

# Law and MPDR Updates 2022

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**University of Montana Skaggs School of Pharmacy**



Montana Department of  
**LABOR & INDUSTRY**

# Disclosure

The presenters declare no actual or potential conflict of interest in relation to this presentation.

# Objectives

1. Review legislative and regulatory updates impacting the practice of pharmacy in Montana
2. Understand new functionality within the Montana Prescription Drug Registry (MPDR)

# Questions

What is the age limit for pharmacists, interns, and technicians to administer COVID-19 vaccines pursuant to the federal PREP Act authority?

- A. Age 3
- B. Age 12
- C. Age 18
- D. No age limits

What newer functionality is available with the Montana Prescription Drug Registry (MPDR)?

- A. Updates to pharmacy data fields and reporting standards
- B. Prescriber reports
- C. Data integration with health information systems
- D. All of the above
- E. None of the above

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**Paul Brand**, Pharmacist

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# Board of Pharmacy

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### 2022 Board Meetings

March 11

June 17

September 23

December 9



# www.pharmacy.mt.gov



- > Business Standards Division
- Board of Pharmacy
- > Board Information
- > License Information
- > Montana Prescription Drug Registry (MPDR)
- > Regulations
- > Service/Links
- FAQ's
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## Montana Board of Pharmacy

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### Welcome to the Montana Board of Pharmacy

The Board of Pharmacy makes every effort to include on this web site all relevant information pertaining to the licensing and regulation of the following license types:

# Law Updates 2022

Montana Code Annotated (MCA)  
Administrative Rules of Montana (ARM)

Access at:

<https://boards.bsd.dli.mt.gov/pharmacy/regulations/>



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# Final Rule MAR 74

## MAR 24-174-74: Amending Various Pharmacy Rules

- **Timeline**
  - Proposed rule issued 8/27/2021
  - Final rule published 11/19/2021
  - Effective 11/20/2021
- **Collaborative practice agreements, ARM 24.174.524**
  - Amended to better reflect current practice, remove burdensome requirements, and clarify information needed in agreement.
- **Prescriptions transfers, ARM 24.174.835**
  - Quantity remaining added to prescription transfer information.
- **Drug kits in certain institutional facilities, ARM 24.71.4.1114 and related rules**
  - Corresponding amendments: definitions, ARM 24.174.301; drug distribution and control in institutional and correctional facilities, ARM 24.174.1111; repeals ARM 24.174.1115, contingency kits as it is combined into one drug kit rule.
  - Creates Drug Kit Endorsement for supplying pharmacies; implementation in progress – contact Board at [dlibsdpha@mt.gov](mailto:dlibsdpha@mt.gov)

# Final Rule MAR 74 cont.

## MAR 24-174-74: Amending Various Pharmacy Rules

- **Listing of controlled substances, ARM 24.174.1412**
  - Aligns with statute amendments SB 274 (2019);
  - Reflect DEA changes from 2019 – 2020, including removal of Schedule V approved cannabidiol drugs, including Epidiolex®.
- **Continuing education (CE) programs, ARM 24.174.2106**
  - Standardizes renewal and audit procedures with Department.
  - Board no longer preapproves programs that are not ACPE approved.
  - Non-ACPE providers must meet requirements and standards outlined in rule to be accepted as credit in a CE audit.
  - A maximum of 1.0 CEU (10 hours) CE credit can be obtained through non-ACPE approved programs per renewal cycle.
- See summary of MAR 74 amendments on [www.pharmacy.mt.gov](http://www.pharmacy.mt.gov)

# COVID-19 – PREP Act

## Public Readiness and Emergency Preparedness Act (PREP Act) and Related Amendments/Declarations

- Authorizes pharmacists to independently order and administer, and trained interns and pharmacy technicians under supervision of a pharmacist, to administer the following:
  - FDA authorized/approved COVID-19 vaccines and tests for ages 3 and older.
  - Vaccines according to the Advisory Committee on Immunization Practices (ACIP) recommendations and schedules for those ages 3 through 18.
  - Influenza vaccine for those 19 and older consistent with ACIP recommendations.
  - Certain COVID-19 therapeutics.
- The PREP Act provides federal authority for qualified pharmacy technicians to assist pharmacists in vaccine administration and other actions as listed above.
  - A legislative change would be needed to provide such authority in Montana.

**Montana Authority:** Pharmacists have independent vaccine authority without a collaborative practice agreement pursuant to 37-7-105, MCA, and ARM 24.174.501, and can utilize interns to assist in administering vaccines.

For additional details and resources, go to the PREP Act online at:

<https://aspr.hhs.gov/legal/PREPAct/Pages/default.aspx>

# COVID-19 – Board Actions

## Governor's Directive

- 3/30/2021, Governor Gianforte issued Directive-3-30-2021-E0, *Directive Implementing Executive Order 2-2021 by waiving strict compliance with Admin. R. Mont. 24.174.711*, to assist in pharmacy staffing for COVID-19 vaccines.
  - Pharmacist to pharmacy technician 1:4 ratio waived for purposes of COVID-19 vaccinations and others as authorized in the federal PREP Act.
  - Allowed for other health care licensees authorized to administer vaccines under their own scope of practice to assist pharmacists in vaccine administration.
  - **Expired 6/30/2021** when state emergency declaration was rescinded.

## Board Temporary Emergency Rule

- 9/14/2021, Board issued **Temporary Emergency Rule 24-174-77** to implement similar provisions as the Directive to help address pharmacy staffing issues
  - Pharmacist to pharmacy technician 1:4 ratio waived for purposes of COVID-19 vaccinations and testing, and other vaccines as authorized in the federal PREP Act.
  - Allowed for other health care licensees authorized to administer vaccines under their own scope of practice to assist pharmacists in vaccine administration.
  - **Expired 1/11/2022**

# Technician Ratio and Staffing

- **Proposed Rule MAR 24-174-78, to amend three rules regarding pharmacy staffing**
  - **Remove the 1:4 pharmacist to pharmacy technician ratio**
    - ARM 24.174.711. ratio of pharmacy technicians and interns to supervising pharmacists; interns still do not count against the ratio.
    - Permanently address pharmacy staffing issues and improves access to vaccines (pursuant to federal PREP Act authority).
    - Outlines oversight/responsibilities of the pharmacist-in-charge in determining appropriate staffing levels to ensure patient safety and compliance with technician utilization plans.
  - **Change technician utilization plan requirements**
    - ARM 24.174.712. application for approval of utilization plan
    - Amendments outline responsibilities of the pharmacist-in-charge for submitting updates to the plan.
  - **Recognize use of other health care licensees to assist in vaccine administration**
    - Limited to those licensees authorized to administer vaccines under their own scope of practice; reflect in technician utilization plan.
    - ARM 24.174.701, pharmacy technician registration requirements
- **Timeline**
  - Proposed rule issued 1/14/2022
  - Board approved final rule language 2/17/2022
  - Final rule and effective date potentially by end of March 2022

# Future Rulemaking

## Next Proposed Rule – in progress to be issued as MAR 79

- New device license type, medical gas supplier revisions
- Montana Prescription Drug Registry (MPDR) reporting standards and required fields
- Renewal dates and clarifications
- Licensing of wholesale drug distributors and separating out license types for third-party logistics providers (3PLs), repackagers, and manufactures

## Future Rule Topics Under Consideration

- Compounding, outsourcing facilities, and hazardous drugs
- Endorsements, facility requirements, inspections, and limited service pharmacies
- These and other potential rule changes will be discussed at next Board meeting

# Medical Practitioner Dispenser

- **Senate Bill 374 (2021), dispensing of drugs by medical practitioners**
  - Creates new dispenser registration through Board of Pharmacy, authorizes inspections, does not include controlled substances.
  - Dispensing limited to scope of practice; patient may choose to have prescription filled at a pharmacy.
  - Drugs dispensed by the medical practitioner must be:
    - Dispensed directly by practitioner to patient at practitioner's office or place of practice;
    - Dispensed only to practitioner's own patients; and
    - Necessary in treatment of condition for which the practitioner is attending the patient
- **Medical Practitioners:** Physicians, physician assistants, podiatrists, optometrists, dentists, and APRNs with prescriptive authority.
- **Authority:**
  - Statute: 37-2-104(1) – (7), MCA
  - Rules: ARM 24.174.1801, 1802, and 1803 regarding qualifications, dispenser requirements, and recordkeeping requirements.
    - Additional background and detail in proposed and final rule notices, MAR 24-174-76
- **Effective Dates:** 10/1/2021; final rules effective 11/20/2021; application available 2/28/2022
- **Next Steps:** Issue new registrations and perform inspections

# THANK YOU

*Presentation continues with Nikki Griffis, PharmD, MPDR Program Manager*



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