



**MONTANA
ADMINISTRATIVE
REGISTER**

**BOARD OF PHARMACY
DEPARTMENT OF LABOR AND INDUSTRY**

NOTICE OF ADOPTION

MAR NOTICE NO. 2026-131.2

Summary

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

Previous Notice(s) and Hearing Information

On July 24, 2026, the Board of Pharmacy (agency) published MAR Notice No. 2026-131.1 regarding the public hearing on the proposed changes to the agency's rules, in the 2026 Montana Administrative Register, Issue No. 14.

On August 14, 2026, a public hearing was held on the proposed changes to the rules via the videoconference and telephonic platform. Comments were received by the comment deadline.

Final Rulemaking Action – Effective September 26, 2026

ADOPT AS PROPOSED

The agency has adopted the following rules as proposed:

NEW RULE 1 (24.174.843) COMPOUNDED NONSTERILE PREPARATIONS

NEW RULE 2 (24.174.844) HAZARDOUS DRUG HANDLING

NEW RULE 3 (24.174.845) OUTSOURCING FACILITIES

AMEND AS PROPOSED

The agency has amended the following rules as proposed:

24.174.803 CHANGE IN LOCATION AND BOARD NOTIFICATION REQUIREMENTS

24.174.835 TRANSFER OF PRESCRIPTIONS

24.174.839 ALTERNATE DELIVERY OF PRESCRIPTIONS

24.174.841 COMPOUNDED STERILE PREPARATIONS

24.174.1101 PERSONNEL

24.174.1802 DISPENSING REQUIREMENTS

24.174.2301 UNPROFESSIONAL CONDUCT

AMEND WITH CHANGES

The agency has amended the following rule with the following changes from the original proposal, stricken matter interlined, new matter underlined:

24.174.301 DEFINITIONS

- (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.
- (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.
- (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.

- (5) "Cleanroom suite" means a classified area that consists of both an anteroom and buffer room in which airflow, pressurization, temperature, and humidity are controlled and monitored.
- (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.
- (7) "Collaborative practice agreement" is defined as set forth in 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.
- (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) 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) 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.
- (10) "DEA" means the Drug Enforcement Administration of the United States Department of Justice.
- (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.
- (12) "Device" is defined in 37-7-101, MCA.
- (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.
- (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.
- (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.
- (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.
- (17) "Electronic signature" means a confidential personalized method of affixing a signature to an electronic document that will guarantee the identity of the prescriber.
- (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.
- (19) "Facility" means an outpatient center for surgical services, a hospital and/or long-term care facility, or a home infusion facility.
- (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.

- (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).
- (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.
- (24) "Immediate use" means a sterile preparation compounded pursuant to the conditions in USP 797 and whose administration must begin within 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.
- (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.
- (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.
- (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.
- (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.
- (29) "Long-term care facility" is defined in 50-5-101, MCA.

- (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.
- (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.
- (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.
- (33) "Multi-dose container" means a 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.
- (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.
- (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.
- (36) "Outpatient center for surgical services" is defined in 50-5-101, MCA.
- (37) "Outsourcing facility" is defined in 37-7-101, MCA.
- (38) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of skin.
- (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.
- (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) "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.
- (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.
- (50) "Single-dose container" means 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.
- (51) "Sterile pharmaceutical" means any dosage form containing no viable microorganisms including, but not limited to, parenterals and ophthalmics.

- (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.
- (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.
- (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), November 1, 2023 version;
 - (b) USP general chapter 797 "Pharmaceutical Compounding – Sterile Preparations" (USP 797), February 1, 2026 version;
 - (c) USP general chapter 800 "Hazardous Drugs – Handling in Healthcare Settings" (USP 800), July 1, 2020 version; and
 - (d) USP general chapter 825 "Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging" (USP 825), January 1, 2024 version.
- (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

Statement of Reasons

The agency has considered the comments and testimony received. A summary of the comments received, and the agency's responses are as follows:

Comment 1: Commenters supported modernization of the board's compounding requirements, including alignment with current USP standards and stronger oversight.

Response 1: The board appreciates all comments received during the rulemaking process.

Comment 2: A commenter requested specific version dates or effective dates for the referenced United States Pharmacopeia (USP) chapters in definition rather than a reference to current chapters.

Response 2: The board agrees with the commenter and inserts the current version dates into the rule for clarity.

Comment 3: Commenters requested pre-endorsement inspections and new provisions defining and disciplining compounding of products that are essentially copies of commercially available drugs.

Response 3: The board thanks the commenters. A pre-endorsement inspection condition, new definition, and separate disciplinary provision would each add material requirements beyond the noticed amendments. However, the board may consider these issues in future rulemaking. In addition, the board already recognizes the Food and Drug Administration's (FDA) prohibition of compounding essentially a copy of commercially available drugs pursuant to section 503A of the Food and Drug Cosmetic Act. Any violation would fall under existing unprofessional conduct rules and compliance procedures through the complaint process.

Comment 4: Commenters requested detailed requirements for certificate-of-analysis and active pharmaceutical ingredients used in drug compounding, mandatory reporting of serious adverse events, and improved documentation requirements regarding compounding.

Response 4: The proposed rules require pharmacies to keep records about ingredients, complaints, adverse events, investigations, and corrective actions for inspection. The board considered the requested new certificate-of-analysis and reporting requirements but will not add them in this rulemaking because they were not included in the proposal notice. The board may consider them in a future rulemaking. The board further clarifies that the current inspection process includes requesting certificate-of-analysis and other compounding documentation.

Comment 5: Commenters requested general compounded-product labeling, patient disclosures, adverse event reporting, and additional enforcement measures.

Response 5: The board considered these requests but will not add them in this rulemaking. They would create new requirements that were not included in the proposal notice. The board may consider them in a future rulemaking.

Comment 6: Commenters requested additional compounding safety measures to investigate quality concerns and patient safety issues.

Response 6: The board appreciates the comments and clarifies there is existing authority for inspecting pharmacy and other facilities licensed by the board and for investigating issues related to complaints.

Comment 7: Several commenters indicated their concerns regarding compounded drugs.

Response 7: The board appreciates the comments but clarifies that compounding is outlined within pharmacists' scope of practice and these rule changes will further enhance patient safety by updating specific references to compounding requirements and standards.

Comment 8: Several commenters support the board establishing an endorsement and rules for 503B outsourcing facilities registered with FDA and performing sterile compounding.

Response 8: The board appreciates all comments received during the rulemaking process.

Comment 9: A commenter requested the board issue guidance reminding licensees that they cannot compound investigational drugs.

Response 9: The board appreciates the comments and clarifies that all licensees of the board, including pharmacists, pharmacies, and outsourcing facilities, are required to follow the statutes and rules of the board and follow FDA requirements.

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Approval

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Approval

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