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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 24.174.501 examination for licensure as a registered pharmacist, 24.174.526 requirements to become a clinical pharmacist practitioner, 24.174.1704 requirements for submitting prescription registry information to the board, and the repeal of 24.174.2401 screening panel, 24.174.2402 complaint procedure, and 24.174.2403 legal suspension or revocation NOTICE OF AMENDMENT AND REPEAL

TO: All Concerned Persons

1. On March 16, 2018, the Board of Pharmacy (board) published MAR Notice No. 24-174-70 regarding the public hearing on the proposed amendment and repeal of the above-stated rules, at page 535 of the 2018 Montana Administrative Register, Issue No. 5.

2. On April 6, 2018, 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 13, 2018, 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>: Several commenters expressed support for the amendments as proposed to the clinical pharmacist practitioner requirements in ARM 24.174.526.

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

<u>COMMENT 2</u>: Numerous commenters expressed support for amendments to the Montana Prescription Drug Registry (MPDR, Registry) reporting requirements, ARM 24.174.1704, and ongoing efforts to improve the program.

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

<u>COMMENT 3</u>: Two commenters supported amendments to MPDR reporting requirements in ARM 24.174.1704 but expressed concerns for meeting the next-day reporting timeline in critical access hospital facilities during weekends and other

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short staffing situations. A commenter requested the board allow at least four days to comply with the reporting requirements or permit an exemption for such facilities.

<u>RESPONSE 3</u>: The board acknowledges the need for more timely reporting of data to the MPDR, but does not believe this rule change will be overly burdensome to the operation of critical access hospitals who manually report MPDR data. Because commenters appeared to believe that critical access hospital staff would need to come in on weekends or holidays to comply with the "next day" rule change, the board is clarifying that MPDR data will need to be reported by the close of the next business day. Therefore, if the pharmacy is not open the day after a prescription is dispensed, the MPDR data must be reported during the next day of operation.

Further, the board surveyed pharmacies throughout the state before proposing this rule change. As provided in the reasonable necessity statement, pharmacies reporting prescription information automatically to the MPDR can already meet a daily reporting requirement. While some pharmacies, including some critical access hospitals, currently report MPDR data manually, the board concluded there is generally a low volume of outpatient prescriptions and staff currently spends approximately 30 to 60 minutes each week on the manual reporting. As well, the board is including additional and more efficient training resources on its MPDR web site regarding manual reporting.

Given the importance of the integrity of the MPDR data in promoting public safety and the minimal impact of the proposed rule change, the board is amending ARM 24.174.1704 exactly as proposed.

<u>COMMENT 4</u>: Several commenters expressed support for all the proposed rule changes in MAR Notice No. 24-174-70.

<u>RESPONSE 4</u>: The board appreciates all comments received in the rulemaking process.

4. The board has amended ARM 24.174.501, 24.174.526, and 24.174.1704 exactly as proposed.

5. The board has repealed ARM 24.174.2401, 24.174.2402, and 24.174.2403 exactly as proposed.

BOARD OF PHARMACY STARLA BLANK, RPh PRESIDENT

<u>/s/ DARCEE L. MOE</u> Darcee L. Moe Rule Reviewer <u>/s/ GALEN HOLLENBAUGH</u> Galen Hollenbaugh, Commissioner DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State August 28, 2018.