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

In the matter of the amendment of ARM 24.174.301 definitions, 24.174.524 collaborative practice agreement requirements, 24.174.835 transfer of prescriptions, 24.174.1111 drug distribution and control in an institutional or correctional facility, 24.174.1114 use of drug kits in certain institutional facilities, 24.174.1412 additions, deletions, and rescheduling of dangerous drugs, 24.174.2106 registered pharmacist continuing education–approved programs, and the repeal of 24.174.1115 use of contingency kits in certain institutional facilities	)))))))))))))	NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT AND REPEAL

TO: All Concerned Persons

1. On September 16, 2021, at 10:00 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/89354285974
Meeting ID: 893 5428 5974, Passcode: 643276
-OR-

b. Dial by telephone, +1 406 444 9999 or +1 646 558 8656
Meeting ID: 893 5428 5974, Passcode: 643276

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 no later than 5:00 p.m., on September 9, 2021, 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) 841-2305; or dlibsdpha@mt.gov (board's e-mail).

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

24.174.301 DEFINITIONS (1) through (6) remain the same.

~~(7)~~ (11) "~~Contingency~~ Drug kit" means a secured kit stored outside of a pharmacy containing those drugs which may be required to meet the short-term therapeutic need of patients within an institution not having an in-house pharmacy or 24-hour access to dispensing services, and which would not be available from any other authorized source in sufficient time, and without which would compromise the quality of care of the patient.

(8) through (11) remain the same but are renumbered (7) through (10).

(12) through (14) remain the same.

(15) "Emergency drug cart" or "crash cart" means a secure lockable cart ~~containing~~ or container in an inpatient setting that stores drugs and devices necessary to meet the immediate therapeutic needs of ~~inpatients or outpatients~~ a patient and which cannot be obtained from any other authorized source in sufficient time to prevent ~~risk or~~ harm ~~or death to patients~~.

~~(16) "Emergency kits" are sealed kits containing those drugs which may be required to meet the immediate therapeutic needs of patients within an institution not having an in-house pharmacy, and which would not be available from any other authorized source in sufficient time to prevent risk or harm or death to patients.~~

(17) through (46) remain the same but are renumbered (16) through (45).

AUTH: ~~37-1-131,~~ 37-7-201, 50-32-314, MCA
IMP: 37-7-102, 37-7-201, 37-7-301, 37-7-321, 37-7-406, 37-7-603, 37-7-604, 37-7-605, 50-32-314, MCA

REASON: The board determined it is reasonably necessary to amend and repeal several rules related to emergency drug kits and contingency drug kits in certain institutional settings to create one drug kit rule that aligns with current practice and removes duplicate and burdensome regulatory language. The amendments are based on requests to address confusion and clarify the rules from pharmacists who provide drug kits to certain practice locations and the board's pharmacy inspectors. The board held subcommittee discussions and received stakeholder input to amend a single rule for drug kits, ARM 24.174.1114, that continues to provide standards and procedures for access to drugs needed to improve patient care when a facility may not have a pharmacist/pharmacy located within the facility. The amendments also outline requirements for the supervising pharmacy providing drug kits and clarifies access, storage, documentation procedures, and inspection requirements.

The board is amending this rule to reflect the drug kit amendments by updating relevant definitions. Authority citations are being amended to accurately reflect the statutory sources of the board's rulemaking authority and remove an erroneous citation.

24.174.524 COLLABORATIVE PRACTICE AGREEMENT REQUIREMENTS

(1) remains the same.

(2) The collaborative practice agreement must include:

(a) ~~the~~ identification ~~and signature of individual practitioner(s) authorized to prescribe drugs and responsible for the delegation of drug therapy management~~ of the practitioner(s) and pharmacist(s) who are parties to the agreement;

(i) remains the same.

~~(b) the identification and signature of individual pharmacist(s) authorized to dispense drugs and engage in drug therapy management;~~

~~(c)~~ (b) the types of ~~drug therapy management~~ decisions that the pharmacist is allowed to make ~~which may include:~~;

(c) a method for the practitioner to monitor compliance with the agreement and clinical outcomes and to intercede where necessary;

(d) a provision that allows the practitioner to override a collaborative practice decision made by the pharmacist whenever the practitioner deems it necessary or appropriate;

(e) a provision that allows either party to cancel the agreement by written notification;

(f) an effective date;

(g) signatures of collaborating pharmacists and practitioners, or a representative from the medical practice or clinic that is authorized to represent its practitioners, who are party to the agreement, as well as dates of signing; and

(h) a procedure for periodic review and renewal within a time frame that is clinically appropriate.

~~(i) a specific description of the types of diseases and drugs involved, and the type of drug therapy management allowed in each case; and~~

~~(ii) a specific description of the procedures and methods, decision criteria and plan the pharmacist is to follow.~~

~~(d) a detailed description of the procedures and patient activities the pharmacist is to follow in the course of the protocol, including the method for documenting decisions made and a plan or mechanism for communication, feedback and reporting to the practitioner concerning specific decisions made. Documentation shall be recorded within 24 hours following each intervention and may be recorded on the patient medication record, patient medical chart, or a separate log book. Documentation of drug therapy management must be kept as part of the patient's permanent record and shall be considered confidential information;~~

~~(e) a method by which adverse events shall be reported to the practitioner;~~

~~(f) a method for the practitioner to monitor clinical outcomes and intercede when necessary;~~

~~(g) a provision that allows the practitioner to override protocol agreements when necessary;~~

~~(h) a provision that allows either party to cancel the agreement by written notification;~~

~~(i) the effective date of the protocol. The duration of each protocol shall not exceed one year;~~

~~(j) the annual date by which review, renewal, and revision, if necessary, will be accomplished;~~

~~(k) the addresses where records of collaborative practice are maintained;~~ ~~and~~

~~(l) the process for obtaining the patient's written consent to the collaborative practice agreement.~~

(3) ~~Patient records shall be maintained by the pharmacist for a minimum of seven years and may be maintained in an automated system pursuant to ARM 24.174.817.~~ Documentation of allowed pharmacist activities must be kept as part of the patient's permanent record and be readily available to other health care professionals providing care to the patient and who are authorized to receive it. Documentation of allowed activities shall be considered protected health information.

(4) Collaborative practice agreements approved by an institutional committee such as the pharmacy and therapeutics committee and that will be used solely for ~~inpatients~~ patients while they are receiving care in the institution are exempt.

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

REASON: The board determined it is reasonably necessary to amend this rule to better reflect current practice and remove burdensome requirements based on requests from pharmacists utilizing collaborative practice agreements with medical practitioners. The amendments allow for more flexibility and adaptation to a variety of pharmacy and medical practice settings, while ensuring adequate public protection.

The revisions clarify what information is needed in a collaborative practice agreement regarding effective date, decisions allowed, documentation, patient records, follow-up and communication between parties, and review of timelines. The board is striking language that is overly specific, not reflective of current practices, and/or may be limiting to the implementation of the statutory definition of collaborative practice agreements (37-7-101, MCA) and the decisions that can be authorized to provide patient care and improve patient safety.

In addition, the amendments clarify that an agreement can be signed by the participating pharmacist(s) and practitioner(s), or a representative for the practitioner(s) from their medical practice or clinic. This amendment was requested by pharmacist stakeholders to reduce administrative burdens of the agreement process.

24.174.835 TRANSFER OF PRESCRIPTIONS (1) through (2)(c)(ii) remain the same.

(iii) the number of refills or quantity remaining; and

(iv) through (3)(c) remain the same.

(d) the original number of refills, number of refills or quantity remaining, and the date of the most recent refill;

(e) through (5) remain the same.

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

REASON: The board is amending this rule in response to comments received in a 2019 rules project, MAR Notice No. 24-174-71. While the board agreed with the

commenters that adding the quantity remaining for a prescription transfer better reflects current practice, the substantive change could only be accomplished in a new MAR notice.

24.174.1111 DRUG DISTRIBUTION AND CONTROL IN AN INSTITUTIONAL OR CORRECTIONAL FACILITY (1) through (6)(b) remain the same.

(c) ~~Emergency~~ Drug kits supplied and maintained by a registered ~~pharmacist~~ pharmacy may be utilized if policies and procedures regulating their use are in place. Such ~~emergency~~ drug kits will comply with the requirements of ARM 24.174.1114.

(d) The pharmacist-in-charge is responsible for policies and procedures for procurement, storage, and administration of prescription medications at jails ~~Jails~~, correctional facilities, and detention facilities without an on-site pharmacy ~~that procures, stores, and administers prescription medications may request technical assistance from the board~~.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-307, 37-7-308, 37-7-406, MCA

REASON: See REASON for ARM 24.174.301.

24.174.1114 USE OF ~~EMERGENCY~~ DRUG KITS IN CERTAIN INSTITUTIONAL FACILITIES (1) In an institutional facility ~~that does not have an in-house pharmacy~~, drugs may be provided for use by authorized personnel through ~~emergency~~ drug kits prepared by the registered pharmacist providing pharmaceutical services to the facility. Such ~~emergency~~ drug kits must meet all of the following requirements:

(a) a registered pharmacist shall prepare and seal the drug kit for a supplying pharmacy;

(b) the supplying ~~pharmacist~~ pharmacy and the designated practitioner or appropriate committee of the institutional facility shall jointly determine the identity and quantity of drugs to be included in the drug kit~~. Such drugs shall then be approved in advance of placement in the emergency kit by the board; unless such drugs are included on a general list of drugs previously approved by the board for use in emergency kits~~;

(c) the drug kit must be locked and stored in a secure area to prevent unauthorized access and to ensure a proper storage environment for the drugs contained therein~~. The kit shall be secured with a seal to be of such a nature that it can be easily identified if it has been broken~~;

(d) all drugs in the drug kit must be properly labeled, including lot number and expiration date, and shall possess any additional information that may be required to prevent risk of harm to the patient;

(e) the exterior of the drug kit must be clearly labeled to indicate:

(i) ~~its use and~~ expiration date of ~~its contents~~ the drug kit. The expiration date of a drug kit must be the earliest date of expiration of any drug supplied in the drug kit. On or before the expiration date, the supplying pharmacy shall replace the expired drug;

(ii) the name, address, and telephone number of the supplying ~~pharmacist~~ pharmacy; and

(iii) a statement indicating that the drug kit is to be used in ~~emergency~~ situations only pursuant to a valid drug order~~.~~;

(f) if a drug kit is being utilized for an emergency drug cart or crash cart in an inpatient setting, as defined in ARM 24.174.301(15):

(i) the pharmacist-in-charge must maintain policies and procedures for access to the cart; and

(ii) a pharmacist must review access to the cart within 72 hours of drug removal.

(2) ~~Drugs shall be removed from emergency kits only by the supplying pharmacist or by authorized personnel pursuant to a valid drug order.~~ Except as provided for in (1)(f), drugs shall be removed from drug kits in compliance with the following:

(a) by authorized licensed personnel pursuant to policies and procedures referenced in (4); and

(b) a pharmacist must:

(i) review the drug order prior to removal of a controlled substance; or

(ii) review the drug order within 72 hours of removal of a non-controlled substance.

(3) ~~Upon notice of any entry into the kit, the supplying pharmacist or another pharmacist designated by the supplying pharmacist shall restock and refill the kit, reseal the kit, and update the drug listing on the exterior of the kit within 72 hours.~~ Removal of any drug from a drug kit by authorized personnel must be recorded in an electronic record or on a suitable form showing the following information:

(a) patient name;

(b) name, strength, and quantity of drug removed;

(c) date and time the drug was removed;

(d) signature of the authorized personnel removing the drug; and

(e) documentation of pharmacy review.

~~(4) The expiration date of a kit must be the earliest date of expiration of any drug supplied in the kit. On or before the expiration date, the supplying pharmacist shall replace the expired drug.~~

~~(5)~~ (4) The supplying ~~pharmacist~~ pharmacy shall, in conjunction with the appropriate institutional committee, be responsible for development and annual review of policies and procedures for safe and appropriate use, access by authorized licensed personnel, restocking, and maintenance of ~~emergency~~ drug kits.

(5) Documentation for all drugs that have been removed from the drug kit shall be kept at the institutional facility and at the supplying pharmacy for two years and be available upon inspection.

(6) The drug kit, policies and procedures, and related records shall be available upon inspection.

(7) The supplying pharmacy and appropriate designated practitioner of a licensed facility will provide adequate controls to prevent drug diversion.

(8) The supplying pharmacy shall submit to the board and have available for inspection:

(a) an application for a drug kit endorsement;

(b) a list of drug kit locations; and
(c) any change to drug kit locations at the time of such change.

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

REASON: See REASON for ARM 24.174.301.

24.174.1412 ADDITIONS, DELETIONS, AND RESCHEDULING OF DANGEROUS DRUGS (1) 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) remains the same.
(b) Schedule II:
~~(i) none at this time;~~
(i) norfentanyl;
(c) Schedule III:
~~(i) methasterone;~~
~~(ii) perampanel; and~~
~~(iii) prostanozol;~~
(i) none at this time;
(d) Schedule IV:
~~(i) tramadol;~~
~~(ii) alfaxalone;~~
~~(iii) suvorexant; and~~
~~(iv) lorcaserin;~~
(i) brexanolone, allopregnanolone;
(ii) soriamfetol;
(iii) lemborexant;
(e) Schedule V:
~~(i) ezogabine.~~
(i) lasmiditan;
(ii) cenobamate.

(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) remains the same.
(b) Schedule II:
~~(i) naloxegol;~~
(i) 6β-naltrexol;
(c) Schedule III:
~~(i) 50-32-226(4)(c) and (d), MCA (hydrocodone combination products);~~
(i) none at this time;
(d) remains the same.
(e) Schedule V:

~~(i) none at this time.~~

(i) approved cannabidiol drugs. A drug product in finished dosage formulation that has been approved by the United States Food and Drug Administration that contains cannabidiol, also known as (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol), derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols, and as authorized by the Agriculture Improvement Act of 2018 (P.L. 115-334).

(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) through (c) remain the same.

(d) Schedule IV:

~~(i) modafinil;~~

(i) none at this time;

(e) remains the same.

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 update and clarify Montana's scheduling of dangerous drugs (controlled substances Schedules I through V). The amendments are based on recent scheduling actions of the U.S. Drug Enforcement Administration (DEA), including removal of U.S. Food and Drug Administration (FDA) approved products containing cannabidiol, and to remove duplicate drug listings implemented as updates to the Montana schedule through 2019 Montana Legislature amendments enacted in Chapter 134, Laws of 2019 (Senate Bill 274).

Currently, dangerous drugs are scheduled by the DEA in the Code of Federal Regulations (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). 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 between 2019 and 2020, and to remove drugs that are duplicate to their listing in statute.

To that end, under (1), the DEA added norfentanyl (Schedule II), brexanolone/allopregnanolone (Schedule IV), soriamfetol (Schedule IV), lemborexant (Schedule IV), lasmiditan (Schedule V), and cenobamate (Schedule V).

Under (2), the DEA deleted 6β-naltrexol (Schedule II) and, as authorized by the Agriculture Improvement Act of 2018 (Public Law 115-334), the DEA deleted FDA-approved cannabidiol drugs (Schedule V) in finished dosage formulation, derived from cannabis, and no more than 0.1% (w/w) residual tetrahydrocannabinols.

24.174.2106 REGISTERED PHARMACIST CONTINUING EDUCATION–APPROVED PROGRAMS (1) Continuing education programs sponsored by providers that are approved by the following organizations will automatically qualify for continuing education credit:

(a) and (b) remain the same.

~~(c) the American Board of Medical Specialties.~~

(c) programs that have been approved for CME by an accredited CME provider.

(2) Pharmacists may receive CEU for programs other than those on the ACPE list of providers ~~by applying for prior approval by the board or its designee on board-approved forms~~. Acceptable non-ACPE programs must focus on protecting the health, safety, and welfare of the public and contribute to the pharmacist's professional knowledge and competence, and must:

(a) directly relate to the scope of practice of pharmacy as defined in board statutes and rules;

(b) review existing concepts and techniques;

(c) convey information beyond the basic professional education;

(d) update knowledge on the practice and advances in pharmacy; and/or

(e) reinforce professional conduct or ethical obligations of the pharmacist.

(3) A maximum of 1.0 CEU (10 hours) of the hours required in ARM 24.174.2104 may be obtained through completion of non-ACPE programs. The programs must comply with (2), and:

(a) be a minimum of 30 minutes in duration;

(b) be provided by an individual(s) competent in the subject matter;

(c) provide a statement and evaluation mechanism of educational objectives; and

(d) provide program materials and/or an agenda, and a certificate of completion that includes the program date, hours of CEU, name of non-ACPE program provider, and name of program presenter.

~~(3) Pharmacists participating in programs that have not received prior approval risk disallowance of credit.~~

(4) In the event a pharmacist is selected for audit, the pharmacist must demonstrate the continuing education meets the above standards and submit non-ACPE information with a form provided by the board, including:

(a) program materials and/or an agenda; and

(b) a certificate of completion.

AUTH: 37-1-319, MCA
IMP: 37-1-306, MCA

REASON: The board is amending this rule to align with the department's standardized renewal and audit procedures regarding continuing education (CE) for pharmacists and to remove administrative burden to the division, board, licensees, and providers of CE programs. Following amendment, the board will no longer preapprove non-ACPE approved programs or courses and instead pharmacist

licensees will be responsible to select CE that meets the professional education objectives and requirements listed in the board's rules.

The amendments set forth clear requirements and standards for non-ACPE approved programs to be accepted as CE credit for pharmacists in compliance with auditing procedures. Non-ACPE program providers will no longer submit preapproval requests to the board but comply with the requirements of this rule.

Past CE programs that have been preapproved by the board have consistently provided the additional information in the amendment and have generally been approved and have been provided by professionals competent in the subject matter. The board expects that providers of non-ACPE programs will maintain and continue similar standards and quality instruction without board preapproval.

To address licensees' questions, the board is amending (1) to remove a reference to a single continuing medical education (CME) provider and provide a more general reference to any accredited CME provider program as being acceptable for pharmacists' CE.

4. The rule proposed to be repealed is as follows:

24.174.1115 USE OF CONTINGENCY KITS IN CERTAIN INSTITUTIONAL FACILITIES

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

REASON: The board is repealing ARM 24.174.1115 as the pertinent provisions are being incorporated into ARM 24.174.1114.

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) 841-2305, or e-mail to dlibsdpha@mt.gov, and must be received no later than 5:00 p.m., September 24, 2021.

6. An electronic copy of this notice of public hearing is available at www.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) 841-2305; 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 24.174.301, 24.174.524, 24.174.835, 24.174.1111, 24.174.1114, 24.174.1412, and 24.174.2106 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 24.174.1115 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) 841-2305; or to dlibsdpha@mt.gov.

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

BOARD OF PHARMACY
TONY KING, PharmD
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 August 17, 2021.