

Board of Pharmacy Updates 2024

MARCIE BOUGH, PharmD
EXECUTIVE OFFICER

March 3, 2024
University of Montana Skaggs School of Pharmacy



1

Disclosure

The presenter declares no actual or potential conflict of interest in relation to this presentation.



2

Objectives

1. List legislative and regulatory changes impacting the practice of pharmacy in Montana
2. Discuss Red Tape Relief efforts to update existing regulations/rules



3

Questions

1. What does the new law SB 112 authorize for pharmacists' prescribing authority?
 - A. Limited independent prescribing authority pursuant to restrictions outlined in statute
 - B. Full independent prescribing authority
 - C. Prescribing authority restricted to collaborative practice agreement only
 - D. Independent prescribing authority restricted to immunizations only
2. What is not a reason why the Board of Pharmacy is focused on the Red Tape Relief effort?
 - A. Key initiative of the Governor for all state agencies
 - B. Reduce regulatory burdens and barriers
 - C. Simplify and improve regulations/rules while still aligning with statutory authority
 - D. Remove certain license types



4

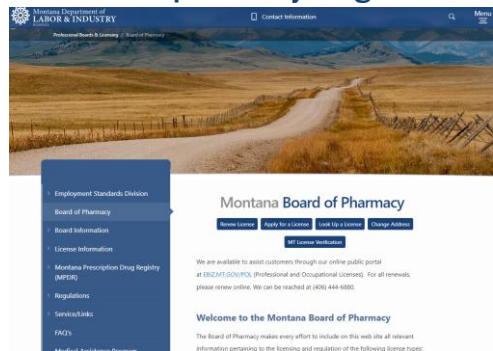
Board of Pharmacy Members

- Jeff Nikolaisen, Pharmacist, Presiding Officer
- Starla Blank, Pharmacist, Vice Presiding Officer
- Tony King, Pharmacist
- Paul Brand, Pharmacist
- Courtney Bahny, Certified Pharmacy Technician
- Gail Tronstad, Public Member



5

www.pharmacy.mt.gov



6

Montana Legislature <https://leg.mt.gov>



7

Legislation, Statutes, and Rules

Legislation:
Senate Bill (SB)
House Bill (HB)
Draft Bill (LC)

Statutes/Laws: Montana Code Annotated (MCA)
Rules/Regulations: Administrative Rules of Montana (ARM)
Rulemaking: Montana Administrative Register (MAR)

Access statutes, rules, and rulemaking at:
<https://boards.bsd.dli.mt.gov/pharmacy/regulations/>



8

SB 112 Pharmacists Prescribing Authority Legislation and Rulemaking



9

SB 112: Pharmacists Prescribing Authority (1 of 5)

- **SB 112, Revise pharmacist prescribing authority**
Sen. Tom McGillivray, (R) Billings
 - PASSED
 - Signed by the Governor May 1, 2023
 - Initiated by the Frontier Institute with support from the Montana Pharmacy Association
 - Modeled after Idaho
 - **Creates new limited independent prescriptive authority for pharmacists for certain conditions**
- New Statute: [37-7-106, MCA, Pharmacist Prescribing Authority - Exceptions](#)



10

SB 112: Pharmacists Prescribing Authority (2 of 5)

Overview

- In Montana, a pharmacist may prescribe a drug or device for a legitimate medical purpose provided a patient-prescriber relationship is established through a **documented patient evaluation** that is adequate to:
 - Establish diagnoses, if the drug or device is being prescribed pursuant to subsection (3)(b), and
 - Identify underlying conditions and contraindications to the treatment.
- A pharmacist's prescribing authority is **limited to drugs and devices that are prescribed for conditions that**:
 - (3)(a) **Do not require a new diagnosis**; or
 - (3)(b)
 - o **Are minor and generally self limiting**; or
 - o **Are diagnosed by or for which clinical decisions are made using a CLIA-waived test**; or
 - o **Are patient emergencies**.



11

SB 112: Pharmacists Prescribing Authority (3 of 5)

Overview Continued:

- A pharmacist may:
 - Prescribe only the drugs/devices for which the pharmacist is **educationally prepared** and for which **competency** has been achieved and maintained; and
 - Bill only for **assessment services** that were necessary, based on the pharmacist's professional judgement, **for the pharmacist's decision to prescribe** a drug/device pursuant to [SB 112]
- A pharmacist may **not** prescribe a controlled substance or an abortion-inducing drug as that term is defined in 50-20-703, MCA.



12

SB 112: Pharmacists Prescribing Authority

(4 of 5)

Overview Continued:

- A pharmacist prescribing a drug or device pursuant to [SB 112] shall:
 - Recognize the limits of the pharmacist's knowledge and experience** and **consult with and refer** to other health care providers as appropriate; and
 - Maintain documentation sufficient to justify the care provided**, including but not limited to the:
 - Information collected as part of the patient record;
 - Prescription record;
 - Provider notification; and
 - Follow-up care plan.
- [SB 112] **does not** apply to a pharmacist who is operating within a **collaborative pharmacy practice agreement**.



13

SB 112: Pharmacists Prescribing Authority

(5 of 5)

Overview Continued:

- Amends the definition of "**Medical practitioner**" under Title 37, Chapter 2, General Provisions Related To Health Care Practitioners, Part 1. Prescribing and Dispensing of Drugs
- 37-2-101, MCA, Definitions.**
 - Added:
 - "**Collaborative pharmacy practice agreement**" has the meaning provided in 37-7-101.
 - Amended:
 - "**Medical practitioner**" means any person licensed by the state of Montana to engage in:
 - ...(b) the practice of pharmacy and authorized to:
 - prescribe immunizations pursuant to 37-7-105; or
 - prescribe drugs pursuant to 37-7-106 or in accordance with a collaborative pharmacy practice agreement; ...



14

SB 112: Rulemaking

(1 of 4)

- 2023 Rule drafting with stakeholder input with ongoing Governor's Office oversight/review
- September 22 Board of Pharmacy approved draft; November 3 [Proposed Rule](#) issued, **MAR 24-174-80**
- November 28 hearing; December 1 comment deadline; December 8 Board finalized
- December 22 [Final Rule](#) issued, **MAR 24-174-80**, with New Rule 1 adopted as proposed; includes summaries of 24 comments received and Board responses
- New Rule: ARM 24.174.505 Pharmacist Prescribing: General Requirements**
 - Final language currently available in proposed rule at: www.pharmacy.mt.gov (click on Regulations/Rule Notices)
 - Soon to be posted online with other Board rules as part of [Subchapter 5](#) at: www.pharmacy.mt.gov (click on Administrative Rules/Chapter 24.174)



15

SB 112: Rulemaking

(2 of 4)

ARM 24.174.505 PHARMACIST PRESCRIBING: GENERAL REQUIREMENTS*[Following language in 1) through 5) is the final rule text]***ARM 24.174.505(1-2)**

- Pursuant to [SB 112(1), L. 2023] and these rules, any pharmacist may independently prescribe.
- The pharmacist prescribing under this rule must obtain adequate information about the patient's health status to make appropriate decisions based on the applicable standard of care and the best available evidence. For each drug or device the pharmacist intends to prescribe, the pharmacist must maintain a patient assessment based on current clinical guidelines, best practice standards, or evidence-based research findings, as applicable.



16

SB 112: Rulemaking

(3 of 4)

ARM 24.174.505(3-4)

- The pharmacist must document an appropriate follow-up care plan, including any monitoring parameters, as indicated by the patient assessment.
- The pharmacist must inquire about the identity of the patient's primary care provider or provider of record. If a provider is identified, the pharmacist must document the information and notify the provider at the earliest reasonable time following the prescribing of a drug or device.



17

SB 112: Rulemaking

(4 of 4)

ARM 24.174.505(5)

- The pharmacist must maintain documentation adequate to justify the care provided, including, but not limited to the information collected as part of the patient assessment, the prescription record, any notification provided as required under this rule, and the follow-up care plan. Records must be made available for inspection by the board.

###



18

Other Legislative Topics



19

Technician Immunization Authority

- **HB 710, Revise pharmacist laws relating to immunizations**
Rep. Casey Knudsen (R), Malta
 - PASSED
 - Amends 37-7-105, MCA, for pharmacists to delegate immunization authority to the following, pursuant to certification/training requirements and supervision:
 - **Interns** (clarifies authority)
 - **Pharmacy technicians** (adds new authority)
- Related Federal Public Readiness and Emergency Preparedness Act (PREP Act) **expires December 31, 2024**, and impacts Montana authority:
 - Independent authority and age limits go back to 37-7-105, MCA, and does not include COVID-19.
 - **COVID-19 will need a collaborative pharmacy practice agreement, age limit 7**, pursuant to 37-7-105, MCA.



20

Controlled Substances and Test Strips

- **SB 67, Generally revise scheduling of dangerous drugs**
Sen. Tom McGillivray, (R) Billings
 - PASSED
 - Amends 50-32-222 through 232, MCA, to update **listing of controlled substances**, Schedules I through V.
 - Aligns with recent DEA updates; reflects findings from the State Crime Lab.
- **SB 284, Require report of drugs taken by or prescribed to a victim of suicide**
Sen. Carl Glimm, (R) Kila
 - PASSED
 - Requires Montana Prescription Drug Registry (MPDR) to provide **de-identified** reports to Department of Public Health and Human Services (DPHHS), Suicide Prevention Officer, of drugs dispensed to victims of suicide.
- **HB 437, Revise drugs laws**
Rep. Katie Zolnikov, (R) Billings
 - PASSED
 - Amends 45-10-103, MCA, criminal prosecution of drug paraphernalia, to remove reference to "test" to provide legal access/sales of **fentanyl test strips**, other drug tests, etc.
 - Amends 61-8-1002, MCA, driving under influence, to remove "delta-9" from the listing of tetrahydrocannabinol.



21

Expanded Scope of Practice

- **SB 100, Revise laws related to naturopaths and natural substances**
Sen. Greg Hertz, (R) Polson
 - PASSED
 - Expands prescribing authority by removing "natural" and "natural substances" as a qualifier to "therapies" and "therapeutic substances" in definitions/scope/formulary list.
- **SB 101, Generally revise naturopathic in-office dispensing laws**
Sen. Greg Hertz, (R) Polson
 - PASSED
 - Adds naturopathic physicians as prescribers eligible to register as a Medical Practitioner Dispenser with the Board of Pharmacy
- **HB 313, Provide for Independent practice of physician assistants**
Rep. Jodee Etchart, (R) Billings
 - PASSED
 - Authorizes physician-assistants to practice independently, except two years post-graduate.
- **HB 392, Generally revise midwifery laws**
Rep. Jodee Etchart, (R) Billings
 - PASSED
 - Expands list of drugs that direct-entry midwives can independently **purchase/administer**.



22

Veterinary Retail Facilities and Dispensing Technicians

- **SB 561, Create veterinary retail facility permits**
Sen. Steve Hinebauch (R-Wibaux), and Rep. Brandon Ler (R-Savage)
 - PASSED
 - Creates two new license types to allow for dispensing of veterinary medications from non-pharmacy facilities
 - New authority addresses FDA requirements for all veterinary antibiotics to be prescription only (June 2023)
- **Board of Pharmacy will license Veterinary Retail Facilities**
 - Inspections; purchase from a wholesale drug distributor or pharmacy; person-in-charge must be licensed as a veterinary dispensing technician; and no dispensing of controlled substances.
- **Board of Veterinary Medicine will license Veterinary Dispensing Technicians**
 - Must attest to review of educational packet; can work at multiple locations.
 - **New Statutes: 37-18-801 through 807, MCA** (includes pharmacy provisions)
- **Rulemaking: MAR 24-225-43**, published 1/12/24, effective 1/13/24
- **Final Rules:**
 - **Pharmacy: ARM 24.174.1901 and 1902**
 - **Veterinary Medicine: ARM 24.225.801 and 802**



23

Red Tape Relief Legislative and Regulatory Efforts



24

Red Tape Relief Initiative - Title 37 Reform

*Directive from Governor Greg Gianforte and
Lieutenant Governor Kristen Juras*

- **Restructure Board Governance**
 - Board structure, composition, efficiencies, boards to programs
- **Modernize Professional Licensing Laws (Title 37, MCA)**
 - Modernize and standardize language, remove outdated/obsolete language
- **Increase License Mobility and Processing Efficiency**
 - Reciprocity/substantially equivalent licensing from other states
 - Temporary (provisional) licensing, continuing education, background checks
- **DLI Outreach Efforts 2022, 2023, and Ongoing**
 - Informational sessions/webinars, educational materials, draft legislation, emails, stakeholder surveys
 - <https://boards.bsd.dli.mt.gov/educational-sessions>
 - **Outcome:** Several Department Red Tape legislative bills in 2023 Session; **2 of 3 bills passed**



25

Department Title 37 Reform Legislation

- **Bills sponsored by Rep. Bill Mercer, (R) Billings**
- **HB 87, Standardize licensing board organization**
 - PASSED
 - All boards now have 4-year terms (2-consecutive)
 - Most all boards had reduction in board members
 - **Pharmacy:** one public member removed
 - *Board of Pharmacy now has four pharmacists, one pharmacy technician, and one public member*
- **HB 115, Consolidate and clarify penalties for unlicensed practice**
 - PASSED
 - **Pharmacy** included with standardization of discipline provisions



26

Department Title 37 Reform Legislation

- **Bill sponsored by Rep. Bill Mercer, (R) Billings**
- **HB 152, Revise laws related to professional and occupational licensure**
 - House hearings held; **DID NOT PASS; died in process; will try again in 2025**
 - Standardize and remove outdated language; update temporary/provisional licensing
 - **Pharmacy provisions would have:**
 - o Updated/clarified Board powers and duties, including licensing/rulemaking authority, device clarification, etc.;
 - o Removed "Notice to Purchaser" sign requirement; and
 - o Removed technician utilization plan (TUP) requirements and remove fee;
 - **NOTE:** *An amendment would have repealed all TUP provisions while keeping definition of pharmacy technician.*



27

Future Rulemaking – Red Tape Relief Initiative

- **Entire Rule Review of ARM 24.174 Board of Pharmacy**
 - Starting with efforts to simplify, clarify, consolidate, remove outdated language, add clarifying language/new rules, technical corrections, and repeal unnecessary rules to reduce burden and barriers – similar to the Title 37 Reform legislative efforts.
 - Rulemaking requires review and approval from the Governor's Office for proof of concept, justification, and is ongoing throughout the process.
- **Focus of current drafting:**
 - Working on **over 50** existing rules as a start.
 - More complex amendments and new rules will address compounding, central fill, and others.
 - Stakeholder input and Board review/action.
 - October 1, 2024, deadline for rulemaking prior to the 2025 Legislative Session.



28

Questions

1. **What does the new law SB 112 authorize for pharmacists' prescribing authority?**
 - A. Limited independent prescribing authority pursuant to restrictions outlined in statute
 - B. Full independent prescribing authority
 - C. Prescribing authority restricted to collaborative practice agreement only
 - D. Independent prescribing authority restricted to immunizations only
2. **What is not a reason why the Board of Pharmacy is focused on the Red Tape Relief effort?**
 - A. Key initiative of the Governor for all state agencies
 - B. Reduce regulatory burdens and barriers
 - C. Simplify and improve regulations/rules while still aligning with statutory authority
 - D. Remove certain license types



29

Questions

1. **What does the new law SB 112 authorize for pharmacists' prescribing authority?**
 - A. **Limited Independent prescribing authority pursuant to restrictions outlined in statute**
 - B. Full independent prescribing authority
 - C. Prescribing authority restricted to collaborative practice agreement only
 - D. Independent prescribing authority restricted to immunizations only
2. **What is not a reason why the Board of Pharmacy is focused on the Red Tape Relief effort?**
 - A. Key initiative of the Governor for all state agencies
 - B. Reduce regulatory burdens and barriers
 - C. Simplify and improve regulations/rules while still aligning with statutory authority
 - D. **Remove certain license types**



30

Board of Pharmacy Contact Information and Meetings

Staff

Marcle Bough, PharmD, Executive Officer
406-841-2371
mbough@mt.gov

Mark Klawitter, RPh, Board Inspector
406-459-8847
mark.klawitter@mt.gov

Genine Pitts, PharmD, Board Inspector
406-431-1952
genine.pitts@mt.gov

Nikki Griffis, PharmD, Program Manager
Montana Prescription Drug Registry (MPDR)
406-841-2240
nikki.griffis@mt.gov
dlibsdmpdr@mt.gov

General Contact Information

Emails:
dlibsdpha@mt.gov
dlibsdmpdr@mt.gov

Websites:
www.pharmacy.mt.gov
www.mpdr.mt.gov

Phone Numbers:
Office: 406-841-2300
Customer Service: 406-444-6880

2024 Board Meetings

March 15
June 7
September 20
December 6



THANK YOU

