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

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In the matter of the amendment of ARM 24.174.401 and the adoption of New Rules I through III pertaining to dispenser registration for medical practitioners NOTICE OF AMENDMENT AND ADOPTION

TO: All Concerned Persons

1. On September 24, 2021, the Board of Pharmacy(board) published MAR Notice No. 24-174-76 regarding the public hearing on the proposed amendment and adoption of the above-stated rules, at page 1164 of the 2021 Montana Administrative Register, Issue No. 18.

2. On October 15, 2021, a public hearing was held on the proposed amendment and adoption of the above-stated rules via the videoconference and telephonic platform. Several comments were received by the October 22, 2021, deadline.

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

<u>COMMENT 1</u>: Numerous commenters expressed support for the board's process in drafting rules, including outreach and engagement of stakeholder involvement, for the proposed amendments and new rules. Commenters also supported the requirements for dispensing medical practitioners to follow the same patient safety standards that pharmacists and pharmacies are already required to meet in Montana.

<u>RESPONSE 1</u>: The board appreciates all comments received during the rulemaking process.

<u>COMMENT 2</u>: Several commenters indicated they do not believe that the rules are unduly burdensome for medical practitioners and that the board thoughtfully crafted the rules to promote patient safety.

<u>RESPONSE 2</u>: The board appreciates all comments received during the rulemaking process.

<u>COMMENT 3</u>: Many commenters generally supported NEW RULE II but asked the board to amend (1)(c) to allow medical practitioners to dispense using mail or common carrier delivery methods. The commenters stated that the board provided no justification for not allowing other delivery models to accommodate patient comfort, circumstances, and telehealth services, and that the board offered no

reason or evidence that patient safety would be at additional risk by allowing other delivery models.

<u>RESPONSE 3</u>: The board determined that it lacks the authority to allow mail or common carrier as delivery options for medical practitioner dispensing because the authorizing statute, 37-2-104(2)(a), MCA, specifically provides that drugs dispensed by a medical practitioner must be dispensed directly by the practitioner at the practitioner's office or place of practice. The board further concluded that a legislative change would be required for such a provision.

<u>COMMENT 4</u>: Several commenters indicated that naturopathic physicians are not included in the proposed rule because they are not included in the statutory definition of a medical practitioner and that a future legislative amendment is being considered.

<u>RESPONSE 4</u>: The board does not have authority to address in rulemaking the exclusion of naturopathic physicians from those medical practitioners allowed to dispense drugs per 37-2-101(7) and 37-2-104, MCA, and agrees that a legislative change would be required.

4. The board has amended ARM 24.174.401 exactly as proposed

5. The board has adopted New Rule I (24.174.1801), New Rule II (24.174.1802), and New Rule III (24.174.1803) exactly as proposed.

BOARD OF PHARMACY TONY KING, RPh PRESIDENT

<u>/s/ DARCEE L. MOE</u> Darcee L. Moe Rule Reviewer

<u>/s/ LAURIE ESAU</u> Laurie Esau, Commissioner DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State November 9, 2021.