BEFORE THE BOARD OF PHARMACY
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

In the matter of the amendment of ARM 24.174.301 definitions, 24.174.411 pharmacist meal/rest breaks, 24.174.602 internship requirements, 24.174.701 registration requirements, 24.174.903 patient counseling, 24.174.1101 personnel, 24.174.1111 drug distribution and control, 24.174.1115 use of contingency kits, 24.174.1704 requirements for submitting prescription registry information, 24.174.2403 legal suspension or revocation, the amendment and transfer of ARM 24.174.510, 24.174.514, and 24.174.523 related to prescription requirements, 24.174.1121 sterile products, the adoption of NEW RULE I quality assurance program requirements, and the transfer of ARM 24.174.511 through 24.174.513, 24.174.515, and 24.174.520 through 24.174.522 related to prescription requirements	)	NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT, AMENDMENT AND TRANSFER, ADOPTION, AND TRANSFER

TO: All Concerned Persons

1. On November 13, 2014, at 1:00 p.m., a public hearing will be held in the basement conference room, Room B-07, 301 South Park Avenue, Helena, Montana, to consider the proposed amendment, amendment and transfer, adoption, and transfer of the above-stated rules.

2. The Department of Labor and Industry (department) will make reasonable accommodations for persons with disabilities who wish to participate in this public hearing or need an alternative accessible format of this notice. If you require an accommodation, contact the Board of Pharmacy (board) no later than 5:00 p.m., on November 6, 2014, to advise us of the nature of the accommodation that you need. Please contact Marcie Bough, Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; telephone (406) 841-2371; Montana Relay 1 (800) 253-4091; TDD (406) 444-2978; facsimile (406) 841-2344; or dlibsdpha@mt.gov (board's e-mail).

3. The rules proposed to be amended provide 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) "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.

~~(1)~~ (3) "Biological safety cabinet" means a ~~contained unit suitable for the preparation of low to moderate risk agents and where there is a need for protection of the product, personnel, and environment according to National Sanitation Foundation Standard 49~~ 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.

(2) and (3) remain the same, but are renumbered (4) and (5).

(6) "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.

(4) through (8) remain the same, but are renumbered (7) through (11).

~~(9)~~ (12) "Drug order" means a written or electronic order issued by an authorized practitioner, or a verbal order promptly ~~reduced to writing~~ transcribed, for the compounding and dispensing of a drug or device to be administered to patients within the facility.

(10) through (17) remain the same, but are renumbered (13) through (20).

(21) "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.

(18) and (19) remain the same, but are renumbered (22) and (23).

(24) "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.

(20) through (23) remain the same, but are renumbered (25) through (28).

(29) "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.

(24) through (33) remain the same, but are renumbered (30) through (39).

(40) "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.

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

(34) and (35) remain the same, but are renumbered (42) and (43).

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

(36) and (37) remain the same, but are renumbered (45) and (46).

AUTH: 37-1-131, 37-7-201, 50-32-314, MCA
IMP: 37-7-102, 37-7-201, 37-7-301, 37-7-321, 37-7-406, 37-7-603, 37-7-604, 37-7-605, 50-32-314, MCA

REASON: The board is amending this rule to update one definition and add several new definitions to accurately reflect current sterile compounding terminology and standards of practice, as these are used and referenced in the amended rules on sterile compounding.

24.174.411 PHARMACIST MEAL/REST BREAKS (1) through (4) remain the same.

(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) through (12) remain the same.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: The board determined it is reasonably necessary to amend this rule to clarify that a pharmacist may also authorize an intern to remain in the prescription department. In 2011-12, the board's biennial rule review identified the need to add interns to this rule. Additionally, both pharmacists and interns had asked the board how, if at all, this rule applied to interns. Because the pharmacist supervises technicians and interns, both types of personnel need to be among those authorized to remain in the department and perform nondiscretionary duties.

24.174.602 INTERNSHIP REQUIREMENTS (1) through (11) remain the same.

(12) The intern shall notify the board of any change of address, employment, or preceptor within ~~ten~~ 30 days.

(13) and (14) remain the same.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: The board is amending this rule to allow interns additional time to notify the board of any address changes and align this requirement with the notification requirement for pharmacist preceptors in ARM 24.174.604.

24.174.701 REGISTRATION REQUIREMENTS (1) through (2)(b) remain the same.

(c) provide the name and address of the pharmacy in which the technician-in-training is employed. A change in place of employment will require submission of updated information within ~~ten~~ 30 working days of the change.

(3) and (4) remain the same.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: The board is amending this rule to allow technicians-in-training additional time to notify the board of any address changes and align this requirement with the notification requirement for pharmacist preceptors in ARM 24.174.604.

24.174.903 PATIENT COUNSELING (1) Upon receipt of a new prescription drug order or refill prescription drug order if deemed necessary by the pharmacist, and following a review of the patient's record, a pharmacist shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of such patient. Such discussion shall be in person, whenever practicable, or by telephone, and shall include appropriate elements of patient counseling. Such elements may include the following:

(a) through (j) remain the same.

(2) Each pharmacy shall have at least one area that offers appropriate visual and auditory patient confidentiality for patient counseling. ~~This requirement shall go into effect three years from the date of enactment.~~

(3) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples ~~to~~ include written information leaflets, pictogram labels, video programs, etc.

(4) and (5) remain the same.

AUTH: 37-7-201, MCA
IMP: 37-7-406, MCA

REASON: It is reasonably necessary to amend this rule and remove the effective date of the patient counseling area requirement, as the requirement became effective in 2003. The board determined this language is no longer needed and potentially confusing.

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 ~~the state of~~ 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) remains the same.

(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.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-307, MCA

REASON: The board concluded it is reasonably necessary to amend certain rules regarding drug compounding to align with the standards of pharmacy practice as published by the United States Pharmacopeia (USP). USP 797 establishes standards for sterile compounding of drugs and is updated frequently, including five times this year. In 2011-12, the board conducted a biennial rule review which demonstrated that the board's current rules on drug compounding are not in line with the standards published in USP 797, nor are the rules current with pharmacy best practices, as recognized by the FDA. The board is amending this rule to require training and testing for personnel who will prepare sterile and nonsterile compounded pharmaceuticals to align with the USP 797 and better ensure the sterility and quality of these preparations as provided to Montana residents.

24.174.1111 DRUG DISTRIBUTION AND CONTROL IN AN INSTITUTIONAL FACILITY (1) and (2) remain the same.

(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. ~~Complete information regarding these drugs and their disposition must be maintained in the facility. The drug monograph and a signed patient consent form must be obtained and made available in accordance with state and federal guidelines.~~

(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) and (6) remain the same.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-307, 37-7-308, 37-7-406, MCA

REASON: The board is amending and reorganizing this rule to comply with formatting requirements of the Secretary of State and increase clarity.

24.174.1115 USE OF CONTINGENCY KITS IN CERTAIN INSTITUTIONAL FACILITIES (1) through (5) remain the same.

(6) ~~All documentation must be readily available for inspection by the board~~ The contents of the contingency kit and all related records shall be made freely available and open for inspection to representatives of the board and when information of possible violations is received.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: The board determined it is reasonably necessary to amend this rule to clarify that contingency kit contents and related records must be made available for board inspection. The board concluded that this clarification will aid board inspectors and staff in performing their inspection and investigation duties and answering licensee questions.

24.174.1704 REQUIREMENTS FOR SUBMITTING PRESCRIPTION REGISTRY INFORMATION TO THE BOARD (1) All prescription ~~dispensing information submitted under this subchapter shall be submitted at least weekly~~ drug order information for controlled substances shall be submitted to the board pursuant to this subchapter.

(2) ~~The information submitted shall be consecutive and complete from the date and time of the submitting pharmacy's last submission, and shall be reported no later than eight days after the date of dispensing~~ A pharmacy shall submit all prescription drug order information for a controlled substance to the board no later than eight days after the date of dispensing the controlled substance.

(3) If a pharmacy that dispenses controlled substances has not dispensed ~~no reportable~~ any controlled substances during a ~~reporting period~~ calendar month, the pharmacy shall ~~submit a timely~~ verify that no controlled substances were dispensed for that month by submitting a "zero report~~.~~" to the board. A "zero report" is due on or before the fifth day of the next month.

(4) A pharmacy that does not dispense controlled substances shall notify the board by submitting an appropriate board-approved form attesting that the pharmacy does not dispense controlled substances.

(a) The form submitted by a pharmacy that does not dispense controlled substances shall be maintained on file with the board and at the pharmacy's location.

(b) If a pharmacy does dispense a controlled substance, it shall then comply with the reporting requirements of this rule.

(4) remains the same, but is renumbered (5).

~~(5)~~ (6) In the event that a pharmacy cannot submit the required information as described in this rule, the pharmacy must timely report that fact ~~on the appropriate board-approved form. This form is due~~ to the board on or before the date ~~that~~ the ~~weekly~~ submission is ~~otherwise~~ due. The board office may grant an extension, at their discretion, when a pharmacy notifies the board that they are unable to submit their report.

~~(6)~~ (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 no later than eight days after the date of the original submission.

AUTH: 37-7-1512, MCA
IMP: 37-7-1503, 37-7-1512, MCA

REASON: The board determined that it is reasonably necessary to amend this rule and further clarify which pharmacies must report information to the Montana Prescription Drug Registry (MPDR), and when that information must be reported. The board has concluded that pharmacies that do not dispense controlled substances are not subject to the reporting requirements of this rule.

The board also concluded that the requirements for submitting a request for extension of time to report information to the MPDR should be amended to make it easier for pharmacies to request an extension. Further, the board determined that it is reasonably necessary to clarify the requirements for resubmitting corrected data to the MPDR so pharmacies are aware that the board expects for errors to be corrected and reported to the MPDR within a reasonable amount of time.

24.174.2403 LEGAL SUSPENSION OR REVOCATION (1) All licensed pharmacists and operators of pharmacies in ~~the state of~~ Montana must adhere to all the laws of ~~the state of~~ Montana and the rules of the board pertaining to pharmacists and operators of pharmacies and any violation thereof may constitute a cause for the revocation of such licenses.

(2) If an intern pharmacist is found or allowed to work in a pharmacy without the supervision of a registered pharmacist, meaning that the intern is allowed to

work ~~a shift~~ by himself/herself, it may be cause for the board to cancel his or her internship in said pharmacy and may be cause for suspension or revocation of his or her intern pharmacist license. The board may in its discretion ask for surrender, suspension, or revocation of the pharmacy license of the pharmacy in which the intern has violated this section of the pharmacy law.

(3) remains the same.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-311, 37-7-321, MCA

REASON: The board determined it is reasonably necessary to amend this rule to clarify the board's intent of when an intern may work without supervision. The board determined that public protection is not measured by unsupervised practice of a certain "shift" period, and is clarifying that interns may not work unsupervised.

4. The rules proposed to be amended and transferred provide as follows, stricken matter interlined, new matter underlined:

24.174.510 (24.174.831) PRESCRIPTION REQUIREMENTS (1) through (3) remain the same.

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

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-505, MCA

REASON: The board determined it is reasonably necessary to amend this rule to define “chart order” to clarify what constitutes a prescription in an institutional setting. The board has received several questions regarding the process and validity of prescriptions stemming from these institutional settings.

The board is transferring this rule and ARM 24.174.514 and 24.174.523 from subchapter 5 (Licensing) to subchapter 8 (Pharmacies) to make it easier for the public and licensees to identify and locate these rules on prescriptions, as they relate more closely to pharmacies than licensure requirements.

24.174.514 (24.174.835) TRANSFER OF PRESCRIPTIONS (1) The ~~manual~~ transfer of ~~original~~ prescription information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

(a) the transfer is communicated directly between two licensed pharmacists/interns; ~~and the transferring pharmacist records the following information:~~

~~(i) write the word 'VOID' on the face of the invalidated prescription,~~

~~(ii) record on the reverse of the invalidated prescription the name and address of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information,~~

~~(iii) record the date of the transfer and the name of the pharmacist transferring the information.~~

~~(b) The pharmacist receiving the transferred prescription information shall reduce to writing the following:~~

~~(i) write the word 'TRANSFER' on the face of the transferred prescription,~~

~~(ii) provide all information required to be on a prescription pursuant to state and federal laws and regulations and include:~~

~~(A) date of issuance of original prescription,~~

~~(B) original number of refills authorized on original prescription,~~

~~(C) date of original dispensing,~~

~~(D) number of valid refills remaining and date of last refill,~~

~~(E) pharmacy's name, address and original prescription number from which the prescription information was transferred,~~

~~(F) name of transferor pharmacist.~~

(b) controlled substances may only be transferred from the original pharmacy to which it was presented; and

(c) for a period of not less than two years, a retrievable audit trail must be maintained that includes the date of transfer and initials or code of the transferring party.

(2) The manual transfer of original prescription information for a controlled (dangerous) substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only, by following the procedures listed ~~above~~ in (1). In addition:

(a) through (3) remain the same.

(4) The electronic transfer of original prescription information for a controlled (dangerous) substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only, by following the procedures listed ~~above~~ in (1) and (3).

(5) and (5)(a) remain the same.

(b) Whenever a consumer objects to their prescription records being made accessible to other pharmacies through the use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy except as provided in (1), (2), and (4) ~~of this rule~~. ~~The pharmacist to whom the consumer communicated the objection shall ask the consumer to sign a form which reads substantially as follows: "I hereby notify (name of pharmacy) that my prescription drug records may not be made accessible to other pharmacies through a common or shared electronic file." The pharmacist shall date and co-sign the form and shall deliver a copy thereof to the patient. The original shall be maintained by the pharmacy for three years from the date of the last filling or refilling of any prescription in the name of the consumer.~~

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

(7) and (8) remain the same.

AUTH: 37-7-201, MCA

IMP: 37-7-201, MCA

REASON: The board is amending this rule to clarify and simplify the processes for transferring prescriptions. The board is amending (1)(a) to address the involvement of interns in current pharmacy practice and to align with process changes due to technological advances. It is reasonably necessary to delete (1)(a)(i) through (1)(b) as the board concluded that these requirements are currently being accomplished electronically through the use of prescription software.

The board is adding new (1)(b) and (c) to further protect against potential fraudulent transactions by limiting the transfer of prescriptions for controlled substances and requiring pharmacies to maintain retrievable audit trails.

The board is amending (5) to remove the requirement that pharmacists obtain and maintain forms when patients object to electronic transmission of their records. Because of technological advancements, the protections afforded by federal law, and other transfer restrictions enumerated in this rule, the board concluded it is no longer necessary for a signed patient form.

24.174.523 (24.174.840) TRANSMISSION OF PRESCRIPTIONS BY ELECTRONIC MEANS (1) remains the same.

(2) A pharmacist may dispense directly a controlled substance in Schedule II, which is a prescription drug as determined by the Federal Food, Drug, and Cosmetic Act (FD&C Act), ~~only~~ pursuant to a written prescription signed by the practitioner. ~~A~~ In addition, a prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy by electronic means, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance or by electronic means that meet all of the federal guidelines for controlled substances that are electronically prescribed. The original prescription shall be maintained in accordance with ARM 24.174.512.

(a) through (c) remain the same.

(3) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V, which is a prescription drug as determined under the FD&C Act, only pursuant to either a written prescription signed by a practitioner or a copy of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy by electronic means, or pursuant to an oral prescription made by an individual practitioner and promptly reduced to hardcopy by the pharmacist, containing all information required or by electronic means that meet all of the federal guidelines for controlled substances that are electronically prescribed. The prescription shall be maintained in accordance with ARM 24.174.512.

(4) through (6) remain the same.

AUTH: 37-7-201, 50-32-103, MCA
IMP: 37-1-101, 37-7-102, 37-7-201, 50-32-208, MCA

REASON: The board is amending (2) by striking "only" to align with federal regulations that permit dispensing by other means, including by electronic methods.

The board is also amending (2) and (3) to align with federal guidelines for transmitting prescriptions electronically and recent changes to the board's definition of "prescription drug order."

24.174.1121 (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) through (4) remain the same.

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

(b) remains the same.

(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) through (8) remain the same.

(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.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-307, 37-7-308, MCA

REASON: The board concluded it is reasonably necessary to amend certain rules regarding drug compounding to align with the standards of pharmacy practice as published by the United States Pharmacopeia (USP). USP 797 establishes standards for sterile compounding of drugs and is updated frequently, including five times this year. In 2011-12, the board conducted a biennial rule review which demonstrated that the board's current rules on drug compounding are not in line with the standards published in USP 797, nor are the rules current with pharmacy best practices, as recognized by the FDA. The board is amending this rule to establish the standards and requirements that are pertinent to the amended and new definitions proposed in ARM 24.174.301 relating to compounding sterile products.

Additionally, the board is transferring this rule related to sterile products from subchapter 11 (Institutional Pharmacies) to subchapter 8 (Pharmacies), after concluding that the issue of compounding sterile products in Montana has expanded beyond institutional pharmacies to include other pharmacy practice settings.

5. The proposed new rule provides as follows:

NEW RULE I QUALITY ASSURANCE PROGRAM REQUIREMENTS

(1) Each pharmacy shall implement or have in place a quality assurance program to detect, identify, and prevent prescription errors. The quality assurance program shall include necessary documentation, internal reporting, and assessment of prescription errors to determine the cause and an appropriate response.

(2) The primary purpose of the quality assurance program shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a prescription error to assess the cause and any contributing factors such as system or process failures.

(3) Each pharmacy, corporation, or health system shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent prescription errors, as well as communicate those findings to all pharmacy personnel.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: The board determined it is reasonably necessary to adopt this new rule; implementation of quality assurance programs is designed to improve patient safety and quality of care through the reporting and assessment of prescription errors.

6. The rules proposed to be transferred provide as follows:

24.174.511 (24.174.832) LABELING FOR PRESCRIPTIONS

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: The board is transferring the rules relating to prescriptions from subchapter 5 (Licensing) to subchapter 8 (Pharmacies) to make it easier for the

public and licensees to identify and locate these rules, as they relate more closely to pharmacies than licensure requirements.

24.174.512 (24.174.833) RECORDS OF DISPENSING found at page 24-19548.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

24.174.513 (24.174.834) COPY OF PRESCRIPTION found at page 24-19548.

AUTH: 37-7-201, MCA
IMP: 37-7-101, MCA

24.174.515 (24.174.836) EMERGENCY PRESCRIPTION REFILLS found at page 24-19551.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

24.174.520 (24.174.837) PRESCRIPTION REQUIRED FOR SCHEDULE V found at page 24-19565.

AUTH: 37-7-201, MCA
IMP: 37-7-102, 37-7-201, MCA

24.174.521 (24.174.838) RETURNED PRESCRIPTION found at page 24-19565.

AUTH: 37-7-201, 37-7-1401, MCA
IMP: 37-7-201, 37-7-1401, MCA

24.174.522 (24.174.839) ALTERNATE DELIVERY OF PRESCRIPTIONS found at page 24-19565.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-301, MCA

7. Concerned persons may present their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513, by facsimile to (406) 841-2344, or e-mail to dlibsdpha@mt.gov, and must be received no later than 5:00 p.m., November 21, 2014.

8. An electronic copy of this notice of public hearing is available at www.pharmacy.mt.gov (department and board's web site). The department strives to make the electronic copy of this notice conform to the official version of the notice, as printed in the Montana Administrative Register, but advises all concerned persons that in the event of a discrepancy between the official printed text of the notice and the electronic version of the notice, only the official printed text will be considered. In addition, although the department strives to keep its web site accessible at all times, concerned persons should be aware that the web site may be unavailable during some periods, due to system maintenance or technical problems, and that technical difficulties in accessing or posting to the e-mail address do not excuse late submission of comments.

9. The board maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this board. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies that the person wishes to receive notices regarding all board administrative rulemaking proceedings or other administrative proceedings. The request must indicate whether e-mail or standard mail is preferred. Such written request may be sent or delivered to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; faxed to the office at (406) 841-2344; e-mailed to dlibsdpha@mt.gov; or made by completing a request form at any rules hearing held by the agency.

10. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

11. With regard to the requirements of 2-4-111, MCA, the board has determined that the amendment of ARM 24.174.301, 24.174.411, 24.174.602, 24.174.701, 24.174.903, 24.174.1101, 24.174.1111, 24.174.1115, 24.174.1704, and 24.174.2403 will not significantly and directly impact small businesses.

With regard to the requirements of 2-4-111, MCA, the board has determined that the amendment and transfer of ARM 24.174.510, 24.174.514, 24.174.523, and 24.172.1121 will not significantly and directly impact small businesses.

With regard to the requirements of 2-4-111, MCA, the board has determined that the adoption of NEW RULE I will not significantly and directly impact small businesses.

With regard to the requirements of 2-4-111, MCA, the board has determined that the transfer of ARM 24.174.511 through 24.174.513, 24.174.515, and 24.174.520 through 24.174.522 will not significantly and directly impact small businesses.

Documentation of the board's above-stated determinations is available upon request to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513, by facsimile to (406) 841-2344, or e-mail to dlibsdpha@mt.gov.

12. Kevin Maki, attorney, has been designated to preside over and conduct this hearing.

BOARD OF PHARMACY
BECKY DESCHAMP, RPh, VICE PRESIDENT

/s/ DARCEE L. MOE
Darcee L. Moe
Rule Reviewer

/s/ PAM BUCY
Pam Bucy, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State October 14, 2014