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

In the matter of the amendment of ARM 24.174.503 administration of vaccines, 24.174.1412 additions, deletions, and rescheduling of dangerous drugs, and the repeal of ARM 24.174.1420 through 24.174.1424 related to scheduling of dangerous drugs	))))))))	NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT AND REPEAL

TO: All Concerned Persons

1. On June 23, 2015, at 1:00 p.m., a public hearing will be held in the Large 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 June 16, 2015, 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 provide as follows, stricken matter interlined, new matter underlined:

24.174.503 ADMINISTRATION OF VACCINES BY PHARMACISTS (1) ~~In order to administer or prescribe vaccinations, a pharmacist must have a collaborative practice agreement with a practitioner authorized to prescribe drugs, or in the case of a public health emergency, a directive from the state medical officer of the Montana Department of Public Health and Human Services.~~ An immunization-certified pharmacist may prescribe and administer those immunizations listed in 37-7-105, MCA, without a collaborative practice agreement in place, as required by the statute.

~~(2) A pharmacist may administer vaccines to persons 18 years of age or older and administer influenza vaccine to persons 12 years of age or older provided that:~~

~~(a) the pharmacist has successfully completed a course of training approved by the Centers for Disease Control and Prevention (CDC), a provider accredited by the Accreditation Counsel on Pharmacy Education (ACPE), or other authority approved by the board;~~

~~(b) the pharmacist holds a current basic cardiopulmonary resuscitation certification issued by the American Heart Association, the American Red Cross, or other recognized provider, and documentation is on file at the practice site;~~

~~(c) the pharmacist and the pharmacist intern must provide a copy of the immunization certificate and CPR certification to the board for initial specialty recognition;~~

~~(d) the vaccines are administered in accordance with an established protocol that includes site-specific emergency measures; and~~

~~(e) the pharmacist has either a current copy of or online access to the most recent edition of the CDC reference "Epidemiology and Prevention of Vaccine-Preventable Diseases."~~

(2) An immunization-certified pharmacist must have a collaborative practice agreement with a practitioner authorized to prescribe drugs to administer immunizations not listed in 37-7-105, MCA, to persons 18 years of age or older; or, in the case of a public health emergency, a directive from the State Medical Officer of the Montana Department of Public Health and Human Services.

(3) An immunization-certified pharmacist, as defined in 37-7-105(3)(a), MCA, shall:

(a) provide a copy of the immunization certificate and current basic cardiopulmonary resuscitation (CPR) certification to the board for initial endorsement on license; and

(b) maintain documentation of immunization endorsement and current CPR certification on file at the practice site.

(4) In order to administer immunizations, with or without a collaborative practice agreement, an immunization-certified pharmacist must:

(a) administer vaccinations in accordance with established protocol that includes site-specific emergency measures;

(b) have access to a current edition of the United States Centers for Disease Control and Prevention (CDC) reference "Epidemiology and Prevention of Vaccine-Preventable Diseases";

~~(3) The pharmacist must give~~

(c) provide a copy of the most current vaccine information statement (VIS) to the patient or the patient's legal representative, ~~for those vaccines which have them, and counsel the patient accordingly.~~ as required by 37-7-105(2)(b), MCA;

~~(4) The pharmacist must~~

(d) maintain the following:

(i) written policies and procedures for the types of immunizations administered;

(ii) specific description of the procedures, methods, and decision criteria to follow for administering the immunization;

(iii) a detailed description of the procedures and patient activities to follow in the course of administering immunizations;

(iv) training for staff procedures and record keeping requirements; and

(v) disposal of used or contaminated supplies~~.~~;

(e) ensure that the individual immunized is assessed for contraindications to immunization, as required by 37-7-105(2)(a), MCA;

~~(5) The pharmacist must~~

(f) report any significant adverse events to the primary care provider if one is identified by the patient, and to the Vaccine Adverse Events Reporting System (VAERS), if applicable~~.~~, as required by 37-7-105(2)(c), MCA; and

~~(6) A pharmacist administering any vaccine shall~~

(g) maintain the following information in the patient's medical records for a period of at least ~~three~~ seven years, as required by 37-7-105(2)(d), MCA, which shall be considered confidential information:

(a) through (g) remain the same, but are renumbered (i) through (vii).

~~(7)~~ (5) The authority of a pharmacist to administer immunizations may not be delegated~~,~~; however, ~~an immunization-certified~~ a pharmacy intern may immunize under the direct supervision of ~~a~~ an immunization-certified pharmacist or other healthcare provider qualified in vaccine administration and deemed appropriate by the preceptor upon meeting the immunization-certified requirements listed in 37-7-105, MCA, and this rule.

~~(8) In order to maintain specialty recognition, an immunization certified pharmacist must maintain a current CPR certification.~~

(9) remains the same, but is renumbered (6).

AUTH: 37-7-201, MCA
IMP: 37-7-101, 37-7-105, 37-7-201, MCA

REASON: The board determined it is reasonably necessary to amend this rule to reflect statutory authority for immunization-certified pharmacists to prescribe and administer certain immunizations. In 2013, the Montana Legislature amended 37-7-105, MCA, to establish standards that allow pharmacists to prescribe and administer certain immunizations without a collaborative practice agreement.

Although the current rule only addresses immunizations prescribed or administered with a collaborative practice agreement, both the statute and rule require the pharmacist to be immunization-certified. The board determined it is reasonably necessary to amend this rule to further implement the legislative changes and clarify the standards that apply to this practice, regardless of whether a collaborative practice agreement exists. The board notes that collaborative practice agreements are still defined and regulated by ARM 24.174.524.

24.174.1412 ADDITIONS, DELETIONS, AND RESCHEDULING OF DANGEROUS DRUGS (1) ~~The Board of Pharmacy adopts the most current schedule of dangerous drugs as defined in 21 CFR 1308, et. seq. April 1, 2009. Copies are available from the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, MT 59620-0513.~~ In addition to those dangerous drugs scheduled in 50-32-222, 50-32-224, 50-32-226, 50-32-229, and 50-32-232, MCA, the board adds the following to dangerous drug schedules after considering federal regulations and/or the criteria enumerated in Title 50, chapter 32, part 2, MCA:

(a) Schedule I:

(i) none at this time;

(b) Schedule II:

(i) none at this time;

(c) Schedule III:

(i) methasterone;
(ii) perampanel; and
(iii) prostanozol;
(d) Schedule IV:
(i) tramadol;
(ii) alfaxalone;
(iii) suvorexant; and
(iv) lorcaserin;
(e) Schedule V:
(i) ezogabine.

(2) The board deletes the following dangerous drugs from the schedules in 50-32-222, 50-32-224, 50-32-226, 50-32-229, and 50-32-232, MCA, after considering federal regulations and/or the criteria enumerated in Title 50, chapter 32, part 2, MCA:

(a) Schedule I:
(i) none at this time;
(b) Schedule II:
(i) naloxegol;
(c) Schedule III:
(i) 50-32-226(4)(c) and (d), MCA (hydrocodone combination products);
(d) Schedule IV:
(i) none at this time;
(e) Schedule V:
(i) none at this time.

(3) After considering federal regulations and/or the criteria enumerated in Title 50, chapter 32, part 2, MCA, the board reschedules the following dangerous drugs from those scheduled in 50-32-222, 50-32-224, 50-32-226, 50-32-229, and 50-32-232, MCA:

(a) Schedule I:
(i) none at this time;
(b) Schedule II:
(i) none at this time;
(c) Schedule III:
(i) none at this time;
(d) Schedule IV:
(i) modafinil;
(e) Schedule V:
(i) none at this time.

AUTH: 50-32-103, 50-32-203, MCA
IMP: 50-32-103, 50-32-202, 50-32-203, 50-32-209, 50-32-222, 50-32-223, 50-32-224, 50-32-225, 50-32-226, 50-32-228, 50-32-229, 50-32-231, 50-32-232, MCA

REASON: The board determined it is reasonably necessary to amend this rule to clarify Montana scheduling requirements for dangerous drugs (controlled substances Schedules I-V). Currently, dangerous drugs are scheduled by the U.S. Drug

Enforcement Administration (DEA) in the Code of Federal Registrations (CFR), by the Montana Legislature in statute (Title 50, chapter 32, MCA), and also by the board in administrative rule (ARM Title 24, chapter 174).

Because dangerous drugs are scheduled by three different government entities and published in three different sources, it may not always be clear to licensees, practitioners, law enforcement, and the public what constitutes the current schedule(s) of dangerous drugs. These proposed rule revisions streamline and clarify the scheduling of dangerous drugs in Montana by adding, deleting, or rescheduling only those dangerous drugs in administrative rule that are updated from statute.

Furthermore, 50-32-203, MCA, requires the board to "similarly control" a drug that is scheduled, rescheduled, or deleted from schedule under federal law through rulemaking. While the board may also hold a public hearing to consider alternatives to federal law, the board is amending this rule to "similarly control" the dangerous drugs which the DEA has recently added, deleted, or rescheduled.

To that end, the DEA added methasterone (schedule III), perampanel (schedule III), prostanozol (schedule III), tramadol (schedule IV), alfaxalone (schedule IV), suvorexant (schedule IV), lorcaserin (schedule IV), and ezogabine (schedule V) to schedule under federal law between 2012 and 2015, and the board is now updating the Montana schedule to include these drugs.

Hydrocodone is a schedule II dangerous drug under Montana and federal law. In August 2014, the DEA deleted hydrocodone combination products from schedule III under federal law; therefore, single ingredient hydrocodone and any hydrocodone combination product are schedule II dangerous drugs. Hydrocodone combination products are currently scheduled in Montana under schedule III at 50-32-226(4)(c) and (d), MCA. Therefore, the board is amending (2)(c)(i) to align Montana with federal law in scheduling single-ingredient hydrocodone and any hydrocodone combination product under schedule II.

In January 2015, the DEA deleted naloxegol (schedule II) from schedule under federal law by excluding it from the list of opiates under schedule II. Therefore, the board is now similarly deleting naloxegol from schedule II under Montana law by excluding it from the list of opiates under 50-32-224, MCA.

Modafinil is listed as a schedule IV dangerous drug under federal law. While the drug is also listed in schedule IV under Montana law, it is incorrectly spelled. Therefore, the board is correcting this error by rescheduling the drug under its correct name.

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

24.174.1420 SCHEDULE I DANGEROUS DRUGS found at ARM page 24-19847.

AUTH: 50-32-103, MCA
IMP: 50-32-103, MCA

REASON: The board determined it is reasonably necessary to clarify Montana scheduling requirements for dangerous drugs, accomplished by listing only those

drugs in administrative rule that update statute. The board concluded that it is no longer necessary to duplicate schedules I-V in administrative rule and statute and is repealing ARM 24.174.1420 through 24.174.1424 accordingly.

24.174.1421 SCHEDULE II DANGEROUS DRUGS found at ARM page 24-19855.

AUTH: 50-32-103, MCA
IMP: 50-32-103, MCA

24.174.1422 SCHEDULE III DANGEROUS DRUGS found at ARM page 24-19858.

AUTH: 50-32-103, MCA
IMP: 50-32-103, MCA

24.174.1423 SCHEDULE IV DANGEROUS DRUGS found at ARM page 24-19865.

AUTH: 50-32-103, MCA
IMP: 50-32-103, MCA

24.174.1424 SCHEDULE V DANGEROUS DRUGS found at ARM page 24-19868.

AUTH: 50-32-103, MCA
IMP: 50-32-103, 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., June 30, 2015.

6. An electronic copy of this notice of public hearing is available at www.pharmacy.mt.gov (department and board's web site). The department strives to make the electronic copy of this notice conform to the official version of the notice, as printed in the Montana Administrative Register, but advises all concerned persons that in the event of a discrepancy between the official printed text of the notice and the electronic version of the notice, only the official printed text will be considered. In addition, although the department strives to keep its web site accessible at all times, concerned persons should be aware that the web site may be unavailable during some periods, due to system maintenance or technical problems, and that technical difficulties in accessing or posting to the e-mail address 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, apply and have been fulfilled. The primary bill sponsor was contacted on July 11, 2013, by telephone.

9. With regard to the requirements of 2-4-111, MCA, the board has determined that the amendment of ARM 24.174.503 and 24.174.1412 will not significantly and directly impact small businesses.

With regard to the requirements of 2-4-111, MCA, the board has determined that the repeal of ARM 24.174.1420 through 24.174.1424 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, by facsimile to (406) 841-2344, or e-mail to dlibsdpha@mt.gov.

10. Kevin Maki, attorney, 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/ PAM BUCY
Pam Bucy, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State May 4, 2015