MONTANA
ADMINISTRATIVE
REGISTER

BOARD OF PHARMACY
DEPARTMENT OF LABOR AND INDUSTRY

NOTICE OF PROPOSED RULEMAKING

MAR NOTICE NO. 2026-131.1

Summary

Amending compounding requirements, addressing prescription transfers and storage, and amending unprofessional conduct rules all pertaining to the Board of Pharmacy

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Hearing Date and Time

Friday, August 14, 2026, at 9:00 a.m.

Virtual Hearing Information

A public hearing will be held via remote conferencing to consider the proposed changes to the agency's rules. There will be no in-person hearing. Interested parties may access the remote conferencing platform in the following ways:

Join Zoom Meeting: https://mt-gov.zoom.us/j/86146403446

Meeting ID: 861 4640 3446; Password: 2539746694

Dial by Telephone: +1 646 558 8656

Meeting ID: 861 4640 3446; Password: 2539746694

Comments

Concerned persons may present their data, views, or arguments at the hearing. Written data, views, or arguments may also be submitted at dli.mt.gov/rules or P.O. Box 1728, Helena, Montana 59624. Comments must be received by Friday, August 21, 2026, at 5:00 p.m.

Accommodations

The agency will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. Requests must be made by Friday, August 7, 2026, at 5:00 p.m.

Contact

Department of Labor and Industry
(406) 444-5466
laborlegal@mt.gov
Montana Relay: 711

General Reasonable Necessity Statement

There is reasonable necessity for the board to amend these rules and adopt new rules now to update pharmacy regulation in Montana so it aligns with current United States Pharmacopeia (USP) compounding standards, reflects current pharmacy practice, improves patient safety, and provides clarifies requirements for compliance, inspection, and enforcement. The proposed changes update outdated terminology, incorporate current sterile and nonsterile compounding concepts, address hazardous drug handling and outsourcing facilities, and respond to identified inspection deficiencies, stakeholder input, and the need for clearer operational standards. The proposed changes also create endorsement identifiers for facility licenses at no cost related to sterile compounding and outsourcing facilities.

Rulemaking Actions

AMEND

The rules proposed to be amended are as follows, stricken matter interlined, new matter underlined:

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)~~(1) "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, or hour and date, after which a compounded sterile preparation (CSP) must not be used and must be discarded pursuant to USP 797.

~~(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)~~(2) "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)~~(3) "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.

(4) "Classified area" means an area that maintains an air quality classification based on the International Organization for Standardization (ISO) standards pursuant to USP 797.

~~(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)~~(5) "Cleanroom suite" means ~~an environment~~ a classified area that consists of both an anteroom and buffer room 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 are controlled and monitored.

~~(8)~~(6) "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)~~(7) "Collaborative practice agreement" is defined as set forth in ~~ARM 24.174.524~~ 37-7-101, MCA.

(8) "Compounded nonsterile preparation" (CNSP) means combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or altering a drug or bulk drug substance to create a nonsterile preparation. For purposes of this chapter, the addition of flavoring to a commercially available medication is not considered compounding.

~~(10)~~(9) "Compounded sterile preparation" (CSP) means~~:~~ combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile preparation.

(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~~ It does not include preparation per approved manufacturer labeling and proprietary bag and vial systems if prepared for a single patient for immediate use.

(b) ~~a preparation containing nonsterile ingredients or employing nonsterile components and devices that must be sterilized before administration~~ Repackaging of a sterile product or preparation from its original container into another container must be performed in accordance with the requirements in USP 797.

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

~~(12)~~(10) "DEA" means the Drug Enforcement Administration of the United States Department of Justice.

~~(13)~~(11) "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)~~(12) "Device" is defined in 37-7-101, MCA.

~~(15)~~(13) "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)~~(14) "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)~~(15) "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)~~(16) "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)~~(17) "Electronic signature" means a confidential personalized method of affixing a signature to an electronic document that will guarantee the identity of the prescriber.

~~(20)~~(18) "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)~~(19) "Facility" means an outpatient center for surgical services, a hospital and/or long-term care facility, or a home infusion facility.

~~(22)~~(20) "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)~~(21) "Formulary" means a current compilation of pharmaceuticals authorized for use within the institution by representatives of the medical staff and pharmacy department.

(22) "Hazardous drugs" means drugs that pose serious health risks to individuals when handled and includes the current list of antineoplastic and hazardous drugs used in healthcare from the National Institute for Occupational Safety and Health (NIOSH).

~~(24)~~(23) "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)~~(24) "Immediate use" means a sterile preparation compounded pursuant to the conditions in ~~ARM 24.174.841~~ USP 797 and whose administration must begin within ~~one hour~~ four hours of preparation or it must be promptly, appropriately, and safely discarded. The term also includes repackaging of a sterile product or preparation from its original container into another container.

~~(26)~~(25) "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)~~(26) "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)~~(27) "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)~~(28) "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)~~(29) "Long-term care facility" ~~has the same meaning as provided~~ is defined 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)~~(30) "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)~~(31) "Medical gas distributor" is a person engaged in the manufacture, processing, packaging, labeling, or wholesale distribution, as defined in 37-7-602, MCA, of a medical gas to a person other than a consumer or patient.

~~(34)~~(32) "Medical gas supplier" is a person engaged in selling, transferring, dispensing, 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)~~(33) "Multi-dose ~~vial~~ container" means a ~~vial~~ container 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. After the multi-dose container is initially punctured, it must not be used for longer than the assigned BUD or 28 days pursuant to USP 797.

~~(36)~~(34) "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)~~(35) "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)~~(36) "Outpatient center for surgical services" is ~~as~~ defined ~~at~~ in 50-5-101, MCA.

(37) "Outsourcing facility" is defined in 37-7-101, MCA.

~~(39)~~(38) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of skin.

~~(40)~~(39) "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 order pharmacy does not have to be licensed in Montana.

~~(41)~~(40) "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.

(41) "Primary engineering control" (PEC) means a device or zone that provides an International Organization for Standardization (ISO) Class 5 or better air quality environment for sterile compounding pursuant to USP 797.

(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 machine or system and which has access to its parent pharmacy and licensed pharmacists via computer, video, and audio link at all times during business hours.

(46) "Remote telepharmacy site" means a licensed site staffed by a licensed pharmacy technician with access to its parent pharmacy and licensed 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 24.174.841, 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)~~(47) "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)~~(48) "Security" or "secure system" means a system to maintain the confidentiality and integrity of patient records, which are being sent electronically.

(49) "Segregated compounding area" (SCA) means an unclassified area where sterile compounding is performed inside of a PEC. The beyond use date (BUD) for

compounded sterile preparations (CSPs) from a SCA is less than 12 hours at room temperature and less than 24 hours under refrigeration.

~~(51)~~(50) "Single-dose ~~vial~~ container" means a ~~sterile medication in a vial without preservatives~~ a container of sterile product for parenteral administration, whether by injection or infusion, that is designed for use with a single patient as a single injection/infusion. Pursuant to USP 797, any unused starting component from a single-dose container must be discarded after use. A single-dose container usually does not contain a preservative.

~~(52)~~(51) "Sterile pharmaceutical" means any dosage form containing no viable microorganisms including, but not limited to, parenterals and ophthalmics.

~~(53)~~(52) "Supervising pharmacist" means the licensed pharmacist who is serving as the pharmacist on duty and is in charge of the day-to-day supervision of the pharmacy personnel.

~~(54)~~(53) "Supervision" means that all drug distribution or dispensing activities, immunizations, or other activities performed by pharmacy personnel are under the direction of a licensed pharmacist.

~~(55)~~(54) "Tech-Check-Tech (TCT)" means a program in a community or institutional pharmacy with an endorsement, in which a pharmacy technician or pharmacist intern performs the final check or product verification of medications prepared by another technician or pharmacist intern in compliance with TCT program requirements in ARM 24.174.715.

(55) "United States Pharmacopeia" (USP) means a scientific organization recognized by the Food and Drug Administration that develops standards for compounded medications. The general chapters are standardized guidelines that establish official quality, purity, and safety requirements for medicines, excipients, and dietary supplements, and they outline analytical tests, storage guidelines, and manufacturing practices to ensure product consistency. USP information and access to the subscription service is available on the USP website at www.usp.org/compounding. The official general USP chapters include, but are not limited to, the following:

(a) USP general chapter 795 "Pharmaceutical Compounding – Nonsterile Preparations" (USP 795);

(b) USP general chapter 797 "Pharmaceutical Compounding – Sterile Preparations" (USP 797);

(c) USP general chapter 800 "Hazardous Drugs – Handling in Healthcare Settings" (USP 800); and

(d) USP general chapter 825 "Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging" (USP 825).

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

Authorizing statute(s): 37-7-201, 37-7-602, 50-32-314, MCA

Implementing statute(s): 37-7-101, 37-7-102, 37-7-201, 37-7-301, 37-7-306, 37-7-321, 37-7-406, 37-7-602, 37-7-603, 37-7-604, 37-7-605, 50-32-314, MCA

Reasonable Necessity Statement

There is reasonable necessity to amend this rule to remove outdated terminology, revise existing definitions, make several technical corrections, and add new definitions needed for the board's updated compounding framework. The board is making this change now to align terminology with USP 795 and USP 797, clarify concepts such as BUD, cleanroom suite, compounded nonsterile preparations, compounded sterile preparations, hazardous drug compounding and handling, immediate use, outsourcing facilities, primary engineering controls, and segregated compounding areas, and provide consistent terminology for compliance and enforcement.

24.174.803 CHANGE IN LOCATION AND BOARD NOTIFICATION REQUIREMENTS

(1) Whenever a facility licensed by the board changes its physical location, including within the existing business location or outside of its existing business location, the license remains the same and the facility~~, it~~ shall notify the board at least 30 days before such a change occurs for approval by the board or its designee. In the notification, the facility shall submit a new schematic or floor plan, ~~for board approval~~ a description of security, storage, access, and, if applicable, a description of privacy for patient counseling.

(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~~ remodels its existing location, or changes its scope of practice, the facility shall notify the board 30 days before such a change occurs for approval by the board or its designee.

Authorizing statute(s): 37-7-201, 37-7-610, 37-7-712, MCA

Implementing statute(s): 37-7-321, 37-7-604, 37-7-605, 37-7-610, 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-706, MCA

Reasonable Necessity Statement

There is reasonable necessity to amend this rule to clarify advance notice and approval requirements when a facility changes location, remodels, or changes scope of practice. The board is making this change now to eliminate ambiguity in the current rule and ensure it receives timely information regarding floor plans, security, storage, access, and patient counseling privacy when needed so it can evaluate compliance before the change occurs. The board is also removing the requirement to issue a new license for a change in location to reduce burden and cost to licensees, and align with DEA procedures.

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. A pharmacy technician may initiate the transfer if reflected in the pharmacy's policies and procedures; 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 or prescriptions 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

Reasonable Necessity Statement

There is reasonable necessity to amend this rule to clarify the process for transferring prescriptions and patient records between pharmacies. The board is making this change now to support continuity of care, timely patient access, and clearer expectations for transfer requests in current pharmacy practice, and align with revisions in unprofessional practice, ARM 24.174.2301.

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. Prescriptions delivered to a prescriber office may be delivered to a secure locker system or related technology holding products already labeled and ready for patient pickup.

(b) Nothing in this rule shall prohibit a ~~registered pharmacist~~ facility licensed as a pharmacy and located in Montana, or a medical practitioner dispenser registered with the board from installing an ~~appropriate secure device as an~~ alternate delivery system in the facility that holds products already labeled and ready for patient pick up, ~~when the pharmacy is closed~~ including, but not limited to, a secure locker system or related technology. The system, including a description of security, access, recordkeeping, and counseling methods must have the prior approval of the board or its designee, and must be available for inspection by the board.

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

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

Reasonable Necessity Statement

There is reasonable necessity to amend this rule to allow secure alternate delivery systems for prescriptions that are already labeled and ready for patient pickup, while preserving board oversight of security, access, recordkeeping, and counseling methods. The board is making this change now to address evolving technology and improve patient access while maintaining regulatory safeguards.

24.174.841 COMPOUNDED STERILE ~~PRODUCTS~~ PREPARATIONS

(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.~~ Any pharmacy facility, including out-of-state mail order pharmacies and outsourcing facilities, engaged in CSP must apply for a sterile compounding endorsement and identify a designated person pursuant to USP 797. The designated person is responsible and accountable for the

performance and operation of the facility and personnel as related to the preparation of CSP.

(2) ~~An institutional pharmacy compounding sterile products must have an isolated area designed to avoid unnecessary traffic and airflow disturbances.~~ A pharmacy facility engaged in sterile compounding must meet the minimum standards set forth in USP 797 to ensure the safety, identity, strength, quality, and purity of the finished product. Policies and procedures must be prepared, developed, and implemented for the compounding, dispensing, delivery, administration, storage, repackaging, and use of sterile pharmaceutical products. If applicable, other USP chapters relevant to the scope of practice must be met. Pharmacies must comply with section 503A of the Food, Drug, and Cosmetic Act including but not limited to compounding pursuant to a patient-specific prescription.

(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.~~ The designated person must have written or electronic documentation to demonstrate compliance with the requirements in USP available for inspection by the board, including but not limited to:

(a) personnel training, competency assessments, and qualification records including corrective actions for any failures;

(b) certification reports, including corrective actions for any failures;

(c) environmental air and surface monitoring procedures and results;

(d) equipment records (e.g., calibration, verification, and maintenance reports);

(e) receipt of components;

(f) standard operating procedures, master formulation records, and compounding records;

(g) release inspection and testing records if applicable; and

(h) information related to complaints and adverse events including investigations and corrective actions.

(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 pharmacy compounding sterile hazardous drugs must meet the standards set forth in USP 797 and USP 800 and be performed in an appropriate negative pressure environment. Policies and procedures must be maintained and address appropriate personal protective equipment, training, proper labeling to identify the drug is hazardous, containment of spills, and proper disposal of waste that complies with applicable local, state, and federal laws.

~~(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.~~ A pharmacy compounding sterile radiopharmaceuticals must meet the minimum standards set forth in USP 825 for the preparation, compounding, dispensing, and repackaging of radiopharmaceuticals.

~~(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

Reasonable Necessity Statement

There is reasonable necessity to amend this rule to align Montana's sterile compounding requirements with current USP standards and current compounding terminology. The board is making this change now to require a sterile compounding endorsement, designate responsible oversight, clarify documentation available for inspection, replace outdated risk-level terminology with current category-based standards, address hazardous drug compounding under USP 797 and USP 800, and add radiopharmaceutical standards under USP 825.

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~~ Licensed and provisionally licensed 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 both 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 (~~for compliance with USP~~) Chapter~~ 795 and USP 797 ~~"Pharmaceutical Compounding - Sterile Preparations"~~ for the initial and ongoing training and ~~testing~~ competency assessments of all personnel ~~and for annual retesting in aseptic manipulative skills for those personnel involved in low- and medium-risk compounding~~ engaged in compounding, pursuant to ARM 24.174.841 and [NEW RULE 1].

~~(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

Reasonable Necessity Statement

There is reasonable necessity to amend this rule to update personnel terminology and require training and competency assessment for personnel engaged in sterile and nonsterile compounding under current USP standards. The board is making this change now to align personnel requirements with the revised compounding rules and ensure that compounding functions are performed by properly trained personnel.

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;

(v) documenting that the final verification check was completed by the registrant; and

(vi) offer counseling to the patient;

(c) prepare, dispense, and deliver the drug, including subsequent fills or refills, to their own patient(s) pursuant to the provisions in 37-2-104(2) and 50-31-307, MCA. In addition:

(i) Health care staff members in the office, or place of practice of the registrant, may convey or dispense the drug on behalf of the registrant if:

(A) the drugs are prepared and sealed with two forms of identification written on the package by the registrant; and

(B) the health care staff member verifies the identity of the patient.

(ii) The drug may not be dispensed, conveyed, or delivered by mail or common carrier.

(iii) A registrant may use an alternate delivery of prescriptions as allowed by ARM 24.174.839.

(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 24.174.901;

(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 24.174.814 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 and [NEW RULE 1];

(f) dispense with the offer to provide patient counseling, pursuant to 37-2-104(2), 37-7-101(31), and 37-7-406, MCA, and ARM 24.174.903; and

(g) 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

Reasonable Necessity Statement

There is reasonable necessity to amend this rule to expressly require medical practitioner dispensers who compound drug products to comply with the updated sterile and nonsterile compounding rules. The board is making this change now to ensure consistent patient safety standards across practice settings.

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 or prescriptions 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

Reasonable Necessity Statement

The board determined it is reasonably necessary to amend ARM 24.174.2301 to clarify that a pharmacy or licensee engages in unprofessional conduct by failing to transfer pertinent and necessary patient records or prescriptions within a timeframe that meets the patient's safety and health needs. The amendment is necessary to protect patient access to prescribed therapy and continuity of care when a patient, the patient's representative, or another licensed pharmacy requests transfer of prescription information or related records. Delayed or refused transfers may interrupt medication therapy, create avoidable health risks, and impede a patient's ability to obtain prescription services from the pharmacy of the patient's choice.

The amendment also supports and is consistent with the board's amendment to prescription-transfer requirements in ARM 24.174.835 by making clear that transfer obligations are professional-conduct obligations, not merely recordkeeping or operational requirements. The board determined that a patient-safety standard is preferable to a fixed deadline because the urgency of a transfer request may vary depending on the medication, the patient's condition, pharmacy access, and other circumstances affecting continuity of care. The amendment therefore provides the board with an enforceable standard while preserving appropriate professional judgment and flexibility to address patient-specific safety and health needs.

ADOPT

The rules proposed to be adopted are as follows:

NEW RULE 1 COMPOUNDED NONSTERILE PREPARATIONS

(1) A pharmacy engaged in nonsterile compounding shall meet the standards set in the USP 795 and any other applicable chapters to ensure the safety, identity, strength, quality, and purity of the finished product.

(2) Each facility must identify a designated person to ensure compliance with USP 795 and ensure all personnel have been properly trained. The designated person must have available for inspection by the board written or electronic documentation to demonstrate compliance with the requirements in USP 795 including but not limited to:

(a) personnel training, competency assessments, and qualification records including corrective actions for any failures;

(b) standard operating procedures, master formulation records, and compounding records;

(c) equipment records (e.g., calibration, verification, and maintenance reports);

(d) receipt and inspection of components;

(e) appropriate cleaning, decontamination, and sanitation;

(f) release inspections and testing records; and

(g) information related to complaints and adverse events including investigations and corrective actions.

(3) Pharmacies must comply with section 503A of the Federal Food, Drug and Cosmetic Act including but not limited to compounding pursuant to a valid patient specific prescription.

(4) A pharmacy compounding nonsterile hazardous drugs must meet the standards set forth in USP 800 pursuant to [NEW RULE 2] and be performed in an appropriate negative pressure environment.

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

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

Reasonable Necessity Statement

There is reasonable necessity to adopt NEW RULE 1 to establish clear standards for nonsterile compounding, including compliance with USP 795, designated oversight, required documentation, section 503A Food and Drug Administration requirements, and USP 800 when nonsterile hazardous drugs are compounded. The board is making this change now because nonsterile compounding is common in community pharmacies, inspection deficiencies have been identified, and clearer direction is needed to meet patient safety expectations.

NEW RULE 2 HAZARDOUS DRUG HANDLING

(1) All personnel who handle hazardous drugs including repackaging solid dosage forms, and all facilities that store, compound, prepare, transport, or administer hazardous drugs must meet the requirements of USP 800.

(2) Each facility must assign a designated person to oversee compliance with the chapter and ensure that all personnel have been trained in hazardous drug handling.

(3) The designated person must have available for inspection by the board written or electronic documentation to demonstrate compliance with the requirements in USP 800 and at minimum include:

(a) personnel training;

(b) current assessment of risk if applicable;

(c) storage and disposal of hazardous drugs;

(d) cleaning and decontamination;

(e) proper use of appropriate personal protective equipment;

(f) management of spills; and

(g) appropriate disposal of hazardous waste.

(4) Each facility must maintain a copy of the current list of antineoplastic and hazardous drugs used in healthcare from the National Institute for Occupational Safety and Health (NIOSH) and it must be reviewed at least every 12 months. Whenever a new agent or dosage form is used, it should be reviewed against the entity's list pursuant to USP 800.

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

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

Reasonable Necessity Statement

There is reasonable necessity to adopt NEW RULE 2 to establish uniform requirements for handling hazardous drugs, including compliance with USP 800, designated oversight, training, documentation, and maintenance of the current NIOSH hazardous drug list. The board is making this change now to provide guidance for USP 800 compliance and to reduce occupational and patient safety risks associated with hazardous drugs.

NEW RULE 3 OUTSOURCING FACILITIES

(1) Any outsourcing facility engaged in CSPs must apply for an outsourcing endorsement and must be licensed as follows:

(a) Any outsourcing facility located outside of Montana dispensing patient-specific medications directly to patients, must obtain an out-of-state mail order pharmacy license.

(b) Any outsourcing facility located in Montana dispensing patient-specific medications directly to patients, must obtain a community pharmacy license.

(c) Any outsourcing facility located in or outside of Montana distributing wholesale or bulk medication to a pharmacy for administration or dispensing, or to a prescriber for administration or dispensing, must obtain a wholesale drug distributor license.

(2) Outsourcing facilities must be registered with the Food and Drug Administration (FDA) as an outsourcing facility and comply with applicable FDA requirements regarding section 503B of the Federal Food, Drug, and Cosmetic Act, FDA definitions, and FDA current good manufacturing practice requirements pursuant to Title 21, CFR, Subsection 211.1 to 211.208 (or successor regulations).

(3) Facilities compounding controlled substances must be in compliance with applicable DEA regulations.

(4) Any drugs compounded in an outsourcing facility shall be compounded by or under the direct supervision of a licensed pharmacist and in accordance with all applicable federal and state laws.

(5) The pharmacist-in-charge shall be responsible for the oversight of current policies and procedures, staff training and competency assessments, and for compliance with all federal and state regulations applicable to outsourcing facilities.

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

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

Reasonable Necessity Statement

There is reasonable necessity to adopt NEW RULE 3 to specify licensure, registration, supervision, and compliance requirements for outsourcing facilities that compound sterile preparations and operate in or distribute into Montana. The board is making this change now to clearly state its expectations for outsourcing facilities, including applicable Montana licensure, FDA registration and compliance, DEA compliance where applicable, pharmacist supervision, and pharmacist-in-charge oversight.

Small Business Impact

The small businesses probably affected by the proposed rules are Montana community pharmacies, including community pharmacies that engage in sterile compounding, nonsterile compounding, hazardous drug compounding, or optional alternate delivery-system services. Montana currently has approximately 251 licensed community pharmacies. The board estimates that more than half of those pharmacies, approximately 125 to 150 pharmacies, may qualify as small businesses. The estimate is based on licensing database information and consultation with board inspectors.

The proposed rules may affect subsets of community pharmacies differently depending on whether a pharmacy chooses to engage in activities not required for licensure, but are optional business models or services, related to sterile compounding, nonsterile compounding, hazardous drug compounding, or the use of alternate delivery systems.

Related to pharmacies that may qualify as small businesses, the board estimates that approximately four community pharmacies currently engage in sterile compounding. In addition, approximately six home infusion centers engage in sterile compounding, but those entities are generally not considered small businesses based on ownership structure because they are owned by or affiliated with a health system, hospital, or chain pharmacy. The board expects very few community pharmacies, approximately one to two, to newly engage in sterile compounding because of or after the rule. For a pharmacy that chooses to engage in sterile compounding, potential direct business costs may include United States Pharmacopeia (USP) subscription access, compounding formularies, policies and procedures, and, depending on current facilities and scope of services, remodeling or building a sterile compounding suite. The estimated annual USP subscription cost is $325 for one user, with higher rates for additional users; the board expects small-business pharmacies generally to purchase one access. The estimated cost of compounding formularies is $300, and the estimated cost of third-party compounding policy and procedure templates is $1,000.

The estimated cost to remodel or build a sterile compounding suite varies by scope of services and type of remodel. For an existing location, the estimated average remodeling cost is approximately $50,000, with a range of approximately $20,000 to $50,000-$80,000. Based on feedback received, very few small-business pharmacies are engaged in sterile compounding, and those that are have generally already purchased equipment to comply with USP 797. The board does not anticipate major costs for critical access hospital pharmacies that may qualify as small businesses when those facilities use USP 797 immediate-use sterile compounding and administration standards and do not need extensive remodels.

Because sterile compounding is not required for licensure and the board is aware of very few pharmacists interested in newly engaging in sterile compounding services, the cumulative small-business cost is expected to be limited and highly dependent on each pharmacy's

business model. If a pharmacy limits activity to immediate-use compounding under USP 797, it may not incur costs associated with the rule change.

The board estimates that approximately 27 community pharmacies currently engage in nonsterile compounding, including nonsterile compounding of hazardous drugs. The board expects very few community pharmacies, approximately one to two, to newly engage in nonsterile compounding because of or after the rule. Pharmacies already engaged in nonsterile compounding may need to invest in equipment or other changes to better comply with USP standards, but the board does not expect the rule to cause a significant number of pharmacies to newly enter this scope of service. The estimated annual USP subscription cost is $325 for one user, with higher rates for additional users; the board expects small-business pharmacies generally to purchase one access. The estimated cost of compounding formularies is $300, and the estimated cost of third-party compounding policy and procedure templates is $1,000.

For a pharmacy that chooses to engage in nonsterile compounding, including nonsterile compounding of hazardous drugs, potential direct business costs vary substantially based on current equipment, facility conditions, ventilation needs, and scope of compounding activity. Estimated costs may range from approximately $10,000 to more than $80,000, including equipment, ventilation systems, USP subscription access, formulary templates, and policy and procedure templates. Some pharmacies engaged in extensive nonsterile compounding have already purchased equipment and remodeled. The board expects ongoing education through the inspection process for current pharmacies engaged in limited nonsterile compounding and corresponding compliance with USP standards.

The cumulative cost for affected pharmacies cannot be stated as a single reliable number because costs vary greatly by existing conditions and business model. Some pharmacies may need only small upgrades to comply for limited compounding, while pharmacies operating an extensive compounding business model may face substantially higher costs.

The proposed rules may affect pharmacies that choose to use alternate delivery systems to improve patient access to prescriptions ready to pick up, such as locker systems or delivery to a prescriber's medical office. Use of an alternate delivery system is voluntary and is not required by the proposed rules. The board is aware of approximately two community pharmacies currently using locker systems. The number of pharmacies currently delivering prescriptions to prescribers' medical offices is unknown, but the board is aware that some pharmacies use that model.

The board estimates approximately 10 to 15 or more pharmacies may install alternate delivery systems, although use by medical practitioner dispensers or locations where prescriptions are currently delivered to a prescriber’s office is unknown. The board is aware of interest in utilizing alternate delivery where prescription volume supports investment in a locker system and where such a system may help improve patient access in the community. The estimated cost to install an alternate delivery system is at least $10,000, but the cost varies depending on the size and configuration of the system.

The proposed rules are expected to reduce administrative and monetary burden for all facilities licensed by the board that relocate by allowing the facility to avoid reapplication for a new license due to the address change. The current application fee for most facilities is $240, including community pharmacy, institutional pharmacy, out-of-state mail order pharmacy, and wholesale drug distributor. The application fee for outpatient surgical center is $45, and $150 for veterinary retail facility. For facilities that need a dangerous drug endorsement for controlled substances, the fee is $75 for dispensing or $100 for distribution. In general, the combined avoided fees for facilities range from $120, $150, $315, or $340 per relocation where reapplication is avoided.

Based on recent historical information, and nearly all small business-related new applications, approximately 10 to 15 community pharmacies changed locations in recent years, with an average of approximately five community pharmacy location changes per year. The board estimates that approximately five to ten community pharmacies may avoid reapplication because of the proposed rule.

The proposed relocation/licensure change is also expected to reduce administrative burden. The board estimates that a new license application requires approximately three to five hours of staff time, and that a license-number change can require approximately 20 hours to update purchasing contracts and approximately 20 hours to update billing and third-party payer records. The estimated avoided administrative work is approximately 45 hours per relocation, involving pharmacist or owner time and technician staff time.

The proposed relocation/licensure provisions are expected to decrease burden for affected community pharmacies by avoiding new-license fees and related administrative costs. For each relocation where reapplication is avoided, the estimated avoided board fees are $315, and the estimated avoided administrative cost is approximately $3,000 to $5,000 in staff time, with additional potential avoided payer re-enrollment costs and avoided delays in payer reimbursement.

The proposed rules do not adopt, increase, or decrease any board fee. There are no fees associated with the new sterile compounding endorsement or outsourcing facility endorsement. Therefore, the board does not identify a proposed new, increased, or decreased fee payable to or receivable from the board for purposes of the monetary-estimate requirement in 2-4-111(1)(b), MCA.

To the extent the proposed rules may result in private business costs, those costs are contingent on the pharmacy's voluntary business model or scope of services. Sterile compounding, nonsterile compounding, or hazardous drug compounding, and alternate delivery-system use are not mandatory for licensure. Estimated private costs are therefore best stated as conditional ranges for pharmacies that choose to engage in those activities, as described above.

Bill Sponsor Notification

The bill sponsor contact requirements do not apply.

Interested Persons

The agency maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by the agency. Persons wishing to have their name added to the list may sign up at dli.mt.gov/rules or by sending a letter to P.O. Box 1728, Helena, Montana 59624 and indicating the program or programs about which they wish to receive notices.

Rule Reviewer

Jennifer Stallkamp

Approval

Sarah Swanson, Commissioner

Approval

Logan Tinsen, Presiding Officer, Board of Pharmacy