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

In the matter of the amendment of 24.174.301 definitions, 24.174.1201 wholesale drug distributor licensing, 24.174.2107 registered pharmacist continuing education and the adoption of NEW RULES I use of contingency kits, II definitions, III information required for submission, IV electronic format required for the transmission of information, V requirements for submitting prescription registry information, VI failure to report prescription information, VII registry information review and unsolicited patient profiles, VIII access to prescription drug registry information, IX registry information retention, X advisory group, XI prescription drug registry fee, XII release of prescription drug registry information to other entities, and XIII interstate exchange of registry information	)))))))))))))))))))	NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT AND ADOPTION

TO: All Concerned Persons

1. On January 3, 2012, at 9:00 a.m., a public hearing will be held in room 439, 301 South Park Avenue, Helena, Montana, to consider the proposed amendment and adoption 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 December 29, 2011, 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. The rules proposed to be amended provide as follows, stricken matter interlined, new matter underlined:

24.174.301 DEFINITIONS ~~In addition to the term defined in 37-7-101, MCA, the following definitions apply to the rules in this chapter.~~

(1) through (3) remain the same.

(4) "Contingency kit" means a secured kit 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.

(4) through (6) remain the same, but are renumbered (5) through (7).

~~(7)~~ (8) "Device" is defined in 37-2-101, MCA, and is required under federal law to bear the label "Caution: Federal law requires dispensing by or on the order of a physician" or "Rx only."

(8) through (12) remain the same, but are renumbered (9) through (13).

~~(13)~~ (14) "Facility" means an outpatient center for surgical services, a hospital and/or ~~long term~~ long-term care facility, or a home infusion facility.

~~(14)~~ (15) "Floor stock" means prescription drugs not labeled for a specific patient, which are maintained at a nursing station or other hospital department other than the pharmacy, and which are administered to patients within the facility pursuant to a valid drug order. Floor stock shall be maintained in a secure manner pursuant to written policies and procedures, which shall include, but not be limited to, automated dispensing devices.

(15) and (16) remain the same, but are renumbered (16) and (17).

~~(17)~~ (18) "Institutional pharmacy" means that physical portion of an institutional facility where drugs, devices, and other material used in the diagnosis and treatment of injury, illness, and disease are dispensed, compounded, and distributed to other ~~health care~~ healthcare professionals for administration to patients within or outside the facility, and pharmaceutical care is provided.

(18) remains the same, but is renumbered (19).

~~(19)~~ (20) "~~Long term~~ Long-term care facility" has the same meaning as provided in 50-5-101, MCA, and means a facility or part of a facility that provides skilled nursing care, residential care, intermediate nursing care, or intermediate developmental disability care to a total of two or more individuals, or that provides personal care.

~~(20)~~ (21) "Medical gas" means any gaseous substance that meets medical purity standards and has application in a medical environment. Examples of medical gases include, but are not limited to, oxygen, carbon dioxide, nitrous oxide, cyclopropane, helium, nitrogen, and air.

(21) through (27) remain the same, but are renumbered (22) through (28).

~~(28)~~ (29) "Provisional pharmacy" means a pharmacy licensed by the Montana Board of Pharmacy and includes, but is not limited to, federally qualified health centers as defined in 42 CFR 405.2401, where prescription drugs are dispensed to appropriately screened, qualified patients.

(29) through (33) remain the same, but are renumbered (30) through (34).

~~(34)~~ (35) "Security" or "secure system" means a system to maintain the confidentiality and integrity of patient records, which are being sent electronically.

~~(35)~~ (36) "Sterile pharmaceutical" means any dosage form containing no viable microorganisms~~,~~ including, but not limited to, parenterals and ophthalmics.

(36) remains the same, but is renumbered (37).

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 add (4) to define and clarify contingency kits as the term is used in proposed New Rule I. Additional amendments correct grammatical errors and renumber or amend punctuation within the rule following internal amendments.

24.174.1201 WHOLESALE DRUG DISTRIBUTOR LICENSING (1) through (3) remain the same.

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

(4) through (6) remain the same, but are renumbered (5) through (7).

AUTH: 37-7-201, 37-7-610, MCA
IMP: 37-7-603, 37-7-604, 37-7-605, 37-7-606, MCA

REASON: The board is amending this rule to address recent concerns of the pharmacy inspector raised after inspecting new wholesale drug distributors. It appears that these new applicants do not have viable business plans and/or adequate facilities to conduct a wholesale drug distribution business. By requiring new licensure applicants to successfully pass an inspection prior to licensure, the board is being proactive and continuing to ensure the safety and efficacy of the drug distribution system. Implementation cites are being amended to accurately reflect all statutes implemented through the rule.

24.174.2107 REGISTERED PHARMACIST CONTINUING EDUCATION - NONCOMPLIANCE (1) ~~Failure to meet the license renewal requirements set forth in ARM 24.101.413 will be cause for the license to lapse. For reinstatement, the applicant shall have completed the continuing education requirements and certify that fact to the board as stated in ARM 24.174.2103.~~ A pharmacist who submits a renewal application, but who has not completed the required continuing education requirements as set forth in ARM 24.101.413 and 24.174.2104, will have sixty days, following the end of the renewal period, to complete the requirements. The pharmacist shall:

(a) notify the board of the continuing education deficiency by checking the appropriate box on the renewal application;

(b) pay a fee equal to one hundred percent of the annual fee for licensure. This fee is in addition to the regular fee for licensure; and

(c) submit to the board office documentation of completion of continuing education requirements.

(2) Failure to complete continuing education requirements may be cause for disciplinary action by the board.

(3) An action taken under (2) is not a "disciplinary action" under ARM 24.101.404, for the purposes of publication and notice on the licensee look-up.

AUTH: 37-1-319, MCA
IMP: 37-1-141, 37-1-306, MCA

REASON: The board is amending the procedure for pharmacists who have not completed the continuing education (CE) requirements for licensure renewal. By allowing sixty days in which to complete the CE, the board seeks to avoid taking official disciplinary action as often, which attaches to the pharmacist's permanent record, while still ensuring competent licensed pharmacists.

4. The proposed new rules provide as follows:

NEW RULE I USE OF CONTINGENCY KITS IN CERTAIN INSTITUTIONAL FACILITIES (1) In an institutional facility that does not have an in-house pharmacy or 24-hour access to dispensing services, medications may be provided for use by authorized personnel through contingency kits, prepared by the registered pharmacist, providing pharmaceutical services to the facility. Such contingency kits must meet all of the following requirements:

(a) the supplying or consultant pharmacist and director of nursing shall designate nursing personnel who may obtain access to the drug supply;

(b) the supplying or consultant pharmacist and the designated practitioner or appropriate committee of the institutional facility shall jointly determine the contents and quantity of drugs to be included in the kit;

(c) the 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;

(d) the supplying pharmacist and director of nursing will provide adequate controls to prevent drug diversion;

(e) medications in the kit must be prepackaged and 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; and

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

(i) its contents and expiration date; and

(ii) the name, address, and telephone number of the supplying pharmacist.

(2) Drugs shall be removed from kits only by the supplying pharmacist or by authorized nursing personnel pursuant to a valid drug order or during inspection of the kit.

(3) Removal of any drug from the contingency kit by authorized nursing or pharmacy personnel must be recorded 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; and

(d) signature of the authorized personnel removing the drug.

(4) The supplying pharmacist shall ensure that:

(a) written policies and procedures are established to implement the requirements of this rule;

(b) all drugs are properly labeled;

(c) only prepackaged drugs are available in amounts sufficient for short-term therapeutic requirements to meet the needs of the facility when dispensing pharmacy services are unavailable;

(d) replacement of medications is performed in a timely manner by authorized personnel;

(e) at a minimum, the kit shall be inspected annually; and

(f) at least one copy of the documentation for all drugs that have been removed from the contingency kit shall be kept at the long-term care facility and one copy at the supplying pharmacy.

(5) 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.

(6) All documentation must be readily available for inspection by the board.

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

REASON: There are situations where long-term care facility residents require immediate care that may easily be provided by an emergency drug kit or a starter dose "contingency kit." These patients, especially those frail and elderly, cannot wait until the next day to receive their medications. The contingency kit allows the patient to receive an immediate dose of a medication not currently on that patient's medical chart.

Use of contingency kits is particularly important in rural areas where the closest pharmacy may be 50 miles away and especially in rural Montana, where often times a pharmacist is not available during evening/night hours, or on weekends and holidays. Additionally, many local pharmacies are unwilling to provide an on-call service twenty-four hours, seven days a week, as required under the Centers for Medicare and Medicaid Services (CMS) requirements for network long-term care pharmacies (NLTCPs). The board is proposing New Rule I to address these situations as they arise in long-term care facilities.

REASONABLE NECESSITY FOR NEW RULES II THROUGH XIII:

The 2011 Montana Legislature enacted Chapter 241, Laws of 2011 (House Bill 83), an act that created a prescription drug registry. The bill was signed by the Governor on April 21, 2011, and became effective on July 1, 2011. The legislation requires the board to electronically collect information on prescription drug orders involving controlled substances. The purpose of the registry is to improve patient safety by making a list of controlled substances prescribed to a patient, available to the patient or to the patient's healthcare provider, and allowing authorized board staff to review the registry for possible misuse and diversion of controlled substances. The board is proposing New Rules II through XIII to coincide with the statutory changes and further implement the legislation.

NEW RULE II DEFINITIONS (1) "Authorized user" means a prescriber, pharmacist, Board of Pharmacy staff, Montana Medicare or Medicaid programs, Tribal Health, Indian Health Service, and Veterans Affairs.

(2) "Authorized agent" means a designated person authorized access by an authorized user. An authorized agent for a pharmacist must be a pharmacy intern or certified pharmacy technician.

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

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

(a) pharmacy name, address, telephone number, and drug enforcement administration number;

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

(c) full name, address, telephone number, and drug enforcement administration registration number of the prescriber;

(d) date the prescription was issued by the prescriber;

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

(f) indication of whether the prescription dispensed is new or a refill;

(g) name, national drug code number, strength, quantity, dosage form, and days' supply of the actual drug dispensed;

(h) prescription number assigned to the prescription order; and

(i) source of payment for the prescription that indicates one of the following:

(i) cash;

(ii) insurance; or

(iii) government subsidy.

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

NEW RULE IV ELECTRONIC FORMAT REQUIRED FOR THE TRANSMISSION OF INFORMATION (1) All prescription information submitted to the board pursuant to [New Rule III], must be transmitted in the format specified by the American Society for Automation in Pharmacy (ASAP), version 4.1, dated 2009, which is adopted and incorporated by reference. A copy of the ASAP standards may be obtained through the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana, 59620-0513.

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

NEW RULE V REQUIREMENTS FOR SUBMITTING PRESCRIPTION REGISTRY INFORMATION TO THE BOARD (1) All prescription dispensing information submitted under this subchapter shall be submitted at least weekly.

(2) The information submitted shall be consecutive and complete from the date and time of the submitting pharmacy's last submission, and shall be reported no later than eight days after the date of dispensing.

(3) If a pharmacy has dispensed no reportable controlled substances during a reporting period, the pharmacy shall submit a timely "zero report."

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

(5) In the event that a pharmacy cannot submit the required information as described in this rule, the pharmacy must report that fact on the appropriate board-approved form. This form is due to the board on or before the date that the weekly submission is otherwise due. The board office may grant an extension, at their discretion, when a pharmacy notifies the board that they are unable to submit their report.

(6) It is the responsibility of the submitting pharmacy to address any errors or questions about information that the pharmacy has submitted to the prescription drug registry.

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

NEW RULE VI FAILURE TO REPORT PRESCRIPTION INFORMATION

(1) A pharmacy that fails to submit prescription information to the board as required is deemed to have committed unprofessional conduct for which discipline may be imposed under 37-1-312, MCA.

AUTH: 37-1-319, 37-7-1512, MCA
IMP: 37-1-312, 37-7-1513, MCA

NEW RULE VII REGISTRY INFORMATION REVIEW AND UNSOLICITED PATIENT PROFILES (1) The board or their designee(s) may review and compile information contained in the registry to identify evidence of possible misuse or diversion of controlled substances.

(2) In instances of possible misuse or diversion, the executive director will promptly report by telephone, e-mail, or postal mail the patient's profile information to practitioners and pharmacists who have provided care to that patient.

(3) The following factors are suggestive, but not conclusive evidence of misuse or diversion:

(a) four or more prescribers in a 60-day period; or

(b) four or more pharmacies in a 60-day period.

AUTH: 37-7-1512, MCA

IMP: 37-7-1502, 37-7-1504, MCA

NEW RULE VIII ACCESS TO PRESCRIPTION DRUG REGISTRY INFORMATION (1) The following persons may have direct online access to prescription drug registry information:

(a) licensed practitioners having authority to prescribe controlled substances, or that practitioner's authorized agent, for the purpose of providing medical and/or pharmaceutical care for their patients, or for patients referred for medical care and/or pharmaceutical care;

(b) licensed pharmacists authorized to dispense controlled substances, or that pharmacist's authorize agent, for the purpose of providing pharmaceutical care for their patients or for patients referred for care;

(c) designated representatives from the Montana Medicare or Medicaid programs, Tribal Health, Indian Health Service, and Veterans Affairs regarding program recipients;

(d) board staff, including executive director, inspectors, and program manager; and

(e) any vendor or contractor establishing or maintaining the prescription drug registry.

(2) To access registry information, each user must first:

(a) successfully complete the board's educational program;

(b) complete the registration form and confidentiality agreement provided by the board;

(c) complete a written agreement assuring that the user's access and use of the prescription drug registry is limited to that authorized by law;

(i) in the case of a licensed practitioner having authority to prescribe controlled substances, or that practitioner's authorized agent, access is restricted to:

(A) the practitioner's own prescribing information; or

(B) prescription records for a patient of the practitioner to whom the practitioner is providing or considering providing medical and/or pharmaceutical care;

(ii) in the case of a licensed pharmacist, pharmacy intern, or certified pharmacy technician, access is restricted to prescription records for a patient for whom the pharmacy is actually dispensing or considering dispensing a prescription;

(iii) in the case of a designated representative of the Montana Medicare or Medicaid programs, Tribal Health, Indian Health Service, and Veteran Affairs, access is restricted to prescription records related to a participant in the program;

(iv) in the case of authorized representatives of the board, access is restricted to:

(A) that necessary to respond to legitimate inquiries; or

(B) that necessary for legitimate inquiries under ARM 24.174.1705;

(v) in the case of an authorized vendor or contractor, access is restricted to technical work necessary to establish or maintain the prescription drug registry databank; or

(vi) in every user's case:

(A) information accessed from the prescription drug registry must be kept confidential;

(B) information accessed from the prescription drug registry must not be disclosed to any unauthorized person; and

(C) user account information, login names, and passwords must not be shared with any person, regardless of whether that person is also an authorized user of the prescription drug registry.

(3) Prior to granting access to the registry, the board shall verify that the applicant is licensed to prescribe or dispense controlled substances or legend drugs, or in the case of an agency applicant, the board shall verify that the applicant is the designated representative of the Montana Medicare or Medicaid programs, Tribal Health, Indian Health Service, or Veterans Affairs.

(4) Upon verification of all requirements, the board shall issue the appropriate information necessary for online access to the prescription drug registry.

(5) Upon receipt of written notification that an authorized user no longer possesses authority to prescribe, dispense, or represent Medicare or Medicaid programs, Tribal Health, Indian Health Services, Veterans Affairs, or the board, the board shall terminate the user's access to the prescription drug information.

(6) Persons authorized in [HB 83 section 7(1)(d)(e)], MCA, to obtain information from the prescription drug registry must apply for that information by:

(a) completing the form provided by the board and returning the completed form, along with proof of identification and authorization required by the board, to the board's office; or

(b) serving upon the board or its designee, an investigative subpoena directing the board to release a profile to the county coroner or a peace officer employed by a federal, state, tribal, or local law enforcement agency.

(7) Individual patients may request their own prescription registry information from the board or their provider. If requesting from the board, the requestor shall personally appear at the program office and produce a positive photo identification at the time of their request. A single copy of the information will be provided at no charge to the individual.

(8) If the prescription drug registry receives evidence of inappropriate or unlawful use or disclosure of prescription registry information by an authorized user, the board shall file a complaint with the user's licensing board.

AUTH: 37-7-1506, 37-7-1512, MCA
IMP: 37-7-1506, 37-7-1512, MCA

NEW RULE IX REGISTRY INFORMATION RETENTION (1) Patient information contained in the registry shall be destroyed three years after the original date of submission of the information to the registry.

(2) Pursuant to 37-7-1508, MCA, a government entity or law enforcement agency may request that specific information in the registry, related to an open investigation, be retained beyond the three-year destruction requirement by submitting a written request to the board on a form provided by the board.

AUTH: 37-7-1512, MCA
IMP: 37-7-1508, MCA

NEW RULE X ADVISORY GROUP (1) The board shall establish a prescription drug registry advisory group, to provide information and advice about the development and operation of the prescription drug registry.

(2) The advisory group shall consist of, but is not limited to, representatives of:

(a) Montana boards of pharmacy, medical examiners, nursing, and dentistry;

(b) Montana pharmacy associations, medical associations, nursing associations, dental associations, and associations that advocate for patients;

(c) tribal health, Medicaid and Medicare, and public health agencies;

(d) the Department of Justice; and

(e) the Montana Legislature.

(3) The members of the advisory group shall serve at the pleasure of their respective appointing authorities.

(4) The members of the advisory group shall elect a chair and a vice chair whose duties shall be established by the advisory group.

(5) The advisory group shall establish policies and procedures necessary to carry out duties.

(6) The board shall establish a time and a place for regular meetings of the advisory group, which shall meet at least once a year.

AUTH: 37-7-1510, 37-7-1512, MCA
IMP: 37-7-1510, MCA

NEW RULE XI PRESCRIPTION DRUG REGISTRY FEE (1) Every person licensed under Title 37, MCA, who is authorized to prescribe or dispense controlled substances, shall pay a fee to the board for the purpose of establishing and maintaining the prescription drug registry.

(2) The fee shall be paid annually to the board.

(3) Upon payment of the fee, the board shall issue authorized prescribers and dispensers a controlled substances registration.

(4) The annual prescription drug registry fee is $15.

AUTH: 37-7-1512, MCA
IMP: 37-7-1511, 37-7-1512, MCA

NEW RULE XII RELEASE OF PRESCRIPTION DRUG REGISTRY INFORMATION TO OTHER ENTITIES (1) The board shall provide prescription registry information to public or private entities for public research, policy, or educational purposes, but only after removing information that identifies or could reasonably be used to identify individuals or entities whose information is contained in the registry.

(2) The board may charge a fee to a person who requests information under this rule.

AUTH: 37-7-1512, MCA
IMP: 37-7-1506, MCA

NEW RULE XIII INTERSTATE EXCHANGE OF REGISTRY INFORMATION

(1) The board may enter into agreements with other states to exchange prescription drug registry information if the other states restrict disclosure and maintain confidentiality to the same extent as provided in 37-7-1506, MCA, and this subchapter.

AUTH: 37-7-1512, MCA
IMP: 37-7-1506, MCA

5. Concerned persons may present their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513, by facsimile to (406) 841-2344, or by e-mail to dlibsdpha@mt.gov, and must be received no later than 5:00 p.m., January 12, 2012.

6. 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.

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

8. The bill sponsor contact requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor was contacted on May 5, 2011, by regular mail.

9. 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 November 28, 2011