

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 definitions,	)	AMENDMENT AND TRANSFER,
24.174.411 pharmacist meal/rest	)	ADOPTION, AND TRANSFER
breaks, 24.174.602 internship	)	
requirements, 24.174.701 registration	)	
requirements, 24.174.903 patient	)	
counseling, 24.174.1101 personnel,	)	
24.174.1111 drug distribution and	)	
control, 24.174.1115 use of	)	
contingency kits, 24.174.1704	)	
requirements for submitting	)	
prescription registry information,	)	
24.174.2403 legal suspension or	)	
revocation, the amendment and	)	
transfer of ARM 24.174.510,	)	
24.174.514, and 24.174.523 related	)	
to prescription requirements,	)	
24.174.1121 sterile products, the	)	
adoption of NEW RULE I quality	)	
assurance program requirements,	)	
and the transfer of ARM 24.174.511	)	
through 24.174.513, 24.174.515, and	)	
24.174.520 through 24.174.522	)	
related to prescription requirements	)	

TO: All Concerned Persons

1. On October 23, 2014, the Board of Pharmacy (board) published MAR Notice No. 24-174-65 regarding the public hearing on the proposed amendment, amendment and transfer, adoption, and transfer of the above-stated rules, at page 2508 of the 2014 Montana Administrative Register, Issue No. 20.

2. On November 13, 2014, a public hearing was held on the proposed amendment, amendment and transfer, adoption, and transfer of the above-stated rules in Helena. Several comments were received by the November 21, 2014 deadline.

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

COMMENT 1: Several commenters supported the proposed rule changes.

RESPONSE 1: The board appreciates all comments made during the rulemaking

process.

Proposed Amendment and Transfer of ARM 24.174.510 (24.174.831)

COMMENT 2: One commenter stated that not all patients described in the definition of "chart order" are "inpatient[s]," as currently proposed. The commenter suggested the board amend the description of patient[s] as follows: "...a patient in a hospital, infusion center, or surgery center."

RESPONSE 2: The board agrees with the need to further clarify when a chart order applies and in what type of setting or settings, as well as providing a more accurate description of a patient, as it relates to a chart order.

In defining "chart order," the board intended to clarify what constitutes a prescription at the time a patient is residing in a facility. However, as the commenter noted, the proposed language in (4) of "inpatient" and "resident of an institutional facility" unintentionally restricts the types of settings in which "chart order" applies, and a patient of a hospital, infusion center, or surgery center may not be classified as an inpatient or resident of an institutional facility.

The board reviewed the comment and concluded that use of "inpatient" fails to account for a patient residing in a facility, but receiving a prescription for outpatient use. Additionally, by defining a patient as a "resident of an institutional facility," the board unintentionally omitted other types of residential settings. As "facility" and "institutional facility" are already defined in ARM 24.174.301(14) and (18), the board is further amending this rule to address the commenter's concerns without further restating or defining these settings.

Proposed Amendment of ARM 24.174.1704:

COMMENT 3: Several commenters thanked the board for creating and maintaining the Montana Prescription Drug Registry (MPDR), and view the MPDR as a tool in combatting prescription drug abuse, misuse, and diversion. The commenters asserted that the MPDR would be more effective if pharmacies reported the dispensing of controlled substance prescriptions more frequently than weekly. The commenters suggested the board amend this rule to encourage pharmacies to immediately report after dispensing, as required in Oklahoma, and require reporting within 24 hours after dispensing. The commenters further suggested the board exempt rural pharmacies from their suggested reporting requirements.

RESPONSE 3: The board appreciates all comments made during the rulemaking process. The board further agrees that requiring pharmacies to report prescription information to the MPDR within 24 hours after dispensing is ideal, and notes that this is the board's long-term goal.

The board established a subcommittee to research reporting requirements and propose amendments to this rule for the board's consideration. The current rule provides two different reporting deadlines and the subcommittee recommended removing the "weekly" reporting requirement and retaining the "eight day" language.

Further, the subcommittee did discuss the feasibility of requiring pharmacies

to report prescription information more frequently than within eight days of dispensing. The subcommittee received feedback that several national chains already report to the MPDR more frequently than required by rule, but that many rural and independent Montana pharmacies may lack the technical capabilities to do so. The board notes that the MPDR advisory group has and will continue to discuss the feasibility of more frequent reporting, including real-time and 24-hour reporting.

Given the subcommittee's findings that some pharmacies already report to the MPDR more frequently than within eight days or weekly, the board concluded that it is unnecessary to encourage pharmacies to do so in rule.

The board notes that the suggestion to require reporting within 24 hours after dispensing is a substantive change to the rule that goes beyond the board's intent of clarifying the reporting requirement and exceeds the scope of this proposal notice. The board is amending this rule exactly as proposed.

4. The board has amended ARM 24.174.301, 24.174.411, 24.174.602, 24.174.701, 24.174.903, 24.174.1101, 24.174.1111, 24.174.1115, 24.174.1704, and 24.174.2403 exactly as proposed.

5. The board has amended and transferred ARM 24.174.514 (24.174.835), 24.174.523 (24.174.840), and 24.174.1121 (24.174.841) exactly as proposed.

6. The board has adopted NEW RULE I (24.174.407) exactly as proposed.

7. The board has transferred ARM 24.174.511 (24.174.832), 24.174.512 (24.174.833), 24.174.513 (24.174.834), 24.174.515 (24.174.836), 24.174.520 (24.174.837), 24.174.521 (24.174.838), and 24.174.522 (24.174.839) exactly as proposed.

8. The board has amended and transferred ARM 24.174.510 (24.174.831) with the following changes, stricken matter interlined, new matter underlined:

24.174.510 (24.174.831) PRESCRIPTION REQUIREMENTS (1) through (3) remain as proposed.

(4) "Chart order" means a lawful order entered on the chart or a medical record of ~~an inpatient~~ a patient or resident of ~~an institutional~~ a facility by a practitioner, or his or her designated agent, for a drug or device and shall be considered a prescription.

BOARD OF PHARMACY  
BECKY DESCHAMP, RPh,  
VICE PRESIDENT

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

/s/ PAM BUCY  
Pam Bucy, Commissioner  
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State March 16, 2015