

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

In the matter of the amendment of)	NOTICE OF AMENDMENT AND
ARM 24.174.303 definitions,)	REPEAL
24.174.501 examination for licensure,)	
24.174.503 administration of)	
vaccines, 24.174.510 prescription)	
requirements, 24.174.602 internship)	
requirements, 24.174.604 preceptor)	
requirements, 24.174.2104 and)	
24.174.2106 registered pharmacist)	
continuing education, and the repeal)	
of ARM 24.174.1010 disciplinary)	
action)	

TO: All Concerned Persons

1. On March 10, 2011, the Board of Pharmacy (board) published MAR notice no. 24-174-61 regarding the public hearing on the proposed amendment and repeal of the above-stated rules, at page 277 of the 2011 Montana Administrative Register, issue no. 5.

2. On April 4, 2011, a public hearing was held on the proposed amendment and repeal of the above-stated rules in Helena. Several comments were received by the April 12, 2011, deadline.

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

COMMENT 1: One commenter suggested changing the reference in ARM 24.174.503(1) from "chief medical officer" to "state medical officer" to reflect the correct position title.

RESPONSE 1: The board agrees with the comment and is amending the rule accordingly.

Comments 2 through 6 address ARM 24.174.510 Prescription Requirements:

COMMENT 2: Three commenters expressed concern that the proposed added language in ARM 24.174.510(1)(e)(i) will mandate that pharmacists dispense a 60-day quantity. The commenters objected to this, arguing that a 60-day supply does not promote patient care and may exceed the quantity for which third-party payors will pay. Two commenters opined that this requirement may conflict with pending federal regulations that may require a seven-day fill in long-term care facilities.

RESPONSE 2: The board considered the special cases of institutional pharmacies and agrees that the proposed language may be unclear. The board is therefore deleting (1)(e)(i) from this rule.

COMMENT 3: One commenter suggested improving ARM 24.174.510(1)(h)(ii)(C), regarding tampering protections for controlled substances in Schedule II, by requiring that the prescription contain the statement, "valid for six months from the date of issue," to align with federal law and common practice.

RESPONSE 3: The board notes that federal law currently provides that prescriptions expire in one year and believes that pharmacists should be allowed to exercise their professional judgment on this issue. The board is amending this subsection exactly as proposed.

COMMENT 4: One commenter suggested that the board could improve ARM 24.174.510(1)(i), pertaining to the number of refills authorized, by amending it to "number of refills authorized, if applicable."

RESPONSE 4: The board considered this comment, but is amending this subsection exactly as proposed.

COMMENT 5: One commenter suggested the board improve ARM 24.174.510(1)(k), regarding the "prescriber's employee or agent" by requiring the disclosure of the name of the prescriber's agent, if applicable.

RESPONSE 5: After considering this comment and other implications of the proposed amendment, the board is deleting proposed (1)(k) from this rule.

COMMENT 6: One commenter said that not a single U.S. board of pharmacy has addressed the special circumstances of long-term care pharmacies. The commenter's employer has tried to operate under the retail pharmacy rules, but those prescription requirements are not always compatible and can result in apparent deficiencies during audits and payors' refusal to pay for prescriptions. The commenter submitted the National Association of Boards of Pharmacy/American Society of Consultant Pharmacists Joint Report: Model Rules for Long-Term Care Pharmacy Practice, and suggested the board consider these model rules to clarify issues particular to long-term care pharmacies and institutional pharmacies.

RESPONSE 6: The board notes that this comment is outside the scope of this rulemaking notice, but that it brings to the board's attention a perceived gap in rules related to long-term care pharmacies. The board will discuss this matter at a future board meeting.

COMMENT 7: One commenter questioned the proposed new ARM 24.174.604(6), which reads, "no more than one intern at a time." Rather than allowing a preceptor to serve more than one intern at a time, the new language prohibits this. The commenter suggested deleting the "no" to conform with the board's intended goal.

RESPONSE 7: The board agrees that using "no" was a clerical error that should be deleted to further the board's intent. The board is amending the rule accordingly.

4. The board has amended ARM 24.174.303, 24.174.501, 24.174.602, 24.174.2104, and 24.174.2106 exactly as proposed.

5. The board has amended ARM 24.174.503, 24.174.510, and 24.174.604 with the following changes, stricken matter interlined, new matter underlined:

24.174.503 ADMINISTRATION OF VACCINES BY PHARMACISTS (1) In order to administer or prescribe vaccinations, a pharmacist must have a collaborative practice agreement with a practitioner authorized to prescribe drugs, or in the case of a public health emergency, a directive from the ~~chief~~ state medical officer of the Montana Department of Public Health and Human Services.

(2) through (10) remain as proposed.

24.174.510 PRESCRIPTION REQUIREMENTS (1) through (1)(e) remain as proposed.

~~(i) the quantity for residents of long-term care facilities must be for 60 days, unless otherwise limited by the prescriber.~~

(f) through (j)(iii) remain as proposed.

~~(k) prescriber's employee or agent;~~

~~(l) (2) prescription~~ Prescription or refill authorization issued by a prescriber may be communicated to a pharmacist or a pharmacist intern by an employee or agent of the prescriber.

(2) remains as proposed but is renumbered (3).

24.174.604 PRECEPTOR REQUIREMENTS (1) through (5) remain as proposed.

(6) A preceptor may ~~serve as a preceptor~~ precept for ~~no~~ more than one intern at a time.

6. The board has repealed ARM 24.174.1010 exactly as proposed.

BOARD OF PHARMACY
LEE ANN BRADLEY, RPH, PRESIDENT

/s/ DARCEE L. MOE
Darcee L. Moe
Alternate Rule Reviewer

/s/ KEITH KELLY
Keith Kelly, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State June 13, 2011