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, 24.174.503 administration of vaccines, 24.174.510 prescriptions, 24.174.523 transmission of prescriptions, 24.174.601 objectives, 24.174.602 internship, 24.174.701 registration requirements, 24.174.703 pharmacy technician, 24.174.817 record keeping, 24.174.1002 registration conditions, 24.174.1114 emergency drug kit, 24.174.2102 and 24.174.2103 renewal, 24.174.2301 unprofessional conduct, and repeal of 24.174.1007 agent of records	))))))))))))))	NOTICE OF AMENDMENT AND REPEAL

TO: All Concerned Persons

1. On July 16, 2009, the Board of Pharmacy (board) published MAR Notice No. 24-174-59 regarding the public hearing on the proposed amendment and repeal of the above-stated rules, at page 1079 of the 2009 Montana Administrative Register, issue no. 13.

2. On August 6, 2009, a public hearing was held on the proposed amendment and repeal of the above-stated rules in Helena. Several comments were received by the August 14, 2009, deadline.

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

Comments and responses 1 through 4 pertain to ARM 24.174.510.

COMMENT 1: A commenter proposed eliminating the dispense-as-written (DAW) designation stating that it does not affect public safety in any form.

RESPONSE 1: The board notes that occasionally, patient safety requires a brand-name medication, because generics are less effective or because the patient may suffer an allergy to the binders, fillers, or other ingredients used in the generic formulation. Following amendment, this rule will ensure that the patient will be reimbursed for a brand-name drug by a third party payer. The board is amending the rule exactly as proposed.

COMMENT 2: A commenter cautioned about potentially inconsistent requirements between the requirements for Medicaid reimbursement under ARM 37.86.1105(1), and the "brand name medically necessary" language of the proposed change.

RESPONSE 2: The board concluded that the use of "brand necessary" or "brand required" from ARM 37.86.1105(1) is not necessarily inconsistent with the new language proposed for ARM 24.174.510, "brand name medically necessary." ARM 37.86.1105(1) sets forth examples of acceptable directives and is not meant to be exclusive. Moreover, the proposed amendment specifies a standard for dispensing and barring generic substitution, while ARM 37.86.1105(1) is geared towards Medicaid reimbursement. Finally, 37-7-502(2), MCA, expressly elevates the physician's standard to "medically necessary" requiring identical language in the rule implementing that statute. The board is amending the rule exactly as proposed.

COMMENT 3: One commenter stated that it would be burdensome to require that physicians manually handwrite "brand name medically necessary" on every prescription. This commenter proposed permitting physicians to use a box check-off indicating "substitution permitted" or "brand name medically necessary," or alternatively, two separate signature lines with the applicable directions allowing or disallowing substitutions under each signature line.

RESPONSE 3: The board notes that ARM 37.86.1105(1) requires a prescriber's directive to be in the prescriber's "own handwriting," and expressly declares, "A check-off box on a form or a rubber stamp is not acceptable." The board is amending the rule exactly as proposed.

COMMENT 4: A commenter seemed to suggest that alternate check-boxes would simplify the prescription delivery process and a handwritten directive is unnecessary.

RESPONSE 4: The board is mindful of the time pressures on practitioners, but notes that ARM 37.86.1105(1) requires a prescriber's directive to be in the prescriber's "own handwriting," and expressly declares, "A check-off box on a form or a rubber stamp is not acceptable." The board is amending the rule exactly as proposed.

COMMENT 5: A commenter noted that Department of Health and Human Services' (DPHHS) rules on Medicaid reimbursement provide specific tamper-resistant measures for handwritten prescriptions.

RESPONSE 5: The board notes that the concern is with handwritten prescriptions and the proposed amendment to ARM 24.174.523 governs electronically produced prescriptions hand-delivered to the patient. The board found no conflict between the two provisions.

COMMENT 6: A commenter observed that an electronic prescription, printed and handed to a patient, is no longer an electronic prescription and, under federal law, requires a traditional handwritten signature.

RESPONSE 6: The board agreed with the commenter and is amending ARM 24.174.523 accordingly.

COMMENT 7: A commenter suggested that the proposed amendment to ARM 24.174.2301 was unclear and could be interpreted to hold all of a facility's staff liable even if just one individual worked without a license.

RESPONSE 7: The board agreed with the commenter and will make no changes to ARM 24.174.2301 at this time.

4. The board has amended ARM 24.174.301, 24.174.503, 24.174.510, 24.174.601, 24.174.602, 24.174.701, 24.174.703, 24.174.817, 24.174.1002, 24.174.1114, 24.174.2102, and 24.174.2103 exactly as proposed.

5. The board has amended ARM 24.174.523 with the following changes, stricken matter interlined, new matter underlined:

24.174.523 TRANSMISSION OF PRESCRIPTIONS BY ELECTRONIC MEANS (1) through (4) remain as proposed.

(5) Computer-generated, electronically signed prescriptions that are handed directly to a patient or to a patient's agent must be authenticated by the prescriber with the prescription hand-signed, with the actual signature of the prescriber. ~~by one of the following methods:~~

~~(a) the prescription must be hand signed with the actual signature of the prescriber; or~~

~~(b) a prescription that is electronically signed by the prescriber must include an additional security feature on the prescription that cannot be reproduced.~~

~~(i) It is the prescriber's responsibility to identify the security feature on the face of the prescription.~~

~~(ii) It is the prescriber's responsibility to indicate on the face of the prescription that the prescription is not valid without the security feature.~~

(6) remains as proposed.

6. The board did not amend ARM 24.174.2301 as proposed.

7. The board has repealed ARM 24.174.1007 exactly as proposed.

BOARD OF PHARMACY
WILLIAM BURTON, 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 January 4, 2010