Montana Department of LABOR & INDUSTRY

Montana Board of Pharmacy
January 6, 2022

Summary of Final Rule MAR Notice 24-174-74
Effective November 20, 2021

The Montana Board of Pharmacy finalized rule changes regarding MAR Notice 24-174-74, amending various pharmacy rules, issued as a proposal rule on August 27, 2021, and issued as a final rule on November 19, 2021, effective November 20, 2021.

A summary of the amended rules, as reflected in the links provided to the Administrative Rules of Montana (ARM), include the following:

- **ARM 24.174.301 Definitions**
  - Amended to reflect changes to the drug kit in ARM 24.174.1114.

- **ARM 24.174.524 Collaborative Practice Agreement Requirements**
  - Amended to better reflect current practice, remove burdensome requirements, and clarify information needed in a collaborative practice agreement (agreement). The amendments include:
    - Requirements for signatures, effective date, monitoring compliance and clinical outcomes, documentation in a patient's permanent record and related access, provisions regarding practitioner override, clinically appropriate review/renewal time frame, and written notification to end an agreement.
    - Signatures and signing dates are required for collaborating pharmacists and practitioners, or a representative of a medical practice or clinic who is authorized to represent its practitioners, who are party to the agreement.
    - Clarification that agreements approved by an institutional committee solely for patients while they are receiving care in the institution are exempt.
    - There is no change to the provision that a copy of the agreement must be available at the pharmacy and any other practice location for inspection by the Board. Agreements are not submitted to the Board office.

- **ARM 24.174.835 Transfer of Prescriptions**
  - Amended to add quantity remaining to prescription transfer information.

- **ARM 24.174.1111 Drug Distribution and Control in an Institutional or Correctional Facility**
  - Amended to align with changes to drug kits in ARM 24.174.1114, and to better reflect drug storage in correctional facilities.

- **ARM 24.174.1114 Use of Drug Kits in Certain Institutional Facilities**
  - Amended to consolidate rules for emergency drug kits and contingency kits into one rule to better align with current practice and remove duplicate language.
    - Definitions (ARM 24.174.301) were updated to reflect relevant changes.

        - ARM 24.174.1115, use of contingency kits in certain institutional settings, was repealed and the pertinent provisions were incorporated into one drug kit rule.
    - Amendments include:
        - Updated drugs kit requirements include expiration dates and replacing expired drugs, use in inpatient settings, requirements for use in emergency/crash cart, recordkeeping policies and procedures for access/review, restocking, annual review, and information available upon inspection.
        - The supplying pharmacy and appropriate designated practitioner of a licensed facility must provide adequate controls to prevent drug diversion.
    - Endorsement:
        - A supplying pharmacy will need to request a drug kit endorsement for the pharmacy license, and include a list of drug kit locations, and provide any updates to drug kit locations at the time of change.
        - An endorsement application will have no cost but is not yet available. Pharmacies seeking a **Drug Kit Endorsement** should contact the Board of Pharmacy at dlibsdpha@mt.gov and staff will follow-up with additional information.

- ARM 24.174.1412 **Additions, Deletions, and Rescheduling of Dangerous Drugs**
    - Amended to update and clarify Montana's scheduling of dangerous drugs (controlled substances) Schedules I through V, to:
        - Remove duplicate drug listings implemented in statute (Senate Bill 274) through the 2019 Montana Legislature; and
        - Reflect recent scheduling changes made by the U.S. Drug Enforcement Administration (DEA), including the removal from Schedule V approved cannabidiol drugs, including Epidiolex®, as described below:
            - A drug product in finished dosage formulation that has been approved by the United States Food and Drug Administration that contains cannabidiol, also known as (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol), derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols, and as authorized by the Agriculture Improvement Act of 2018 (P.L. 115-334).

- ARM 24.174.2106 **Registered Pharmacist Continuing Education – Approved Programs**
    - Amended to align with the Department's standardized renewal and audit procedures regarding continuing education for pharmacists and to remove administrative burden. The board will no longer preapprove programs that are not approved by the American Council on Pharmaceutical Education (ACPE) and instead outlines requirements and standards that such program must meet to be accepted as non-ACPE programs in a CE audit.
        - Acceptable non-ACPE approved programs must focus on protecting the health, safety, and welfare of the public and contribute to the pharmacist's professional knowledge and competence, and must:
            - Review existing concepts and techniques;
            - Convey information beyond the basic professional education;
            - Update knowledge on the practice and advances; and/or

        - Reinforce professional conduct or ethical obligations of the pharmacist.
    - A maximum of 1.0 CEU (10 hours) of the hours required in ARM 24.174.2104 (1.5 CEU including 0.5 CEU group program, or 2.0 CEU with no group), may be obtained through completion of non-ACPE approved programs. The non-ACPE program must also:
        - Be a minimum of 30 minutes;
        - Be provided by an individual(s) competent in the subject matter;
        - Provide a statement and evaluation mechanism of educational objectives; and
        - Provide program materials and/or an agenda, and a certificate of completion that includes the program date, hours of CEU, name of non-ACPE program provider, and name of program presenter.
    - In the event a pharmacist is selected for audit, the pharmacist must demonstrate the continuing education meets the standards stated in rule and submit non-ACPE information with a form provided by the Board that includes program materials and/or an agenda, and a certificate of completion.
- Programs will automatically qualify for credit if obtained from an ACPE-approved provider, a Continuous Medical Education (CME) provider approved by a state Board of Medical Examiners or equivalent, or a CME-accredited program.

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