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

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 PUBLIC HEARING ON PROPOSED AMENDMENT AND REPEAL

TO: All Concerned Persons

1. On April 6, 2018, at 9:00 a.m., a public hearing will be held in the Small Conference Room, 301 South Park Avenue, 4th Floor, Helena, Montana, to consider the proposed amendment and repeal of the above-stated rules.

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 March 30, 2018, to advise us of the nature of the accommodation that you need. Please contact Marcie Bough, Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; telephone (406) 841-2371; Montana Relay 1 (800) 253-4091; TDD (406) 444-2978; facsimile (406) 841-2344; or dlibsdpha@mt.gov (board's e-mail).

3. The rules proposed to be amended are as follows, stricken matter interlined, new matter underlined:

<u>24.174.501 EXAMINATION FOR LICENSURE AS A REGISTERED PHARMACIST</u> (1) The board has selected the National Association of Boards of Pharmacy (NABP) licensure examination (NAPLEX) to be administered to candidates for licensure in Montana. The examination shall be prepared to measure the competence of the applicant to engage in the practice of pharmacy. A score of 75 shall be a passing score for this examination. A candidate who does not attain this score may retake the examination ~~after a 90-day waiting period from the date of the exam~~ <u>pursuant to NABP requirements</u>.

(2) through (4) remain the same.

AUTH: 37-1-131, 37-7-201, MCA

IMP: 37-1-131, 37-7-201, 37-7-302, MCA

REASON: The board is amending this rule to reflect new testing and retesting provisions implemented on November 1, 2016, by the National Association of Boards of Pharmacy (NABP), the administrator of the NAPLEX pharmacist licensure examination for the board. The new provisions reduced the waiting period for NAPLEX exam retakes from 90 to 45 days. NABP made this change because it transitioned to a new exam platform that makes it easier to manage exam retakes while ensuring the integrity of the exam process. Based on the NABP change, the board is amending (1) to reference "NABP requirements" instead of stating the specific waiting period to eliminate the need for rule amendment should NABP make future changes to the exam retake process.

24.174.526 REQUIREMENTS TO BECOME A CLINICAL PHARMACIST PRACTITIONER (1) An applicant for a clinical pharmacist practitioner registration shall:

(a) through (c) remain the same.

(d) have completed ~~five years~~ the years of clinical practice experience that meet the requirements for Board of Pharmacy Specialties (BPS) certification or other equivalent national certification, ~~or have completed a pharmacy residency and two years clinical practice experience~~ and hold one of the following active certifications:

(i) remains the same.

(ii) nationally recognized certification equivalent to BPS certification standards in an area of practice as approved by the board and the Board of Medical Examiners (BME).

(e) submit a signed collaborative practice agreement to the board that includes a description of the type of supervision the collaborating ~~physician~~ practitioner will exercise over the clinical pharmacist practitioner;

(f) through (2) remain the same.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-306, MCA

REASON: The board determined it is reasonably necessary to amend this rule to reflect recent changes made by the Board of Pharmacy Specialties (BPS) certification authority regarding eligibility requirements for pharmacists applying for BPS certification, and the years of experience necessary to obtain certification. Further, BPS offers eleven certification specialties that require different levels of practice experience and/or recognition of post-graduate year residency training. To reflect the certification changes, and because BPS may continue adding new certification specialties, the board is amending this rule to reference BPS certification without listing specific requirements and avoid having to amend the rule each time new specialties are added.

The board is amending (1)(d) to require a "nationally recognized certification" that is "equivalent to BSP certification standards" to clarify what other programs are acceptable without the need to amend the rule each time new certification programs

are created. The board is changing "physician" to "practitioner" in (1)(e) to align with terminology in 37-2-102(5), MCA, after board staff noticed the error.

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 to the board no later than ~~eight days~~ close of the next business day after the date of dispensing the controlled substance.

(3) and (4) remain the same.

~~(5) For the purposes of establishing a data history at the initiation of the prescription drug registry, each certified pharmacy and out-of-state mail service pharmacy shall submit a one-time batch submission of controlled substances, dispensed to Montana patients from July 1, 2011 forward to the date the registry is operational.~~

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

~~(7)~~ (6) 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 ~~eight days~~ close of the next business day after the date of the original submission.

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

REASON: The board is amending this rule to improve accuracy and timeliness of the prescription information available in the Montana Prescription Drug Registry (MPDR). Prescribers and dispensers rely on the prescription information available in the MPDR when providing medical and pharmaceutical treatment to patients and requiring that pharmacies report the information earlier ensures continually current and up-to-date data. Presently, 44 states with prescription drug registries require at least daily reporting of prescription information. Additionally, the board recently surveyed Montana pharmacies to analyze the capability and impact of changing the reporting requirement and based on the responses, concluded the changes are feasible. The board's subcommittee studied this issue when the board last amended the rule in 2015, and some pharmacies indicated they already reported daily while others expressed concern over software limitations and potential cost to implement daily reporting. As the board's recent survey indicated, advancements in software now allow pharmacies that report prescription information automatically to the MPDR to meet a daily reporting requirement. While some pharmacies that manually report prescription information to the MPDR expressed concern with daily reporting, the board determined the impact to these pharmacies will be minimal. The board's recent survey indicated those pharmacies reporting manually spend approximately 30 to 60 minutes per week submitting the prescription information.

The board is repealing (5) because the provision was written when the MPDR launched in November 2012, and it was necessary to collect a one-time batch of prescription information dating back to the enactment of the MPDR (on July 1, 2011). The one-time batch collection was successful and is no longer necessary.

4. The rules proposed to be repealed are as follows:

24.174.2401 SCREENING PANEL

AUTH: 37-7-201, MCA
IMP: 37-1-307, MCA

REASON: The board is repealing this rule, ARM 24.174.2402, and 24.174.2403 as the rules are unnecessary and duplicative. ARM 24.174.2401 requires a specific composition of board members to serve on its screening panel. However, the board has experienced challenges in establishing a quorum of the screening panel if a member is unavailable or must be recused from a case. Repealing the rule allows the board greater flexibility in assigning members to its two panels, a process already governed by 37-1-307(1)(d), MCA.

ARM 24.174.2402 and 24.174.2403 are unnecessarily duplicative of the department's standardized complaint and disciplinary procedures that are supported by Title 37, chapter 1, parts 1 through 3, MCA.

24.174.2402 COMPLAINT PROCEDURE

AUTH: 37-7-201, MCA
IMP: 37-1-308, 37-1-309, MCA

24.174.2403 LEGAL SUSPENSION OR REVOCATION

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-311, 37-7-321, MCA

5. 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) 841-2344, or e-mail to dlibsdpha@mt.gov, and must be received no later than 5:00 p.m., April 13, 2018.

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

7. The board maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this board. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies that the person wishes to receive notices regarding all board administrative rulemaking proceedings or other administrative proceedings. The request must indicate

whether e-mail or standard mail is preferred. Such written request may be sent or delivered to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; faxed to the office at (406) 841-2344; e-mailed to dlibsdpha@mt.gov; or made by completing a request form at any rules hearing held by the agency.

8. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

9. Regarding the requirements of 2-4-111, MCA, the board has determined that the amendment of ARM 24.174.501, 24.174.526, and 24.174.1704 will not significantly and directly impact small businesses.

Regarding the requirements of 2-4-111, MCA, the board has determined that the repeal of ARM 24.174.2401, 24.174.2402, and 24.174.2403 will not significantly and directly impact small businesses.

Documentation of the board's above-stated determinations is available upon request to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; telephone (406) 841-2371; facsimile (406) 841-2344; or to dlibsdpha@mt.gov.

10. Marcie Bough, Executive Officer, has been designated to preside over and conduct this hearing.

BOARD OF PHARMACY
STARLA BLANK, RPh
PRESIDENT

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

/s/ GALEN HOLLENBAUGH
Galen Hollenbaugh, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State March 6, 2018.