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, 24.174.402 dangerous drug fee schedule, 24.174.503 administration of vaccines by pharmacists, 24.174.523 transmission of prescriptions, 24.174.1003 identification of pharmacist-in-charge, 24.174.1202 minimum information required for licensure, 24.174.1302 telepharmacy operations, 24.174.1503 acceptable cancer drugs, the adoption of NEW RULES I emergency prescription refills, II remote medication order processing services, III schedule I dangerous drugs, IV schedule II dangerous drugs, V schedule III dangerous drugs, VI schedule IV dangerous drugs, VII schedule V dangerous drugs, VIII through XVI board-established medical assistance program, XVII through XXII quality improvement program, XXIII limited service pharmacy, and the repeal of ARM 24.174.813 class IV facility	))	NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT, ADOPTION, AND REPEAL

TO: All Concerned Persons

1. On January 23, 2012, at 9:00 a.m., a public hearing will be held in room B-07, 301 South Park Avenue, Helena, Montana, to consider the proposed amendment, adoption, 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 January 18, 2012, to advise us of the nature of the accommodation that you need. Please contact Ronald Klein, 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; e-mail dlibsdpha@mt.gov.

3. GENERAL STATEMENT OF REASONABLE NECESSITY: The board determined it is reasonably necessary to amend the rules throughout to eliminate outdated, redundant, and unnecessary provisions, and to align terminology with current national trends, curricula, industry usage, and standards. Other changes replace out-of-date terminology for current board and department processes, and amend rules for grammatical accuracy, consistency, simplicity, better organization, and ease of use. Punctuation and rule numbering is amended to comply with ARM formatting requirements. Where additional specific bases for a proposed action exist, the board will identify those reasons immediately following that rule.

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

24.174.301 DEFINITIONS (1) through (26) remain the same.

(27) "Pharmacist-in-charge" means a pharmacist licensed in Montana who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy, who assures that the pharmacy and all pharmacy personnel working in the pharmacy have current and appropriate licensure and certification, and who is personally in full and actual charge of such pharmacy. The pharmacist-in-charge at an out-of-state mail service pharmacy does not have to be licensed in Montana.

(28) through (36) remain the same.

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 office has recently received numerous inquiries from mail order pharmacies and mail order pharmacy applicants regarding pharmacist-in-charge licensure requirements. The board is amending this rule to address confusion and clarify that pharmacists-in-charge for out-of-state mail service pharmacies are not required to be licensed in Montana.

24.174.402 DANGEROUS DRUG FEE SCHEDULE (1) The fees to be assessed for registration to manufacture, distribute, dispense, conduct research, or analyze~~,~~ a dangerous drug shall be assessed according to the following schedule:

(a) through (1)(c)(i) remain the same.

(ii) ~~ambulatory surgical facilities~~
outpatient centers for surgical services 75

(d) remains the same.

AUTH: 37-1-134, 37-7-201, 50-32-103, 50-32-314, MCA
IMP: 37-1-134, 37-7-201, 37-7-321, 50-32-103, 50-32-314, MCA

REASON: The board is amending this rule to update terminology as used in board statute at 37-3-101(20), MCA, and as defined in 50-5-101, MCA.

24.174.503 ADMINISTRATION OF VACCINES BY PHARMACISTS (1) remains the same.

(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) through (6) remain the same.

(7) The authority of a pharmacist to administer immunizations may not be delegated, however, an immunization-certified intern may immunize under the direct supervision of a pharmacist or other ~~health care~~ healthcare provider qualified in vaccine administration and deemed appropriate by the preceptor.

(8) and (9) remain the same.

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

REASON: The 2011 Montana Legislature enacted Chapter 119, Laws of 2011 (Senate Bill 189), an act allowing pharmacists to administer the influenza vaccine to individuals who are 12 years of age or older. The bill was signed by the Governor on April 1, 2011, and became effective on October 1, 2011. The board determined it is reasonably necessary to amend this rule to align with and implement the new legislation. Implementation cites are being amended to reflect the new statute implemented through this rule.

24.174.523 TRANSMISSION OF PRESCRIPTIONS BY ELECTRONIC MEANS (1) A pharmacist may dispense directly any legend drug, which requires a prescription to dispense (except as provided in (2) and (3) below for Schedule II, III, IV, and V, controlled substances)~~,~~ pursuant to either a written prescription signed by a practitioner or a prescription transmitted by the practitioner or the practitioner's agent to the pharmacy by electronic means, or pursuant to an oral prescription made by an individual practitioner and promptly reduced to ~~hard copy~~ hardcopy by the pharmacist, containing all information required. The prescription shall be maintained in accordance with ARM 24.174.512.

(2) A pharmacist may dispense directly a controlled substance in Schedule II, which is a prescription drug as determined by the Federal Food, Drug, and Cosmetic Act (FD&C Act), only pursuant to a written prescription signed by the practitioner. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy by electronic means provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance. The original prescription shall be maintained in accordance with ARM 24.174.512.

(a) A signed prescription for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the ~~home infusion~~ pharmacy by electronic means. The electronic transmission serves as the original written prescription for the purpose of this rule and it shall be maintained in accordance with ARM 24.174.512.

(b) A signed prescription for a Schedule II substance for a resident of a ~~long term~~ long-term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by electronic means. The electronic transmission serves as the original written prescription for purposes of this rule and it shall be maintained in accordance with ARM 24.174.512.

(c) A signed prescription for a Schedule II substance for a patient enrolled in a hospice care program, certified and/or paid for by Medicare under Title XVIII of the Social Security Act, or a hospice program which is licensed by the state of Montana, may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by electronic means. The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient. The electronic transmission serves as the original written prescription for purposes of this rule and it shall be maintained in accordance with ARM 24.174.512.

(3) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V, which is a prescription drug as determined under the ~~Federal Food, Drug and Cosmetic~~ FD&C Act, only pursuant to either a written prescription signed by a practitioner or a copy of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy by electronic means, or pursuant to an oral prescription made by an individual practitioner and promptly reduced to ~~hard copy~~ hardcopy by the pharmacist, containing all information required. The prescription shall be maintained in accordance with ARM 24.174.512.

(4) through (4)(b) remain the same.

(c) An electronically transmitted prescription shall contain all information required by state and federal law, including the date and time of transmission, the prescriber's telephone number for verbal confirmation, and the name of the prescriber's agent transmitting the order, if other than the prescriber;

(d) through (4)(i) remain the same.

(j) A pharmacist or pharmacy shall not provide a computer or computer modem, personal digital assistant, facsimile machine, or any other electronic device to a prescriber or ~~health care~~ healthcare facility for the purpose of providing an incentive to refer patients to a particular pharmacy.

(5) and (6) remain the same.

AUTH: 37-7-201, 50-32-103, MCA
IMP: 37-7-102, 37-7-201, 50-32-208, MCA

REASON: In addition to grammatical corrections, the board is deleting home infusion from (2)(a) because any pharmacy is authorized to prepare an infusion for administration.

24.174.1003 IDENTIFICATION OF PHARMACIST-IN-CHARGE OF DISPENSING TO MONTANA (1) Each out-of-state mail service pharmacy that ships, mails, ~~or~~ delivers prescription drugs and/or devices and oversees the pharmacy services provided to ~~a patient~~ patients in ~~the state of~~ Montana shall identify a ~~pharmacist in charge~~ pharmacist-in-charge of dispensing prescriptions for shipment to Montana and oversee the pharmacy services provided. Each pharmacist so identified shall meet the following requirements:

(a) through (3) remain the same.

AUTH: 37-7-201, 37-7-712, MCA
IMP: 37-7-101, 37-7-201, 37-7-703, MCA

REASON: The board is amending this rule in response to recent complaints before the screening panel concerning the adequacy of patient counseling by mail service pharmacies, particularly the pharmacies' failure to offer counseling to patients. Evolving pharmacy practice and standards of practice now include significant patient counseling, not just the delivery of the drug product to the patient. It is necessary to amend the rule at this time to include the proper supervision of the delivery of pharmaceutical care, including counseling, drug utilization, and drug regimen review, and to hold the pharmacist-in-charge accountable for delivery of pharmaceutical care to Montana patients.

Authority and implementation cites are being amended to accurately reflect all statutes implemented through the rule and provide the complete sources of the board's rulemaking authority.

24.174.1202 MINIMUM INFORMATION REQUIRED FOR LICENSURE

(1) through (1)(b) remain the same.

(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) through (2) remain the same.

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

REASON: The board is amending the rule to clarify (1)(c), which permitted uncertainty about the duties and responsibilities of the designated person in charge. The board's screening panel has encountered difficulties with numerous corporations and businesses that operate from multiple sites and multiple warehouses. At times, the person in charge of the warehouse is located at another distant site. To maintain the integrity of the prescription drug distribution system, the board determined it is necessary to amend this rule to require there be a responsible individual overseeing the operation of a warehouse who is familiar with its operation. Implementation cites are being amended to accurately reflect all statutes implemented through the rule.

24.174.1302 TELEPHARMACY OPERATIONS (1) remains the same.

(2) A site cannot be licensed as a remote telepharmacy site if it is located within a ~~ten~~ twenty-mile radius of an existing pharmacy.

(3) A remote telepharmacy site manned by a registered pharmacy technician shall access and use the parent pharmacy's central processing unit or common database.

(4) through (4)(b)(i) remain the same.

(ii) be currently certified with the Pharmacy Technician Certification Board (PTCB), or Exam for the Certification of Pharmacy Technicians (ExCPT), or other board-approved certifying entity; and

(iii) have at least ~~six months of active~~ 500 hours experience as a pharmacy technician, technician-in-training, or experience deemed as equivalent by the board.

(c) and (d) remain the same.

(e) All prescription records and consecutive prescription numbers must be maintained at the parent pharmacy or remote site. The remote telepharmacy site must transmit copies of new prescriptions via secure electronic means to the parent pharmacy, keeping the original prescription blank at the remote telepharmacy site.

(f) remains the same.

(g) Daily reports for both the parent pharmacy and remote telepharmacy site must be maintained at the parent pharmacy or telepharmacy site.

(h) and (i) remain the same.

(j) All records must be stored at the parent pharmacy or telepharmacy site, except those required by DEA to be at a DEA registered site.

(k) through (p) remain the same.

(q) The computer, video, and audio link must be operational ~~and the remote telepharmacy site must be closed if the link malfunctions, unless a pharmacist is working at the remote site~~ at all times. In the event of connectivity loss to the parent location, no new prescriptions may be processed, filled, or dispensed from the telepharmacy site until connectivity is reestablished. Refill prescriptions that have a final check by the pharmacist may be dispensed.

(r) and (s) remain the same.

(t) The pharmacist shall offer to counsel the patient or the patient's agent via video ~~and~~ and/or audio link on all new prescriptions~~, but may provide counseling on refills only when the pharmacist deems additional counseling necessary~~.

(u) remains the same.

(v) The license holder, agent of the parent pharmacy, or the pharmacist-in-charge of the parent pharmacy, or the pharmacist-in-charge of the remote site, if different from the parent pharmacist-in-charge, shall apply for a license for the remote telepharmacy site.

(w) and (x) remain the same.

(y) The pharmacist at the parent pharmacy shall perform an ongoing analysis of incident reports and outcomes, with appropriate corrective action taken when necessary, to ensure patient safety.

(z) remains the same.

AUTH: 37-7-201, MCA
IMP: 37-7-101, 37-7-201, 37-7-321, MCA

REASON: Following a biennial rule review, the board is amending this rule to encourage the practice of telepharmacy operations to promote pharmaceutical care in rural areas of Montana.

The board is amending (2) to address issues raised by a rural Montana pharmacist. The board is increasing the required distance for remote telepharmacy

sites from ten to twenty miles to help ensure necessary access to pharmaceutical care by maintaining viable local community pharmacies.

The board determined it is reasonably necessary to amend (3) to allow remote telepharmacy sites to use a common database. The board concluded this will allow a pharmacy operation to avoid the purchase of duplicative computer equipment and promote efficient use of resources.

The board is amending (4)(b)(ii) to acknowledge the pharmacy technician certification tests currently accepted by the board and coordinate with ARM 24.174.701(3) and 24.174.702(1)(d).

It is reasonably necessary to amend (4)(b)(iii) to quantify in hours the training requirement for pharmacy technicians in a telepharmacy operation and allow experience obtained as a technician-in-training. The board notes that telepharmacy operations have found it difficult to employ certified technicians with the experience requirement. The board is also amending (4) to clarify record-keeping requirements for both parent and telepharmacy operations, so that all necessary records are being maintained consistent with ARM 24.174.512.

The board is amending (4)(q) to no longer require that telepharmacies close in the event of power or communication failure, as the board concluded it is an onerous and unnecessary burden on telepharmacy operations. The amendment specifies that only refill prescriptions may be dispensed during a failure, and that new prescriptions may only be processed once the connectivity has been restored.

It is reasonably necessary to amend (4)(t) to clarify patient counseling requirements and harmonize them with ARM 24.174.903(1). The board is amending (4)(v) to clarify who may apply for a license to operate a telepharmacy to reflect current business practices.

24.174.1503 ACCEPTABLE CANCER DRUGS (1) remains the same.

~~(2) Any cancer drug donated to the program must have at least six months remaining before its expiration date occurs.~~

(3) remains the same, but is renumbered (2).

AUTH: 37-7-1401, MCA
IMP: 37-7-1401, 37-7-1404, 37-7-1405, MCA

REASON: The board is amending this rule to correct an inadvertent error when the rule was originally adopted. The board never intended to put a six-month expiration date limit on donated cancer drugs, as it is not necessary to ensure the public's protection. This amendment will provide for the maximum possible use of drugs donated to the cancer repository program, while assuring their safety and efficacy before expiring.

5. The proposed new rules provide as follows:

NEW RULE I EMERGENCY PRESCRIPTION REFILLS (1) A pharmacist may refill a prescription without practitioner authorization when:

(a) the pharmacist is unable to contact the practitioner after reasonable effort; and

(b) in the professional judgment of the pharmacist, failure to refill the prescription may result in an interruption of a therapeutic regimen or cause patient suffering.

(2) If a prescription is not refillable, a pharmacist dispensing an emergency refill:

(a) may exercise professional judgment to dispense a minimum sufficient quantity until authorization can be obtained from a prescriber:

(i) for drugs which must be dispensed in their original containers, the pharmacist may dispense the smallest trade size available;

(b) may not dispense a prescription medication listed in Schedule II;

(c) must inform the patient or the patient's representative at the time of dispensing that the refill is being provided without the practitioner's authorization, and that practitioner authorization is required for any future refill;

(d) must inform the practitioner of the emergency refill at the earliest reasonable time; and

(e) comply with all applicable record-keeping requirements.

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

REASON: The board determined it is reasonably necessary to propose this new rule to address recurrent practice issues raised by pharmacists. This new rule will provide for emergency prescription refills when optimal patient care requires a prescription refill, but the practitioner cannot be reached to authorize a refill.

NEW RULE II REMOTE MEDICATION ORDER PROCESSING SERVICES

(1) A hospital pharmacy may outsource medication order processing to another pharmacy provided the pharmacies have the same owner or the pharmacy has entered into a written contract or agreement with an outsourcing company that outlines the services to be provided and the responsibilities and accountabilities of each party to the contract or agreement in compliance with federal and state statutes and regulations.

(2) The hospital pharmacy must provide a copy of the contract or agreement to the board and receive approval from the board or its designee prior to initiation of remote order entry services.

(3) A hospital pharmacy utilizing remote order entry shall ensure that all pharmacists providing such services have been trained on the pharmacy's policies and procedures relating to medication order processing. The training of each pharmacist shall be documented. Such training shall include, but is not limited to, policies on drug and food allergy documentation, abbreviations, administration times, automatic stop orders, substitution, and formulary compliance. The pharmacy and the pharmacy/outsourcing company shall jointly develop a procedure to communicate changes in formulary and changes in policies and procedures related to medication order processing.

(4) A hospital pharmacy utilizing a remote order entry pharmacist shall maintain a record of the name and address of such pharmacist, evidence of current

licensure in Montana, and the address of each location where the pharmacist will be providing remote order entry services.

(5) The director of pharmacy shall ensure that any remote order entry pharmacist shall have secure electronic access to the hospital pharmacy's patient information system and to other electronic systems that the on-site pharmacist has access to when the pharmacy is open.

(6) The remote order entry pharmacist must be able to contact the prescribing practitioner to discuss any concerns identified during the pharmacist's review of patient information and the drug order. A procedure must be in place to communicate any problems identified with the practitioner and the nursing staff providing direct patient care.

(7) Each remote entry record must comply with all recordkeeping requirements and shall identify by name or other unique identifier, the pharmacist involved in the review and verification of the drug order.

(8) A pharmacy utilizing remote order entry processing services is responsible for maintaining records of all orders entered into their information system, including orders entered from a remote location. The system shall have the ability to audit the activities of the individuals remotely processing medication orders.

(9) All records shall be readily available upon request by the board, its designee, or agent of the board for inspection, copying, or production.

(10) A pharmacy utilizing remote order entry processing services shall maintain a policy and procedure manual. A remote pharmacy/order processing company shall maintain a copy of those portions of the policy and procedure manual that relate to that pharmacy's operations. Each manual shall:

(a) outline the responsibilities of the pharmacy and the remote pharmacy/order processing company;

(b) include a list of the names, addresses, telephone numbers, and all license numbers of the pharmacies/pharmacists involved in remote order entry processing; and

(c) include policies and procedures for:

(i) protecting the confidentiality and integrity of patient information;

(ii) maintaining appropriate records of each pharmacist involved in order processing;

(iii) complying with federal and state statutes and regulations;

(iv) annually reviewing the written policies and procedures and documentation of the annual review; and

(v) annually reviewing the competencies of pharmacists providing remote order entry processing services.

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

REASON: The board is proposing New Rule II to address advances in pharmaceutical care for hospital inpatients. The board notes that while it is impractical for many of the hospitals in Montana to have a pharmacist present at all times, technological advances allow a pharmacist at a remote location to prospectively review all drug orders. The board determined that the remote

medication order procedures in this new rule will enhance pharmaceutical care of hospital inpatients and promote the delivery of appropriate drug therapy.

6. REASONABLE NECESSITY FOR NEW RULES III THROUGH VII: The board is proposing New Rules III through VII to implement 50-32-103, MCA, and address concerns raised by the Crime Lab of the Montana Forensic Science Division regarding the state's inability to prosecute drug offenses with newly synthesized drugs not currently found in the drug schedules. The new rules harmonize Montana and federal law by clearly setting forth the newly synthesized drugs and provide both law enforcement and the general public with a current list of controlled substances.

NEW RULE III SCHEDULE I DANGEROUS DRUGS (1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in this rule.

(2) Opiates. Unless specifically excepted or listed in another schedule, any of the following are opiates, including isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of those isomers, esters, ethers, and salts is possible within the specific chemical designation:

(a) acetyl-alpha-methylfentanyl, also known as N-(1-(1-Methyl-2-phenethyl)-4-piperidinyl)-N-phenylacetamide;

(b) acetylmethadol, also known as 4-(dimethylamino)-1-ethyl-2,2-diphenylpentyl acetate or methadyl acetate;

(c) allylprodine, also known as 1-methyl-4-phenyl-3-(prop-2-en-1-yl)piperidin-4-yl propanoate;

(d) alphacetylmethadol, except levo-alphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM;

(e) alphameprodine;

(f) alphamethadol;

(g) alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide, 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

(h) alpha-methylthiofentanyl, also known as N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide;

(i) benzethidine;

(j) betacetylmethadol;

(k) beta-hydroxyfentanyl, also known as N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide;

(l) beta-hydroxy-3-methylfentanyl, also known as N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide;

(m) betameprodine;

(n) betamethadol;

(o) betaprodine;

(p) clonitazene;

(q) dextromoramide;

(r) diampromide;

(s) diethylthiambutene;

(t) difenoxin;

(u) dimenoxadol;

(v) dimepheptanol;
(w) dimethylthiambutene;
(x) dioxaphetyl butyrate;
(y) dipipanone;
(z) ethylmethylthiambutene;
(aa) etonitazene;
(ab) etoxeridine;
(ac) furethidine;
(ad) hydroxypethidine;
(ae) ketobemidone;
(af) levomoramide;
(ag) levophenacylmorphan;
(ah) 3-methylfentanyl, also known as N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide;
(i) for the purposes of (2)(ah), the term "isomer" includes the optical, position, and geometric isomers;
(ai) 3-methylthiofentanyl, also known as N-[3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide;
(aj) morpheridine;
(ak) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);
(al) noracymethadol;
(am) norlevorphanol;
(an) normethadone;
(ao) norpipanone;
(ap) para-fluorofentanyl, also known as N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]propanamide;
(aq) PEPAP(1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);
(ar) phenadoxone;
(as) phenampromide;
(at) phenomorphan;
(au) phenoperidine;
(av) piritramide;
(aw) proheptazine;
(ax) properidine;
(ay) propiram;
(az) racemoramide;
(ba) thiofentanyl, also known as N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide;
(bb) tilidine; and
(bc) trimeperidine.
(3) Opium derivatives. Unless specifically excepted or listed in another schedule, any of the following are opium derivatives, including salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:
(a) acetorphine;
(b) acetyldihydrocodeine;
(c) benzylmorphine;

(d) codeine methylbromide;
(e) codeine-N-oxide;
(f) cyprenorphine;
(g) desomorphine;
(h) dihydromorphine;
(i) drotebanol;
(j) etorphine, except hydrochloride salt;
(k) heroin;
(l) hydromorphinol;
(m) methyldesorphine;
(n) methyldihydromorphine;
(o) morphine methylbromide;
(p) morphine methylsulfonate;
(q) morphine-N-oxide;
(r) myrophine;
(s) nicocodeine;
(t) nicomorphine;
(u) normorphine;
(v) pholcodine;
(w) thebacon; and
(x) for the purposes of (3), the term "isomer" includes the optical, position, and geometric isomers.

(4) Hallucinogenic substances. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following is a hallucinogenic substance, including salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) alpha-ethyltryptamine. Trade or other names include etryptamine, monase, alpha-ethyl-1H-indole-3-ethanamine, 3-(2-aminobutyl) indole, alpha-ET, and AET;
(b) alpha-methyltryptamine, also known as AMT;
(c) 4-bromo-2,5-dimethoxy-amphetamine. Trade or other names include 4-bromo-2, 5-dimethoxy-alpha-methylphenethylamine, and 4-bromo-2,5-DMA;
(d) 4-bromo-2,5-dimethoxyphenethylamine. Trade or other names include 2-(4-bromo-2, 5-dimethoxyphenyl)-1-aminoethane, alpha-desmethyl DOB, and 2C-B, Nexus;
(e) 2,5-dimethoxyamphetamine. Trade or other names include 2,5-dimethoxy-alpha-methylphenothylamine and 2,5-DMA;
(f) 2,5-dimethoxy-4-(N)-propylthiopenenthylamine, also known as 2C-T-7;
(g) 3,4-methylenedioxy amphetamine;
(h) 2,5-dimethoxy-4-ethylamphetamine. A trade or other name is DOET;
(i) 5-methoxy-N,N-diisopropyltryptamine, also known as 5-MeO-DIPT;
(j) 5-methoxy-N,N-dimethyltriptamine, also known as 5-MeO-DMT;
(k) 4-methoxyamphetamine. A trade or other name is 4-methoxy-alpha-methylphenethylamine;
(l) 5-methoxy-3,4-methylenedioxy amphetamine;

(m) 4-methyl-2,5-dimethoxy-amphetamine. Trade or other names include 4-methyl-2, 5-dimethoxy-alpha-methylphenethylamine, DOM, and STP;

(n) 3,4-methylenedioxy amphetamine;

(o) 3,4-methylenedioxymethamphetamine (MDMA);

(p) 3,4-methylenedioxy-N-ethylamphetamine, also known as N-ethyl-alpha-methyl-3,4(methylenedioxy)phenethylamine, N-ethyl MDA, MDE, and MDEA;

(q) N-hydroxy-3,4-methylenedioxyamphetamine, also known as N-hydroxy-alpha-methyl-3,4(methylenedioxy)phenethylamine and N-hydroxy MDA;

(r) 3,4,5-trimethoxy amphetamine;

(s) bufotenine. Trade and other names include 3-(beta-dimethylaminoethyl)-5-hydroxyindole, 3-(2-dimethylaminoethyl)-5-indolol, N,N-dimethylserotonin, 5-hydroxy-N,N-dimethyltryptamine, and mappine;

(t) diethyltryptamine. Trade and other names include N,N-diethyltryptamine and DET;

(u) dimethyltryptamine. A trade or other name is DMT;

(v) ibogaine. Trade or other names include 7-ethyl-6,6-beta,7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido [1', 2':1,2] azepine [5,4-b] indole and tabernanthe iboga;

(w) lysergic acid diethylamide;

(x) marijuana;

(y) mephedrone;

(z) mescaline;

(aa) methylenedioxypyrovalerone (MDPV);

(ab) methylone;

(ac) parahexyl. Trade or other names include 3-hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran and synhexyl;

(ad) peyote, meaning all parts of the plant presently classified botanically as lophophora williamsii lemaire, whether growing or not; the seed of the plant; any extract from any part of the plant; and every compound, manufacture, salts, derivatives, mixture, or preparation of the plant, its seed, or extracts;

(ae) N-ethyl-3-piperidyl benzilate;

(af) N-methyl-3-piperidyl benzilate;

(ag) psilocybin;

(ah) psilocyn;

(ai) tetrahydrocannabinols, including synthetic equivalents of the substances contained in the plant or in the resinous extractives of cannabis, sp, or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity, such as those listed in (4)(ai)(i) through (4)(ai)(iii). Because nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered, are included in the category as follows:

(i) delta 1 (delta 9) cis or trans tetrahydrocannabinol and its optical isomers;

(ii) delta 6 cis or trans tetrahydrocannabinol and its optical isomers;

(iii) delta 3,4 cis or trans tetrahydrocannabinol and its optical isomers; and

(iv) section (4)(ai) does not apply to synthetic cannabinoids approved by the U.S. Food and Drug Administration and obtained by a lawful prescription through a licensed pharmacy. The Department of Public Health and Human Services shall

adopt a rule listing the approved cannabinoids and shall update the rule as necessary to keep the list current.

(aj) ethylamine analog of phencyclidine. Trade or others names include N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl)ethylamine, N-(1-phenylcyclohexyl)ethylamine, cyclohexamine, and PCE;

(ak) pyrrolidine analog of phencyclidine. Trade or other names include 1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, and PHP;

(al) thiophene analog of phencyclidine. Trade or other names include 1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienyl analog of phencyclidine, TPCP, and TCP;

(am) 1-[1-(2-thienyl)cyclohexyl]pyrrolidine. A trade or other name is TCPy;

(an) synthetic cannabinoids:

(i) 1-pentyl-3-(1-naphthoyl)indole, also known as JWH-018;

(ii) (6aR,10aR)-9-(hydroxymethyl)-6, 6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol, also known as HU-210 or 1,1-dimethylheptyl-11-hydroxy-delta8-tetrahydrocannabinol;

(iii) 2-(3-hydroxycyclohexyl)-5-(2-methyloctan-2-yl)phenol, also known as CP-47,497, and the dimethylhexyl, dimethyloctyl, and dimethylnonyl homologues of CP-47,497;

(iv) 1-butyl-3-(1-naphthoyl)indole, also known as JWH-073;

(v) 1-(2-(4-(morpholinyl)ethyl))-3-(1-naphthoyl) indole, also known as JWH-200;

(vi) 1-pentyl-3-(2-methoxyphenylacetyl)indole, also known as JWH-250;

(vii) 1-hexyl-3-(1-naphthoyl)indole, also known as JWH-019;

(viii) 1-pentyl-3-(4-chloro-1-naphthoyl)indole, also known as JWH-398;

(ix) JWH-081: 1-pentyl-3-(4-methoxy-1-naphthoyl)indole, also known as 4-methoxynaphthalen-1-yl- (1-pentylindol-3-yl)methanone;

(x) the following substances, except where contained in cannabis or cannabis resin, namely tetrahydro derivatives of cannabinol and 3-alkyl homologues of cannabinol or of its tetrahydro derivatives:

(A) 2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo [1,2,3-de]-1,4-benzoxazin-6-yl]-1-napthalenylmethanone, also known as WIN-55,212-2;

(B) dimethylheptyl-11-hydroxyhexahydrocannabinol, also known as HU-243; or

(C) [9-hydroxy-6-methyl-3-[5-phenylpentan-2-yl]oxy-5,6,6a,7,8,9,10,10a octahydrophenanthridin-1-yl]acetate;

(xi) any compound structurally derived from 3-(1-naphthoyl)indole or 1H-indol-3-yl-(1-naphthyl)methane by substitution at the nitrogen atom of the indole ring by alkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(xii) any compound structurally derived from 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring by alkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, or 2-(4-morpholinyl)ethyl, whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(xiii) any compound structurally derived from 1-(1-naphthylmethyl)indene by substitution at the 3-position of the indene ring by alkyl, alkenyl, cycloalkylmethyl,

cycloalkylethyl, or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(xiv) any compound structurally derived from 3-phenylacetylindole by substitution at the nitrogen atom of the indole ring with alkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent; or

(xv) any compound structurally derived from 2-(3-hydroxycyclohexyl)phenol by substitution at the 5-position of the phenolic ring by alkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, or 2-(4-morpholinyl)ethyl, whether or not substituted in the cyclohexyl ring to any extent;

(ao) Salvia divinorum: Salvinorin A (2S,4aR,6aR,7R,9S,10aS,10bR)-9-(acetyloxy)-2-(3-furanyl)dodechydro-6a,10b-dimethyl-4, 10-dioxo-2H-naphtho[2,1-c] pyran-7-carboxylic acid methyl ester;

(ap) any compound (not being bupropion, nor any compound listed in another Administrative Rule regulating controlled substances, the Montana Code Annotated, or approved for use by the U.S. Food and Drug Administration) structurally derived from 2-amino-1-phenyl-1-propanone by modification in any of the following ways:

(i) by substitution in the phenyl ring to any extent with alkyl, alkoxy, alkylenedioxy, haloalkyl or halide substituents, whether or not further substituted in the phenyl ring by one or more other univalent substituents;

(ii) by substitution at the 3-position with an alkyl substituent;

(iii) by substitution at the nitrogen atom with alkyl or dialkyl groups, or by inclusion of the nitrogen atom in a cyclic structure; and

(iv) any lengthening of the propanone chain between carbons 1 and 2 to any extent with alkyl groups, whether further substituted or not;

(aq) any compound (not being already listed in another Administrative Rule regulating controlled substances, the Montana Code Annotated, or approved for use by the U.S. Food and Drug Administration) structurally derived from 2-amino-1-phenyl-1-propane by modification in any of the following ways:

(i) by substitution in the phenyl ring to any extent with alkyl, alkoxy, alkylenedioxy, haloalkyl or halide substituents, whether or not further substituted in the phenyl ring by one or more other univalent substituents;

(ii) by substitution at the 3-position with an alkyl substituent;

(iii) by substitution at the nitrogen atom with alkyl or dialkyl groups, or by inclusion of the nitrogen atom in a cyclic structure; and

(iv) any lengthening of the propane chain between carbons 1 and 2 to any extent with alkyl groups, whether further substituted or not.

(5) Depressants. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a depressant having a depressant effect on the central nervous system, including salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) gamma-hydroxybutyric acid, also known as gamma-hydroxybutyrate, 4-hydroxybutyrate, 4-hydroxybutanoic acid, sodium oxybate, sodium oxybutyrate, and GHB;

(b) mecloqualone; and

(c) methaqualone.

(6) Stimulants. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a stimulant having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(a) aminorex. Trade or other names include aminoxaphen, 2-amino-5-phenyl-2-oxazoline, and 4,5-dihydro-5-phenyl-2-oxazolamine;

(b) cathinone. Trade or other names include 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone;

(c) fenethylline;

(d) methcathinone. Trade or other names include 2-(methylamino)-propiophenone, alpha-(methylamino)propiophenone, 2-(methylamino)-1-phenylpropan-1-one, alpha-N-methylaminopropiophenone, monomethylpropion, ephedrone, N-methylcathinone, methylcathinone, AL-464, AL-422, AL-463, and UR1432, including its salts, optical isomers, and salts of optical isomers;

(e) 4-Methylaminorex (cis isomer), also known as U4Euh, McN-422;

(f) (levo-dextro) cis-4-methylaminorex, also known as (levo-dextro) cis-4, 5-dihydro-4-methyl-5-phenyl-2-oxazolamine;

(g) N-benzylpiperazine, also known as 1-benzylpiperazine or BZP;

(h) N-ethylamphetamine; and

(i) N,N-dimethylamphetamine, also known as N,N-alpha-trimethyl-benzeneethamine and N,N-alpha-trimethylphenethylamine.

(7) Substances subject to emergency scheduling. Any material, compound, mixture, or preparation that contains any quantity of the following substances is included in this category:

(a) N-[1-benzyl-4-piperidyl]-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts, and salts of isomers); and

(b) N-[1-(2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide (thenylfentanyl), its optical isomers, salts, and salts of isomers).

(8) If prescription or administration is authorized by the Federal Food, Drug, and Cosmetic Act, then any material, compound, mixture, or preparation containing tetrahydrocannabinols listed in (4) must automatically be rescheduled from Schedule I to Schedule II.

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

NEW RULE IV SCHEDULE II DANGEROUS DRUGS (1) Schedule II consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in this rule.

(2) Substances, vegetable origin or chemical synthesis. Unless specifically excepted or listed in another schedule, any of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin,

independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, are included in this category:

(a) opium and opiate and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone, and naltrexone and their respective salts, but including the following:

(i) raw opium;

(ii) opium extracts;

(iii) opium fluid;

(iv) powdered opium;

(v) granulated opium;

(vi) tincture of opium;

(vii) codeine;

(viii) dihydroetorphine;

(ix) ethylmorphine;

(x) etorphine hydrochloride;

(xi) hydrocodone;

(xii) hydromorphone;

(xiii) metopon;

(xiv) morphine;

(xv) oripavine;

(xvi) oxycodone;

(xvii) oxymorphone; and

(xviii) thebaine;

(b) any salt, compound, derivative, or preparation of them that is chemically equivalent or identical with any of the substances referred to in (1)(a), except that these substances do not include the isoquinoline alkaloids of opium;

(c) opium poppy and poppy straw;

(d) coca leaves and any salt, compound, derivative, or preparation of coca leaves, including cocaine and ecgonine and their salts, isomers, derivatives, and salts of isomers, and derivatives, and any salt, compound, derivative, or preparation of them that is chemically equivalent or identical with any of these substances, except that these substances do not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine; and

(e) concentrate of poppy straw, the crude extract of poppy straw in either liquid, solid, or powder form that contains the phenanthrene alkaloids of the opium poppy.

(3) Opiates. Unless specifically excepted or listed in another schedule, any of the following are opiates, including isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of those isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

(a) alfentanil;

(b) alphaprodine;

(c) anileridine;

(d) bezitramide;

(e) bulk dextropropoxyphene (non-dosage forms);

(f) carfentanil;
(g) dihydrocodeine;
(h) diphenoxylate;
(i) fentanyl;
(j) isomethadone;
(k) levo-alphacetylmethadol. Other names include levo-alpha-acetylmethadol, levomethadyl acetate, and LAAM;
(l) levomethorphan;
(m) levorphanol;
(n) metazocine;
(o) methadone;
(p) methadone-intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;
(q) moramide-intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid;
(r) pethidine, also known as meperidine;
(s) pethidine-intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;
(t) pethidine-intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate;
(u) pethidine-intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;
(v) phenazocine;
(w) piminodine;
(x) racemethorphan;
(y) racemorphan;
(z) remifentanil;
(aa) sufentanil; and
(ab) tapentadol.

(4) Stimulants. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a stimulant having a stimulant effect on the central nervous system:
(a) amphetamine, its salts, optical isomers, and salts of its optical isomers;
(b) phenmetrazine and its salts;
(c) methamphetamine, its salts, isomers, and salts of its isomers;
(d) methylphenidate; and
(e) lisdexamfetamine, its salts, isomers, and salts of its isomers.

(5) Depressants. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a depressant having a depressant effect on the central nervous system, including salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:
(a) amobarbital;
(b) glutethimide;
(c) pentobarbital;
(d) phencyclidine; and
(e) secobarbital.

(6) Hallucinogenic substances include the following:

(a) dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration-approved drug product. Other names for dronabinol include (6-alpha-R-trans)-6-alpha,7,8,10-alpha-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo [b, d]pyran-1-ol or (-)-delta-9-(trans)-tetrahydrocannabinol; and

(b) nabilone. Another name for nabilone is (levo-dextro)-trans-3-(1, 1-dimethylheptyl)-6,6-alpha,7,8,10,10-alpha-hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzo[b, d] pyran-9-one.

(7) Immediate precursors. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is an immediate precursor:

(a) 4-Anilino-N-phenethyl-4-piperidine (ANPP);

(b) phenylacetone, an immediate precursor to amphetamine and methamphetamine. Trade or other names for phenylacetone include phenyl-2-propanone, P2P, benzyl methyl ketone, and methyl benzyl ketone; and

(c) 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile (PCC), immediate precursors to phencyclidine (PCP).

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

NEW RULE V SCHEDULE III DANGEROUS DRUGS (1) Schedule III consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in this rule.

(2) Stimulants. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a stimulant having a stimulant effect on the central nervous system, including salts, isomers (whether optical, position, or geometric), and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) benzphetamine;

(b) chlorphentermine;

(c) clortermine; and

(d) phendimetrazine.

(3) Depressants. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a depressant having a depressant effect on the central nervous system:

(a) any compound, mixture, or preparation containing amobarbital, secobarbital, or pentobarbital or any salt of any of these drugs and one or more other active medicinal ingredients that are not listed in any schedule;

(b) any suppository dosage form containing amobarbital, secobarbital, or pentobarbital or any salt of any of these drugs approved by the U.S. Food and Drug Administration for marketing only as a suppository;

(c) any substance that contains any quantity of a derivative of barbituric acid or any salt of barbituric acid;

(d) aprobarbital;

(e) butabarbital, also known as secbutabarbital;
(f) butalbital;
(g) butobarbital, also known as butethal;
(h) chlorhexadol;
(i) embutramide;
(j) gamma hydroxybutyric acid preparations;
(k) ketamine, its salts, isomers, and salts of its isomers, also known as (±)-2-(2-chlorophenyl)-2-(methylamino)cyclohexanone;
(l) lysergic acid;
(m) lysergic acid amide;
(n) methyprylon;
(o) sulfondiethylmethane;
(p) sulfonethylmethane;
(q) sulfonmethane;
(r) talbutal;
(s) tiletamine and zolazepam or any of their salts. A trade or other name for a tiletamine-zolazepam combination product is telazol. A trade or other name for tiletamine is 2-(ethylamino)-2-(2-thienyl)-cyclohexanone. A trade or other name for zolazepam is 4-(2-fluorophenyl)-6,8-dihydro-1,3,8-trimethylpyrazolo-[3,4-e] [1,4]-diazepin-7(1H)-one, flupyrazapon;
(t) thiamylal;
(u) thiopental; and
(v) vinbarbital.
(4) Nalorphine.
(5) Narcotic drugs. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation containing any of the following is a narcotic drug, including its salts calculated as the free anhydrous base or alkaloid in the following limited quantities:
(a) not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;
(b) not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
(c) not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium;
(d) not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
(e) not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
(f) not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(g) not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(h) not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts; or

(i) any material, compound, mixture, or preparation containing buprenorphine.

(6) Anabolic steroids. The term "anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, and corticosteroids that promotes muscle growth. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances is an anabolic steroid, including salts, isomers, and salts of isomers whenever the existence of those salts of isomers is possible within the specific chemical designation:

(a) androstanedione, also known as 5-alpha-androstan-3,17-dione;

(b) 1-androstenediol, also known as 3-beta,17-beta-dihydroxy-5-alpha-androst-1-ene, or 3-alpha,17-beta-dihydroxy-5-alpha-androst-1-ene;

(c) 1-androstenedione, also known as 5-alpha-androst-1-en-3,17-dione;

(d) 3-alpha,17-beta-dihydroxy-5-alpha-androstane;

(e) 3-beta,17-beta-dihydroxy-5-alpha-androstane;

(f) 4-androstenediol, also known as 3-beta,17-beta-dihydroxy-androst-4-ene;

(g) 4-androstenedione, also known as androst-4-en-3,17-dione;

(h) 4-dihydrotestosterone, also known as 17-beta-hydroxyandrostan-3-one;

(i) 4-hydroxy-19-nortestosterone, also known as 4,17-beta-dihydroxy-estr-4-en-3-one;

(j) 4-hydroxytestosterone, 4,17-beta-dihydroxy-androst-4-en-3-one;

(k) 5-androstenediol, also known as 3-beta,17-beta-dihydroxy-androst-5-ene;

(l) 5-androstenedione, also known as androst-5-en-3,17-dione;

(m) 13-beta-ethyl-17-beta-hydroxygon-4-en-3-one;

(n) 17-alpha-methyl-3-alpha, 17-beta-dihydroxy-5-alpha-androstane;

(o) 17-alpha-methyl-3-beta, 17-beta-dihydroxy-5-alpha-androstane;

(p) 17-alpha-methyl-3-beta, 17-beta-dihydroxyandrost-4-ene;

(q) 17-alpha-methyl-4-hydroxynandrolone, also known as 17-alpha-methyl-4-hydroxy-17-beta-hydroxyestr-4-en-3-one;

(r) 17-alpha-methyl-delta, 1-dihydrotestosterone, also known as 17-beta-hydroxy-17-alpha-methyl-5-alpha-androst-1-en-3-one, 17-alpha-methyl-1 testosterone;

(s) 19-nor-4-androstenediol, also known as 3-beta-17-beta-dihydroxyestr-4-ene, or 3-alpha-17-beta-dihydroxyestr-4-ene;

(t) 19-nor-4-androstenedione, also known as estr-4-en-3,17-dione;

(u) 19-nor-5-androstenediol, also known as 3-beta,17-beta-dihydroxyestr-5-ene, or 3-alpha,17-beta-dihydroxyestr-5-ene;

(v) 19-nor-5-androstenedione, also known as estr-5-en-3,17-dione;

(w) calusterone, also known as 7-beta,17-alpha-dimethyl-17-beta-hydroxyandrost-4-en-3-one);

(x) 19-Nor-4,9(10)-androstadienedione, also known as estra-4,9(10)-diene-3,17-dione;

(y) bolasterone, also known as (7-alpha-dimethyl)-17-beta-hydroxyandrost-4-ene-3-one;

(z) boldenone, also known as 17-beta-hydroxyandrost-1,4,-diene-3-one;

(aa) boldione, also known as androsta-1,4-diene-3,17-dione;

(ab) chlorotestosterone, also known as 4-chlortestosterone;

(ac) clostebol;

(ad) delta-1-dihydrotestosterone, also known as (17-beta-hydroxy-5-alpha-androst-1-en-3-one), 1-testosterone;

(ae) dehydrochloromethyltestosterone, also known as 4-chloro-17-beta-hydroxy-17-alpha-methylandrost-1,4-dien-3-one;

(af) desoxymethyltestosterone, also known as 17-alpha-methyl-5-alpha-androst-2-en-17-beta-ol;

(ag) dihydrochlormethyltestosterone;

(ah) dihydrotestosterone, also known as 4-dihydrotestosterone;

(ai) drostanolone, also known as 17-beta-hydroxy-2-alpha-methyl-5-alpha-androstan-3-one;

(aj) ethylestrenol, also known as 17-alpha-ethyl-17-beta-hydroxyestr-4-ene;

(ak) fluoxymesterone, also known as 9-fluoro-17-alpha-methyl-11-beta, 17-beta-dihydroxyandrost-4-en-3-one;

(al) formebulone, also known as 2-formyl-17-alpha-methyl-11-alpha,17-beta-dihydroxyandrost-1,4-dien-3-one or formebolone;

(am) furazabol, also known as 17-alpha-methyl-17-beta-hydroxyandrostano-[2,3-c]-furazan;

(an) methandienone, also known as 17-alpha-methyl-17-beta-hydroxyandrost-1,4-diene-3-one;

(ao) mestanolone, also known as 17-alpha-methyl-17-beta-hydroxy-5-alpha-androstan-3-one;

(ap) mesterolone, also known as 1-alpha-methyl-17-beta-hydroxy-(5-alpha)-androstan-3-one;

(aq) methandienone, also known as 17-alpha-methyl-17-beta-hydroxyandrost-1,4-dien-3-one;

(ar) methandranone;

(as) methandriol, also known as 17-alpha-methyl-3-beta,17-beta-dihydroxyandrost-5-one;

(at) methandrostenolone, also known as (17-beta)-17-hydroxy-17-methylandrosta-1,4-dien-3-one;

(au) methenolone, also known as 1-methyl-17-beta-hydroxy-5-alpha-androst-1-en-3-one;

(av) methyldienolone, also known as 17-alpha-methyl-17-beta-hydroxyestra-4,9-(10)-dien-3-one;

(aw) methyltestosterone, also known as 17-alpha-methyl-17-beta-hydroxyandrost-4-en-3-one;

(ax) methyltrienolone, also known as 17-alpha-methyl-17-beta-hydroxyestra-4,9,11-trien-3-one;

(ay) mibolerone, also known as 17-alpha,17-alpha-dimethyl-17-beta-hydroxyestr-4-en-3-one;

(az) nandrolone, also known as 17-beta-hydroxyestr-4-en-3-one;

(ba) norbolethone, also known as 13-beta,17-alpha-diethyl-17-beta-hydroxygon-4-en-3-one;

(bb) norclostebol, also known as 4-chloro-17-beta-hydroxyestr-4-en-3-one;

(bc) norethandrolone, also known as 17-alpha-ethyl-17-beta-hydroxyestr-4-en-3-one;

(bd) normethandrolone, also known as 17-alpha-methyl-17-beta-hydroxyestr-4-en-3-one;

(be) oxandrolone, also known as 17-alpha-methyl-17-beta-hydroxy-2-oxa-(5-alpha)-androstan-3-one;

(bf) oxymestrone, also known as 17-alpha-methyl-4,17-beta-dihydroxyandrost-4-en-3-one;

(bg) oxymetholone, also known as 17-alpha-methyl-2-hydroxymethylene-17-beta-hydroxy-(5-alpha)-androstan-3-one;

(bh) stanolone;

(bi) stanozolol, also known as 17-alpha-methyl-17-beta-hydroxy-(5-alpha)-androst-2-eno-(3,2-c)-pyrazole;

(bj) stenbolone, also known as 17-beta-hydroxy-2-methyl-5-alpha-androst-1-en-3-one;

(bk) talbutal, also known as 5-(1-methylpropyl)-5-(2-propenyl)-2,4,6(1*H*,3*H*,5*H*)-pyrimidinetrione;

(bl) testolactone, also known as 13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone;

(bm) testosterone, also known as 17-beta-hydroxyandrost-4-en-3-one;

(bn) trenbolone, also known as 17-beta-hydroxyestr-4,9,11-trien-3-one; and

(bo) tetrahydrogestrinone, also known as 13-beta,17-alpha-diethyl-17-beta-hydroxygon-4,9,11-trien-3-one.

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

NEW RULE VI SCHEDULE IV DANGEROUS DRUGS (1) Schedule IV consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in this rule.

(2) Narcotic drugs. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotics is a drug, including its salts calculated as the free anhydrous base or alkaloid in the following limited quantities:

(a) not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit;

(b) dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane);

(c) butorphanol;

(d) difenoxin 1mg/25ug $AtSO_4$/du; and

(e) pentazocine.

(3) Depressants. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a depressant, including salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) alprazolam;
(b) barbital;
(c) bromazepam;
(d) camazepam;
(e) chloral betaine;
(f) chloral hydrate;
(g) chlordiazepoxide;
(h) clobazam;
(i) clonazepam;
(j) clorazepate;
(k) clotiazepam;
(l) cloxazolam;
(m) delorazepam;
(n) diazepam;
(o) dichloralphenazone;
(p) estazolam;
(q) ethchlorvynol;
(r) ethinamate;
(s) ethyl loflazepate;
(t) fludiazepam;
(u) flunitrazepam;
(v) flurazepam;
(w) fospropofol, also known as lusedra;
(x) halazepam;
(y) haloxazolam;
(z) ketazolam;
(aa) loprazolam;
(ab) lorazepam;
(ac) lormetazepam;
(ad) mebutamate;
(ae) medazepam;
(af) meprobamate;
(ag) methohexital;
(ah) methylphenobarbital, also known as mephobarbital;
(ai) midazolam;
(aj) nimetazepam;
(ak) nitrazepam;
(al) nordiazepam;
(am) oxazepam;
(an) oxazolam;
(ao) paraldehyde;
(ap) petrichloral;

(aq) phenobarbital;
(ar) pinazepam;
(as) prazepam;
(at) quazepam;
(au) temazepam;
(av) tetrazepam;
(aw) triazolam;
(ax) zaleplon;
(ay) zolpidem; and
(az) zopiclone.

(4) Fenfluramine. Any material, compound, mixture, or preparation that contains any quantity of fenfluramine, including its salts, isomers (whether optical, position, or geometric), and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible.

(5) Stimulants. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a stimulant having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(a) cathine, also known as (+)-norpseudoephedrine;
(b) diethylpropion;
(c) fencamfamin;
(d) fenproporex;
(e) mazindol;
(f) mefenorex;
(g) modanfinil;
(h) pemoline, including organometallic complexes and chelates thereof;
(i) phentermine;
(j) pipradrol;
(k) sibutramine; and
(l) SPA ((-)-1-dimethylamino-1,2-diphenylethane).

(6) Ephedrine.

(a) Except as provided in (6)(b), any material, compound, mixture, or preparation that contains any quantity of ephedrine having a stimulant effect on the central nervous system, including its salts, enantiomers (optical isomers), and salts of enantiomers (optical isomers) when ephedrine is the only active medicinal ingredient or is used in combination with therapeutically insignificant quantities of another active medicinal ingredient.

(b) Ephedrine does not include materials, compounds, mixtures, or preparations labeled in compliance with the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. 321, et seq., that contain only natural ephedra alkaloids or extracts of natural ephedra alkaloids.

(c) Ephedrine may be immediately accessible for use by a licensed physician in a patient care area if it is under the physician's direct supervision.

(7) Other substances. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of pentazocine or butorphanol, including its salts, isomers, and salts of its isomers.

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

NEW RULE VII SCHEDULE V DANGEROUS DRUGS (1) Schedule V consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in this rule.

(2) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following is a narcotic drug, including its salts, calculated as the free anhydrous base or alkaloid in limited quantities as set forth in (2)(a) through (2)(f), which include one or more nonnarcotic, active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities, other than those possessed by narcotic drugs alone:

(a) not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;

(b) not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;

(c) not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;

(d) not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(e) not more than 100 milligrams of opium per 100 milliliters or per 100 grams; and

(f) not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(3) Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of pyrovalerone is a stimulant having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers.

(4) Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances is a depressant having a depressant effect on the central nervous system, including salts, isomers, and salts of isomers.

(a) lacosamide, also known as (R)-2-acetoamido-N-benzyl-3-methoxy-propionamide or vimpat; and

(b) pregabalin, also known as (S)-3-(aminomethyl)-5-methylhexanoic acid or lyrica.

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

7. REASONABLE NECESSITY FOR NEW RULES VIII THROUGH XVI: The 2011 Montana Legislature enacted Chapter 122, Laws of 2011 (House Bill 25), an act that revised laws relating to certain licensing boards' medical assistance programs. The bill was signed by the Governor on April 7, 2011, and became effective on October 1, 2011, authorizing the board to establish a medical assistance program to assist and rehabilitate licensees. The board determined it is reasonably

necessary to adopt New Rules VIII through XVI to align with and implement the recent legislation.

NEW RULE VIII MEDICAL ASSISTANCE PROGRAM PURPOSE

(1) The Montana Board of Pharmacy has established a medical assistance program which provides assistance, rehabilitation, and aftercare monitoring to pharmacists, pharmacist interns, certified pharmacy technicians, and pharmacy technicians-in-training under the jurisdiction of the board, who are suspected and/or found to be physically or mentally impaired by habitual intemperance or the excessive use of addictive drugs, alcohol, or any other drug or substance, or by mental or chronic physical illness.

(2) The board encourages and shall permit the rehabilitation of licensees if, in the board's opinion, public health, safety, and welfare can be assured. Early intervention and referral are paramount to promoting public health, safety, and welfare.

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

NEW RULE IX REPORTING OF SUSPECTED IMPAIRMENT

(1) Individuals, entities, or associations may report information to the board of suspected impairment of a licensee or license applicant, as provided in 37-7-201, MCA.

(2) Individuals, entities, or associations may report information of suspected impairment of a licensee or license applicant to the appropriate personnel of the medical assistance program established by the board, in lieu of reporting to the board, as provided in 37-7-201, MCA.

(3) Reports received by the board of suspected impaired licensees may be referred to the medical assistance program at the board's discretion through the nondisciplinary track, without formal disciplinary action against the licensee.

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

NEW RULE X PROTOCOL FOR SELF-REPORTING TO A BOARD-ESTABLISHED MEDICAL ASSISTANCE PROGRAM (1) If a licensee chooses to self-report to the board-established medical assistance program, and the medical assistance program has determined that the licensee needs assistance or supervision, the licensee shall be required to:

(a) enter into a contractual agreement with the medical assistance program for the specified length of time determined by the medical assistance program; and

(b) abide by all the requirements set forth by the medical assistance program.

(2) Self-reporting by a licensee may still result in disciplinary action by the board if:

(a) the medical assistance program determines that the self-reporting licensee poses a danger to themselves or to the public;

(b) the licensee is noncompliant with a contractual agreement with the medical assistance program;

(c) the licensee has not completed evaluation, treatment, or aftercare monitoring as recommended by the medical assistance program; or

(d) the screening panel otherwise determines that disciplinary action is warranted.

(3) The medical assistance program shall notify the board, disclose the identity of the licensee involved, and provide all facts and documentation to the board whenever:

(a) the licensee:

(i) has committed an act described in ARM 24.174.2301;

(ii) is noncompliant with a recommendation of the medical assistance program for evaluation, treatment, or aftercare monitoring contract; or

(iii) is the subject of credible allegations that the licensee has put a patient or the public at risk or harm; or

(b) the screening panel otherwise determines disciplinary action is warranted.

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

NEW RULE XI RESPONSIBILITIES OF MEDICAL ASSISTANCE PROGRAM (1) The medical assistance program established by the board as set forth in 37-7-201, MCA, shall fulfill the terms of its contract with the board, which will include, but not be limited to, the following:

(a) providing two tracks for assistance of licensees:

(i) a disciplinary track; and

(ii) a nondisciplinary track;

(b) providing recommendations to licensees for appropriate evaluation and treatment facilities;

(c) recommending to the board terms and conditions of treatment, rehabilitation, and monitoring of licensees known to the board; and

(d) monitoring all aftercare of participants under contract to ensure public safety and compliance with agreed treatment recommendations propounded by one or more of the following:

(i) the board, through stipulations and/or final orders;

(ii) treatment centers; or

(iii) the medical assistance program established by the board.

(2) The medical assistance program shall consult with the board regarding medical assistance program processes and procedures to ensure program responsibilities are met, consistent with board orders, requests, and contract terms.

(3) The medical assistance program shall provide information to and consult with the board upon the board's request.

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

NEW RULE XII PROTOCOL FOR DISCIPLINARY TRACK (1) All licensees who participate in the medical assistance program under the disciplinary track shall be reported to the board by name.

(2) A licensee is placed in the disciplinary track by one or more of the following:

(a) as a condition of licensure imposed by a board final order;

(b) as a result of a sanction imposed by a board final order;

(c) as a result of noncompliance with the licensee's contractual agreement with the program; or

(d) pursuant to an agreement between the licensee and the screening panel or the full board upon licensure.

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

NEW RULE XIII PROTOCOL FOR NONDISCIPLINARY TRACK

(1) A licensee who participates in the medical assistance program under the nondisciplinary track shall be reported to the board by participant number.

(2) The identity of the participant who is noncompliant or refuses a reasonable request by the medical assistance program shall be reported to the board.

(3) If the board determines that a participant does not abide by all terms and conditions of the medical assistance program, the participant will be referred to the screening panel of the board for appropriate action under the disciplinary track.

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

NEW RULE XIV REPORTING TO THE BOARD (1) The screening panel of the board must receive a written compliance status report from the medical assistance program at intervals established by the contract between the program and the board regarding each program participant:

(a) under a monitoring agreement;

(b) referred to the program; or

(c) in the process of evaluation or treatment.

(2) The full board shall receive a written compliance status report from the medical assistance program at intervals established by contract between the program and the board regarding each participant:

(a) under a monitoring agreement;

(b) referred to the program; or

(c) in the process of evaluation or treatment.

(3) The identity of a participant in the nondisciplinary track must be reported to the full board by participant number except as required by [NEW RULE X and XIII].

(4) The identity of a participant in the disciplinary track must be reported to the full board by name.

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

NEW RULE XV PARTICIPANT DISCHARGE REQUIREMENTS (1) The medical assistance program shall facilitate participant discharge from the program.

(2) The discharge criteria must be determined by the board in conjunction with the recommendations of the medical assistance program.

(3) The following are required upon discharge of a participant from the endorsed medical assistance program:

(a) report of the discharge of the participant to the board:

(i) verification of satisfactory completion of monitoring, program requirements, and appropriate assurance of public safety;

(ii) completion of board final order terms and conditions with medical assistance program recommendation for discharge and release; and

(iii) request by a participant to transfer assistance into an appropriate endorsed medical assistance program in another jurisdiction; such transfer to be confirmed by the program.

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

NEW RULE XVI RELAPSE REPORTING (1) The medical assistance program shall define what constitutes "relapse" for each particular participant and determine if and when relapse has occurred.

(a) A participant who has a single episode of relapse and/or early detection of relapse with nominal substance abuse may be reported to the board by the medical assistance program.

(b) A participant who has a second or severe relapse must be reported by the medical assistance program to the board screening panel for review.

(c) The board shall take disciplinary action against the license of a person in a medical assistance program if, in the period under contract, the licensee has on three separate occasions returned to the use of a prohibited or proscribed substance.

(2) Any of the following may be required by the board upon the recommendation of the medical assistance program when a participant suffers a relapse:

(a) the participant may be required to withdraw from practice;

(b) the participant may undergo further recommended evaluation and/or treatment as determined by the medical assistance program;

(c) the participant's monitoring agreement required by the medical assistance program must be reassessed and may be modified;

(d) the participant may be required to comply with other recommendations of the medical assistance program; or

(e) the participant may be subject to discipline as imposed by a board final order.

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

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

8. REASONABLE NECESSITY FOR NEW RULES XVII THROUGH XXII: The board determined it is reasonably necessary to propose New Rules XVII through XXII to implement recent trends in pharmaceutical practice and regulations recognizing that internal controls improve the quality of pharmaceutical care and patient safety. The board concluded that requiring these quality controls is a proactive measure that will enhance the practice of pharmacy care.

NEW RULE XVII QUALITY IMPROVEMENT PROGRAM DEFINITIONS

(1) "Continuous Quality Improvement Program" or CQI program means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

(2) "Quality-related event" or QRE means the incorrect dispensing of a prescribed medication that is received by a patient including:

(a) a variation from the prescriber's prescription order including, but not limited to:

(i) dispensing an incorrect drug;

(ii) dispensing an incorrect drug strength;

(iii) dispensing an incorrect dosage form;

(iv) dispensing a drug to the wrong patient; or

(v) providing inadequate or incorrect packaging, labeling, or directions;

(b) failure to identify and manage:

(i) overutilization;

(ii) therapeutic duplication;

(iii) drug-disease contraindications;

(iv) drug-drug interactions;

(v) incorrect drug dosage or duration of drug treatment;

(vi) drug allergy interactions; or

(vii) clinical abuse or misuse.

(3) "Near-miss QRE" means that an error occurred at some point in the dispensing process, but it was caught and corrected before being given to a patient.

(4) "Pharmacy" means a pharmacy or a group of pharmacies under common ownership and control of one entity licensed by the board.

(5) "Pharmacy personnel" mean pharmacist, pharmacist intern, and pharmacy technician.

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

NEW RULE XVIII CONTINUOUS QUALITY IMPROVEMENT PROGRAM

(1) Each pharmacy shall establish a Continuous Quality Improvement (CQI) program for the purpose of detecting, documenting, assessing, and preventing quality-related events (QREs). At a minimum, a CQI program shall include provisions to:

(a) identify and document QREs;

(b) minimize impact of QREs on patients;

(c) analyze data collected in response to QREs to assess causes and any contributing factors;

(d) use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs; and

(e) provide ongoing education and feedback to pharmacy personnel in the area of CQI, and specific findings from the CQI program.

(2) The pharmacist-in-charge (PIC) is responsible for monitoring CQI program compliance.

(3) CQI program requirements shall be implemented by each pharmacy within six months of the effective date of this rule.

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

NEW RULE XIX QUALITY-RELATED EVENT DISCOVERY, NOTIFICATION, AND DOCUMENTATION (1) All pharmacy personnel shall be trained to bring any quality-related event (QRE) to the attention of the pharmacist on duty or the pharmacist-in-charge (PIC) immediately upon discovery. The pharmacist who has discovered or been informed of a QRE shall immediately provide:

(a) notification to the patient or patient's representative;

(b) notification of the prescriber and other members of the healthcare team if indicated in the professional judgment of the pharmacist;

(c) directions for correcting the error; and

(d) instructions for minimizing the negative impact on the patient.

(2) A QRE shall be initially documented by the pharmacist who has discovered or been informed of the QRE on the same day the QRE is discovered by or described to the pharmacist.

(3) QRE documentation shall include a description of the event that is sufficient to permit categorization and analysis of the event. QRE documentation shall include:

(a) the date when the pharmacist discovered or received notification of the QRE and the names of the persons who notified the pharmacy;

(b) the names and titles of the persons recording the QRE information and performing the QRE analysis;

(c) a description of the QRE reviewed; and

(d) documentation of the contact with the patient or patient's representative and the prescribing practitioner and other members of the healthcare team (if indicated in the professional judgment of the pharmacist).

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

NEW RULE XX QUALITY-RELATED EVENT ANALYSIS AND RESPONSE

(1) The investigative and other pertinent data collected in response to a quality-related event (QRE) shall be analyzed individually and collectively to assess the cause and any contributing factors such as system or process failures. The QRE analysis and assessment shall include:

(a) consideration of the effects on quality assurance related to workflow processes, technological support, personnel training, and staffing levels; and

(b) any recommended remedial changes to pharmacy policies, procedures, systems, or processes.

(2) Each pharmacy shall inform pharmacy personnel of changes to pharmacy policies, procedures, systems, or processes resulting from recommendations generated by the Continuous Quality Improvement Program.

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

NEW RULE XXI DUTY TO REPORT (1) A pharmacy licensed by the board is required to report any quality-related event (QRE) to the Institute for Safe Medication Practices (ISMP). Near-miss QREs are encouraged to be treated as a QRE and reported to the ISMP.

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

NEW RULE XXII RECORDS (1) Each pharmacy shall maintain a copy of its Continuous Quality Improvement Program (CQI) description on the pharmacy premises. The CQI program description shall be readily available to all pharmacy personnel.

(2) Each pharmacy shall maintain a record of all quality-related event (QRE) documentation for a minimum period of two years from the date of the QRE report.

(3) QRE records shall be maintained in an orderly manner and accessible for the pharmacy compliance officer.

(4) The date and name of the person filing the Institute for Safe Medication Practices report will be kept as part of the QRE record.

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

NEW RULE XXIII LIMITED SERVICE PHARMACY (1) A limited service pharmacy is defined as a family planning clinic:

(a) operating under contract with the Department of Public Health and Human Services (DPHHS); or

(b) providing pharmaceutical care under the review of a consulting pharmacist and dispensing legend drugs, but which is not under contract with DPHHS.

(2) Each limited service pharmacy must apply for a license from the board and submit the required fee.

(3) The board shall grant a license to operate a limited service pharmacy to qualified applicants. A licensed family planning clinic may operate satellite locations under the same license if identified on the application.

(4) A limited service pharmacy must display its license in a conspicuous place at the facility.

(5) A limited service pharmacy is not required to employ a licensed pharmacist.

(6) A limited service pharmacy dispensing legend drugs other than factory, prepackaged contraceptives must disclose the name, address, telephone number, and title of the designated person in charge of the limited service pharmacy. The person in charge is responsible for the limited service pharmacy's compliance with all applicable state and federal statutes and rules. A person in charge may be responsible for multiple sites.

(7) The board may annually inspect limited service pharmacies, including any satellite locations. The board may inspect more often for cause. Such inspections must include assurance that the limited service pharmacy provides adequate:

(a) drug labeling;

(b) counseling materials to all patients, including the name of the limited service pharmacy's consulting pharmacist, where required;

(c) contact information of a knowledgeable individual at the clinic in the event of an adverse reaction;

(d) records maintenance and retention; and

(e) drug storage and security.

(8) Nothing in this rule is meant to limit or restrict the authority of a registered nurse employed by a family planning clinic, operating under contract with DPHHS, from dispensing factory, prepackaged contraceptives as authorized by 37-2-104, 37-7-103, or 50-31-307, MCA.

(9) A registered nurse or provider with prescriptive authority, employed by a family planning clinic operating under contract with DPHHS, may dispense oral antibiotics used to treat Chlamydia to a patient diagnosed with Chlamydia and to a sexual contact or partner of a patient diagnosed with Chlamydia. All appropriate records shall be maintained on-site. The antibiotics dispensed must:

(a) be prepackaged and properly labeled in accordance with state law;

(b) include appropriate counseling materials informing the patient of the potential risks involved in taking the drug; and

(c) contain contact information for the healthcare provider or a consulting pharmacist to provide advice or answer questions.

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

REASON: The board determined it is reasonably necessary to adopt New Rule XXIII to reflect current medical and pharmacy practice standards through the registration of family planning clinics dispensing legend prescription drugs and the board's inspection of these facilities. The board concluded that inspection is necessary to ensure the public's safety as these facilities maintain legend drug stocks and may be located in remote areas of the state.

This new rule addresses additional medical practitioners with prescriptive authority as defined at 37-2-101, MCA, and provides for the dispensing of oral antibiotic medication to timely treat patients with certain sexually transmitted diseases. Montana's chief medical officer requested the board adopt rules to

address this serious public health concern. New Rule XXIII will replace ARM 24.174.813, which is proposed for repeal in this notice.

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

24.174.813 CLASS IV FACILITY found at ARM page 24-19669.

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

REASON: The board is repealing ARM 24.174.813 Class IV Facility, and replacing it with proposed New Rule XXIII. Previous rule amendments repealed Class I, II, and III facilities, leaving only Class IV. This rule also references a contraceptive drug or device law which was repealed in 1989.

10. 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 by e-mail to dlibsdpha@mt.gov, and must be received no later than 5:00 p.m., January 31, 2012.

11. An electronic copy of this Notice of Public Hearing is available through the department and board's web site on the World Wide Web at www.pharmacy.mt.gov. 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.

12. 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 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.

13. The bill sponsor contact requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor was contacted on September 20, 2011, by regular mail.

14. Mike Fanning, attorney, has been designated to preside over and conduct this hearing.

BOARD OF PHARMACY
LEE ANN BRADLEY, RPH, PRESIDENT

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

/s/ KEITH KELLY
Keith Kelly, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State December 12, 2011