eff. 5/20/72; AMD, 1977 MAR p. 106, Eff. 9/23/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1997 MAR p. 2060, Eff. 11/18/97; AMD, 2000 MAR p. 2005, Eff. 7/28/00; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2019 MAR p. 1633, Eff. 9/21/19; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.613 REVOCATION OR SUSPENSION OF CERTIFICATE (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, Eff. 5/20/72; AMD, 1977 MAR p. 106, Eff. 9/23/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.701 PHARMACY TECHNICIAN REGISTRATION REQUIREMENTS

(1) To be registered as a pharmacy technician in this state, the applicant shall:

(a) be of good moral character;

(b) submit an application on a form prescribed by the board;

(c) pay application fees as prescribed by the board; and

(d) submit a copy of proof of certification by the Pharmacy Technician Certification Board (PTCB), National Healthcareer Association (ExCPT), or other board-approved certifying entity.

(i) The board recognizes other Montana health care licensing boards as certifying entities for which licensees can assist the pharmacist(s) in administering vaccines, in compliance with state and federal requirements, under the supervision of a pharmacist, pursuant to the following restrictions:

(A) The health care licensee is in good standing with their licensing board and is authorized to administer vaccines under their own scope of practice. The health care licensee does not need a separate pharmacy technician license issued by the board.

(B) The pharmacist(s) is authorized to prescribe, dispense, and administer vaccines, pursuant to 37-7-105, MCA, and ARM 24.174.503, and in compliance with state and federal requirements.

(ii) The technician utilization plan must reflect use of health care licensees to assist pharmacists in administration of vaccines as authorized in (i) and their license must be conspicuously displayed at the pharmacy.

(2) An applicant for registration as a pharmacy technician in this state may apply for a temporary practice permit as authorized by 37-1-305, MCA, valid for two years from the date the permit was issued.

(3) No pharmacist, intern, or health care licensee whose license has been denied, revoked, or is currently suspended, or restricted for disciplinary purposes shall be eligible to be registered as a pharmacy technician.

Authorizing statute(s): 37-1-131, 37-7-201, MCA

Implementing statute(s): 37-1-305, 37-7-201, MCA

History: NEW, 2002 MAR p. 86, Eff. 1/18/02; AMD, 2010 MAR p. 74, Eff. 1/15/10; AMD, 2015 MAR p. 302, Eff. 3/27/15; AMD, 2019 MAR p. 1633, Eff. 9/21/19; AMD, 2022 MAR p. 401, Eff. 3/26/22; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.702 QUALIFICATIONS OF PHARMACY TECHNICIAN

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-301, 37-7-307, MCA

History: NEW, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 2002 MAR p. 86, Eff. 1/18/02; TRANS, from Commerce, 2002 MAR p. 904; REP, 2019 MAR p. 1633, Eff. 9/21/19.

24.174.703 USE OF PHARMACY TECHNICIAN

(1) A pharmacy technician may not perform tasks which require the exercise of the pharmacist's independent professional judgment, including but not limited to, patient counseling, drug product selection, drug interaction review or drug regimen review.

(2) A pharmacy technician must work under the provisions of a technician utilization plan and the plan must be made available for inspection by the board.

(3) When a pharmacist is not in the prescription department, there shall be no dispensing of new prescriptions that the pharmacist has checked and that are waiting to be picked up, nor shall counseling be provided by the pharmacy technician.

(4) No medication may be released to a patient without review by a registered pharmacist for the accuracy and appropriateness of the prescription drug order.

(5) All technicians and auxiliary staff shall be made visually identifiable by name and job title utilizing letters of 16 point or larger on a name badge.

(6) All pharmacy technician licenses must be conspicuously displayed at all times in the place of business.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, 37-7-201, 37-7-301, 37-7-307, MCA

History: NEW, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 2000 MAR p. 2005, Eff. 7/28/00; AMD, 2002 MAR p. 86, Eff. 1/18/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2010 MAR p. 74, Eff. 1/15/10; AMD, 2019 MAR p. 1633, Eff. 9/21/19.

24.174.704 PHARMACY TECHNICIAN TRAINING

(1) A supervising pharmacist shall:

(a) provide initial training to a pharmacy technician that relates to the tasks the technician may perform pursuant to the supervising pharmacist's utilization plan; and

(b) prepare and maintain a written record of initial and inservice training for on-site inspection by the board. The record shall contain the following information:

(i) name and signature of the person receiving the training;

(ii) dates of the training;

(iii) general description of the topics covered; and

(iv) name and signature of the person supervising the training.

(2) An initial training program must include on-the-job practical training and didactic education that is commensurate with the tasks and functions a pharmacy technician may perform. A supervising pharmacist must obtain the board's approval of an initial training program prior to undertaking the training of a pharmacy technician pursuant to the program.

(3) Verification of completion of training, by test or otherwise, shall be recorded by the supervising pharmacist, and shall be available for inspection with the training record.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-307, MCA

History: NEW, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 2002 MAR p. 86, Eff. 1/18/02; TRANS, from Commerce, 2002 MAR p. 904.

24.174.705 TASKS AND FUNCTIONS OF PHARMACY TECHNICIAN

(1) Only a registered pharmacy technician may perform the following tasks or functions under the provisions of an approved utilization plan:

(a) remove a stock bottle from the shelf and count or pour the contents into a suitable container. The stock bottle must be quarantined together with the prescription until the supervising pharmacist performs a final check or bar coding or other available technology verifies the bottle contents;

(b) type a prescription label and affix it and auxiliary labels to a prescription bottle, with final review by the registered pharmacist;

(c) enter prescription information into an automated system under the supervision of a pharmacist who must be able to check all entries;

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

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

(f) answer the telephone, properly identify themselves as a technician, accept verbal orders for refill prescriptions from medical practitioners or their designated agents and issue refill requests to the prescriber;

(g) a pharmacy technician may act as agent in charge of the pharmacy to assure its integrity when a registered pharmacist is not physically present, but may not perform any duties which require the exercise of the pharmacist's independent professional judgment. The technician may not be left in charge for more than 30 minutes; and

(h) compounding if a mechanism for verification by the supervising pharmacist exists that includes checking of: the original order; additives; dosages; and clarity of IV solution, where appropriate.

(2) The board reserves the right to evaluate and amend the functions allowable by a pharmacy technician, with final determination in the sole discretion of the board.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, 37-7-201, 37-7-301, 37-7-307, MCA

History: NEW, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 2002 MAR p. 86, Eff. 1/18/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06.

24.174.711 RATIO OF PHARMACY TECHNICIANS AND INTERNS TO SUPERVISING PHARMACISTS

(1) The ratio of pharmacy technicians to pharmacist(s) on duty is to be determined by the pharmacist-in-charge. A pharmacist intern does not count against the pharmacist to pharmacy technician ratio.

(2) The pharmacist-in-charge will ensure that the number of pharmacy technicians on duty can be satisfactorily supervised by the pharmacist(s) on duty to ensure patient safety and a safe work environment, provided:

(a) in the professional judgment of the pharmacist on duty,

the ratio and supervision of pharmacy technicians is adequate and manageable based on the technician's scope of practice, education, skill and experience, the policy and procedures of the pharmacy must allow for safe and accurate filling and labeling of prescriptions, and the ratio must be assessed with regard to the pharmacy's quality assurance program , pursuant to ARM 24.174.407;

(b) a technician utilization plan, as described in ARM 24.174.712, must include the policy and procedures and shall be reviewed annually. All affected supervising pharmacists and pharmacy technicians must be familiar with the contents and any changes made must be reported to the board; and

(c) a copy of the policy and procedures must be available for inspection by the board.

(3) No pharmacy shall modify a board-approved technician utilization plan without the prior written approval of the board.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, 37-7-201, 37-7-307, 37-7-308, 37-7-309, MCA

History: NEW, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 1997 MAR p. 2060, Eff. 11/18/97; AMD, 2002 MAR p. 86, Eff. 1/18/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2019 MAR p. 1633, Eff. 9/21/19; AMD, 2022 MAR p. 401, Eff. 3/26/22.

24.174.712 APPLICATION FOR APPROVAL OF UTILIZATION PLAN

(1) The pharmacist-in-charge may apply to the board for approval to use the services of a pharmacy technician, including the use of authorized health care licensees, as described in ARM 24.174.701(1)(d), to assist pharmacists in the administration of vaccines, in compliance with state and federal requirements, by submitting to the board:

(a) an application on a form prescribed by the board;

(b) a summary of the technician utilization plan, to include information showing compliance with all requirements set forth in these rules, plus all other requirements of 37-7-307, 37-7-308, and 37-7-309, MCA, and this chapter;

(c) the appropriate fee for initial approval of the technician utilization plan;

(d) any changes in the technician utilization plan, including technician training and use of other health care licensees for administration of vaccines, as described in ARM 24.174.701(1)(d), must be provided upon inspection by the board.

(2) Any number of registered pharmacists employed in the same pharmacy may sign as supervising pharmacist of a pharmacy technician on a single technician utilization plan submitted for approval to the board by that pharmacy.

(3) A pharmacist-in-charge may apply to the board to designate that pharmacy as a technician training site for a board-approved academic program curriculum. If the pharmacy training site does not have an approved technician utilization plan in place, the pharmacy may substitute an academic program training plan, assessment criteria and periodic contact plan for board approval, for the purpose of providing on-the-job experience for technician trainees.

(4) A technician utilization plan must be available for inspection by the board.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-308, 37-7-309, MCA

History: NEW, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 1997 MAR p. 2060, Eff. 11/18/97; AMD, 2002 MAR p. 86, Eff. 1/18/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2022 MAR p. 401, Eff. 3/26/22; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.713 CONTENTS OF TRAINING COURSE

(1) A pharmacy technician training course must include instruction in:

(a) orientation to the practice of pharmacy;

(b) pharmacy terminology and basic pharmaceutics;

(c) state and federal laws relating to the practice of pharmacy;

(d) pharmaceutical calculations;

(e) processing prescription drug orders;

(f) telephone procedure and communication including taking refill requests;

(g) pharmaceutical compounding;

(h) intravenous admixture, if applicable; and

(i) use of pharmacy computer systems, if applicable.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-307, MCA

History: NEW, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 2002 MAR p. 86, Eff. 1/18/02; TRANS, from Commerce, 2002 MAR p. 904.

24.174.714 INSPECTION OF UTILIZATION PLAN AND TRAINING RECORD

(1) The supervising pharmacist shall make the utilization plan available for inspection by the board during the normal business hours of the pharmacy.

(2) The pharmacy technician shall make their training record available for inspection by the board during the normal business hours of the pharmacy.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-308, MCA

History: NEW, 1992 MAR p. 1608, Eff. 7/31/92; AMD, 2002 MAR p. 86, Eff. 1/18/02; TRANS, from Commerce, 2002 MAR p. 904.

24.174.715 TECHNICIAN CHECK TECHNICIAN PROGRAM

(1) To participate in a technician check technician (TCT) program an institutional pharmacy within a hospital must meet the following requirements:

(a) the pharmacy must include TCT as a technician duty, submitted to the Board of Pharmacy by the pharmacist-in-charge as part of the technician utilization plan;

(b) develop a site-specific training program tailored to the patient population and medication distribution system;

(c) designate one pharmacist to be responsible for meeting the TCT program training and validation requirements;

(d) staffing must be adequate to support a consistent utilization of the TCT program;

(e) a pharmacist must review all orders against a medication profile containing pertinent clinical information about the patient (allergies, current medication, etc.);

(f) the medication description on the batch fill list must contain the same description as the labeling on the unit dose package;

(g) the drug distribution system must be structured so that at least one additional check of dispensed medications is completed prior to administration;

(h) develop policies and procedures which include a list of the types of work that a technician may check and the types of work that are excluded from being checked by a technician; and

(i) utilize the TCT program as a tool to redirect pharmacists from distributive tasks to cognitive and patient centered activities.

(2) In order to participate in a TCT program a technician must:

(a) be a registered pharmacy intern in good standing with the board with at least three months experience in unit dose filling; or

(b) be a certified pharmacy technician in good standing with the board working full or part time with six months equivalent experience in unit dose filling; and

(c) complete site specific training in the TCT program.

(3) A TCT training program must include:

(a) didactic lecture (or equivalent training with a self-learning packet);

(b) practical sessions (one-on-one training) which consist of observation of a pharmacist checking a unit dose medication batch and/or cart;

(c) initial validation (and revalidation if needed); and

(d) regular quality assurance audits performed quarterly for the first year then every six months thereafter.

(4) Approval from the Board of Pharmacy or designee is required prior to program implementation.

(5) If at any time a technician loses their validation, that individual must not function as a TCT until they are retrained and revalidated.

(6) All TCT program materials should be readily retrievable for review by the board inspector.

(7) Any facility that is not within an institutional pharmacy within a hospital must come before the board.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, 37-7-201, 37-7-301, 37-7-307, MCA

History: NEW, 2007 MAR p. 1936, Eff. 11/22/07.

24.174.801 GENERAL LICENSE REQUIREMENTS

(1) The board shall issue a license for the operation of a pharmacy in the state of Montana when:

(a) the owner of the pharmacy is a registered pharmacist in good standing in the state of Montana; or

(b) the manager or supervisor of the pharmacy is a registered pharmacist in good standing in the state of Montana and that the pharmacist will be actively and regularly engaged and employed in, and responsible for the management, supervision and operation of such pharmacy.

(2) The license registers the pharmacy to which it is issued and is not transferable. It is issued on the application of the registered pharmacist in charge, and which contains the sworn statement that the pharmacy will be operated in accordance with the provisions of the law.

(3) To operate, maintain, open, or establish more than one pharmacy, separate applications shall be made and separate licenses issued for each.

(4) No license may be issued whose intended place of business is a personal residence.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-321, MCA

History: NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 970, Eff. 3/14/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.802 NEW PHARMACY

(1) Prior to conducting business, a pharmacy must secure a license and be registered with the board. Application for a license to operate a new pharmacy must be reviewed by the board or its designee before the license may be issued.

(2) A corporation or unregistered owner, may secure a license on the affidavit of the registered pharmacist charged with the management and supervision of the pharmacy.

(3) All new pharmacies shall be in compliance with ARM 24.174.801 and 24.174.814 at the time the pharmacy is opened for business.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-321, MCA

History: NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 970, Eff. 3/14/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.803 CHANGE IN LOCATION

(1) Whenever a facility licensed by the board changes its physical location, including within the existing business location, it shall submit a new schematic or floor plan, for board approval.

(2) Whenever a facility changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. A new license application, including a new schematic and floor plan of the new location, shall be submitted for the board's approval at least 30 days before such change occurs.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-321, MCA

History: NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 970, Eff. 3/14/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.804 CHANGE IN OWNERSHIP

(1) When a pharmacy, or other facility licensed by the board, changes ownership, a new license must be obtained by the new owner or owners. The owner shall submit a new license application at least 30 days prior to the change in ownership. The application must be reviewed by the board or its designee before the license may be issued. The original license will expire at the time of license renewal unless the board is notified of an alternative closure date.

(2) A change in ownership for the purposes of this rule shall be deemed to occur when more than 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

(3) A change due to corporate restructuring or business structure for legal or tax purposes does not constitute an ownership change unless the provisions of (2) are met. The licensee shall notify the board of the change but a new application and license are not required.

(4) The board must be notified in writing when five to 50 percent of the equitable ownership of a facility business license is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-321, MCA

History: NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 970, Eff. 3/14/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.805 CHANGE OF PHARMACIST-IN-CHARGE OR PERSON-IN-CHARGE

(1) When service as the pharmacist-in-charge of a pharmacy ends, the pharmacist is responsible for notifying the board in writing of such termination of services.

(2) Within ten days of termination of services of the pharmacist-in-charge, a new pharmacist-in-charge must be designated in writing on the appropriate board-approved form and filed with the board.

(3) The requirements in (1) and (2) apply to a person-in-charge for other facilities licensed by the board for which a pharmacist is not required to be the person-in-charge.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-321, MCA

History: NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 970, Eff. 3/14/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2010 MAR p. 2968, Eff. 12/24/10; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.806 FACILITY LICENSES TO BE POSTED

(1) The pharmacy license or other facility license issued by the board must be posted in a conspicuous place in the facility.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-321, MCA

History: NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 970, Eff. 3/14/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.807 CLOSURE OF A FACILITY

(1) Upon permanent closure of a pharmacy or other facility licensed by the board, the original license becomes void.

(2) Whenever a facility permanently closes, the owner shall notify the board of the closing no later than 15 days prior to the anticipated date of closing. The notice shall be submitted in writing and shall include the following information:

(a) the date of closure;

(b) the names and addresses of the persons who will have custody of the closing pharmacy's:

(i) prescription files;

(ii) bulk compounding records;

(iii) repackaging records; and

(iv) controlled substance inventory records.

(c) the names and addresses of any persons who will acquire any prescription drugs from the closing facility, if known at the time the notice is filed; and

(d) the name and phone number of the property owner.

(3) No later than 15 days after the facility has closed, the owner shall submit to the board written confirmation that:

(a) all prescription drugs have been either:

(i) destroyed; or

(ii) transferred to an authorized person(s), including the names and addresses of the person(s) to whom the prescription drugs were transferred.

(b) controlled substances were transferred, including:

(i) names and addresses of the person(s) to whom the substances were transferred;

(ii) the substances transferred;

(iii) the amount of each substance transferred; and

(iv) the date on which the transfer took place.

(c) the DEA registration and all unused DEA 222 forms (order forms) were returned to the DEA;

(d) all facility labels and blank prescriptions which were in the possession of the facility were destroyed;

(e) all signs and symbols indicating the presence of the facility have been removed; and

(f) all contents of medication collection receptacles or disposal kiosks, if any, have been shipped and the containers have been removed.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-321, MCA

History: NEW, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.810 CLASS I FACILITY

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201 (2), 37-7-321 (2), MCA

History: NEW, Eff. 3/21/71; AMD, Eff. 8/4/76; AMD, Eff. 1/31/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic. , Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904; REP, 2002 MAR p. 3605, Eff. 12/27/02.

24.174.811 CLASS II FACILITY

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201 (2), 37-7-321 (2), MCA

History: NEW, Eff. 3/21/71; AMD, Eff. 8/4/76; AMD, Eff. 1/31/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic. , Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904; REP, 2002 MAR p. 3605, Eff. 12/27/02.

24.174.812 CLASS III FACILITY

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201 (2), 37-7-321 (2), MCA

History: NEW, Eff. 3/21/71; AMD, Eff. 8/4/76; AMD, Eff. 1/3/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic. , Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904; REP, 2002 MAR p. 3605, Eff. 12/27/02.

24.174.813 CLASS IV FACILITY

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-321, MCA

History: NEW, Eff. 3/21/71; AMD, Eff. 8/4/76; AMD, Eff. 1/31/77; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; TRANS, from Commerce, 2002 MAR p. 904; REP, 2012 MAR, p. 896, Eff. 4/27/12.

24.174.814 SECURITY OF PHARMACY AND RECORDS

(1) Each pharmacist, while on duty, shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of drugs.

(a) A Schedule II controlled substance perpetual inventory shall be maintained and routinely reconciled in all pharmacies.

(2) The pharmacy shall be secured at all times by either a physical barrier with suitable locks and/or an electronic barrier to detect entry by unauthorized persons at any time. Such barrier shall be approved by the board or its designee before being put into use.

(3) Prescription and other patient health care information shall be maintained in a manner that protects the integrity and confidentiality of such information as provided by the rules of the board.

(4) An automated prescription record keeping system(s) (system) may be employed for prescription record keeping.

(a) The system shall contain adequate safeguards or security of the records to maintain the confidentiality and accuracy of the prescription or drug order information. Safeguards against unauthorized changes in data after the information has been entered and verified by the registered pharmacist shall be provided by the system.

(b) The system must comply with all applicable state and federal privacy and security requirements.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2002 MAR p. 794, Eff. 2/1/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.817 AUTOMATED RECORD KEEPING SYSTEMS (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 1985 MAR p. 1017, Eff. 7/26/85; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2010 MAR p. 74, Eff. 1/15/10; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.818 SECURITY (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 1985 MAR p. 1017, Eff. 7/26/85; TRANS, from Commerce, 2002 MAR p. 904; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.819 SANITATION AND EQUIPMENT REQUIREMENTS

(1) Pharmacies shall at all times be operated by a registered pharmacist in a sanitary manner, pursuant to 50-31-103 and 50-31-305, MCA. There must be in use a safe and pure water supply and facilities for the proper storage and handling of supplies and stocks.

(2) Pharmacies shall have adequate space where prescriptions are filled or drugs compounded, containing suitable equipment in order to provide for an efficient pharmacy operation.

(3) Pharmacies shall contain and have ready for use all up-to-date items which are necessary in filling prescriptions, compounding drugs and the efficient operation of the pharmacy.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 970, Eff. 3/14/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1983 MAR p. 344, Eff. 4/29/83; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.822 CENTRAL FILLING BY HUB PHARMACIES

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-321, MCA

History: NEW, 2006 MAR p. 1615, Eff. 6/23/06; REP, 2007 MAR p. 1936, Eff. 11/22/07.

24.174.823 CENTRALIZED FILLING AND REMOTE ORDER PROCESSING OF PRESCRIPTIONS IN COMMUNITY PHARMACIES

(1) Central or remote prescription processing services may be utilized by a licensed pharmacy if the following conditions have been met:

(a) remote licensed staff must be licensed in Montana as a pharmacist or a pharmacy technician or, if located out-of-state, be licensed in their home state and work under the authority of a pharmacy licensed in Montana pursuant to (8); and

(b) policies and procedures must be in place for remote licensed staff working off-site to process prescriptions or other applicable duties to ensure appropriate tasks, security, and privacy provisions are met. The policies and procedures shall:

(i) be reviewed and documented annually;

(ii) include a continuous quality improvement program;

(iii) comply with federal and state statutes and regulations; and

(iv) be available for inspection by the board.

(2) A pharmacy that outsources prescription filling or processing to another pharmacy shall, prior to outsourcing a prescription:

(a) notify the patient or the patient's agent that prescription filling or processing may be outsourced to another pharmacy and accommodate patient choice not to have the prescription outsourced;

(b) provide the name of the pharmacy that will be filling or processing the prescription or, if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may fill or process the prescription, the patient shall be notified of this fact; and

(c) clearly show the name, address, and telephone number of the delivering pharmacy on the prescription container.

(3) Each pharmacy engaging in centralized prescription processing shall be jointly responsible for properly filling the prescription.

(4) The delivering pharmacy is responsible for providing patient counseling. All central filling of prescriptions must be completed in a licensed pharmacy.

(5) Pharmacies providing central processing or central filling services to pharmacies in the state of Montana must be licensed in Montana.

(6) An out-of-state pharmacy providing central processing or central filling services to pharmacies in the state of Montana must be registered as an out-of-state mail service pharmacy and comply with all Montana statutes and rules.

(7) Policies and procedures relating to centralized filling or processing activities shall be maintained at all pharmacies involved in centralized filling or processing and shall be available for inspection by the board. The policies and procedures shall:

(a) include the annual review of the competencies of pharmacists providing remote and/or centralized prescription processing or filling services;

(b) be reviewed and documented annually;

(c) include a continuous quality improvement program;

(d) comply with federal and state statutes and regulations; and

(e) be available for inspection by the board.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-321, MCA

History: NEW, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.830 LIMITED SERVICE PHARMACY

(1) A limited service pharmacy is defined as a family planning clinic:

(a) operating under contract with the state to provide such services; or

(b) providing pharmaceutical care under the review of a consulting pharmacist and dispensing prescription drugs, but which is not under contract with the state.

(2) Each limited service pharmacy must apply for a license from the board and submit the required fee for each separate location.

(3) A limited service pharmacy must display its license in a conspicuous place at the facility.

(4) A limited service pharmacy is not required to employ a licensed pharmacist.

(5) A limited service pharmacy dispensing prescription drugs other than factory, prepackaged contraceptives must disclose the name, address, telephone number, and title of the designated person-in-charge of the limited service pharmacy.

(a) The person-in-charge is responsible for the limited service pharmacy's compliance with all applicable state and federal statutes and rules.

(b) A person-in-charge may be responsible for multiple sites.

(6) The board may annually inspect limited service pharmacies. The board may inspect more often for cause. Such inspections must include assurance that the limited service pharmacy provides adequate:

(a) drug labeling;

(b) counseling materials to all patients, including the name of the limited service pharmacy's consulting pharmacist, where required;

(c) contact information of a knowledgeable individual at the clinic in the event of an adverse reaction;

(d) records maintenance and retention; and

(e) drug storage and security.

(7) Nothing in this rule is meant to limit or restrict the authority of a registered nurse employed by a family planning clinic, operating under contract with the state, from dispensing factory, prepackaged contraceptives as authorized by 37-2-104, 37-7-103, or 50-31-307, MCA.

(8) A registered nurse or provider with prescriptive authority, employed by a family planning clinic operating under contract with the state, may dispense medications used to treat sexually transmitted diseases, including but not limited to conditions listed in 50-16-1004 and 50-18-101, MCA, and to a sexual contact or partner of a patient diagnosed with a sexually transmitted disease. All appropriate records shall be maintained on-site.

(9) The medications dispensed must:

(a) be prepackaged and properly labeled in accordance with state law;

(b) include appropriate counseling materials informing the patient of the potential risks involved in taking the drug; and

(c) contain contact information for the healthcare provider or a consulting pharmacist to provide advice or answer questions.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-321, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.831 PRESCRIPTION REQUIREMENTS

(1) Prescriptions shall include, but not be limited to:

(a) patient's name;

(b) name of drug, device, or biological;

(c) strength of drug or biological, if applicable;

(d) dosage form of drug or biological, if applicable;

(e) quantity of drug, device, or biological prescribed;

(f) directions for use;

(g) date of issuance;

(h) prescriber's name;

(i) number of refills authorized.

(2) A prescription and any refills for a non-controlled drug, device, or biologic are valid for one year from date of issuance.

(3) Prescriptions shall comply with all federal DEA requirements for prescriptions, dispensing, and refills of controlled substance in Schedules II, III, IV, and V, pursuant to 21 CFR 1306.

(4) If the prescription is written, it must contain the prescriber's hand-written signature the name of the prescriber stamped, typed, printed, or clearly handwritten in addition to the signature, must be tamper-resistant, and contain:

(a) one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;

(b) one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription pad by the prescriber; and

(c) one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

(5) if the prescription is for a controlled substance, all state and federal requirements must be met, and the following additional information is required to be on the prescription:

(a) patient's address;

(b) prescriber's address; and

(c) prescriber's DEA registration number.

(6) Prescription or refill authorization issued by a prescriber may be communicated to a pharmacist or a pharmacist intern by an employee or agent of the prescriber.

(7) "Brand name medically necessary" shall be handwritten (or printed if electronically generated) on the face of the prescription if it is medically necessary that an equivalent drug product not be selected.

(8) Prescription records may be electronically stored and maintained if they remain legible and are in a readily retrievable format, and if federal law does not require them to be kept in a hard copy format, pursuant to DEA requirements in 21 CFR 1304.06.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-505, MCA

History: NEW, 1985 MAR p. 1017, Eff. 7/26/85; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2010 MAR p. 74, Eff. 1/15/10; AMD, 2011 MAR p. 1148, Eff. 6/24/11; AMD and TRANS, from ARM 24.174.510, 2015 MAR p. 302, Eff. 3/27/15; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.832 LABELING FOR PRESCRIPTIONS

(1) On prescription drugs, the label shall contain the name, address and phone number of the dispenser, name of prescriber, name of patient, name and strength of the drug, directions for use and date of filling.

(2) The prescription label must be securely attached to the outside of the container in which the prescription is dispensed, with the exception of medical oxygen.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, Eff. 7/19/68; AMD, 1978 MAR p. 393, Eff. 3/25/78; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2001 MAR p. 783, Eff. 5/11/01; TRANS, from Commerce, 2002 MAR p. 904; TRANS, from ARM 24.174.511, 2015 MAR p. 302, Eff. 3/27/15; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.833 RECORDS OF DISPENSING, PURCHASES, AND DISTRIBUTION

(1) Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for at least two years and shall include, but not be limited to:

(a) quantity dispensed, if different;

(b) date of dispensing;

(c) prescription number or equivalent if an institution;

(d) the identification of the pharmacist responsible for dispensing;

(e) documentation of satisfaction of state requirements for drug product selection;

(f) records of refills to date; and

(g) if the pharmacy is distributing to another licensee through wholesale distribution activities, the invoice number and invoice, and, pursuant to 21 CFR 205.50, retain distribution records for three years.

(2) All records must be available for printing and available for inspection by the board.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 1985 MAR p. 1017, Eff. 7/26/85; TRANS, from Commerce, 2002 MAR p. 904; TRANS, from ARM 24.174.512, 2015 MAR p. 302, Eff. 3/27/15; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.834 COPY OF PRESCRIPTION (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, MCA

History: NEW, Eff. 6/7/66; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; TRANS, from ARM 24.174.513, 2015 MAR p. 302, Eff. 3/27/15; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.835 TRANSFER OF PRESCRIPTIONS

(1) The transfer of prescription information for the purpose of dispensing is permissible between pharmacies subject to DEA regulations and the following requirements:

(a) the transfer is communicated directly between two licensed pharmacists/interns, or is faxed or electronically transmitted by a pharmacy technician under the direct supervision of a pharmacist; and

(b) a retrievable audit trail, including the date of transfer and initials or code of the transferring parties, is maintained for a period of two years; and

(c) the transfer of pertinent and necessary patient records to another licensed pharmacy, when requested by the patient or the patient's legally designated representative, is completed in a timeline that meets patient safety and health needs, subject to the pharmacist's professional judgment.

(2) The transferring pharmacy shall:

(a) render the prescription void; and

(b) enter the name, address, and DEA number if required of the receiving pharmacy into the database of the transferring pharmacy.

(3) The receiving pharmacy shall maintain documentation including:

(a) a notation that the prescription was received by transfer;

(b) the date on which the prescription was written;

(c) the original prescription number of the transferred prescription;

(d) the original number of refills, number of refills or quantity remaining, and the date of the most recent refill;

(e) the name, address, and DEA number if required of the transferring pharmacy;

(f) all other prescription information required by state and federal laws and regulations; and

(g) a record of each prescription transferred.

(4) Two or more pharmacies sharing common electronic files to maintain dispensing information are not required to transfer prescription information between these pharmacies, provided all common electronic files maintain complete and accurate records of each prescription and refill dispensed, and the total number of refills authorized is not exceeded.

(a) Pharmacies sharing common electronic files shall have policies and procedures in place for handling patient exceptions.

(5) In an emergency, a pharmacy may transfer original prescription information for a noncontrolled substance to a second pharmacy for the purpose of dispensing up to a seven-day supply, without voiding the original prescription.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 1985 MAR p. 1017, Eff. 7/26/85; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD and TRANS, from ARM 24.174.514, 2015 MAR p. 302, Eff. 3/27/15; AMD, 2019 MAR p. 1633, Eff. 9/21/19; AMD, 2021 MAR p. 1671, Eff. 11/20/21; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.836 EMERGENCY PRESCRIPTION REFILLS

(1) A pharmacist may refill a prescription without practitioner authorization when:

(a) the pharmacist is unable to contact the practitioner after reasonable effort; and

(b) in the professional judgment of the pharmacist, failure to refill the prescription may result in an interruption of a therapeutic regimen or cause patient suffering.

(2) If a prescription is not refillable, a pharmacist dispensing an emergency refill:

(a) may exercise professional judgment to dispense a minimum sufficient quantity until authorization can be obtained from a prescriber;

(b) may not dispense a controlled substance prescription medication listed in Schedule II through Schedule V;

(c) must inform the patient or the patient's representative at the time of dispensing that the refill is being provided without the practitioner's authorization, and that practitioner authorization is required for any future refill;

(d) must inform the practitioner of the emergency refill at the earliest reasonable time; and

(e) must comply with all applicable record-keeping requirements.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; TRANS, from ARM 24.174.515, 2015 MAR p. 302, Eff. 3/27/15; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.837 PRESCRIPTION REQUIRED FOR SCHEDULE V

(1) All products which are presently defined as exempt narcotics (Schedule V) of the Comprehensive Controlled Substances Act, Public Law (91-513) shall require a prescription from one with the authority to prescribe.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-102, 37-7-201, MCA

History: NEW, Eff. 9/16/71; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904; TRANS, from ARM 24.174.520, 2015 MAR p. 302, Eff. 3/27/15.

24.174.838 RETURNED PRESCRIPTION

(1) In the best interest of, and for the safety and protection of public health and the pharmacy, no pharmacist shall place in stock for reuse or resale the contents of any prescription, which has been returned after leaving the pharmacy except as provided in ARM 24.174.1141.

Authorizing statute(s): 37-7-201, 37-7-1401, MCA

Implementing statute(s): 37-7-201, 37-7-1401, MCA

History: NEW, Eff. 6/12/57; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; TRANS, from ARM 24.174.521, 2015 MAR p. 302, Eff. 3/27/15.

24.174.839 ALTERNATE DELIVERY OF PRESCRIPTIONS

(1) Under the provisions of 37-7-301, MCA, it shall be deemed a violation of the pharmacy law for any person or corporation holding a pharmacy license to participate in any arrangement or agreement whereby prescriptions may be left at, picked up from, accepted by or delivered to any store, shop or any other establishment not licensed by the board as a "pharmacy".

(a) Nothing in this rule shall prohibit a licensed pharmacy from picking up prescriptions or delivering prescriptions at the office or home of the prescriber, and at the residence of the patient or at the hospital in which a patient is confined, by means of an employee or a common carrier.

(b) Nothing in this rule shall prohibit a registered pharmacist from installing an appropriate secure device as an alternate delivery system, when the pharmacy is closed. The system and counseling methods must have the prior approval of the board or its designee.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-301, MCA

History: NEW, Eff. 9/24/61; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; TRANS, from ARM 24.174.522, 2015 MAR p. 302, Eff. 3/27/15.

24.174.840 ELECTRONIC TRANSMISSION OF PRESCRIPTIONS

(1) Unless otherwise prohibited by law, an electronic prescription may be transmitted from the prescriber or an authorized agent directly to the dispensing pharmacy and must contain all information required by state and federal law.

(2) Electronic prescriptions for Schedules II through V controlled substances shall comply with DEA requirements, as outlined in 21 CFR 1311.120, and any security or other requirements of federal law.

(3) All electronic prescriptions shall comply with all security requirements of state and federal law related to privacy of protected health information.

(4) A pharmacy receiving an electronic prescription shall maintain the prescription record in accordance with ARM 24.174.833.

(5) An electronic prescription shall be transmitted only to the pharmacy of the patient's choice.

(6) Computer-generated, electronically signed prescriptions for controlled substances that are handed directly to a patient or to a patient's agent, of faxed to a pharmacy, must contain the actual signature of the prescriber, and comply with prescription requirements outlined in ARM 24.174.831 if a hard copy prescription. Computer-generated, electronically signed prescriptions for noncontrolled substances do not require an additional wet signature.

Authorizing statute(s): 37-7-201, 50-32-103, MCA

Implementing statute(s): 37-1-101, 37-7-102, 37-7-201, 50-32-208, MCA

History: NEW, 1995 MAR p. 2689, Eff. 12/8/95; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2010 MAR p. 74, Eff. 1/15/10; AMD, 2012 MAR p. 896, Eff. 4/27/12; AMD and TRANS, from ARM 24.174.523, 2015 MAR p. 302, Eff. 3/27/15; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.841 STERILE PRODUCTS

(1) Policies and procedures must be prepared for the compounding, dispensing, delivery, administration, storage, and use of sterile pharmaceutical products. The policies must include a quality assurance program for monitoring personnel qualifications and training in sterile technique, product storage, stability standards, and infection control. Policies and procedures must be current and available for inspection by a designee of the Board of Pharmacy.

(2) An institutional pharmacy compounding sterile products must have an isolated area designed to avoid unnecessary traffic and airflow disturbances.

(3) An institutional pharmacy compounding sterile products must utilize an appropriate aseptic environmental control device such as a laminar flow biological safety cabinet capable of maintaining Class 100 conditions during normal activity, or have policies and procedures in place limiting the pharmacy's scope of sterile product preparation.

(4) An institution preparing cytotoxic drugs must have a vertical flow Class II biological safety cabinet. Cytotoxic drugs must be prepared in a vertical flow Class II biological safety cabinet.

(a) Protective apparel including nonvinyl gloves, gowns, and masks must be available, and gloves must be worn at all times.

(b) Appropriate containment techniques must be used in addition to aseptic techniques required for sterile product preparation.

(c) Prepared doses of cytotoxic drugs must be clearly identified, labeled with proper precautions, and dispensed in a manner to minimize risk of cytotoxic spills.

(d) Disposal of cytotoxic waste must comply with all applicable local, state, and federal laws.

(e) Written procedures for handling cytotoxic spills must be included in the policies and procedures manual.

(5) All parenteral admixtures must be labeled with date of preparation and expiration date clearly indicated, patient name and room number, name and strength and/or amount of drug and base solution, and any special handling or storage instructions.

(6) All aseptic environmental control devices must be certified by an independent contractor for operational efficiency at least every 12 months or when relocated, according to Federal Standard 209E. Prefilters must be inspected periodically and replaced if needed.

(7) Inspection and replacement dates must be documented and maintained for a period of at least two years.

(8) Documented records of ongoing quality assurance programs, justification of expiration dates chosen, and employee training records and technique audits must be available for inspection by the Board of Pharmacy.

(9) The board expects pharmacies/pharmacists engaged in compounding to have policies and procedures to adhere to those guidelines that apply to their practice setting and in all situations to comply with the spirit of United States Pharmacopeia (USP) Chapter 795 "Compounding Nonsterile Preparations" and USP Chapter 797 "Pharmaceutical Compounding-Sterile Preparations."

(10) Immediate use compounds defined in ARM 24.174.301(21) are prepared in an air quality environment that does not meet International Organization of Standardization (ISO) Class 5 or better conditions. A preparer of immediate use compounds is not required to wear gloves or gown if the compounds are prepared using aseptic manipulation, only sterile ingredients, products, components, and devices, and the following conditions are met:

(a) no more than three sterile ingredients, products, components, and devices are used;

(b) only simple manipulation techniques are employed;

(c) the preparer completes the preparation without interruption and with no direct contact contamination;

(d) the administration must begin within one hour of preparation;

(e) if prepared by someone other than the person who will administer the drug, labeling must include patient name, name and quantity of ingredients, name of person who prepared it, and exact one hour "beyond use date"; and

(f) preparations do not involve the use of hazardous materials.

(11) Multi-dose vial defined in ARM 24.174.301(29) may be used until the expiration date noted on the vial. The beyond use date (BUD) may be up to one month or the manufacturer's assigned BUD, whichever is shorter from the time of initial entry, in accordance with the pharmacy policies and procedures.

(12) A same-day use product, defined in ARM 24.174.301(41), that is prepared using aseptic manipulation in a controlled environment with ISO 5 or better class air quality conditions, using only sterile ingredients, products, components, and devices, may be classified as low- or medium-risk provided that it meets all of the following conditions:

(a) only simple manipulation techniques employed;

(b) the environment meets or exceeds the following conditions:

(i) the mixing cabinet is located in an area that restricts airflow to prevent drafts and reduce particle counts;

(ii) there is a partitioned area around the mixing cabinet to create a buffer zone, which must be at least the width of the hood in front of the mixing cabinet; and

(iii) the buffer zone must be clearly identified to prevent cardboard or outer packing material intruding into the buffer zone and to prevent any intrusion during the compounding process.

(c) the environment is cleaned daily;

(d) batch preparation will not exceed eight CSPs;

(e) administration of the preparation must begin within 24 hours of preparation; and

(f) the preparer must use gloves, shoe covers or dedicated shoes, hair covers, gown, and a mask.

(13) The beyond use date (BUD), as defined in ARM 24.174.301(2), for a single-dose vial:

(a) shall be no greater than one hour from the time of initial entry if accessed in an environment of less than ISO 5; or

(b) may be up to 24 hours from the time of initial entry if appropriately stored and accessed only in an environment equal to or better than ISO 5.

(14) Low-risk and medium-risk level compounded sterile preparation (CSP) is determined by the potential for microbial contamination during preparation, and high-risk level CSP by the potential for not being properly sterilized before administration to patients.

(a) Low-risk conditions:

(i) CSPs prepared using aseptic manipulation with an air quality environment that is equal to or better than ISO Class 5, using only sterile ingredients, products, components, and devices;

(ii) no more than three commercially manufactured sterile products and entries into one container of sterile product during preparation;

(iii) manipulations limited to:

(A) aseptically opening ampoules;

(B) penetrating sterile stoppers on vials with sterile needles and syringes; and

(C) transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and sterile containers for storage and dispensing.

(iv) in the absence of sterility testing, preparations must be properly stored prior to administration as follows:

(A) BUD less than or equal to 48 hours at controlled room temperature;

(B) BUD up to 14 days under refrigeration; or

(C) BUD up to 45 days in solid frozen state at minus 20 degrees centigrade.

(b) Medium-risk conditions:

(i) CSPs compounded aseptically under low-risk conditions, but with the addition of one or more of the following conditions:

(A) multiple individual or small doses of sterile precuts are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions;

(B) the compounding process includes complex aseptic manipulations other than single volume transfer; or

(C) the compounding process requires unusually long duration, such as that required to complete dissolution or homogenous mixing.

(ii) In the absence of sterility testing, preparations must be properly stored prior to administration as follows:

(A) BUD less than or equal to 30 hours at controlled room temperature;

(B) BUD up to nine days under refrigeration; or

(C) BUD up to 45 days in solid frozen state at minus 20 degrees centigrade.

(c) High-risk conditions:

(i) CSPs compounded from nonsterile ingredients including products manufactured for other routes of administration, or a nonsterile device is employed before terminal sterilization;

(ii) exposure to an air quality environment that does not meet ISO 5 or better conditions for more than one hour for any of the following:

(A) sterile contents of commercially manufactured products;

(B) CSPs that lack effective antimicrobial preservatives; or

(C) sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.

(iii) Prior to terminal sterilization:

(A) nonsterile procedures including weighing and mixing occur in an air quality environment that does not meet ISO 7 or better conditions;

(B) compounding personnel are improperly gloved or garbed; or

(C) water containing preparations are stored for more than six hours.

(iv) in the absence of sterility testing, preparations must be properly stored prior to administration as follows:

(A) BUD less than or equal to 24 hours at controlled room temperature;

(B) BUD up to three days under refrigeration; or

(C) BUD up to 45 days in solid frozen state at minus 20 degrees centigrade.

(v) all nonsterile devices must be rinsed thoroughly with sterile, pyrogen-free water, then thoroughly drained or dried immediately before use.

(vi) terminal sterilization is required as follows:

(A) CSP solutions passed through a filter with a nominal porosity not larger than 1.2 micron preceding or during filling into their final containers to remove particulate matter; or

(B) sterilization of high-risk level CSPs by filtration must be performed with a sterile 0.22 micron pore filter entirely within an air quality environment better than or equal to ISO 5.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-307, 37-7-308, MCA

History: NEW, 2002 MAR p. 3605, Eff. 12/27/02; AMD and TRANS, from ARM 24.174.1121, 2015 MAR p. 302, Eff. 3/27/15.

24.174.842 POSITIVE IDENTIFICATION FOR CONTROLLED SUBSTANCE PRESCRIPTIONS

(1) The board authorizes the following allowable identifications in addition to those listed in 37-7-410, MCA:

(a) a valid government-issued photo identification, including but not limited to passport, military, or state-issued identification.

Authorizing statute(s): 37-7-201, 37-7-410, MCA

Implementing statute(s): 37-7-410, MCA

History: NEW, 2020 MAR p. 43, Eff. 1/18/20.

24.174.901 PATIENT RECORDS AND DRUG UTILIZATION REVIEW

(1) A patient record system shall be maintained by all pharmacies for patients for whom prescriptions are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription is presented for dispensing. The pharmacist or pharmacy technician shall make a reasonable effort to obtain, record, and maintain the following information:

(a) full name of the patient;

(b) address and telephone number of the patient;

(c) patient's age or date of birth;

(d) patient's gender;

(e) known allergies or drug intolerances;

(f) chronic conditions;

(g) other prescription or non-prescription medications; and

(h) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) A pharmacist shall review the patient record and complete a drug utilization review as defined in 37-7-101, MCA. Upon recognizing any potential therapeutic problems, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber.

(3) A patient record shall be maintained for a period of not less than two years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-406, MCA

History: NEW, 1993 MAR p. 293, Eff. 2/26/93; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.902 PROSPECTIVE DRUG REVIEW (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-406, MCA

History: NEW, 1993 MAR p. 293, Eff. 2/26/93; TRANS, from Commerce, 2002 MAR p. 904; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.903 PATIENT COUNSELING

(1) Upon receipt of a new, refill, or transfer prescription if deemed necessary by the pharmacist, each patient or caregiver, agent, or representative of the patient shall be offered the opportunity to discuss matters which will enhance or optimize drug therapy with the pharmacist. The discussion shall be in person, whenever practicable, or by telephone, and shall include appropriate elements of patient counseling. Pharmacy personnel may make the offer to counsel, but the pharmacist must personally conduct the counseling.

(2) Each pharmacy shall have at least one area that offers appropriate visual and auditory patient confidentiality for patient counseling.

(3) Alternative forms of patient information shall be used to supplement patient counseling when appropriate and when required. Examples include written information leaflets, pictogram labels, video programs, QR codes, etc. The pharmacy shall provide medication guides or confirm patient access to the medication guides and/or patient package inserts, comply with risk evaluation and mitigation strategies, and/or other labeling requirements as required by the U.S. Food and Drug Administration.

(4) Patient counseling, as described above and defined in this Act shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s). Any pharmacist dispensing medication to be self-administered outside an institution shall comply with all patient counseling statutes and rules.

(5) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses consultation. A record of the refusal shall be maintained.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-406, MCA

History: NEW, 1993 MAR p. 293, Eff. 2/26/93; AMD, 2000 MAR p. 2005, Eff. 7/28/00; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2015 MAR p. 302, Eff. 3/27/15; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1001 REGISTRATION OF OUT-OF-STATE MAIL SERVICE PHARMACIES

(1) No out-of-state pharmacy shall ship, mail or deliver prescription drugs and/or devices to a patient in this state unless registered by the Montana Board of Pharmacy.

Authorizing statute(s): 37-7-712, MCA

Implementing statute(s): 37-7-703, MCA

History: NEW, 1994 MAR p. 571, Eff. 3/18/94; AMD, 1996 MAR p. 1297, Eff. 5/10/96; TRANS, from Commerce, 2002 MAR p. 904.

24.174.1002 CONDITIONS OF REGISTRATION

(1) As conditions of registration, the out-of-state mail service pharmacy must comply with the following:

(a) be a legal entity registered and in good standing with the Montana Secretary of State with a registered agent in Montana for service of process designated;

(b) be registered and in good standing with the National Association of Boards of Pharmacy verified internet pharmacy practice sites (VIPPS) if registered after June 1, 2001;

(c) maintain, in readily retrievable form, records of legend drugs and/or devices dispensed to Montana patients;

(d) supply upon request, all information needed by the Montana Board of Pharmacy to carry out the board's responsibilities under the statutes and regulations pertaining to out-of-state mail service pharmacies;

(e) maintain pharmacy hours that permit the timely dispensing of drugs to Montana patients and provide reasonable access for the Montana patients to consult with a licensed pharmacist about such patients' medications;

(f) provide toll-free telephone communication consultation between a Montana patient and a pharmacist at the pharmacy who has access to the patient's records, and ensure that said telephone number(s) will be placed upon the label affixed to each legend drug container. A toll-free telephone number shall also be provided to the board to allow for compliance with all information requests by the board.

Authorizing statute(s): 37-7-201, 37-7-712, MCA

Implementing statute(s): 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-706, MCA

History: NEW, 1994 MAR p. 571, Eff. 3/18/94; AMD, 1996 MAR p. 1297, Eff. 5/10/96; AMD, 2001 MAR p. 783, Eff. 5/11/01; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2010 MAR p. 74, Eff. 1/15/10.

24.174.1003 IDENTIFICATION OF PHARMACIST-IN-CHARGE OF DISPENSING TO MONTANA

(1) Each out-of-state mail service pharmacy that ships, mails, delivers prescription drugs and/or devices and oversees the pharmacy services provided to patients in Montana shall identify a pharmacist-in-charge of dispensing prescriptions for shipment to Montana and oversee the pharmacy services provided. Each pharmacist so identified shall meet the following requirements:

(a) be licensed in good standing in the state in which the out-of-state mail service pharmacy is located;

(b) be properly listed on the application form prescribed by the board;

(c) comply with all applicable Montana laws and rules; and

(d) notify the Montana board promptly in writing of any changes in the licensure status of the pharmacist-in-charge and any disciplinary actions initiated and/or finalized against the pharmacist's license.

(2) When the pharmacist-in-charge of an out-of-state mail service pharmacy ceases to be the pharmacist-in-charge, the pharmacist will be held responsible for notifying the board in writing of such termination of services.

(3) Within 72 hours of termination of services of the pharmacist-in-charge, a new pharmacist-in-charge must be designated in writing on the appropriate board-approved form and filed with the board.

Authorizing statute(s): 37-7-201, 37-7-712, MCA

Implementing statute(s): 37-7-101, 37-7-201, 37-7-703, MCA

History: NEW, 1994 MAR p. 571, Eff. 3/18/94; AMD, 1996 MAR p. 1297, Eff. 5/10/96; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2010 MAR p. 2968, Eff. 12/24/10; AMD, 2012 MAR p. 896, Eff. 4/27/12.

24.174.1004 CHANGE IN LOCATION

(1) Whenever a mail service pharmacy changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. The mail service pharmacy shall submit a new license application for the new location at least 30 days before such change occurs.

Authorizing statute(s): 37-7-201, 37-7-712, MCA

Implementing statute(s): 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-706, MCA

History: NEW, 2007 MAR p. 1936, Eff. 11/22/07.

24.174.1005 CHANGE IN OWNERSHIP

(1) When a mail service pharmacy changes ownership, the original license becomes void and must be surrendered to the board, and a new license obtained by the new owner. The owner shall submit a new license application at least 30 days prior to the change in ownership.

(2) A change in ownership for the purposes of this rule shall be deemed to occur when more than 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

(3) The board must be notified in writing when five to 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

Authorizing statute(s): 37-7-201, 37-7-712, MCA

Implementing statute(s): 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-706, MCA

History: NEW, 2007 MAR p. 1936, Eff. 11/22/07.

24.174.1007 AGENT OF RECORD

(REPEALED)

Authorizing statute(s): 37-7-712, MCA

Implementing statute(s): 37-7-703, MCA

History: NEW, 1994 MAR p. 571, Eff. 3/18/94; AMD, 1996 MAR p. 1297, Eff. 5/10/96; TRANS, from Commerce, 2002 MAR p. 904; REP, 2010 MAR p. 74, Eff. 1/15/10.

24.174.1008 USE OF PHARMACY TECHNICIANS BY OUT-OF-STATE MAIL SERVICE PHARMACIES

(1) Any application for out-of-state mail service pharmacy registration from a facility located in a state which does not regulate the use of pharmacy technicians 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.

(2) Any application for out-of-state mail service pharmacy licensure from a facility located in a state which does regulate the use of pharmacy technicians shall provide information on the supervisor to technician ratio allowed in the resident state, and submit a utilization plan for the employment of pharmacy technicians.

Authorizing statute(s): 37-7-712, MCA

Implementing statute(s): 37-7-703, MCA

History: NEW, 1994 MAR p. 571, Eff. 3/18/94; AMD, 1996 MAR p. 1297, Eff. 5/10/96; TRANS, from Commerce, 2002 MAR p. 904.

24.174.1009 COMPLIANCE

(1) Each out-of-state mail service pharmacy shall comply with the following:

(a) all statutory and regulatory requirements of the state of Montana for controlled substances, including those that are different from federal law or regulation, unless compliance would violate the pharmacy drug laws or regulations of the state in which the pharmacy is located;

(b) all statutory and regulatory requirements of the state of Montana regarding drug product selection laws, unless compliance would violate the laws or regulations of the state in which the pharmacy is located;

(c) labeling of all prescriptions dispensed, to include but not be limited to identification of the product and quantity dispensed;

(d) all the statutory and regulatory requirements of the state of Montana for dispensing prescriptions in accordance with the quantities indicated by the prescriber, unless compliance would violate laws or regulations of the state in which the pharmacy is located.

Authorizing statute(s): 37-7-712, MCA

Implementing statute(s): 37-7-701, 37-7-703, MCA

History: NEW, 1994 MAR p. 571, Eff. 3/18/94; AMD, 1996 MAR p. 1297, Eff. 5/10/96; TRANS, from Commerce, 2002 MAR p. 904.

24.174.1010 DISCIPLINARY ACTION

(REPEALED)

Authorizing statute(s): 37-7-712, MCA

Implementing statute(s): 37-7-703, 37-7-704, 37-7-711, MCA

History: NEW, 1994 MAR p. 571, Eff. 3/18/94; AMD, 1996 MAR p. 1297, Eff. 5/10/96; TRANS, from Commerce, 2002 MAR p. 904; REP, 2011 MAR p. 1148, Eff. 6/24/11.

24.174.1101 PERSONNEL

(1) Each institutional pharmacy must be directed by a pharmacist-in-charge who is licensed to engage in the practice of pharmacy in Montana and who is responsible for the storage, compounding, repackaging, dispensing, and distribution of drugs within the facility. Depending upon the needs of the facility, pharmacy services may be provided on a full or part-time basis, with a mechanism for emergency service provided at all times. Contractual providers of pharmacy services shall meet the same requirements as pharmacies located within the institution.

(2) Registered pharmacy technicians or technicians-in-training may be utilized pursuant to the written policies and procedures of the institutional pharmacy. Exemptions to established ratios as defined in ARM 24.174.711 may be granted with board approval.

(3) Personnel shall be provided with appropriate training before beginning to prepare sterile and nonsterile compounded pharmaceuticals, including training in the theoretical principles and practical skills of aseptic manipulations when performing compounded sterile preparation (CSP). The pharmacist-in-charge shall establish pharmacy policies and procedures that contain protocols in accordance with the guidelines in the United States Pharmacopeia (USP) Chapter 797 "Pharmaceutical Compounding - Sterile Preparations" for the initial training and testing of all personnel and for annual retesting in aseptic manipulative skills for those personnel involved in low- and medium-risk compounding.

(4) Personnel involved in high-risk compounding must be retested in aseptic manipulative skills at least semi-annually.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-307, MCA

History: NEW, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2015 MAR p. 302, Eff. 3/27/15.

24.174.1104 INSTITUTIONAL PHARMACIST AND PHARMACIST-IN-CHARGE RESPONSIBILITY

(1) The pharmacy director/pharmacist-in-charge shall provide forapplicable policies and procedures to ensure:

(a) mechanisms for receiving and verifying drug orders from prescribers and evaluating them for safety and therapeutic appropriateness based on patient parameters and dosing guidelines;

(b) appropriate filling and proper labeling of all containers from which drugs are to be dispensed or administered on an inpatient or outpatient basis;

(c) a system for the admixture of parenteral products accomplished within the pharmacy, and verification that the facility's department of nursing willprovideeducation and training of nursing personnel regarding sterile technique, stability and compatibility of parenteral products not mixed within the pharmacy;

(d) appropriate clinical services and monitoring of outcomes, and the development of new areas of pharmaceutical care appropriate for that institution;

(e) a policy by which an offer is made to convey the discharge medication regimen to a patient's pharmacies;

(f) maintaining and distributing a list of emergency drugs, antidotes, and their doses throughout the institution;

(g) pharmacy participation in formulary development;

(h) participation in drug utilization review and monitoring of adverse drug reactionsand development of procedures to avoid problems identified;

(i) evaluation of reported medication errors and development of procedures to prevent those errors;

(j) proper acquisition and secure, temperature-controlledstorage of all prescription drugs;

(k) quality control of sterile and nonsterile pharmaceutical products, including procedures for identifying, removing and destroying outdated products;

(l) pharmacy safety and security;

(m) utilization of registered technicians or technicians in training;

(n) accurate distribution systems and secure,temperature-controlled storage of pharmaceutical products throughout the institution;

(o) unit-dosing of bulk pharmaceuticals, compounding and sterilization of drug products if applicable;

(p) the appropriate use, security and accountability of controlled substances;

(q) staff development and competency evaluation;

(r) maintenance of all required records; and

(s) compliance with all other requirements of the Montana Board of Pharmacy.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-307, 37-7-308, MCA

History: NEW, 2002 MAR p. 3605, Eff. 12/27/02.

24.174.1107 ABSENCE OF PHARMACIST IN INSTITUTIONAL SETTINGS

(1) During times that an institutional pharmacy does not have a pharmacist in attendance, arrangements must be made in advance by the pharmacist-in-charge for provision of drugs to the medical staff and other authorized personnel by use of night cabinets, floor stock and, in emergency circumstances, by access to the pharmacy. A mechanism for providers and nursing to obtain pharmacy consultation must be available at all times in accordance with ARM 24.174.1101.

(2) If night cabinets are used to store drugs in the absence of a pharmacist, they must be locked and sufficiently secure to deny access to unauthorized persons, and must be located outside of the pharmacy area. Contents of night cabinets must be prepackaged. Only specifically authorized personnel may obtain access by key or combination, pursuant to a valid prescription order. The pharmacist-in-charge shall, in conjunction with the appropriate committee of the facility, develop inventory listings of drugs included in these cabinets and determine who may have access.

(3) A complete verification audit of all inpatient orders and activity concerning the night cabinet or after-hours pharmacy entry must be conducted by a pharmacist, pharmacy technician, or other licensed designee of that pharmacist within 72 hours of the drugs having been removed from the night cabinet or pharmacy.

(4) Whenever any drug is not available from floor stock or night cabinets, and that drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from the pharmacy by an authorized registered nurse or licensed practical nurse in accordance with established policies and procedures. The responsible nurse shall be designated by the appropriate committee of the institutional facility.

(a) Removal of any drug from the pharmacy, floor stock, or night cabinet by an authorized nurse must be recorded on a suitable form showing the following information:

(i) patient name;

(ii) the patient's room number if applicable;

(iii) the name, strength, and quantity of drug removed;

(iv) the date and time the drug was removed;

(v) the signature of the nurse removing the drug; and

(vi) documentation of pharmacy review.

(b) in cases of medication not unit-dosed, the NDC number of the drug removed must also be recorded.

(5) The pharmacist-in-charge shall ensure that:

(a) written policies and procedures are established to implement the requirements of this rule;

(b) all drugs are properly labeled; and

(c) only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements.

(6) A copy of the original drug order with the NDC number or other identifying code of the drug(s) provided may be faxed to the pharmacist. If the patient is an inpatient, a patient profile containing the patient's name, location, allergies, current medication regimen, and relevant laboratory values must be reviewed by a pharmacist within 72 hours.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06.

24.174.1111 DRUG DISTRIBUTION AND CONTROL IN AN INSTITUTIONAL OR CORRECTIONAL FACILITY

(1) The pharmacist-in-charge shall establish written policies and procedures for the safe and efficient distribution of drugs and provision of pharmaceutical care, including the mechanism by which drug review will be accomplished and documented. A current copy of such procedures must be on hand for inspection by the Board of Pharmacy.

(2) Automated dispensing devices must be stocked with drugs only by or under the supervision of a registered pharmacist. At the time of removal of any drug, the device must automatically make an electronic record indicating the date of removal, the name, strength, and quantity of drug removed, name of the patient for whom the drug was ordered, and the name or other identification of the person removing the drug. These records must be maintained for a period of two years.

(3) Drugs or herbal/alternative food supplement products brought into an institutional facility by a patient must not be administered, unless they can be identified and their quality assured by a pharmacist and their use has been authorized by the attending physician. If such drugs are not to be administered, the pharmacist-in-charge shall develop policies and procedures for storing them for return to the patient upon discharge or transferring them to an adult member of the patient's immediate family.

(4) Investigational drugs must be stored in and dispensed from the pharmacy only pursuant to written policies and procedures.

(a) Complete information regarding these drugs and their disposition must be maintained in the facility prior to their initial dispensing.

(b) The drug monograph and a signed patient consent form must be obtained and made available in accordance with state and federal guidelines.

(5) A sample drug policy must be established if samples are used.

(6) The safe handling, storage, and administration of medications within jails, correctional facilities, and detention facilities without onsite pharmacies shall be regulated as follows:

(a) Jails, correctional facilities, and detention facilities must have written policies and procedures in place, written by the responsible practitioner or authority, for the safe handling, storage, and administration of medications. Such policies shall address security of medications, procurement, proper storage and disposal of medications, training for those administering medication, methods for documenting that medications were given or refused, procedures for confirming that the inmate has ingested each medication, and the disposition of medications at discharge. Medications brought by or with an inmate upon admission to the jail, correctional

facility, or detention facility must not be used unless specifically authorized by a physician at the jail, correctional facility, or detention facility or that physician's designee, and medication identity has been confirmed by a licensed health care professional. Prescription medications brought by an inmate from outside must be recorded on the inmate property record. If they are not used while the patient is incarcerated, they must be stored in a secure area until the inmate's release.

(b) Patient medications may be transferred from one jail, correctional facility, or detention facility to another if there is a secure method for ensuring that individual inmate prescriptions are not tampered with between locations and that containers are properly labeled. During transfer, medications requiring storage at room temperature should be subjected to external temperatures no greater than 86 degrees Fahrenheit. A method of transferring refrigerated medications from one jail, correctional facility, or detention facility to another must be addressed in policy and procedure. Medications transferred pursuant to the above regulations, in control of the transferring official at all time, may continue to be used for that patient.

(c) Drug kits supplied and maintained by a registered pharmacy may be utilized if policies and procedures regulating their use are in place. Such drug kits will comply with the requirements of ARM 24.174.1114.

(d) The pharmacist-in-charge is responsible for policies and procedures for procurement, storage, and administration of prescription medications at jails, correctional facilities, and detention facilities without an on-site pharmacy.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-307, 37-7-308, 37-7-406, MCA

History: NEW, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2015 MAR p. 302, Eff. 3/27/15; AMD, 2021 MAR p. 1671, Eff. 11/20/21.

24.174.1112 REMOTE MEDICATION ORDER PROCESSING SERVICES

(1) A hospital pharmacy may outsource medication order processing to another pharmacy provided the pharmacies have the same owner or the pharmacy has entered into a written contract or agreement with an outsourcing company that outlines the services to be provided and the responsibilities and accountabilities of each party to the contract or agreement in compliance with federal and state statutes and regulations.

(2) The hospital pharmacy must provide a copy of the contract or agreement to the board and receive approval from the board or its designee prior to initiation of remote order entry services.

(3) A hospital pharmacy utilizing remote order entry shall ensure that all pharmacists providing such services have been trained on the pharmacy's policies and procedures relating to medication order processing. The training of each pharmacist shall be documented. Such training shall include, but is not limited to, policies on drug and food allergy documentation, abbreviations, administration times, automatic stop orders, substitution, and formulary compliance. The pharmacy and the pharmacy/outsourcing company shall jointly develop a procedure to communicate changes in formulary and changes in policies and procedures related to medication order processing.

(4) A hospital pharmacy utilizing a remote order entry pharmacist shall maintain a record of the name and address of such pharmacist, evidence of current licensure in Montana, and the address of each location where the pharmacist will be providing remote order entry services.

(5) The director of pharmacy shall ensure that any remote order entry pharmacist shall have secure electronic access to the hospital pharmacy's patient information system and to other electronic systems that the on-site pharmacist has access to when the pharmacy is open.

(6) The remote order entry pharmacist must be able to contact the prescribing practitioner to discuss any concerns identified during the pharmacist's review of patient information and the drug order. A procedure must be in place to communicate any problems identified with the practitioner and the nursing staff providing direct patient care.

(7) Each remote entry record must comply with all recordkeeping requirements and shall identify by name or other unique identifier, the pharmacist involved in the review and verification of the drug order.

(8) A pharmacy utilizing remote order entry processing services is responsible for maintaining records of all orders entered into their information system, including orders entered from a remote location. The system shall have the ability to audit the activities of the individuals remotely processing medication orders.

(9) All records shall be readily available upon request by the board, its designee, or agent of the board for inspection, copying, or production.

(10) A pharmacy utilizing remote order entry processing services shall maintain a policy and procedure manual. A remote pharmacy/order processing company shall maintain a copy of those portions of the policy and procedure manual that relate to that pharmacy's operations. Each manual shall:

(a) outline the responsibilities of the pharmacy and the remote pharmacy/order processing company;

(b) include a list of the names, addresses, telephone numbers, and all license numbers of the pharmacies/pharmacists involved in remote order entry processing; and

(c) include policies and procedures for:

(i) protecting the confidentiality and integrity of patient information;

(ii) maintaining appropriate records of each pharmacist involved in order processing;

(iii) complying with federal and state statutes and regulations;

(iv) annually reviewing the written policies and procedures and documentation of the annual review; and

(v) annually reviewing the competencies of pharmacists providing remote order entry processing services.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12.

24.174.1114 USE OF DRUG KITS IN CERTAIN INSTITUTIONAL FACILITIES

(1) In an institutional facility, drugs may be provided for use by authorized personnel through drug kits prepared by the registered pharmacist providing pharmaceutical services to the facility. Such drug kits must meet all of the following requirements:

(a) a registered pharmacist shall prepare and seal the drug kit for a supplying pharmacy;

(b) the supplying pharmacy and the designated practitioner or appropriate committee of the institutional facility shall jointly determine the identity and quantity of drugs to be included in the drug kit;

(c) the drug kit must be locked and stored in a secure area to prevent unauthorized access and to ensure a proper storage environment for the drugs contained therein;

(d) all drugs in the drug kit must be properly labeled, including lot number and expiration date, and shall possess any additional information that may be required to prevent risk of harm to the patient;

(e) the exterior of the drug kit must be clearly labeled to indicate:

(i) expiration date of the drug kit. The expiration date of a drug kit must be the earliest date of expiration of any drug supplied in the drug kit. On or before the expiration date, the supplying pharmacy shall replace the expired drug;

(ii) the name, address, and telephone number of the supplying pharmacy; and

(iii) a statement indicating that the drug kit is to be used in situations only pursuant to a valid drug order;

(f) if a drug kit is being utilized for an emergency drug cart or crash cart in an inpatient setting, as defined in ARM 24.174.301(15):

(i) the pharmacist-in-charge must maintain policies and procedures for access to the cart; and

(ii) a pharmacist must review access to the cart within 72 hours of drug removal.

(2) Except as provided for in (1)(f), drugs shall be removed from drug kits in compliance with the following:

(a) by authorized licensed personnel pursuant to policies and procedures referenced in (4); and

(b) a pharmacist must:

(i) review the drug order prior to removal of a controlled substance; or

(ii) review the drug order within 72 hours of removal of a non-controlled substance.

(3) Removal of any drug from a drug kit by authorized personnel must be recorded in an electronic record or on a suitable form showing the following information:

(a) patient name;

(b) name, strength, and quantity of drug removed;

(c) date and time the drug was removed;

(d) signature of the authorized personnel removing the drug; and

(e) documentation of pharmacy review.

(4) The supplying pharmacy shall, in conjunction with the appropriate institutional committee, be responsible for development and annual review of policies and procedures for safe and appropriate use, access by authorized licensed personnel, restocking, and maintenance of drug kits.

(5) Documentation for all drugs that have been removed from the drug kit shall be kept at the institutional facility and at the supplying pharmacy for two years and be available upon inspection.

(6) The drug kit, policies and procedures, and related records shall be available upon inspection.

(7) The supplying pharmacy and appropriate designated practitioner of a licensed facility will provide adequate controls to prevent drug diversion.

(8) The supplying pharmacy shall submit to the board and have available for inspection:

(a) an application for a drug kit endorsement;

(b) a list of drug kit locations; and

(c) any change to drug kit locations at the time of such change.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2010 MAR p. 74, Eff. 1/15/10; AMD, 2021 MAR p. 1671, Eff. 11/20/21.

24.174.1115 USE OF CONTINGENCY KITS IN CERTAIN INSTITUTIONAL FACILITIES

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2012 MAR p. 506, Eff. 3/9/12; AMD, 2015 MAR p. 302, Eff. 3/27/15; REP, 2021 MAR p. 1671, Eff. 11/20/21.

24.174.1121 STERILE PRODUCTS

(TRANSFERRED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-307, 37-7-308, MCA

History: NEW, 2002 MAR p. 3605, Eff. 12/27/02; AMD and TRANS, to ARM 24.174.841, 2015 MAR p. 302, Eff. 3/27/15.

24.174.1122 OUTPATIENT CENTERS FOR SURGICAL SERVICES

(1) The board shall annually register and inspect all outpatient centers for surgical services in Montana, regardless of pharmacy status.

(2) In an outpatient center for surgical services without an on-site pharmacy, drug distribution must be directed by a physician or consulting pharmacist licensed to practice in Montana and who is responsible for the security, storage, and distribution of drugs within the facility.

(3) The physician director or consulting pharmacist shall provide for applicable policies and procedures to ensure:

(a) proper acquisition and secure, temperature-controlled storage of all pharmaceuticals;

(b) security and accountability of controlled substances;

(c) quality control of sterile and nonsterile pharmaceutical products including procedures for identifying, removing, and destroying outdated products;

(d) evaluation of reported medication errors and development of procedures to prevent those errors;

(e) maintenance of all required records; and

(f) compliance with all requirements of the board.

(4) Ambulatory surgical centers that store and/or administer controlled substances shall register with the board and with the DEA, and shall comply with all applicable state, local, and DEA regulations.

Authorizing statute(s): 50-32-314, MCA

Implementing statute(s): 50-32-314, MCA

History: NEW, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2008 MAR p. 1151, Eff. 6/13/08.

24.174.1141 RETURN OF MEDICATION FROM LONG TERM CARE FACILITIES -- DONATED DRUG PROGRAM

(1) In facilities licensed by the Montana Department of Public Health and Human Services where United States pharmacopeia storage requirements are assured, unit-dosed legend drugs, with the exception of controlled substances, no longer needed by the patient for whom they were prescribed, may be transferred to a provisional permitted pharmacy for relabeling and dispensing free of charge to patients who are uninsured, indigent or have insufficient funds to obtain needed prescription drugs. Prescription medications may be dispensed pursuant to a valid prescription order. A usual and customary dispensing fee may be charged at the pharmacist's discretion.

(2) The pharmacist-in-charge of the provisional permitted pharmacy shall be responsible for determining the suitability of the legend drug for use. Medications must be unopened in sealed, unaltered unit dose containers that meet USP standards for light, moisture and air permeation. No product in which drug integrity cannot be assured shall be accepted for redispensing by the pharmacist.

(3) A redispensed prescription medication must be assigned the expiration date stated on the unit dose packaging. Medications packaged in unit dose form within a pharmacy must be given an expiration date of one year or actual date of expiration of the medication, whichever comes first, and must not be repackaged.

(4) No medication can be redistributed more than once.

(5) Only authorized personnel shall carry out the physical transfer of medication in either facility, pursuant to established policies and procedures.

(6) The patient's name and other identifying marks must be obliterated from packaging prior to transfer. The drug name, strength, lot number and expiration date must remain clearly visible on the packaging.

(7) An inventory list of drugs transferred, including expiration dates, must accompany the drugs, and must be maintained in the provisional permitted pharmacy for a period of two years.

(8) Policies and procedures to document safe storage and transfer of unneeded medications must be written and adhered to by the facilities involved, and must be available for inspection by an authorized representative of the Montana Board of Pharmacy or Department of Public Health and Human Services.

Authorizing statute(s): 37-7-201, 37-7-1401, MCA

Implementing statute(s): 37-7-201, 37-7-1401, 37-7-1402, MCA

History: NEW, 2002 MAR p. 3605, Eff. 12/27/02.

24.174.1201 WHOLESALE DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER LICENSING

(1) Every person engaged in wholesale distribution of drugs or prescription devices, which includes reverse wholesale distribution and medical gases, or engaged as a third-party logistics provider (3PL), as defined in 37-7-602, MCA, shall be licensed annually by the board. Each applicant shall:

(a) be a legal entity registered and in good standing with the Montana Secretary of State;

(b) file an application on a form prescribed by the board;

(c) pay the appropriate licensing and registration fees;

(d) meet the requirements of 37-7-604, MCA; and

(e) designate a person-in-charge of the facility and for purposes of meeting requirements of 37-7-611, MCA, regarding a criminal background check at time of initial licensure or any change in person-in-charge, complete the requirements included on a form prescribed by the board.

(i) The person-in-charge must notify the board of any changes or termination of services.

(ii) Within 30 days of termination of services, a new person-in-charge must be designated in writing on the appropriate board-approved forms and filed with the board.

(2) The board will independently verify the applicant's standing through the National Practitioner Data Bank (NPDB) and National Association of Boards of Pharmacy Clearinghouse.

(3) The license shall be posted in a conspicuous place in the wholesaler's place of business for which it is issued.

(4) No license may be issued to any applicant whose intended place of business is a personal residence.

(5) Wholesale distributors located in Montana, applying for initial licensure, shall pass an inspection by a pharmacy inspector or other agent of the Board of Pharmacy before a license is issued.

(6) A separate license is required for each separate location, in-state and/or out-of-state, where drugs or devices are stored and directly distributed to Montana.

(7) Wholesale distributors shall operate in compliance with applicable federal, state, and local laws and regulations. Wholesale distributors who distribute controlled substances shall register with the board, to obtain an appropriate dangerous drug endorsement, and with the DEA.

(8) Wholesale distributors shall submit proof of surety bond upon initial licensure and at time of renewal as identified on forms prescribed by the board in compliance with state and federal requirements.

Authorizing statute(s): 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-603, 37-7-604, 37-7-605, 37-7-606, 37-7-611, 37-7-612, MCA

History: NEW, 1992 MAR p. 2135, Eff. 8/14/92; AMD, 1999 MAR p. 2438, Eff. 10/22/99; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2010 MAR p. 2968, Eff. 12/24/10; AMD, 2012 MAR p. 506, Eff. 3/9/12; AMD, 2022 MAR p. 1842, Eff. 9/24/22.

24.174.1202 MANUFACTURER AND REPACKAGER LICENSING

(1) Every person seeking licensure or renewal as a manufacturer or repackager, as defined in 37-7-602, MCA, shall:

(a) be a legal entity registered and in good standing with the Montana Secretary of State;

(b) file an application on a form prescribed by the board;

(c) pay the appropriate licensing and registration fees;

(d) meet the requirements of 37-7-604, MCA; and

(e) designate a person-in-charge of the facility.

(i) The person-in-charge must notify the board of any changes or termination of services.

(ii) Within 30 days of termination of services, a new person-in-charge must be designated in writing on the appropriate board-approved forms and filed with the board.

(2) The board will independently verify the applicant's standing through the National Practitioner Data Bank (NPDB) and National Association of Boards of Pharmacy Clearinghouse.

(3) The license shall be posted in a conspicuous place in the place of business for which it is issued.

(4) No license may be issued to any applicant whose intended place of business is a personal residence.

(5) Applicants located in Montana, applying for initial licensure, shall pass an inspection by a pharmacy inspector or other agent of the Board of Pharmacy before a license is issued.

(6) A separate license is required for each separate location where drugs or devices are stored, repackaged, and/or directly distributed to Montana. For manufacturers, a license shall be issued to a facility meeting the requirements that is located in Montana.

(7) Licensees shall operate in compliance with applicable federal, state, and local laws and regulations. Licensees who distribute controlled substances shall register with the board, obtain an appropriate dangerous drug endorsement, register with the DEA, and shall comply with all applicable state, local, and DEA regulations.

Authorizing statute(s): 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-201, 37-7-604, 37-7-605, 37-7-610, MCA

History: NEW, 1992 MAR p. 2135, Eff. 8/14/92; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2012 MAR p. 896, Eff. 4/27/12; AMD, 2022 MAR p. 1842, Eff. 9/24/22.

24.174.1203 PERSONNEL

(1) Each licensee under this subchapter shall require each person employed in any prescription drug wholesale activity to have sufficient education, training, and experience in any combination, sufficient for that person to:

(a) complete assigned work in a manner which maintains the quality, safety, and security of the drug or device products in accordance with Title 37, MCA;

(b) assume responsibility for compliance with the licensing requirements of Title 37, MCA.

Authorizing statute(s): 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-604, 37-7-610, MCA

History: NEW, 1992 MAR p. 2135, Eff. 8/14/92; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2022 MAR p. 1842, Eff. 9/24/22.

24.174.1204 MEDICAL GAS DISTRIBUTOR

(1) Every person engaged in the manufacture or distribution of medical gases other than to the consuming public or a patient, in the state of Montana, shall register annually with the board. Each applicant shall:

(a) provide proof of registration with the Food and Drug Administration (FDA) as a medical gas manufacturer and comply with all FDA requirements;

(b) register with the board as a wholesale drug distributor;

(c) file an application to register as a medical gas distributor on a form prescribed by the board; and

(d) pay the appropriate registration fee.

(2) The wholesale drug distributor license with the medical gas distributor endorsement shall be posted in a conspicuous place in the wholesaler's place of business for which it is issued.

(3) A medical gas distributor shall establish and implement written procedures for maintaining records pertaining to medical gas production, processing, labeling, packaging, quality control, distribution, complaints, and any information required by federal or state law.

(a) Records shall be retained for at least two years after distribution or one year after the expiration date of the medical gas, whichever is longer.

(b) Records shall be readily available for review by the board, its inspector, or the FDA.

Authorizing statute(s): 37-1-134, 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-604, 37-7-605, MCA

History: NEW, 2007 MAR p. 1936, Eff. 11/22/07.

24.174.1205 MEDICAL GAS SUPPLIER

(1) Every person engaged in supplying medical gases to the consuming public, or to a patient or a patient's agent, in the state of Montana that is not a licensed pharmacy shall register annually with the board. Each applicant shall:

(a) register with the board as a wholesale drug distributor;

(b) file an application to register as a medical gas supplier on a form prescribed by the board; and

(c) pay the appropriate registration fee.

(2) The wholesale drug distributor license with the medical gas supplier endorsement shall be posted in a conspicuous place in the wholesaler's place of business for which it is issued.

(3) A medical gas supplier shall not:

(a) supply prescription medications, except medical gases, without appropriate licensure as a pharmacy;

(b) manufacture or distribute medical gases without appropriate licensure as a medical gas distributor; or

(c) instruct patients regarding clinical use of equipment, or provide any monitoring, assessment, or other evaluation of therapeutic effects without appropriate licensure as a respiratory care practitioner.

(4) A medical gas supplier shall supply medical gas only pursuant to prescription order by an authorized prescriber.

(5) A medical gas supplier must label each medical gas container with the name, address, and telephone number of the supplier.

(6) A medical gas supplier shall establish and implement written procedures for maintaining records pertaining to the acquisition and supply of, and complaints related to, medical gases.

(7) Records shall be retained for at least three years after supply to a patient or one year after the expiration date of the medical gas, whichever is longer.

(8) Records shall be readily available for review by the board or its inspector.

Authorizing statute(s): 37-1-134, 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-604, 37-7-605, MCA

History: NEW, 2007 MAR p. 1936, Eff. 11/22/07.

24.174.1206 MEDICAL GAS FEE SCHEDULE (REPEALED)

(REPEALED)

Authorizing statute(s): 37-1-134, 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-604, 37-7-605, MCA

History: NEW, 2007 MAR p. 1936, Eff. 11/22/07; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1207 CHANGE IN LOCATION

(1) Whenever a facility licensed under this subchapter changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. The facility shall submit a new license application for the new location at least 30 days before such change occurs.

Authorizing statute(s): 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-604, 37-7-605, 37-7-610, MCA

History: NEW, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2022 MAR p. 1842, Eff. 9/24/22.

24.174.1208 CHANGE IN OWNERSHIP

(1) When a facility licensed under this subchapter changes ownership, the original license becomes void and must be surrendered to the board, and a new license obtained by the new owner. The owner shall submit a new license application at least 30 days prior to the change in ownership.

(2) A change in ownership for the purposes of this rule shall be deemed to occur when more than 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

(3) The board must be notified in writing when five to 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

Authorizing statute(s): 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-604, 37-7-605, 37-7-610, MCA

History: NEW, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2022 MAR p. 1842, Eff. 9/24/22.

24.174.1211 MINIMUM FACILILTY REQUIREMENTS

(1) All facilities licensed under this subchapter shall:

(a) establish, maintain, and adhere to written policies and procedures for receipt, recordkeeping, security, storage, inventory control, and distribution of drugs or devices;

(b) comply with state and federal law requirements including, but not limited to:

(i) 37-7-602, 37-7-604, 37-7-609, and 37-7-610, MCA; and

(ii) 21 CFR § 205 as established by the Food and Drug Administration (FDA); and

(c) comply with product track and trace transaction requirements established by the FDA.

(2) Inventories and records shall be made available for inspection and photocopy by authorized federal, state, or local law enforcement agency officials for a period of two years following distribution of inventory.

(3) Records described in this subchapter that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at central locations apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of a federal, state, or local law enforcement agency.

Authorizing statute(s): 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-604, 37-7-610, MCA

History: NEW, 1992 MAR p. 2135, Eff. 8/14/92; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2022 MAR p. 1842, Eff. 9/24/22.

24.174.1212 MINIMUM REQUIREMENTS FOR ESTABLISHMENT AND MAINTENANCE OF DRUG DISTRIBUTION RECORDS

(REPEALED)

Authorizing statute(s): 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-604, 37-7-609, MCA

History: NEW, 1992 MAR p. 2135, Eff. 8/14/92; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; REP, 2022 MAR p. 1842, Eff. 9/24/22.

24.174.1213 NATIONAL CLEARINGHOUSE FOR WHOLESALE DRUG DISTRIBUTOR LICENSING

(REPEALED)

Authorizing statute(s): 37-7-201, 37-7-610, MCA

Implementing statute(s): 37-7-604, 37-7-605, 37-7-606, 37-7-607, MCA

History: NEW, 1992 MAR p. 2135, Eff. 8/14/92; TRANS, from Commerce, 2002 MAR p. 904; REP, 2022 MAR p. 1842, Eff. 9/24/22.

24.174.1302 TELEPHARMACY OPERATIONS

(1) A remote telepharmacy site shall be connected to its parent pharmacy via computer, video, and audio link.

(2) A site cannot be licensed as a remote telepharmacy site if it is located within a twenty-mile radius of an existing pharmacy.

(3) A remote telepharmacy site manned by a registered pharmacy technician shall access and use the parent pharmacy's central processing unit or common database.

(4) A remote telepharmacy site shall comply will all the requirements of pharmacy rules and statutes of Montana. The remote telepharmacy site is considered to be under the personal charge of the pharmacist at the parent pharmacy.

(a) The remote telepharmacy site must have a registered pharmacy technician present and a working computer, video, and audio link to a pharmacist at the parent pharmacy to have the prescription area open.

(b) The technician at the remote telepharmacy site must:

(i) be currently registered with the board;

(ii) be currently certified with the Pharmacy Technician Certification Board (PTCB), or Exam for the Certification of Pharmacy Technicians (ExCPT), or other board-approved certifying entity; and

(iii) have at least 500 hours experience as a pharmacy technician, technician-in-training, or experience deemed as equivalent by the board.

(c) The technician may unlock the prescription and storage areas. While the technician is on duty, the prescription area may remain open. Security standards for pharmacies shall be maintained at all times pursuant to ARM 24.174.814.

(d) The technician will be subject to all rules of ARM 24.174.701 through 24.174.714.

(e) All prescription records and consecutive prescription numbers must be maintained at the parent pharmacy or remote site. The remote telepharmacy site must transmit copies of new prescriptions via secure electronic means to the parent pharmacy, keeping the original prescription blank at the remote telepharmacy site.

(f) Prescriptions filled at the remote telepharmacy site must be distinguishable in some manner from those filled at the parent pharmacy.

(g) Daily reports for both the parent pharmacy and remote telepharmacy site must be maintained at the parent pharmacy or telepharmacy site.

(h) The remote telepharmacy site may have a prescription inventory. Prescription medications including controlled substances shall be securely maintained at the remote telepharmacy site in accordance with current Montana pharmacy statutes and rules.

(i) If controlled substances are dispensed or handled, both the remote telepharmacy site and the parent pharmacy must be registered with the DEA and must obtain individual DEA numbers.

(j) All records must be stored at the parent pharmacy or telepharmacy site, except those required by DEA to be at a DEA registered site.

(k) The software system utilized must be able to generate labels from the parent pharmacy or at the remote telepharmacy site.

(l) The input of drug information may be done by a pharmacist at the parent pharmacy or a technician at either location if verified by a pharmacist.

(m) New prescriptions may be received at the parent pharmacy and entered there with a label printing at the remote telepharmacy site.

(n) New prescriptions received at the remote telepharmacy site may be entered into the computer system at the remote telepharmacy site. The pharmacist at the parent pharmacy remains responsible for all verification, interaction checking, and profile review.

(o) All filled prescriptions must have a label meeting the requirements of ARM 24.174.511 attached to the final drug container before the pharmacist verifies the dispensing process.

(p) Unless the remote telepharmacy site is a remote telepharmacy dispensing machine site, a pharmacist shall compare via video link the stock bottle, drug dispensed, and strength. The entire label must be checked for accuracy on the video link.

(q) The computer, video, and audio link must be operational at all times. In the event of connectivity loss to the parent location, no new prescriptions may be processed, filled, or dispensed from the telepharmacy site until connectivity is reestablished. Refill prescriptions that have a final check by the pharmacist may be dispensed.

(r) A code containing both the pharmacist's and technician's initials must appear on the fill screen, patient profile, and prescription label.

(s) No prescription medication may be released to a patient until approved by a pharmacist in person or via the computer, video, and audio link.

(t) The pharmacist shall offer to counsel the patient or the patient's agent via video and/or audio link on all new prescriptions.

(u) When the technician is not present, dispensing and counseling via video and audio link may be done using a secure alternate delivery system with prior approval of the board.

(v) The license holder, agent of the parent pharmacy, or the pharmacist-in-charge of the parent pharmacy, or the pharmacist-in-charge of the remote site, if different from the parent pharmacist-in-charge, shall apply for a license for the remote telepharmacy site.

(w) As dispensing is considered to be done by the pharmacist, the pharmacist shall be responsible for and held accountable for dispensing at the remote telepharmacy site.

(x) Policies and procedures must be in place to ensure the safe and effective distribution of pharmaceutical products and delivery of required pharmaceutical care.

(y) The pharmacist at the parent pharmacy shall perform an ongoing analysis of incident reports and outcomes, with appropriate corrective action taken when necessary, to ensure patient safety.

(z) The pharmacist at the parent pharmacy or that person's designee shall conduct and complete monthly inspections of the remote telepharmacy site. Inspection criteria must be included in the policies and procedures for the site. The inspection report must be available for review at the next board inspection.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, 37-7-201, 37-7-321, MCA

History: NEW, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2010 MAR p. 2968, Eff. 12/24/10; AMD, 2012 MAR p. 896, Eff. 4/27/12.

24.174.1303 REMOTE TELEPHARMACY DISPENSING MACHINE SITES

(1) Remote telepharmacy dispensing machine sites contain prescription inventory which is secured in an automated dispensing device connected to the central processing unit at the parent pharmacy.

(2) A site cannot be licensed as a remote telepharmacy dispensing machine site if it is located within a ten mile radius of an existing pharmacy.

(3) A pharmacist must approve all outpatient prescriptions before they are dispensed, unless the prescription is directly dispensed by a person authorized to prescribe.

(4) All filled prescriptions must have a label that meets the requirements of ARM 24.174.511 attached to the final drug container.

(5) A licensed pharmacist at the parent site shall perform counseling and professional consultation via audio and video link as required by ARM 24.174.903, unless the prescription is directly dispensed by a person authorized to prescribe.

(6) Registered technicians involved in stocking and removal of prescription medications under this rule must have at least 80 hours of pretraining in bar coding technology. All requirements of ARM 24.174.701 through 24.174.714 will apply, excluding the technician certification requirement of ARM 24.174.702.

(7) Policies and procedures of the parent pharmacy and the remote telepharmacy dispensing machine site must address all aspects of the telepharmacy operation, including stocking procedures and removal of outdated prescription medications.

(8) The pharmacist at the parent pharmacy shall perform an ongoing analysis of incident reports and outcomes, with appropriate corrective action taken when necessary to ensure patient safety.

(9) The pharmacist-in-charge of the parent pharmacy or that person's designee shall conduct and complete monthly inspections of the remote telepharmacy dispensing machine site. Inspection criteria must be included in the policies and procedures for the site. The inspection reports must be available for review at the next board inspection.

(10) Remote telepharmacy dispensing machine sites must be licensed with the board by November 30 of each year, and will be subject to random inspection by board inspectors.

(11) This rule does not apply to institutional satellite pharmacies as defined in ARM 24.174.301.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-101, 37-7-201, 37-7-321, MCA

History: NEW, 2006 MAR p. 1615, Eff. 6/23/06.

24.174.1401 REQUIREMENTS FOR REGISTRATION

(1) The board shall register a person to manufacture dangerous drugs (as defined in 50-32-101 , MCA) included in Schedules I through V upon the following conditions:

(a) applicant is registered for such purposes pursuant to the Federal Controlled Substances Act of 1970;

(b) the applicant has made proper application and has paid the applicable fee; and

(c) the category of manufacturer as above-stated shall include only those applicants who are engaged in the manufacturing of dangerous drugs within the state of Montana.

(2) The board shall register a person or entity to distribute dangerous drugs included in Schedules I through V under the following conditions:

(a) applicant is registered for such purpose pursuant to the Federal Controlled Substances Act of 1970;

(b) the applicant has made proper application and paid the applicable fee;

(c) the category of distributor as above-stated shall include any person or entity who distributes dangerous drugs or samples thereof within the state of Montana and may include a manufacturer not otherwise required to be registered if such manufacturer also distributes dangerous drugs or samples thereof within the state of Montana; and

(d) representatives of drug manufacturers who distribute controlled substance samples to licensed practitioners shall be exempt from the requirement of registration.

(3) The board shall register a person to analyze or conduct research with narcotic dangerous drugs in Schedules II through V upon making proper application and paying the applicable fee.

(4) The board shall register a person to analyze or conduct research with dangerous drugs in Schedule I, if:

(a) the applicant is a practitioner licensed under the laws of this state;

(b) the applicant has furnished the board evidence of registration for such purpose pursuant to the Federal Controlled Substances Act of 1970;

(c) the applicant has furnished the board a complete resume of all research proposed relative to any dangerous drugs. Such resume must be a duplicate of an application submitted to the DEA; and

(d) the applicant has made proper application and paid the applicable fee.

Authorizing statute(s): 50-32-103, MCA

Implementing statute(s): 50-32-306, 50-32-308, MCA

History: NEW, Eff. 8/4/74; AMD, Eff. 2/4/75; AMD, Eff. 12/5/75; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic. , Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06.

24.174.1402 RENEWALS

(1) All applications for registration shall be made on forms provided by the board and shall be filed with the board.

(2) Renewal notices will be sent as specified in ARM 24.101.414.

(3) The provisions of ARM 24.101.408 apply.

(4) The registrant shall prominently display the certificate of registration to be visible to the public.

Authorizing statute(s): 50-32-103, MCA

Implementing statute(s): 37-1-141, 50-32-301, MCA

History: NEW, Eff. 8/4/74; AMD, Eff. 2/4/75; AMD, Eff. 12/5/75; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic. , Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 1999 MAR p. 2438, Eff. 10/22/99; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1583, Eff. 7/1/06.

24.174.1403 APPLICATION FORMS

(1) If any person is required to be registered and is not so registered and is applying for registration to manufacture or distribute dangerous drugs in Schedules I through V, the person shall apply on a form prescribed by the board.

(2) If any person is required to be registered and is not so registered and is applying for registration to dispense dangerous drugs in Schedules II through V, the person shall apply on a form prescribed by the board.

(3) If any person is required to be registered and is not so registered and is applying for registration to analyze or conduct research with dangerous drugs in Schedules I through V, the person shall apply on a form prescribed by the board.

(4) Any licensee applying for renewal of registration to manufacture or distribute dangerous drugs in Schedules I through V, the licensee shall apply on a form prescribed by the board.

(5) Any licensee applying for renewal to dispense dangerous drugs in Schedules II through V, the licensee shall apply on a form prescribed by the board.

Authorizing statute(s): 50-32-103, MCA

Implementing statute(s): 50-32-306, 50-32-308, MCA

History: NEW, Eff. 8/4/74; AMD, Eff. 2/4/75; AMD, Eff. 12/5/75; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic. , Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904.

24.174.1404 REQUIRED RECORDS

(1) As used in this subchapter, the term "records" means:

(a) those records and inventories maintained by persons registered to manufacture, distribute, analyze or dispense dangerous drugs or samples thereof in conformance with record keeping and inventory requirements of federal statute and regulation, (21 CFR 304) , and as they may be amended from time-to-time.

(2) Manufacturers and distributors shall be required to keep such records as are required by federal statutes and regulations, (21 CFR 304) , and as they may be amended from time-to-time.

(3) Separate records required:

(a) registrants' inventories and records of dangerous drugs listed in Schedules I and II shall be maintained separately from all records of the registrant; and

(b) registrants' inventories and records of dangerous drugs listed in Schedules III through V shall be maintained according to federal statutes and regulations as they may be amended from time-to-time.

Authorizing statute(s): 50-32-103, MCA

Implementing statute(s): 50-32-309, MCA

History: NEW, Eff. 8/4/74; AMD, Eff. 2/4/75; AMD, Eff. 12/5/75; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic. , Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; TRANS, from Commerce, 2002 MAR p. 904.

24.174.1411 SECURITY REQUIREMENTS

(1) All applicants and registrants shall establish and maintain effective written controls and procedures to guard against theft and diversion of dangerous drugs into other than legitimate medical, scientific or industrial channels.

(2) The registrant shall not employ as an agent or employee any person who has access to dangerous drugs, who has had a federal or state application for registration denied or his registration revoked at any time, or has been convicted of a felony offense under any state or federal law relating to dangerous drugs or convicted of any other felony.

(3) The registrant shall notify the Board of Pharmacy in writing by forwarding a copy of the applicable DEA form reporting the theft or loss of any dangerous drugs upon discovery of such theft or loss. The notification shall contain a list of all dangerous drugs stolen or lost.

(4) The registrant shall notify law enforcement officials of any theft or loss of any dangerous drug promptly upon discovery of such theft or loss.

Authorizing statute(s): 50-32-103, MCA

Implementing statute(s): 50-32-106, MCA

History: NEW, Eff. 8/4/74; AMD, Eff. 2/4/75; AMD, Eff. 12/5/75; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic. , Ch. 274, L. 1981, Eff. 7/1/81; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2002 MAR p. 3605, Eff. 12/27/02.

24.174.1412 ADDITIONS, DELETIONS, AND RESCHEDULING OF DANGEROUS DRUGS

(1) In addition to those dangerous drugs scheduled in 50-32-222, 50-32-224, 50-32-226, 50-32-229, and 50-32-232, MCA, the board adds the following to dangerous drug schedules after considering federal regulations and/or the criteria enumerated in Title 50, chapter 32, part 2, MCA:

(a) Schedule I:

(i) none at this time;

(b) Schedule II:

(i) none at this time;

(c) Schedule III:

(i) none at this time;

(d) Schedule IV: none at this time;

(e) Schedule V: none at this time.

(2) The board deletes the following dangerous drugs from the schedules in 50-32-222, 50-32-224, 50-32-226, 50-32-229, and 50-32-232, MCA, after considering federal regulations and/or the criteria enumerated in Title 50, chapter 32, part 2, MCA:

(a) Schedule I:

(i) none at this time;

(b) Schedule II:

(i) none at this time;

(c) Schedule III:

(i) none at this time;

(d) Schedule IV:

(i) none at this time;

(e) Schedule V: none at this time.

(3) After considering federal regulations and/or the criteria enumerated in Title 50, chapter 32, part 2, MCA, the board reschedules the following dangerous drugs from those scheduled in 50-32-222, 50-32-224, 50-32-226, 50-32-229, and 50-32-232, MCA:

(a) Schedule I:

(i) none at this time;

(b) Schedule II:

(i) none at this time;

(c) Schedule III:

(i) none at this time;

(d) Schedule IV:

(i) none at this time;

(e) Schedule V:

(i) none at this time.

Authorizing statute(s): 50-32-103, 50-32-203, MCA

Implementing statute(s): 50-32-103, 50-32-202, 50-32-203, 50-32-209, 50-32-222, 50-32-223, 50-32-224, 50-32-225, 50-32-226, 50-32-228, 50-32-229, 50-32-231, 50-32-232, MCA

History: NEW, Eff. 9/16/71; EMERG, AMD, Eff. 5/5/74; AMD, Eff. 9/4/75; AMD, Eff. 2/5/76; AMD, Eff. 3/7/76; AMD, Eff. 4/5/76; AMD, Eff. 9/5/76; AMD, 1978 MAR p. 393, Eff. 3/25/78; AMD, 1978 MAR p. 1740, Eff. 12/29/78; AMD, 1979 MAR p. 199, Eff. 3/1/79; AMD, 1980 MAR p. 1720, Eff. 6/27/80; AMD, 1981 MAR p. 625, Eff. 6/26/81; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1984 MAR p. 589, Eff. 4/13/84; AMD, 1984 MAR p. 1567, Eff. 10/26/84; AMD, 1985 MAR p. 1017, Eff. 7/16/85; AMD, 1986 MAR p. 1957, Eff. 11/29/86; AMD, 1988 MAR p. 271, Eff. 2/12/88; AMD, 1989 MAR p. 1193, Eff. 8/18/89; AMD, 1995 MAR p. 2689, Eff. 12/8/95; AMD, 1999 MAR p. 344, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2010 MAR p. 2968, Eff. 12/24/10; AMD, 2015 MAR p. 1491, Eff. 9/25/15; AMD, 2021 MAR p. 1671, Eff. 11/20/21; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1420 SCHEDULE I DANGEROUS DRUGS

(REPEALED)

Authorizing statute(s): 50-32-103, MCA

Implementing statute(s): 50-32-103, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; REP, 2015 MAR p. 1491, Eff. 9/25/15.

24.174.1421 SCHEDULE II DANGEROUS DRUGS

(REPEALED)

Authorizing statute(s): 50-32-103, MCA

Implementing statute(s): 50-32-103, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; REP, 2015 MAR p. 1491, Eff. 9/25/15.

24.174.1422 SCHEDULE III DANGEROUS DRUGS

(REPEALED)

Authorizing statute(s): 50-32-103, MCA

Implementing statute(s): 50-32-103, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; REP, 2015 MAR p. 1491, Eff. 9/25/15.

24.174.1423 SCHEDULE IV DANGEROUS DRUGS

(REPEALED)

Authorizing statute(s): 50-32-103, MCA

Implementing statute(s): 50-32-103, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; REP, 2015 MAR p. 1491, Eff. 9/25/15.

24.174.1424 SCHEDULE V DANGEROUS DRUGS

(REPEALED)

Authorizing statute(s): 50-32-103, MCA

Implementing statute(s): 50-32-103, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; REP, 2015 MAR p. 1491, Eff. 9/25/15.

24.174.1501 PARTICIPATION AND REGISTRATION

(1) A pharmacy or facility may fully participate in the cancer drug repository program by accepting, storing and dispensing, or administering donated drugs and supplies, or may limit its participation to only accepting and storing donated drugs and supplies. If a pharmacy or facility chooses to limit its participation, the pharmacy or facility shall distribute any donated drugs to a fully participating repository.

(2) Any patient who is diagnosed with cancer is eligible to receive drugs or supplies under the cancer drug repository program.

(3) The program is voluntary, and any pharmacy or facility must notify the board of their interest in participating in the program.

(4) There is no limitation on the number of doses that can be donated to the program as long as the donated drugs meet the requirements of these regulations.

(5) Any person or entity (donor) may donate cancer drugs to the program. The donor must contact a pharmacy or facility to obtain a form on which the donor must specify the drug(s) to be donated. The board will supply the form to be used which will include the provisions of 37-7-1405, MCA, and the:

(a) name and quantity of the drug; and

(b) name of the person the drug was originally prescribed, their relationship with the donor, the signature of the donor, and the date the form was signed.

(6) The board may inspect a pharmacy or facility participating in the program for compliance with the storage and record-keeping requirements. The board may terminate participation in the program for noncompliance.

(7) The board shall establish and maintain a list of any pharmacy or facility participating in the program by issuing an endorsement on the license at no cost. The endorsement application information must include the entity's name, address, telephone number, and if it is a practitioner's office, pharmacy, clinic, or hospital, in compliance with 37-7-1403, MCA. The pharmacy or facility must notify the board of any changes to their registration information, including when they stop participating in the program.

(8) The board will make the pharmacy or facility registry information available to any person or entity wishing to donate cancer drugs to the program, and will make the information available on the board webpage or by contacting the board office.

Authorizing statute(s): 37-7-1401, MCA

Implementing statute(s): 37-7-1401, 37-7-1403, 37-7-1405, MCA

History: NEW, 2010 MAR p. 2968, Eff. 12/24/10; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1502 DONATION OF CANCER DRUGS (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-1401, MCA

Implementing statute(s): 37-7-1401, 37-7-1403, MCA

History: NEW, 2010 MAR p. 2968, Eff. 12/24/10; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1503 ACCEPTABLE AND NONACCEPTABLE CANCER DRUGS

(1) The following categories of cancer drugs are acceptable for dispensing or distribution under the program, if in compliance with 37-7-1404, MCA, the cancer drug:

(a) is in its original, unopened, sealed, and tamper-evident packaging;

(b) is packaged in single unit doses if the outside packaging is opened, but the single unit dose packaging is unopened; and

(c) does not have temperature or storage requirements other than controlled room temperature.

(2) Any cancer drug donated to the program cannot be used past its expiration date.

(3) The following categories of cancer drugs are not acceptable for dispensing or distribution under the program, because the effectiveness and safety of the cancer drugs cannot be ensured or is otherwise prohibited if the cancer drugs:

(a) are adulterated or misbranded;

(b) do not comply with the requirements in (1);

(c) are controlled substances; and

(d) have expired before dispensing to the patient.

Authorizing statute(s): 37-7-1401, MCA

Implementing statute(s): 37-7-1401, 37-7-1404, 37-7-1405, MCA

History: NEW, 2010 MAR p. 2968, Eff. 12/24/10; AMD, 2012 MAR p. 896, Eff. 4/27/12; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1504 NONACCEPTABLE CANCER DRUGS (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-1401, MCA

Implementing statute(s): 37-7-1401, 37-7-1404, 37-7-1405, MCA

History: NEW, 2010 MAR p. 2968, Eff. 12/24/10; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1505 DISPENSING AND DISTRIBUTION OF CANCER DRUGS

(1) A pharmacy or facility must comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of donated cancer drugs.

(2) Cancer drugs may only be dispensed pursuant to a prescription issued by a prescribing practitioner. Cancer drugs may be:

(a) dispensed to a cancer drug patient or to a patient's agent or caregiver; or

(b) distributed to another pharmacy or facility for dispensing.

(3) Cancer drugs donated under the program may not be resold.

(4) Patients for whom cancer drugs are dispensed under the program must be notified by the prescribing practitioner or dispensing pharmacy that the cancer drugs they received were originally dispensed to another patient and were returned for redispensing through the program.

Authorizing statute(s): 37-7-1401, MCA

Implementing statute(s): 37-7-1401, 37-7-1405, MCA

History: NEW, 2010 MAR p. 2968, Eff. 12/24/10; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1506 STORAGE AND RECORD-KEEPING REQUIREMENTS

(1) The pharmacy or facility that receives donated cancer drugs for dispensing or distribution must:

(a) ensure the proper and secure storage of cancer drugs donated to the program; and

(b) maintain the inventory of donated cancer drugs separate from all other drug inventory of the pharmacy or facility.

(2) A pharmacy or facility must maintain a perpetual inventory log book of all donated cancer drugs received, dispensed, or distributed that must include the information outlined in 37-7-1405, MCA, including:

(a) name, quantity, expiration date, dosage form, and lot number;

(b) name of pharmacy or facility;

(c) name of person or entity who donated the cancer drug;

(d) name of the person to whom the cancer drug was dispensed and date dispensed;

(e) name of the prescribing practitioner who wrote the prescription for the cancer drug to be dispensed under the program;

(f) name of the pharmacy or facility which the cancer drug was distributed and date distributed;

(g) date of destruction of the expired cancer drug; and

(h) the amount of the handling fee charged, if any.

Authorizing statute(s): 37-7-1401, MCA

Implementing statute(s): 37-7-1401, 37-7-1404, 37-7-1405, MCA

History: NEW, 2010 MAR p. 2968, Eff. 12/24/10; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1507 RECORD-KEEPING REQUIREMENTS (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-1401, MCA

Implementing statute(s): 37-7-1401, 37-7-1405, MCA

History: NEW, 2010 MAR p. 2968, Eff. 12/24/10; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1508 HANDLING FEE (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-1401, MCA

Implementing statute(s): 37-7-1401, 37-7-1405, MCA

History: NEW, 2010 MAR p. 2968, Eff. 12/24/10; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1509 PHARMACY OR FACILITY REGISTRY (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-1401, MCA

Implementing statute(s): 37-7-1401, 37-7-1403, MCA

History: NEW, 2010 MAR p. 2968, Eff. 12/24/10; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1510 INSPECTIONS AND TERMINATION FROM PROGRAM (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-1401, MCA

Implementing statute(s): 37-7-1401, MCA

History: NEW, 2010 MAR p. 2968, Eff. 12/24/10; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1601 MEDICAL ASSISTANCE PROGRAM PURPOSE (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1602 REPORTING OF SUSPECTED IMPAIRMENT (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1603 PROTOCOL FOR SELF-REPORTING TO A PROFESSIONAL ASSISTANCE PROGRAM

(1) If a licensee or license applicant chooses to self-report to the assistance program, and the program has determined that the licensee or license applicant needs assistance or supervision, the licensee or license applicant shall be required to:

(a) enter into a contractual agreement with the medical assistance program for the specified length of time determined by the medical assistance program; and

(b) abide by all the requirements set forth by the medical assistance program.

(2) Self-reporting by a licensee or license applicant may still result in disciplinary action by the board if:

(a) the medical assistance program determines that the self-reporting licensee or license applicant poses a danger to themselves or to the public;

(b) the licensee or license applicant is noncompliant with a contractual agreement with the medical assistance program;

(c) the licensee or license applicant has not completed evaluation, treatment, or aftercare monitoring as recommended by the medical assistance program; or

(d) the screening panel otherwise determines that disciplinary action is warranted.

(3) The program shall notify and disclose to the board the identity of a new license applicant who is determined by the program to have significant impairment issues.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1604 RESPONSIBILITIES OF PROFESSIONAL ASSISTANCE PROGRAM

(1) The professional assistance program established by the board as set forth in 37-7-201, MCA, shall:

(a) provide two tracks for assistance of licensees:

(i) a disciplinary track; and

(ii) a nondisciplinary track;

(b) provide recommendations to licensees or license applicants for appropriate evaluation and treatment facilities;

(c) recommend terms and conditions of treatment, rehabilitation, and monitoring of licensees or license applicants known to the board; and

(d) monitoring all aftercare of participants under contract to ensure public safety and compliance with agreed treatment recommendations propounded by one or more of the following:

(i) the board, through stipulations and/or final orders;

(ii) treatment centers; or

(iii) the medical assistance program established by the board.

(e) report to the board the discharge of a participant, and if applicable, provide to the board:

(i) verification of the participant's satisfactory completion of monitoring and program requirements as appropriate for public safety;

(ii) verification of the participant's completion of board final order terms and conditions with recommendation of the program for discharge; and/or

(iii) notification that the participant is transferring to another jurisdiction.

(2) The medical assistance program shall consult with the board regarding medical assistance program processes and procedures to ensure program responsibilities are met, consistent with board orders, requests, and contract terms.

(3) The medical assistance program shall provide information to and consult with the board upon the board's request.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1605 PROTOCOL FOR DISCIPLINARY TRACK

(1) All licensees who participate in the assistance program under the disciplinary track shall be reported to the board by name.

(2) A licensee or license applicant is placed in the disciplinary track by one or more of the following:

(a) as a condition of licensure imposed by a board final order;

(b) as a result of a sanction imposed by a board final order.

(3) The program shall also report licensees who have discharged from the program.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1606 PROTOCOL FOR NONDISCIPLINARY TRACK

(1) A licensee or license applicant who participates in the medical assistance program under the nondisciplinary track shall be reported to the board by participant number.

(2) The identity of the participant who is noncompliant or refuses a reasonable request by the medical assistance program shall be reported to the board.

(3) If the board determines that a participant does not abide by all terms and conditions of the medical assistance program, the participant will be referred to the screening panel of the board for appropriate action under the disciplinary track.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1607 REPORTING TO THE BOARD (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1608 PARTICIPANT DISCHARGE REQUIREMENTS (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1609 RELAPSE REPORTING (REPEALED)

(REPEALED)

Authorizing statute(s): 37-1-131, 37-7-201, MCA

Implementing statute(s): 37-1-131, 37-7-201, MCA

History: NEW, 2012 MAR p. 896, Eff. 4/27/12; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1701 DEFINITIONS

(1) "Authorized user" means a prescriber, pharmacist, Board of Pharmacy staff, Montana Medicare or Medicaid programs, Tribal Health, Indian Health Service, and Veterans Affairs.

(2) "Authorized agent" means a designated person authorized access by an authorized user. An authorized agent for a pharmacist must be a pharmacy intern or certified pharmacy technician.

Authorizing statute(s): 37-7-1512, MCA

Implementing statute(s): 37-7-1512, MCA

History: NEW, 2012 MAR p. 506, Eff. 3/9/12.

24.174.1702 REQUIREMENTS FOR SUBMITTING PRESCRIPTION REGISTRY INFORMATION TO THE BOARD

(1) All prescription information for controlled substances shall be submitted to the board pursuant to this subchapter.

(2) Each facility licensed by the board as a community pharmacy or as an out-of-state mail service pharmacy that dispenses to patients in Montana shall provide controlled substances dispensing information or zero report by no later than the close of the next business day to the board as outlined in the Montana Prescription Drug Registry (MPDR) Data Submission Guide available on the Board of Pharmacy's MPDR website at www.mpdr.mt.gov.

(3) Each facility licensed by the board as an institutional pharmacy shall provide controlled substance dispensing information if they dispense controlled substances in an outpatient, discharge, starter packet, or other related capacity in which the controlled substance(s) leaves their premises. Institutional pharmacies are not required to submit zero reports.

(4) Controlled substance dispensing information reported to the MPDR must include the following:

(a) pharmacy name, address, telephone number, and drug enforcement administration number;

(b) full name, address, telephone number, gender, species code, and date of birth for whom the prescription was written;

(c) full name, address, telephone number, and drug enforcement administration registration number of the prescriber;

(d) date the prescription was issued by the prescriber;

(e) date the prescription was filled and sold by the pharmacy;

(f) number of refills;

(g) indication of whether the prescription dispensed is new or a refill;

(h) name, national drug code number, strength, quantity, dosage form, and days' supply of the actual drug dispensed;

(i) number assigned to the prescription; and

(j) source of payment for the prescription that indicates one of the following:

(i) cash;

(ii) insurance; or

(iii) government subsidy.

(5) All prescription information submitted to the board must be transmitted in the format specified by the American Society for Automation in Pharmacy (ASAP), version 4.2A, dated 2016, at a minimum, which is adopted and incorporated by reference. ASAP 4.2A specifications are available in the MPDR Data Submission Guide available at the board's MPDR website at www.mpdr.mt.gov.

(a) The acceptable methods of electronic reporting are Secure File Transfer Protocol (SFTP), file upload, and manual data entry of prescription information via the secure web-based interface provided by the system vendor maintained by the board.

(6) In the event that a pharmacy cannot submit the required information as described in this rule, the pharmacy must timely notify the board on or before the date the submission is due. Upon notification, the board may grant an extension, at their discretion.

(7) It is the responsibility of the submitting pharmacy to address any errors or questions about information that the pharmacy has submitted to the prescription drug registry and resubmit corrected data within seven days after the date of notification of the error.

(8) A pharmacy that does not dispense controlled substances may notify the board by submitting an appropriate board-approved form attesting that the pharmacy does not dispense controlled substances to Montana patients. A pharmacy is not exempt from reporting requirements until it receives approval from the board.

(a) The board-approved form submitted by a pharmacy that does not dispense controlled substances shall be maintained on file with the board.

(b) A pharmacy's exempt status does not expire unless the pharmacy is issued a new license number or the pharmacy dispenses a controlled substance.

Authorizing statute(s): 37-7-1512, MCA

Implementing statute(s): 37-7-1502, 37-7-1503, 37-7-1512, 37-7-1513, MCA

History: NEW, 2012 MAR p. 506, Eff. 3/9/12; AMD, 2022 MAR p. 1842, Eff. 9/24/22; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1703 ELECTRONIC FORMAT REQUIRED FOR THE TRANSMISSION OF INFORMATION (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-1512, MCA

Implementing statute(s): 37-7-1503, 37-7-1512, MCA

History: NEW, 2012 MAR p. 506, Eff. 3/9/12; AMD, 2022 MAR p. 1842, Eff. 9/24/22; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1704 REQUIREMENTS FOR SUBMITTING PRESCRIPTION REGISTRY INFORMATION TO THE BOARD (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-1512, MCA

Implementing statute(s): 37-7-1503, 37-7-1512, MCA

History: NEW, 2012 MAR p. 506, Eff. 3/9/12; AMD, 2015 MAR p. 302, Eff. 3/27/15; AMD, 2018 MAR p. 1825, Eff. 9/8/18; AMD, 2022 MAR p. 1842, Eff. 9/24/22; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1705 FAILURE TO REPORT PRESCRIPTION INFORMATION (REPEALED)

(REPEALED)

Authorizing statute(s): 37-1-319, 37-7-1512, MCA

Implementing statute(s): 37-1-312, 37-7-1513, MCA

History: NEW, 2012 MAR p. 506, Eff. 3/9/12; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1706 REGISTRY INFORMATION REVIEW AND UNSOLICITED PATIENT PROFILES

(1) The board or their designee(s) may review and compile information contained in the registry to identify evidence of possible misuse or diversion of controlled substances.

(2) Registered prescribers and pharmacists will be notified electronically, through vendor functionality, of instances of possible misuse or diversion for patients under their care

(3) The following factors are suggestive, but not conclusive evidence of misuse or diversion:

(a) four or more prescribers in a 60-day period; or

(b) four or more pharmacies in a 60-day period.

Authorizing statute(s): 37-7-1512, MCA

Implementing statute(s): 37-7-1502, 37-7-1504, MCA

History: NEW, 2012 MAR p. 506, Eff. 3/9/12; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1708 ACCESS TO PRESCRIPTION DRUG REGISTRY INFORMATION

(1) The following persons may have direct online access to prescription drug registry information:

(a) licensed practitioners having authority to prescribe prescription drugs, or that practitioner's authorized agent, for the purpose of providing medical and/or pharmaceutical care for their patients, or for patients referred for medical care and/or pharmaceutical care;

(b) licensed pharmacists authorized to dispense prescription drugs, or that pharmacist's authorized agent, for the purpose of providing pharmaceutical care for their patients or for patients referred for care;

(c) designated representatives from the Montana Medicare or Medicaid programs, Tribal Health, Indian Health Service, and Veterans Affairs regarding program recipients;

(d) board staff for administrative and compliance purposes; and

(e) any vendor or contractor establishing or maintaining the prescription drug registry.

(2) To access registry information, each user must first complete the registration form, terms of use or equivalent agreement, and confidentiality agreement provided by the board. The board will provide educational material about the MPDR program online at www.mpdr.mt.gov.

(3) Access for user is restricted:

(a) in the case of a licensed practitioner having authority to prescribe prescription drugs, or that practitioner's authorized agent, to:

(i) the practitioner's own prescribing information; or

(ii) prescription records for a patient of the practitioner to whom the practitioner is providing or considering providing medical and/or pharmaceutical care;

(b) in the case of a licensed pharmacist, or that pharmacist's authorized agent, to prescription records for a patient for whom the pharmacist is providing pharmaceutical care, dispensing, or considering dispensing a prescription;

(c) in the case of a designated representative of the Montana Medicare or Medicaid programs, Tribal Health, Indian Health Service, and Veterans Affairs, to prescription records related to a participant in the program;

(d) in the case of authorized representatives of the board, to:

(i) that necessary to respond to legitimate inquiries; or

(ii) that necessary for legitimate inquiries under ARM 24.174.1706;

(e) in the case of an authorized vendor or contractor, to technical work necessary to establish or maintain the prescription drug registry databank.

(4) For each user:

(a) information accessed from the prescription drug registry must be kept confidential;

(b) information accessed from the prescription drug registry must not be disclosed to any unauthorized person; and

(c) user account information, login names, and passwords must not be shared with any person, regardless of whether that person is also an authorized user of the prescription drug registry.

(5) Prior to granting access to the registry, the board shall verify that the applicant is licensed to prescribe or dispense prescription drugs, or in the case of an agency applicant, the board shall verify that the applicant is the designated representative of the Montana Medicare or Medicaid programs, Tribal Health, Indian Health Service, or Veterans Affairs.

(6) Upon verification of all requirements, the board shall issue the appropriate information necessary for online access to the prescription drug registry.

(7) Upon notification that an authorized user no longer possesses authority to prescribe, dispense, or represent Medicare or Medicaid programs, Tribal Health, Indian Health Services, Veterans Affairs, or the board, the board shall terminate the user's access to the prescription drug information.

(8) Persons authorized in 37-7-1506(1)(d) and (e), MCA, to obtain information from the prescription drug registry must apply for that information by:

(a) completing the registration form, terms of use or equivalent agreement, and confidentiality agreement provided by the board and provide appropriate credentialing; or

(b) serving upon the board or its designee, an investigative subpoena directing the board to release a profile to the county coroner or a peace officer employed by a federal, state, tribal, or local law enforcement agency.

(9) Individual patients may request their own prescription registry information from the board or their provider. If requesting from the board, the requester shall complete and return the form provided by the board. A copy of the information will be provided at no charge to the individual.

(10) If the prescription drug registry receives evidence of inappropriate or unlawful use or disclosure of prescription registry information by an authorized user, the board shall file a complaint with the user's licensing board.

Authorizing statute(s): 37-7-1506, 37-7-1512, MCA

Implementing statute(s): 37-7-1506, 37-7-1512, MCA

History: NEW, 2012 MAR p. 506, Eff. 3/9/12; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1709 REGISTRY INFORMATION RETENTION

(1) Patient information contained in the registry shall be destroyed three years after the original date of submission of the information to the registry.

(2) Pursuant to 37-7-1508, MCA, a government entity or law enforcement agency may request that specific information in the registry, related to an open investigation, be retained beyond the three-year destruction requirement by submitting a request to the board.

Authorizing statute(s): 37-7-1512, MCA

Implementing statute(s): 37-7-1508, MCA

History: NEW, 2012 MAR p. 506, Eff. 3/9/12; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1711 ADVISORY GROUP

(1) The board shall establish a prescription drug registry advisory group, to provide information and recommendations about the development, operation, enhancement, and clinical application of the prescription drug registry.

Authorizing statute(s): 37-7-1510, 37-7-1512, MCA

Implementing statute(s): 37-7-1510, MCA

History: NEW, 2012 MAR p. 506, Eff. 3/9/12; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1712 PRESCRIPTION DRUG REGISTRY FEE

(1) Every person licensed under Title 37, MCA, to prescribe or dispense prescription drugs shall pay a fee to the board for the purpose of establishing and maintaining the prescription drug registry.

(2) The fee is considered a renewal fee and shall be collected by the department when the license is renewed.

(3) The annual prescription drug registry fee is $30.

Authorizing statute(s): 37-1-134, 37-7-1511, 37-7-1512, MCA

Implementing statute(s): 37-1-134, 37-1-141, 37-7-1511, 37-7-1512, MCA

History: NEW, 2012 MAR p. 506, Eff. 3/9/12; AMD, 2017 MAR p. 1144, Eff. 7/22/17; AMD, 2019 MAR p. 2240, Eff. 12/7/19.

24.174.1713 RELEASE OF PRESCRIPTION DRUG REGISTRY INFORMATION TO OTHER ENTITIES (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-1512, MCA

Implementing statute(s): 37-7-1506, MCA

History: NEW, 2012 MAR p. 506, Eff. 3/9/12; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1715 INTERSTATE EXCHANGE OF REGISTRY INFORMATION (REPEALED)

(REPEALED)

Authorizing statute(s): 37-7-1512, MCA

Implementing statute(s): 37-7-1506, MCA

History: NEW, 2012 MAR p. 506, Eff. 3/9/12; REP, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.1801 QUALIFICATIONS FOR DISPENSER REGISTRATION

(1) An applicant for a registration to dispense drugs as a medical practitioner, pursuant to 37-2-104, MCA, shall:

(a) be a licensed medical practitioner as defined in 37-2-101(7), MCA;

(b) be in good standing as that term is defined in this chapter;

(c) complete the application on a form supplied by the board;

(d) pay the required application fee and renewal fee; and

(e) be located in Montana.

(2) The applicant shall:

(a) state each location in Montana at which prescription drugs will be dispensed; and

(b) grant permission to the board to inspect each location at which prescription drugs will be dispensed during the normal business hours.

(3) Registrants must conspicuously display the dispenser license at all times in the place of business for which the license is issued.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-2-104, 37-7-201, MCA

History: NEW, 2021 MAR p. 1673, Eff. 11/20/21.

24.174.1802 DISPENSING REQUIREMENTS

(1) A dispenser registrant shall:

(a) create a written or electronic prescription drug order for each drug dispensed and maintain such information in the patient's chart or record, pursuant to ARM 24.174.831, and 37-7-101(43) and 50-31-307, MCA, which shall include the following, but not be limited to:

(i) patient's name;

(ii) name of drug;

(iii) strength;

(iv) dosage form;

(v) quantity;

(vi) directions for use;

(vii) date of issuance; and

(viii) prescriber's name;

(b) perform in person the final verification check of each drug prior to dispensing that, at a minimum, includes the following:

(i) ensuring the prescription drug product and label match the prescription drug order and the information on the manufacturer's label with respect to drug, dosage form, strength, quantity, and drug identification number;

(ii) verifying the prescription product label matches the prescription drug information with respect to prescription requirements in ARM 24.174.831;

(iii) verifying the drug has not expired and will not expire within the duration of use;

(iv) ensuring the registrant has completed a prospective drug utilization review after reviewing the patient profile; and

(v) documenting that the final verification check was completed by the registrant; and

(c) directly prepare, dispense, and deliver the drug, including subsequent fills or refills, in person to their patient(s) pursuant to the provisions in 37-2-104(2) and 50-31-307, MCA. The drug may not be dispensed or delivered by mail or common carrier.

(2) A registrant shall comply with all federal and state statutes and regulations regarding dispensing of prescription drugs, including all requirements for the registrant to:

(a) perform a prospective drug utilization review, pursuant to 37-7-101(17) and 37-7-406, MCA, and ARM 24.174.902;

(b) provide patient labeling, pursuant to 37-7-101(14), MCA, and ARM 24.174.301(23), 24.174.832, and 24.174.833, including:

(i) the prescription label shall contain the name, address, and phone number of the registrant, name of patient, name and strength of drug, directions for use, and date of filling;

(ii) the prescription label must be securely attached to the outside of the container in which the drug is dispensed; and

(iii) the registrant shall provide Medication Guides and/or Patient Package Inserts, comply with Risk Evaluation and Mitigation Strategies, and/or other labeling requirements as required by the U.S. Food and Drug Administration;

(c) develop a protocol to manage, store, and secure prescription drug dispensing inventory, pursuant to ARM 24.174.301(43), 24.174.814, 24.174.818, and 24.174.819, including:

(i) operating in a sanitary manner;

(ii) restricting access only to authorized individuals as determined by the registrant;

(iii) assuring that physical access to prescription drugs for dispensing is denied to all individuals at all times when a registrant is not on the premises, except with regard to dispensing pursuant to 37-2-104(8), MCA;

(d) maintain recordkeeping, pursuant to ARM 24.174.833, with records available for inspection by the board;

(e) compound drug products, including non-sterile and sterile products, pursuant to ARM 24.174.841;

(f) provide patient counseling, pursuant to 37-7-101(31) and 37-7-406, MCA, and ARM 24.174.903;

(g) provide notification that the patient may request dispensing of a less expensive therapeutically equivalent generic or interchangeable biologic product pursuant to 37-7-502 and 37-7-506, MCA, if applicable; and

(h) implement and have in place a quality assurance program to detect, identify, and prevent prescription errors, pursuant to ARM 24.174.407.

(3) With regard to inspections by the board or its designee, a registrant shall resolve conditions identified in an inspection report, if applicable.

(4) Prescription drugs dispensed by a registrant may not be transferred to another practitioner or pharmacist for subsequent filling or refills.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-2-104, 37-7-201, MCA

History: NEW, 2021 MAR p. 1673, Eff. 11/20/21.

24.174.1803 DISPENSER RECORDKEEPING REQUIREMENTS

(1) A registrant shall keep readily retrievable at each dispensing location records of dispensing and inventory, pursuant to ARM 24.174.833:

(a) a copy of the registrant's dispenser license;

(b) a record of each final verification check by the registrant;

(c) the registrant's protocols for handling drug recalls, including the arrangements for notifying patients;

(d) the registrant's protocols for disposal of drugs;

(e) with respect to a supplier from whom the registrant purchased prescription drugs:

(i) the name, address, and phone number of each wholesale drug distributor supplier, as defined in 37-7-602(8), MCA, and ARM 24.174.1201; and

(ii) documentation including:

(A) for each wholesale drug distributor supplier, the number and the expiration date of the license issued by the board; and

(B) for any pharmacy supplier acting as a wholesale drug distributor, the number and the expiration date of the pharmacy license issued by the board;

(f) any other purchasing, inventory, and dispensing records required by state or federal statutes or regulations;

(g) a manual or electronic dispensing record must be maintained separately from the patient medical record and kept for a minimum of two years. If an electronic health information system, as defined in 37-7-101(22), MCA, is utilized, the system must be able to produce a separate dispensing record; and

(h) the dispensing record must show, at a minimum, the following for original and subsequent fills or refills, in compliance with ARM 24.174.833:

(i) name of patient;

(ii) unique identifier;

(iii) dose, dosage form, quantity dispensed, and either the brand name of drug or generic name and name of manufacturer;

(iv) directions for use;

(v) date of dispensing; and

(vi) initials of registrant dispensing the prescription.

(2) In addition to meeting the requirements of ARM 24.174.1802, the registrant shall comply with any other state or federal law or regulation relating to dispensing of prescription drugs.

(3) Records must be available for inspection by the board.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-2-104, 37-7-201, MCA

History: NEW, 2021 MAR p. 1673, Eff. 11/20/21.

24.174.1901 VETERINARY RETAIL FACILITY LICENSE REQUIREMENTS

(1) Applicants for licensure as a veterinary retail facility must:

(a) submit a completed application form;

(b) pay the required application fee or renewal fee;

(c) designate a registered veterinary dispensing technician as person-in-charge; and

(d) comply with the provisions of 37-18-803, MCA.

(2) Veterinary retail facilities must notify the board within 30 days of the following changes:

(a) designated person-in-charge; and

(b) termination in service.

Authorizing statute(s): 37-18-803, MCA

Implementing statute(s): 37-18-803, MCA

History: NEW, 2024 MAR p. 84, Eff. 1/13/24.

24.174.1902 VETERINARY RETAIL FACILITY REQUIREMENTS

(1) A veterinary retail facility may dispense veterinary prescription drugs as defined in 37-18-801, MCA, upon receipt of a Montana licensed veterinarian's prescription, standing order, or other order for use in livestock. Drugs must be dispensed by a veterinary dispensing technician registered with the Board of Veterinary Medicine.

(2) A veterinary retail facility may refill a prescription only if the initial prescription authorizes a specific number of refills, or as identified in a standing order or other appropriate authorization from the prescribing veterinarian.

(3) All licensed veterinary retail facilities shall:

(a) maintain readily accessible written or electronic records of veterinary prescription drug inventory and prescriptions for two years after dispensing, and make the records available for board inspection;

(b) provide for secure storage of and accurate recordkeeping for veterinary prescription medications, records, and drug inventory;

(c) limit access to veterinary prescription medications and records to the facility's person-in-charge and registered veterinary dispensing technician(s) only;

(d) store veterinary prescription drugs separately from over-the-counter drugs and as recommended by the manufacturer;

(e) operate in a sanitary manner;

(f) purchase veterinary prescriptions drugs, as defined in 37-18-801, MCA, from a wholesale distributor or pharmacy licensed by the board;

(g) maintain policies and procedures to manage and dispose of outdated, expired, damaged, or returned drugs to prevent such drugs from being dispensed, distributed, or resold. Facilities may utilize a reverse distributor licensed as a wholesale distributor by the board; and

(h) create and maintain a dispensing record and a client information sheet that includes the following:

(i) name, address, and telephone number of the Montana licensed prescribing veterinarian;

(ii) client name;

(iii) identification of animals or herds treated;

(iv) date(s) each prescription was written, and the drugs dispensed;

(v) name and quantity of dispensed drug;

(vi) directions for the drug's dosage, frequency, and duration for use;

(vii) manufacturer's cautionary statements; and

(viii) manufacturer's expiration date.

(4) If the information in (3)(h) is included on the manufacturer's label, it is unnecessary to repeat the same information on the client's information sheet, but it must be included in the dispensing record.

Authorizing statute(s): 37-18-803, MCA

Implementing statute(s): 37-18-803, 37-18-804, MCA

History: NEW, 2024 MAR p. 84, Eff. 1/13/24.

24.174.2101 PHARMACIES - ANNUAL RENEWAL

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-321, MCA

History: NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; AMD, 1980 MAR p. 970, Eff. 3/14/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1999 MAR p. 2438, Eff. 10/22/99; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; REP, 2019 MAR p. 1633, Eff. 9/21/19.

24.174.2102 PHARMACY TECHNICIAN - RENEWAL

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-1-141, 37-7-201, MCA

History: NEW, 2002 MAR p. 86, Eff. 1/18/02; AMD, 2010 MAR p. 74, Eff. 1/15/10; REP, 2019 MAR p. 1633, Eff. 9/21/19.

24.174.2103 RENEWALS

(REPEALED)

Authorizing statute(s): 37-1-319, 37-7-201, MCA

Implementing statute(s): 37-1-131, 37-1-141, 37-1-306, 37-7-201, MCA

History: NEW, 1978 MAR p. 1740, Eff. 12/29/78; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 1999 MAR p. 2438, Eff. 10/22/99; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1583, Eff. 7/1/06; AMD, 2010 MAR p. 74, Eff. 1/15/10; REP, 2019 MAR p. 1633, Eff. 9/21/19.

24.174.2104 REGISTERED PHARMACIST CONTINUING EDUCATION - REQUIREMENTS

(1) The nationally accepted measurement of continuing education, the continuing education unit (CEU), will be the measurement employed by the board. Ten hours of approved continuing education credit equal one CEU.

(2) The board will require:

(a) 1.5 CEU for each fiscal year if a pharmacist takes at least 0.5 CEU in an approved group program; or

(b) 2.0 CEU for each fiscal year if a pharmacist does not take at least 0.5 CEU in an approved group program.

(3) The annual CEU requirement will not pertain to a pharmacist applying as a new graduate for his or her first license renewal.

(4) Only an additional 1.5 CEU may be accumulated and applied to the following year.

(5) All licensees shall affirm an understanding of their recurring duty to comply with CE requirements as a part of annual license renewal.

Authorizing statute(s): 37-1-319, MCA

Implementing statute(s): 37-1-306, MCA

History: NEW, 1978 MAR p. 1740, Eff. 12/29/78; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2011 MAR p. 1148, Eff. 6/24/11; AMD, 2019 MAR p. 1633, Eff. 9/21/19; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.2105 REGISTERED PHARMACIST CONTINUING EDUCATION -SUBJECTS

(1) Continuing pharmaceutical education will include, but will not be limited to, appropriate professional post graduate education in any of the following subjects:

(a) properties and actions of drugs and dosage forms;

(b) etiology, pathophysiology, clinical course, therapy and prognosis of diseases;

(c) pharmacy practice; and

(d) legal, psychological and socioeconomic aspects of health care delivery.

Authorizing statute(s): 37-1-319, MCA

Implementing statute(s): 37-1-306, MCA

History: NEW, 1978 MAR p. 1740, Eff. 12/29/78; TRANS, from Dept. of Prof. & Occup. Lic. , Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; TRANS, from Commerce, 2002 MAR p. 904.

24.174.2106 REGISTERED PHARMACIST CONTINUING EDUCATION - APPROVED PROGRAMS

(1) Continuing education programs sponsored by providers that are approved by the following organizations will automatically qualify for continuing education credit:

(a) the American Council on Pharmaceutical Education (ACPE);

(b) programs that have been approved for Continuing Medical Education (CME) by a state Board of Medical Examiners or its equivalent; or

(c) programs that have been approved for CME by an accredited CME provider.

(2) Pharmacists may receive CEU for programs other than those on the ACPE list of providers. Acceptable non-ACPE programs must focus on protecting the health, safety, and welfare of the public and contribute to the pharmacist's professional knowledge and competence, and must:

(a) directly relate to the scope of practice of pharmacy as defined in board statutes and rules;

(b) review existing concepts and techniques;

(c) convey information beyond the basic professional education;

(d) update knowledge on the practice and advances in pharmacy; and/or

(e) reinforce professional conduct or ethical obligations of the pharmacist.

(3) A maximum of 1.0 CEU (10 hours) of the hours required in ARM 24.174.2104 may be obtained through completion of non-ACPE programs. The programs must comply with (2), and:

(a) be a minimum of 30 minutes in duration;

(b) be provided by an individual(s) competent in the subject matter;

(c) provide a statement and evaluation mechanism of educational objectives; and

(d) provide program materials and/or an agenda, and a certificate of completion that includes the program date, hours of CEU, name of non-ACPE program provider, and name of program presenter.

(4) In the event a pharmacist is selected for audit, the pharmacist must demonstrate the continuing education meets the above standards and submit non-ACPE information with a form provided by the board, including:

(a) program materials and/or an agenda; and

(b) a certificate of completion.

Authorizing statute(s): 37-1-319, MCA

Implementing statute(s): 37-1-306, MCA

History: NEW, 1978 MAR p. 1740, Eff. 12/29/78; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1986 MAR p. 945, Eff. 5/30/86; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2003 MAR p. 109, Eff. 12/27/02; AMD, 2011 MAR p. 1148, Eff. 6/24/11; AMD, 2021 MAR p. 1671, Eff. 11/20/21.

24.174.2107 REGISTERED PHARMACIST CONTINUING EDUCATION - NONCOMPLIANCE

(REPEALED)

Authorizing statute(s): 37-1-319, MCA

Implementing statute(s): 37-1-141, 37-1-306, MCA

History: NEW, 1978 MAR p. 1740, Eff. 12/29/78; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 1999 MAR p. 2438, Eff. 10/22/99; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1583, Eff. 7/1/06; AMD, 2012 MAR p. 506, Eff. 3/9/12; REP, 2019 MAR p. 1633, Eff. 9/21/19.

24.174.2108 ADMINISTRATIVE SUSPENSION

(1) The board authorizes the department to:

(a) administratively suspend licenses for deficiencies set forth in 37-1-321(1)(a) though (e), MCA; or

(b) file a complaint pertaining to the deficiencies in (1) that are based on repeated or egregious conduct, or that have co-occurring misconduct allegations that directly implicate public safety and may warrant formal disciplinary action.

(2) An administrative suspension is not a negative, adverse, or disciplinary action under Title 37, MCA, and is not reportable under federal law and regulations implementing the Healthcare Practitioner Databank or the department's licensee lookup and license verification databank.

Authorizing statute(s): 37-1-131, MCA

Implementing statute(s): 37-1-321, MCA

History: NEW, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.2301 UNPROFESSIONAL CONDUCT

(1) The board defines "unprofessional conduct" as follows:

(a) engaging in any activity which violates state and federal statutes and rules governing the practice of pharmacy;

(b) dispensing an outdated or questionable product;

(c) dispensing a cheaper product and charging for a more expensive product;

(d) charging for more dosage units than are actually dispensed;

(e) altering prescriptions or other records which the law requires pharmacies and pharmacists to maintain;

(f) dispensing medication without proper authorization;

(g) defrauding any persons or government agency receiving pharmacy services;

(h) placing a signature on any affidavit pertaining to any phase of the practice of pharmacy which the pharmacist knows to contain false information;

(i) any act performed in the practice of pharmacy which is hostile to the public health and which is knowingly committed by the holder of a license;

(j) buying, selling, purchasing or trading any prescription drug samples or offering to sell, purchase or trade drug samples. A "drug sample," as used herein, is defined to mean a unit of a prescription drug which is not intended to be sold and is intended to promote the sale of a drug;

(k) conviction, including conviction following a plea of nolo contendere, of an offense involving moral turpitude, whether misdemeanor or felony, and whether or not an appeal is pending;

(l) fraud, misrepresentation, deception or concealment of a material fact in applying for or securing a license, or license renewal, or in taking an examination required for licensure; as used herein, "material" means any false or misleading statement or information;

(m) use of a false, fraudulent or deceptive statement in any document connected with the practice of pharmacy;

(n) having been subject to disciplinary action of another state or jurisdiction against a license or other authorization to practice pharmacy, based upon acts or conduct by the licensee similar to acts or conduct that would constitute grounds for disciplinary actions under Title 37, chapter 7, MCA or these rules; a certified copy of the record of the action taken by the other state or jurisdiction is evidence of unprofessional conduct.

(o) willful disobedience of a rule adopted by the board, or an order of the board regarding evaluation or enforcement of discipline of a licensee;

(p) habitual intemperance or excessive use of an addictive drug, alcohol or any other substance to the extent that the use impairs the user physically or mentally;

(q) failing to furnish to the board or its investigators or representatives information legally requested by the board.

(r) failing to cooperate with a lawful investigation conducted by the board;

(s) conviction or violation of a federal or state law regulating the possession, distribution or use of a controlled substance, as defined by the federal food and drug administration or successors, whether or not an appeal is pending;

(t) failure to transfer pertinent and necessary patient records to another licensed pharmacy, the patient or the patient's representative when requested to do so by the patient or the patient's legally designated representative in a timeline that meets patient safety and health needs;

(u) failure to comply with an agreement the licensee has entered into with the assistance program;

(v) failure to follow policies or procedures defined in the practice situation to safeguard patient care;

(w) failure to comply with the scope of practice of a clinical pharmacist practitioner and the authority of a collaborative practice agreement, as authorized in 37-7-306, MCA;

(x) failure to submit controlled substance dispensing information to the prescription drug registry, pursuant to 37-7-1503, MCA; and

(y) filling a prescription from a pharmacy-produced copy as a pharmacy-produced copy of a prescription cannot be used to fill or dispense a prescription.

Authorizing statute(s): 37-1-319, 37-7-201, MCA

Implementing statute(s): 37-1-316, MCA

History: NEW, 1981 MAR p. 625, Eff. 6/26/81; AMD, 1989 MAR p. 1193, Eff. 8/18/89; AMD, 1998 MAR p. 3103, Eff. 11/20/98; AMD, 2001 MAR p. 783, Eff. 5/11/01; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2024 MAR p. 84, Eff. 1/13/24; AMD, 2024 MAR p. 2219, Eff. 9/21/24.

24.174.2401 SCREENING PANEL

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-1-307, MCA

History: NEW, 1998 MAR p. 3103, Eff. 11/20/98; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2006 MAR p. 1615, Eff. 6/23/06; REP, 2018 MAR p. 1825, Eff. 9/8/18.

24.174.2402 COMPLAINT PROCEDURE

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-1-308, 37-1-309, MCA

History: NEW, 1998 MAR p. 3103, Eff. 11/20/98; TRANS, from Commerce, 2002 MAR p. 904; REP, 2018 MAR p. 1825, Eff. 9/8/18.

24.174.2403 LEGAL SUSPENSION OR REVOCATION

(REPEALED)

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-311, 37-7-321, MCA

History: NEW, Eff. 3/21/55; AMD, 1980 MAR p. 126, Eff. 1/18/80; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1998 MAR p. 3103, Eff. 11/20/98; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2015 MAR p. 302, Eff. 3/27/15; REP, 2018 MAR p. 1825, Eff. 9/8/18.