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

In the matter of the amendment of ARM 24.101.413, 24.174.401, 24.174.1201, 24.174.1202, 24.174.1203, 24.174.1207, 24.174.1208, 24.174.1211, 24.174.1702, 24.174.1703, and 24.174.1704 and the repeal of ARM 24.174.1212 and 24.174.1213 pertaining to the Board of Pharmacy	)))))))))))	NOTICE OF AMENDMENT AND REPEAL

TO: All Concerned Persons

1. On July 22, 2022, the Department of Labor and Industry (department) and the Board of Pharmacy (board) published MAR Notice No. 24-174-79 regarding the public hearing on the proposed amendment and repeal of the above-stated rules, at page 1216 of the 2022 Montana Administrative Register, Issue No. 14.

2. On August 12, 2022, a public hearing was held on the proposed amendment and repeal of the above-stated rules via the videoconference and telephonic platform. Comments were received by the August 19, 2022, 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 generally supported the rule changes, including the outline of different license categories and the expected process for implementation of Senate Bill 68. They further asked the board to provide resources to guide existing licensees in obtaining the appropriate license.

RESPONSE 1: The board will provide instructions on the implementation and to assist transition on the board's webpage and through direct licensee communication.

COMMENT 2: Several commenters requested clarification on ARM 24.174.1201, and specifically when facilities will need separate wholesale distributor and/or third-party logistics provider (3PL) licenses based on a facility's scope of services, ownership of product, and when performing multiple wholesale distribution and 3PL services activities.

RESPONSE 2: The board agrees that clarification is needed and is further amending ARM 24.174.1201(1). Facilities that provide services meeting the requirements of this rule as a wholesaler, a 3PL, or both, will need separate licenses for each activity. For example, when providing wholesale and 3PL services, a facility

will need both a wholesale distributor license and a 3PL license. The board will also clarify the requirements in outreach, education materials, and in applications.

COMMENT 3: Several commenters were concerned with the requirements in ARM 24.174.1201 to designate a new person-in-charge and notify the board within 72 hours of the change. The commenters believed this timeline could be difficult for smaller facilities under certain circumstances, and suggested a 30-day notification that other states offer.

RESPONSE 3: The board recognizes that a 72-hour timeline could pose challenges for licensees in the distribution supply chain and notes that per current rule, the timeline for board notification is 30 days. The board also believes it could be difficult for wholesale distributors and 3PLs to identify a new person-in-charge and submit fingerprints for the required criminal background checks in 72 hours. Therefore, the board is amending ARM 24.174.1201 and 24.174.1202 to remove the shortened timeline and retain the 30-day notification. If facility contact is needed during a change of person-in-charge, the board will contact the owner(s) or other staff.

COMMENT 4: Several commenters requested clarification on board-approved forms given the new process for criminal background check procedures, including fingerprint, application, and timeline forms.

RESPONSE 4: Board-approved forms will be available on the board's website (www.pharmacy.mt.gov) and through the application process which outlines the division's standard procedures and details for fingerprint and criminal background checks.

COMMENT 5: Several commenters requested clarification on the need for multiple facility licenses when a manufacturer serves as their own wholesale distributor for their own labeled products and/or products of a partner/sister manufacturer which they do not own.

RESPONSE 5: ARM 24.174.1202(6) provides that a manufacturer is only licensed when located in Montana. A facility may need multiple separate licenses if providing services as a manufacturer, wholesale distributor, 3PL (which does not take ownership of a product as a wholesaler does), and/or repackager, per ARM 24.174.1201 and 24.174.1202.

COMMENT 6: Multiple commenters generally supported the rule changes, as they supported the board's efforts during the legislative process in creating the licensure framework to comply with the federal Drug Supply Chain Security Act (DSCSA), as implemented by the U.S. Food and Drug Administration (FDA).

RESPONSE 6: The board agrees that the final rules create a licensure framework to comply with future DSCSA requirements.

COMMENT 7: Multiple commenters believed the board's proposed rules to be an initial step towards complying with DSCSA and the FDA's future final rule regarding "National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers." They asserted the FDA's final rule will establish uniform national licensure regulations to ensure regulatory clarity and consistency, help prevent counterfeits, discourage gray market activities, and further enhance the safety and efficiency of the drug supply chain.

RESPONSE 7: The board understands the importance of future rulemaking to ensure Montana's compliance with federal DSCSA national standards once the FDA issues its final rule outlining state requirements. The board expects that the licensing framework created in these rules will provide a pathway to implement future FDA requirements by separating the license types and services of wholesale distributors, 3PLs, repackagers, and manufacturers within the drug supply chain.

COMMENT 8: Several commenters stated their commitment to a secure prescription drug supply chain and look forward to working with the board on subsequent rules once the FDA finalizes its rule to comply with DSCSA.

RESPONSE 8: See RESPONSE 7.

4. The department has amended ARM 24.101.413 exactly as proposed.

5. The board has amended ARM 24.174.401, 24.174.1203, 24.174.1207, 24.174.1208, 24.174.1211, 24.174.1702, 24.174.1703, and 24.174.1704 exactly as proposed.

6. The board has repealed ARM 24.174.1212 and 24.174.1213 exactly as proposed.

7. The board has amended ARM 24.174.1201 and 24.174.1202 with the following changes, stricken matter interlined, new matter underlined:

24.174.1201 WHOLESALE DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER LICENSING (1) Every person engaged in wholesale distribution of drugs or prescription devices, which includes reverse wholesale distribution~~,~~ and medical gases, or engaged as a third-party logistics provider (3PL), as defined in 37-7-602, MCA, shall be licensed annually by the board. Each applicant shall:

(a) through (e)(i) remain as proposed.

(ii) Within ~~72 hours~~ 30 days of termination of services, a new person-in-charge must be designated in writing on the appropriate board-approved forms and filed with the board.

(2) through (8) remain as proposed.

AUTH: 37-7-201, 37-7-610, MCA
IMP: 37-7-603, 37-7-604, 37-7-605, 37-7-606, 37-7-611, 37-7-612, MCA

24.174.1202 MANUFACTURER AND REPACKAGER LICENSING

(1) through (1)(e)(i) remain as proposed.

(ii) Within ~~72 hours~~ 30 days of termination of services, a new person-in-charge must be designated in writing on the appropriate board-approved forms and filed with the board.

(2) through (7) remain as proposed.

AUTH: 37-7-201, 37-7-610, MCA
IMP: 37-7-201, 37-7-604, 37-7-605, 37-7-610, MCA

BOARD OF PHARMACY
TONY KING, PHARMACIST,
PRESIDENT

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

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

Certified to the Secretary of State September 13, 2022.