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

In the matter of the amendment of ARM 24.174.301 definitions, 24.174.402 dangerous drug fee schedule, 24.174.503 administration of vaccines by pharmacists, 24.174.523 transmission of prescriptions, 24.174.1003 identification of pharmacist-in-charge, 24.174.1202 minimum information required for licensure, 24.174.1302 telepharmacy operations, 24.174.1503 acceptable cancer drugs, the adoption of NEW RULES I emergency prescription refills, II remote medication order processing services, III schedule I dangerous drugs, IV schedule II dangerous drugs, V schedule III dangerous drugs, VI schedule IV dangerous drugs, VII schedule V dangerous drugs, VIII through XVI board-established medical assistance program, XVII through XXII quality improvement program, XXIII limited service pharmacy, and the repeal of ARM 24.174.813 class IV facility	)	NOTICE OF AMENDMENT, ADOPTION, AND REPEAL

TO: All Concerned Persons

1. On December 22, 2011, the Board of Pharmacy (board) published MAR notice no. 24-174-62 regarding the public hearing on the proposed amendment, adoption, and repeal of the above-stated rules, at page 2761 of the 2011 Montana Administrative Register, issue no. 24.

2. On January 23, 2012, a public hearing was held on the proposed amendment, adoption, and repeal of the above-stated rules in Helena. Several comments were received by the January 31, 2012, deadline.

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

<u>ARM 24.174.523 Transmission of Prescriptions by Electronic Means:</u>

COMMENT 1: One commenter asserted that the reasonable necessity statement for the proposed deletion of home infusion from (2)(a) is incomplete since it does not mention the mandatory Montana home infusion therapy license issued through the Department of Public Health and Human Services (DPHHS). The commenter concluded that while the proposed amendments need not be altered, the board and staff should be cautious to avoid imprecise language that could mislead licensees.

RESPONSE 1: The board agrees with the commenter that the statement of reasonable necessity omitted mention of the DPHHS's statute defining "home infusion therapy agencies" as "healthcare facilities" that must be licensed through DPHHS. See §§50-5-101(23)(a), 50-5-201(2), MCA; ARM 37.86.1502(2). As the commenter acknowledged, the comment does not touch on the substance of the proposed amendments and the board is amending this rule exactly as proposed.

COMMENT 2: One commenter stated that the proposed amendments to (2) are inconsistent with federal regulations at 21 C.F.R. Part 1311, which provide an electronically transmitted prescription may serve as the record of the prescription as long as it can be stored and retrieved consistent with applicable record-keeping requirements. The commenter suggested that the inconsistent requirement for collection of "the original, signed prescription" prior to dispensing should be deleted in favor of substitute language consistent with federal regulations.

RESPONSE 2: Noting that electronic prescriptions have not been fully implemented, the board concluded that until such an electronic system is in place, Montana must still require pharmacists to maintain a hardcopy record. With an electronic system on the horizon, the board resolved to be proactive and revisit this issue in July 2012, and update the rule, if necessary, to conform to the national picture. The board is amending this rule exactly as proposed.

COMMENT 3: One commenter supported the adoption of New Rules III through VII, Dangerous Drug schedules, noting that recently, new drugs have emerged designed to circumvent health and safety laws. Though these drugs have yet to be studied, reports from emergency room doctors, law enforcement officers, and family members of abusers report that the "new designer drugs" have severe physiological and behavioral side effects. The commenter believed that the new rules will protect the citizens of Montana and offer the criminal justice system tools with which to prosecute the use and distribution of these drugs.

RESPONSE 3: The board appreciates all comments received in the rulemaking process and is adopting New Rules III through VII exactly as proposed.

COMMENT 4: One commenter offered support for proposed New Rule III that includes in Schedule I Dangerous Drugs, compounds commonly called "bath salts": Mephedrone, Methylene-dioxypyrovalerone (MDPV), or Methylone. The commenter asserted that the use, manufacture, and distribution of bath salts is a growing menace in Montana and requires law enforcement officers to face unpredictable and violent behavior from abusers. Such conduct was not prosecutable, because bath

salts were not listed among the schedules. The commenter supported scheduling these drugs, so they could be prosecuted under the criminal statutes in Title 45, chapter 9.

RESPONSE 4: The board appreciates all comments received in the rulemaking process and is adopting New Rule III exactly as proposed.

NEW RULE XVII – XXII Quality Improvement Program

COMMENT 5: One commenter objected to the proposed requirement in New Rules XVII and XXI that licensed pharmacies report "near-miss" quality-related events. The commenter stated that many pharmacies already have quality assurance programs and are committed to patient safety and initiatives to reduce medication errors, and argued that the quality improvement program need not track events that had no effect on the patient. The commenter opined that the fact that no actual quality-related event occurred would demonstrate the effectiveness of the existing quality assurance program. The commenter recommended deleting references to "near-miss" events in New Rules XVII and XXI.

The commenter also recommended the board amend New Rule XXI to require QRE reports be submitted to a "federally-certified patient safety organization," rather than the Institute for Safe Medicine Practices.

COMMENT 6: One commenter suggested the board amend New Rule XVII(5), by adding individuals employed as pharmacy clerks to the definition of pharmacy personnel. The commenter noted that errors could occur at the clerk's stage if the clerk presented a properly prepared prescription to the wrong patient.

RESPONSES 5 and 6: The board considered comments 5 and 6, and discussed the design of the quality improvement program rules which was modeled after a program approved by the National Association of Boards of Pharmacy. Among other things, the board debated whether near-miss events should be reported, how nonlicensees such as pharmacy clerks should be factored, what clearinghouse(s) should collect the reports, the board's intent that the system be nonpunitive and geared toward improving the practice, and whether the rules should be more specific. Following this discussion, the board decided not to adopt New Rules XVII through XXII at this time and will revisit these issues at a future board meeting.

4. The board has amended ARM 24.174.301, 24.174.402, 24.174.503, 24.174.523, 24.174.1003, 24.174.1202, 24.174.1302, and 24.174.1503 exactly as proposed.

5. The board has adopted NEW RULES I (24.174.515), II (24.174.1112), III (24.174.1420), IV (24.174.1421), V (24.174.1422), VI (24.174.1423), VII (24.174.1424), VIII (24.174.1601), IX (24.174.1602), X (24.174.1603), XI (24.174.1604), XII (24.174.1605), XIII (24.174.1606), XIV (24.174.1607), XV (24.174.1608), XVI (24.174.1609), and XXIII (24.174.830) exactly as proposed.

6. The board has repealed ARM 24.174.813 exactly as proposed.

7. The board did not adopt NEW RULES XVII through XXII 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 April 16, 2012