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 PUBLIC HEARING ON PROPOSED AMENDMENT AND REPEAL

TO: All Concerned Persons

1. On August 12, 2022, at 9:00 a.m., a public hearing will be held via remote conferencing to consider the proposed amendment and repeal of the above-stated rules. There will be no in-person hearing. Interested parties may access the remote conferencing platform in the following ways:

a. Join Zoom Meeting, https://mt-gov.zoom.us/j/88594773367
Meeting ID: 885 9477 3367, Passcode: 801817
-OR-

b. Dial by telephone, +1 406 444 9999 or +1 646 558 8656
Meeting ID: 885 9477 3367, Passcode: 801817

The hearing will begin with a brief introduction by department staff to explain the use of the videoconference and telephonic platform. All participants will be muted except when it is their time to speak.

2. The Department of Labor and Industry (department) will make reasonable accommodations for persons with disabilities who wish to participate in this public hearing or need an alternative accessible format of this notice. If you require an accommodation, contact the Board of Pharmacy (board) no later than 5:00 p.m., on August 5, 2022, to advise us of the nature of the accommodation that you need. Please contact Marcie Bough, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; telephone (406) 841-2371; Montana Relay 711; facsimile (406) 841-2305; or dlibsdpha@mt.gov (board's e-mail).

3. GENERAL REASONABLE NECESSITY: The board determined it is reasonably necessary to amend several rules regarding the licensing and requirements of wholesale distributors to implement provisions of Chapter 33, Laws of 2017 (Senate Bill 68), codified at 37-7-601 through 37-7-612, MCA. The 2017 legislative amendments reflect federal provisions required through the U.S. Food and Drug Administration (FDA) specific to the Drug Supply Chain Security Act (DSCSA), Public Law 113-54.

While Senate Bill 68 became effective February 2017, the board delayed initial rulemaking while awaiting final FDA rules. When the FDA rules were not released by December 2019, the board met and received input from stakeholders. Rulemaking was again paused in 2020 for COVID-19 priorities as well as action regarding new Montana Prescription Drug Registry staff and vendor selection. The board has met several times and received further stakeholder input on these rule changes between March 2021 and February 2022.

Similar to many other states, the board currently issues one "wholesale drug distributor" license for all entities operating within the drug supply chain. The DSCSA and Senate Bill 68 require Montana to separate the multiple entities currently grouped under the single license. The proposed amendments will implement the bill by establishing a more specific wholesale distributor license (37-7-602(8), MCA), for purposes of wholesale distribution (37-7-602(7), MCA), both of which reflect DSCSA. The board is further separating entities/facilities from the wholesale distributor license that no longer meet the requirements of DSCSA by creating license types for third-party logistics providers (3PLs), repackagers, and manufacturers, as defined in 37-7-602, MCA.

The DSCSA also requires states to standardize licensing of wholesale distributors and 3PLs. The FDA released guidance on such standards and is currently working on rules to provide requirements for states to further implement. The board determined it is reasonably necessary to propose these amendments now to implement the provisions of Senate Bill 68 and establish the core license types as based on currently available information. The board expects that once the FDA publishes final rules and outlines additional standards for wholesale and 3PL licensing, further amendments will be proposed. Having four distinct license types will clarify a facility's scope of practice and role within the drug supply chain, better identify the different types of facilities licensed by the board, and set a base for implementation of DSCSA licensing requirements.

Accordingly, the board has determined that reasonable necessity exists to amend certain rules to reflect Senate Bill 68 and DSCSA by establishing license fees and requirements for wholesale distributors, 3PLs, repackagers, and manufacturers. Other amendments standardize requirements for all facilities generally. Authority and implementation citations are being amended to accurately reflect all statutes implemented through the rules and provide the complete sources of the board's rulemaking authority. Where additional specific bases for a proposed action exist, the board will identify those reasons immediately following that rule.

4. The department is proposing to amend the following rule. The rule proposed to be amended is as follows, stricken matter interlined, new matter underlined:

24.101.413 RENEWAL DATES AND REQUIREMENTS (1) through (4) remain the same.

(5) Renewals for medical practitioners, as defined in 37-2-101, MCA, who also have a dispenser registration through the Board of Pharmacy, pursuant to 37-2-104, MCA, and ARM 24.174.1801, will renew their dispenser registration at the time of renewing their medical practitioner's license.

~~(5)~~ (6) The following are renewal dates for the professions and occupations listed:

(a) through (x) remain the same.

	BOARD OR PROGRAM JURISDICTION	LICENSE CATEGORY	FREQUENCY	RENEWAL DATE
(y)	Pharmacy	Dangerous Drug ~~License~~ Dispenser/Distributor/Manufacturer Endorsement	Annually	November 30
		Out-of-State Mail Order Pharmacy	Annually	November 30
		Pharmacist	Annually	June 30
		Community and Institutional Pharmacy	Annually	November 30
		Pharmacy Technician	Annually	June 30
		~~Pharmacy Technician in Training~~	~~Nonrenewable~~	
		Pharmacy Technician Utilization Plan Endorsement	Annually	November 30
		~~Telepharmacies~~ Telepharmacy Endorsement	Annually	November 30
		Wholesale ~~Drug~~ Distributor	Annually	November 30
		Limited Service Pharmacy	Annually	November 30
		Clinical Pharmacist Practitioner Endorsement	Annually	June 30

(z) through (am) remain the same.

~~(6)~~ (7) The following are nonrenewable licenses:

(a) through (c) remain the same.

(d) ~~pharmacy technicians in training~~ pharmacist intern;

(e) remains the same.

(7) remains the same but is renumbered (8).

AUTH: 37-1-101, 37-1-141, MCA
IMP: 37-1-101, 37-1-141, MCA

REASON: The department is amending this rule on renewal dates to clarify current license types, identify the different license endorsements, and update appropriate renewal dates.

The department is adding (5) to align renewal of dispenser registration with the renewal of the medical practitioner's primary license, as provided in Senate Bill 374 (2021), and codified at 37-2-104, MCA. When the board initially implemented

the bill in MAR Notice No. 24-174-76 (2021), the board created the registration and renewal fees, but inadvertently missed clarifying the renewal timing in this rule. Adding a new subsection is clearer and preferred over having the clarification four times in this department rule, once for each medical practitioner's renewal.

It is reasonably necessary to amend (6) to update licenses, endorsements, and renewal dates to align with amendments to ARM 24.174.401, and pursuant to Senate Bill 68. Staff discovered that while not new, the clinical pharmacist practitioner endorsement had not been previously included in this renewal rule.

While reviewing the license types in this rule, staff noted that the board replaced the technician-in-training license type in 2019 with a provisional certified pharmacy technician license. Additionally, staff noticed that the intern license, which is nonrenewable, was also omitted. It is reasonably necessary at this time to strike the obsolete license type from (7), and add the nonrenewable pharmacist intern license.

5. The board is proposing to amend the following rules. The rules proposed to be amended are as follows, stricken matter interlined, new matter underlined:

24.174.401 FEE SCHEDULE

(1) through (5) remain the same.

(6) ~~Certified~~ Community and institutional pharmacy original certification (includes original, change in location, and change in ownership) 240

(7) ~~Certified~~ Community and institutional pharmacy annual renewal fee 150

(8) through (15) remain the same.

(16) Wholesale ~~drug~~ distributor license 240

(17) Annual wholesale ~~drug~~ distributor renewal 240

(18) through (24) remain the same.

(25) Third-party logistics provider (3PL) initial license and annual renewal fee 240

(26) Repackager initial license and annual renewal fee 240

(27) Manufacturer initial license and annual renewal fee 240

(25) remains the same but is renumbered (28).

AUTH: 37-1-134, 37-2-104, 37-7-201, 37-7-604, 50-32-314, MCA
IMP: 37-1-134, 37-2-104, 37-7-201, 37-7-306, 37-7-321, 37-7-604, 37-7-605, 37-7-703, 50-32-314, MCA

REASON: As part of the post-legislative rule review, the board determined it is reasonably necessary to update licensure types. The board is amending (6) and (7) to clarify the specific pharmacy license types and align with the current licensing naming convention for these pharmacies.

The board is adding initial license and annual renewal fees for third-party logistics providers, repackagers, and manufacturers in (26) through (28) per Senate Bill 68. The fees are the same as current wholesale distributor licensees pay.

Because most current wholesale drug distributor licensees will switch to either third-party logistics providers, repackagers, and manufacturers licenses at no cost, the board estimates that these fee changes will be budget neutral.

24.174.1201 WHOLESALE ~~DRUG~~ DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER LICENSING (1) Every person engaged in ~~manufacturing,~~ wholesale distribution of drugs or prescription devices, which includes reverse wholesale distribution, ~~or selling of drugs, medicines, chemicals, poisons for medicinal purposes,~~ medical gases, ~~or legend devices other than to the consuming public or patient in the state of Montana~~ or 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) and (b) remain the same.

(c) pay the appropriate licensing and registration fees; ~~and~~

(d) meet the requirements of 37-7-604, MCA~~.~~ ; and

(e) designate a person-in-charge of the facility and for purposes of meeting requirements of 37-7-611, MCA, regarding a criminal background check at time of initial licensure or any change in person-in-charge, complete the requirements included on a form prescribed by the board.

(i) The person-in-charge must notify the board of any changes or termination of services.

(ii) Within 72 hours 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) The board will independently verify the applicant's standing through the National Practitioner Data Bank (NPDB) and National Association of Boards of Pharmacy Clearinghouse.

~~(2)~~ (3) The ~~wholesale drug distributor~~ license shall be posted in a conspicuous place in the wholesaler's place of business for which it is issued.

~~(3)~~ (4) No license may be issued to any ~~wholesale distributor~~ applicant whose intended place of business is a personal residence.

~~(4)~~ (5) Wholesale ~~drug~~ distributors located in Montana, applying for initial licensure, shall pass an inspection by a pharmacy inspector or other agent of the Board of Pharmacy before a license is issued.

~~(5)~~ (6) A separate license is required for each separate location, in-state and/or out-of-state, where drugs or devices are stored and directly distributed to Montana. ~~If a wholesaler distributes prescription drugs from more than one facility, the wholesaler must obtain a license for each facility.~~

~~(6)~~ (7) Wholesale ~~drug~~ distributors shall operate in compliance with applicable federal, state, and local laws and regulations. Wholesale ~~drug~~ distributors who ~~deal in~~ distribute controlled substances shall register with the board, to obtain an appropriate dangerous drug endorsement, and with the DEA~~, and shall comply with all applicable state, local, and DEA regulations~~.

~~(7) Manufacturers, distributors, and suppliers of medical gases shall operate in compliance with applicable federal, state, and local laws and regulations. Manufacturers, distributors, and suppliers of medical gases shall register with the~~

~~board to obtain the appropriate endorsement on their wholesale drug distributor license.~~

(8) Wholesale distributors shall submit proof of surety bond upon initial licensure and at time of renewal as identified on forms prescribed by the board in compliance with state and federal requirements.

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 ~~MINIMUM INFORMATION REQUIRED FOR LICENSURE~~ MANUFACTURER AND REPACKAGER LICENSING (1) ~~The following information shall be supplied by each applicant for wholesale drug distributor licensure or renewal~~ Every person seeking licensure or renewal as a manufacturer or repackager, as defined in 37-7-602, MCA, shall:

~~(a) the name, full business address, and telephone number of the licensee~~;

~~(b) all trade or business names used by the licensee~~;

~~(c) the name, address, telephone number, and title of the designated person in charge of the facility who will serve as the responsible individual of the wholesale drug distributor with the board and who is actively involved in and aware of the actual daily operation of the wholesale drug distributor~~

~~(d) whether the ownership or operation is a partnership, corporation, or sole proprietorship;~~

~~(e) proof of registration with the Montana Secretary of State;~~

~~(f) if out-of-state, proof of corresponding licensure in good standing in the state in which the applicant resides;~~

~~(g) the federal tax identification number of the company; and~~

~~(h) written documentation in compliance with the information required under 37-7-604, MCA.~~

(a) be a legal entity registered and in good standing with the Montana Secretary of State;

(b) file an application on a form prescribed by the board;

(c) pay the appropriate licensing and registration fees;

(d) meet the requirements of 37-7-604, MCA; and

(e) designate a person-in-charge of the facility.

(i) The person-in-charge must notify the board of any changes or termination of services.

(ii) Within 72 hours 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) Any changes in information contained in (1) shall be submitted to the board within 30 days of the change. Any changes in location or ownership require that a new license application be filed with the board at least 30 days prior to the change.~~

(2) The board will independently verify the applicant's standing through the National Practitioner Data Bank (NPDB) and National Association of Boards of Pharmacy Clearinghouse.

(3) The license shall be posted in a conspicuous place in the place of business for which it is issued.

(4) No license may be issued to any applicant whose intended place of business is a personal residence.

(5) Applicants located in Montana, applying for initial licensure, shall pass an inspection by a pharmacy inspector or other agent of the Board of Pharmacy before a license is issued.

(6) A separate license is required for each separate location where drugs or devices are stored, repackaged, and/or directly distributed to Montana. For manufacturers, a license shall be issued to a facility meeting the requirements that is located in Montana.

(7) Licensees shall operate in compliance with applicable federal, state, and local laws and regulations. Licensees who distribute controlled substances shall register with the board, obtain an appropriate dangerous drug endorsement, register with the DEA, and shall comply with all applicable state, local, and DEA regulations.

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

24.174.1203 PERSONNEL (1) Each ~~wholesale drug distributor~~ licensee under this subchapter shall require each person employed in any prescription drug wholesale activity to have sufficient education, training, and experience in any combination, sufficient for that person to:

(a) complete assigned work in a manner which maintains the quality, safety, and security of the drug or device products in accordance with Title 37, MCA;

(b) remains the same.

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

24.174.1207 CHANGE IN LOCATION (1) Whenever a ~~wholesale drug distributor~~ facility licensed under this subchapter changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. The ~~wholesale drug distributor~~ facility shall submit a new license application for the new location at least 30 days before such change occurs.

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

24.174.1208 CHANGE IN OWNERSHIP (1) When a ~~wholesale drug distributor~~ facility licensed under this subchapter changes ownership, the original license becomes void and must be surrendered to the board, and a new license obtained by the new owner. The owner shall submit a new license application at least 30 days prior to the change in ownership.

(2) and (3) remain the same.

AUTH: 37-7-201, 37-7-610, MCA

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

24.174.1211 MINIMUM ~~REQUIREMENTS FOR STORAGE AND HANDLING OF DRUGS~~ FACILITY REQUIREMENTS (1) All facilities ~~at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed~~ licensed under this subchapter shall:

~~(a) be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;~~

~~(b) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;~~

~~(c) have a physically separate area for storage of all prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;~~

~~(d) be maintained in a clean and orderly condition; and~~

~~(e) be free from infestation by insects, rodents, birds, or vermin of any kind.~~

(a) establish, maintain, and adhere to written policies and procedures for receipt, recordkeeping, security, storage, inventory control, and distribution of drugs or devices;

(b) comply with state and federal law requirements including, but not limited to:

(i) 37-7-602, 37-7-604, 37-7-609, and 37-7-610, MCA; and

(ii) 21 CFR § 205 as established by the Food and Drug Administration (FDA); and

(c) comply with product track and trace transaction requirements established by the FDA.

~~(2) All facilities used for wholesale drug distribution shall be secure from unauthorized entry as provided for in 37-7-604, MCA, and as follows:~~

~~(a) access from outside the premises shall be kept to a minimum and be well-controlled;~~

~~(b) the outside perimeter of the premises shall be well-lighted; and~~

~~(c) entry into areas where prescription drugs are held shall be limited to authorized personnel.~~

~~(3) All facilities shall be equipped with a security system to detect entry after hours.~~

~~(4) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.~~

~~(5) All drugs shall be stored at temperatures and under conditions in accordance with the requirements, if any, in the labeling of such drugs, or with requirements in the current edition of the United States Pharmacopeia/National Formulary, published by the United States Pharmacopeia Convention Inc., which is available for inspection at the pharmacy library at the University of Montana School of Pharmacy and Allied Health Sciences, Missoula, MT 59812-1075.~~

~~(a) If no storage requirements are established for a drug, the drug may be held at "controlled room temperature," as defined in the United States~~

~~Pharmacopeia/National Formulary, to help ensure that its identity, strength, quality and purity are not adversely affected.~~

~~(b) Manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be used to document proper storage of prescription drugs.~~

~~(c) The record keeping requirements in these rules shall be followed for all stored drugs.~~

~~(6) A stock of prescription drugs, adequate to service the ordinary needs of practitioners and pharmacies with which the wholesaler transacts business, must be maintained.~~

~~(7) A wholesaler may not maintain a stock of controlled substances unless the wholesaler ordinarily sells controlled substances to practitioners and pharmacies with which the wholesaler transacts business.~~

(2) Inventories and records shall be made available for inspection and photocopy by authorized federal, state, or local law enforcement agency officials for a period of two years following distribution of inventory.

(3) Records described in this subchapter that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at central locations apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of a federal, state, or local law enforcement agency.

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

REASON: The board is amending this rule to set forth minimum compliance requirements for all facility licensees regarding policies and procedures for receipt, recordkeeping, security, storage, inventory control and distribution, including compliance with national licensing standards for wholesale distributors and 3PLs pursuant to FDA rulemaking as required by DSCSA. Additionally, the amendments include compliance with drug product track and trace requirements of DSCSA as implemented by the FDA regarding security of the drug supply chain. It is reasonable to strike (4) through (7) as the provisions are outdated, duplicated elsewhere in statute or rule, or being consolidated into other rules.

24.174.1702 INFORMATION REQUIRED FOR SUBMISSION (1) Each entity ~~registered~~ licensed by the board as a ~~certified~~ community pharmacy or as an out-of-state mail service pharmacy that dispenses to patients in Montana shall provide the following controlled substances dispensing information to the board:

(a) remains the same.

(b) full name, address, telephone number, gender, species code, and date of birth for whom the prescription was written;

(c) and (d) remain the same.

(e) date the prescription was filled and sold by the pharmacy;

(f) number of refills;

(f) through (i) remain the same but are renumbered (g) through (j).

(2) Each entity licensed by the board as an institutional pharmacy shall comply with the reporting requirements listed in this rule if they dispense controlled substances in an outpatient, discharge, starter packet, or other related capacity in which the controlled substance(s) leaves their premises. Institutional pharmacies are not required to submit zero reports.

AUTH: 37-7-1512, MCA
IMP: 37-7-1502, 37-7-1503, 37-7-1512, MCA

REASON: The board is amending this rule and ARM 24.174.1703 and 24.174.1704, relating to the Montana Prescription Drug Registry (MPDR), in response to recommendations in a June 2019 Montana Legislative Audit Division report, *Montana Prescription Drug Registry* (18DP-01), Original Information Systems Audit, issued to the Legislative Audit Committee. The department and the board agreed with the audit recommendations to update the reporting standards and data fields that pharmacies are required to report to the MPDR and committed to such changes in the department's June 2019 audit report response and June 2021 follow-up response. The transition of the MPDR database to a new system vendor in March 2021 provided the necessary functionality to implement the updated reporting standards and related revisions.

It is reasonably necessary to amend these three rules to clarify institutional pharmacy reporting requirements, update required data reporting fields, incorporate a more current and robust electronic reporting standard, and explain acceptable electronic reporting methods. Further amendments describe zero reporting requirements, and update the time for resubmitting error reports to seven days from original submission to better represent frontline pharmacy practice and align with compliance monitoring functionality and logistics of the new system vendor.

24.174.1703 ELECTRONIC FORMAT REQUIRED FOR THE TRANSMISSION OF INFORMATION (1) All prescription information submitted to the board pursuant to ARM 24.174.1702, must be transmitted in the format specified by the American Society for Automation in Pharmacy (ASAP), version ~~4.1~~ 4.2A, dated ~~2009~~ 2016, at a minimum, which is adopted and incorporated by reference. ~~A copy of the ASAP standards may be obtained through the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana, 59620-0513.~~

(a) Entities must contact ASAP directly to obtain the technical specification of the ASAP standard; and

(b) The acceptable methods of electronic reporting are Secure File Transfer Protocol (SFTP), file upload via a secure web-based interface, and/or manual data entry of prescription information via a secure web-based interface. The secure web-based interface is provided by the system vendor maintained by the board.

(2) Reporting entities shall refer to the Montana Prescription Drug Registry (MPDR) Data Submission Guide for the ASAP format and MPDR required fields available on the Board of Pharmacy's MPDR website at www.mpdr.mt.gov.

AUTH: 37-7-1512, MCA
IMP: 37-7-1503, 37-7-1512, MCA

24.174.1704 REQUIREMENTS FOR SUBMITTING PRESCRIPTION REGISTRY INFORMATION TO THE BOARD (1) remains the same.

(2) A pharmacy shall submit all prescription drug order information for a controlled substance or a zero report to the board no later than close of the next business day after the date of dispensing the controlled substance or the zero report.

~~(3) If a pharmacy that dispenses controlled substances has not dispensed any controlled substances during a calendar month, the pharmacy shall verify that no controlled substances were dispensed for that month by submitting a "zero report" to the board. A "zero report" is due on or before the fifth day of the next month.~~

~~(4)~~ (3) A pharmacy that does not dispense controlled substances shall notify the board by submitting an appropriate board-approved form attesting that the pharmacy does not dispense controlled substances. A pharmacy is not exempt from reporting requirements until it receives approval from the board.

(a) The board-approved form submitted by a pharmacy that does not dispense controlled substances shall be maintained on file with the board and at the pharmacy's location.

(b) ~~If a~~ A pharmacy's exempt status does not end unless the pharmacy is either issued a new license number or until the pharmacy ~~does dispense~~ dispenses a controlled substance~~, it shall then comply with the reporting requirements of this rule~~.

(5) remains the same but is renumbered (4).

~~(6)~~ (5) It is the responsibility of the submitting pharmacy to address any errors or questions about information that the pharmacy has submitted to the prescription drug registry and resubmit corrected data ~~no later than close of the next business day~~ within seven days after the date of the original submission.

AUTH: 37-7-1512, MCA
IMP: 37-7-1503, 37-7-1512, MCA

6. The board is proposing to repeal the following rules:

24.174.1212 MINIMUM REQUIREMENTS FOR ESTABLISHMENT AND MAINTENANCE OF DRUG DISTRIBUTION RECORDS

AUTH: 37-7-201, 37-7-610, MCA
IMP: 37-7-604, 37-7-609, MCA

REASON: The board is repealing ARM 24.174.1212 to remove outdated and/or duplicative language. Relevant provisions are being consolidated into ARM 24.174.1211.

24.174.1213 NATIONAL CLEARINGHOUSE FOR WHOLESALE DRUG DISTRIBUTOR LICENSING

AUTH: 37-7-201, 37-7-610, MCA
IMP: 37-7-604, 37-7-605, 37-7-606, 37-7-607, MCA

REASON: The board is repealing ARM 24.174.1213 as outdated and irrelevant. To the board's knowledge, the clearinghouse process has never been utilized in Montana as described in this rule. A new clearinghouse tool from the National Association of Boards of Pharmacy is being added to ARM 24.174.1201(2) and will be used to check home state licensure, discipline, and other information for licensure applicants.

7. Concerned persons may present their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513, by facsimile to (406) 841-2305, or e-mail to dlibsdpha@mt.gov, and must be received no later than 5:00 p.m., August 19, 2022.

8. An electronic copy of this notice of public hearing is available at www.pharmacy.mt.gov. Although the department strives to keep its websites accessible at all times, concerned persons should be aware that websites may be unavailable during some periods, due to system maintenance or technical problems, and that technical difficulties in accessing a website do not excuse late submission of comments.

9. The board maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this board. Persons wishing to have their name added to the list shall make a written request that includes the name and e-mail or mailing address of the person to receive notices and specifies the intent to receive notices of all board administrative rulemaking proceedings or a particular subject matter. The request must indicate whether e-mail or standard mail is preferred and may be sent or delivered to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; faxed to (406) 841-2305; e-mailed to dlibsdpha@mt.gov; or by completing a request form at any rules hearing held by the board.

10. The bill sponsor contact requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor was contacted on May 6, 2022, by telephone.

11. Pursuant to 2-4-111, MCA, the board has determined that the rule changes proposed in this notice will not have a significant and direct impact upon small businesses.

12. Department staff has been designated to preside over and conduct this hearing.

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 July 12, 2022.