

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

In the matter of the amendment of) NOTICE OF AMENDMENT,
ARM 24.174.301, 24.174.401,) ADOPTION, AND REPEAL
24.174.407, 24.174.503, 24.174.526,)
24.174.602, 24.174.604, 24.174.701,)
24.174.712, 24.174.801, 24.174.802,)
24.174.803, 24.174.804, 24.174.805,)
24.174.806, 24.174.807, 24.174.814,)
24.174.819, 24.174.823, 24.174.830,)
24.174.831, 24.174.832, 24.174.833,)
24.174.835, 24.174.836, 24.174.840,)
24.174.901, 24.174.903, 24.174.1412,)
24.174.1501, 24.174.1503,)
24.174.1505, 24.174.1506,)
24.174.1603, 24.174.1604,)
24.174.1605, 24.174.1606,)
24.174.1702, 24.174.1706,)
24.174.1708, 24.174.1709,)
24.174.1711, 24.174.2104, and)
24.174.2301, the adoption of NEW)
RULE I, and the repeal of ARM)
24.174.303, 24.174.402, 24.174.504,)
24.174.507, 24.174.525, 24.174.527,)
24.174.528, 24.174.601, 24.174.603,)
24.174.605, 24.174.611, 24.174.612,)
24.174.613, 24.174.817, 24.174.818,)
24.174.834, 24.174.902, 24.174.1206,)
24.174.1502, 24.174.1504,)
24.174.1507, 24.174.1508,)
24.174.1509, 24.174.1510,)
24.174.1601, 24.174.1602,)
24.174.1607, 24.174.1608,)
24.174.1609, 24.174.1703,)
24.174.1704, 24.174.1705,)
24.174.1713, and 24.174.1715)
pertaining to the Board of Pharmacy)

TO: All Concerned Persons

1. On July 26, 2024, the Board of Pharmacy (agency) published MAR Notice No. 24-174-81 regarding the public hearing on the proposed changes to the above-stated rules, at page 1659 of the 2024 Montana Administrative Register, Issue No. 14.

2. On August 15, 2024, a public hearing was held on the proposed changes to the above-stated rules via the videoconference and telephonic platform. Comments were received by the deadline.

3. The agency has thoroughly considered the comments received. A summary of the comments and the agency responses are as follows:

Comment 1: Several commenters support the recognition that preceptors can include both pharmacists and other healthcare professionals as indicated in the changes to ARM 24.174.604.

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

Comment 2: Several commenters were supportive of the amendment to ARM 24.174.830(8), allowing a provider with prescriptive authority or a registered nurse employed by a family planning clinic to dispense medications to treat additional sexually transmitted diseases for the purposes of addressing public health efforts.

Response 2: The board appreciates all comments received during the rulemaking process.

Comment 3: Several commenters were supportive of the proposed amendment to ARM 24.174.836(2)(b), a clarification that a pharmacist dispensing an emergency refill may not dispense a controlled substance listed in Schedule II through Schedule V.

Response 3: The board appreciates all comments received during the rulemaking process.

Comment 4: Several commenters expressed concern regarding the reduction in patient retention record requirements to two years. The requirement for patient record maintenance should align with requirements of other locations of care which is ten years for an adult and longer for a minor child. The commenters were especially concerned about the records of vaccines administered by pharmacists. The commenters request, at minimum, pharmacists maintain records for three years.

Response 4: The board amended patient recordkeeping requirements from three years to two years in ARM 24.174.901 to align with the standard pharmacy prescription recordkeeping of two years as required in ARM 24.174.833. The two-year amendment also aligns with recordkeeping requirements for medical practitioner dispensers registered with the board, pursuant to ARM 24.174.1803. The board clarifies that it is requiring recordkeeping of three years for pharmacies engaged in wholesale distribution activities to align with FDA requirements, as amended in ARM 24.174.833. The board recognizes that other recordkeeping requirements may apply to patient records outside of the board's jurisdiction.

Comment 5: Several commenters recommended the board require pharmacy reporting of vaccine administration to the Montana Immunization Information System (imMTrax), which is administered by the Montana Department of Public Health and Human Services.

Response 5: Amending ARM 24.174.503 to require mandatory reporting to the imMTrax program is outside the scope of this rulemaking and would require a statutory change. Specifically, 37-7-105(4)(f), MCA indicates that a pharmacist who administers an immunization must offer the patient the opportunity to have the immunization information reported to the state immunization information system. The board is aware that pharmacies already voluntarily report vaccine information to the imMTrax program for patients who opt-in to the reporting of their information to the program.

4. The agency has amended ARM 24.174.301, 24.174.401, 24.174.407, 24.174.503, 24.174.526, 24.174.602, 24.174.604, 24.174.701, 24.174.712, 24.174.801, 24.174.802, 24.174.803, 24.174.804, 24.174.805, 24.174.806, 24.174.807, 24.174.814, 24.174.819, 24.174.823, 24.174.830, 24.174.832, 24.174.833, 24.174.835, 24.174.836, 24.174.840, 24.174.901, 24.174.903, 24.174.1412, 24.174.1501, 24.174.1503, 24.174.1505, 24.174.1506, 24.174.1603, 24.174.1604, 24.174.1605, 24.174.1606, 24.174.1702, 24.174.1706, 24.174.1708, 24.174.1709, 24.174.1711, 24.174.2104, and 24.174.2301 as proposed.

5. The agency has adopted NEW RULE I (24.174.2108) as proposed.

6. The agency has repealed ARM 24.174.303, 24.174.402, 24.174.504, 24.174.507, 24.174.525, 24.174.527, 24.174.528, 24.174.601, 24.174.603, 24.174.605, 24.174.611, 24.174.612, 24.174.613, 24.174.817, 24.174.818, 24.174.834, 24.174.902, 24.174.1206, 24.174.1502, 24.174.1504, 24.174.1507, 24.174.1508, 24.174.1509, 24.174.1510, 24.174.1601, 24.174.1602, 24.174.1607, 24.174.1608, 24.174.1609, 24.174.1703, 24.174.1704, 24.174.1705, 24.174.1713, and 24.174.1715 as proposed.

7. The agency has amended ARM 24.174.831 with the following changes, stricken matter interlined, new matter underlined:

24.174.831 PRESCRIPTION REQUIREMENTS (1) through (5)(b) remain as proposed.

(iii) remains as proposed but is renumbered (c).

(6) through (8) remain as proposed.

AUTH: 37-7-201, MCA

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

REASON: It is necessary to make this change because the agency inadvertently missed renumbering the subsection (iii) in the original proposal.

BOARD OF PHARMACY, JEFF
NIKOLAISEN, CHAIR

/s/ JENNIFER STALLKAMP
Jennifer Stallkamp
Rule Reviewer

/s/ SARAH SWANSON
Sarah Swanson, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State September 10, 2024.