



# Montana Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## Proposed Rule Notice

On October 23, 2014, the Montana Board of Pharmacy published a proposed rule, Montana Administrative Rule Notice No. 24-174-65, to amend and transfer existing rules related to sterile compounding, interns, technicians, prescriptions, and the Montana Prescription Drug Registry (MPDR) program, and to adopt a new rule related to quality assurance. The notice is available online at [www.pharmacy.mt.gov](http://www.pharmacy.mt.gov) (click on "Regulations," then "Rule Notices").

A public hearing was held on November 13, 2014, and comments were due November 21, 2014. At the next Board meeting on January 9, 2015, the Board will discuss the comments received and consider action steps for final adoption and publication.

General summaries of the proposed rules are listed below.

### Proposed Amendments

- ◆ **24.174.301 Definitions** – Updates and adds several new definitions to accurately reflect current sterile compounding terminology and standards of practice.
- ◆ **24.174.411 Pharmacist Meal/Rest Breaks** – Clarifies that a pharmacist may also authorize an intern to remain in the prescription department.
- ◆ **24.174.602 Internship Requirements** – Allows interns additional time to notify the Board of any address change, similar to the time allotted to a pharmacist preceptor.
- ◆ **24.174.701 Registration Requirements** – Allows technicians-in-training additional time to notify the Board of any address change, similar to the time allotted to a pharmacist preceptor.
- ◆ **24.174.903 Patient Counseling** – Removes the effective date of the patient counseling area requirements, which became effective in 2003.
- ◆ **24.174.1101 Personnel** – Amends the rule by including additional requirements when compounding drugs that align with standards of pharmacy practice, as published by United States Pharmacopeial Convention (USP).
- ◆ **24.174.1111 Drug Distribution and Control in an Institutional Facility** – Amends and clarifies the rule regarding requirements for information that must be obtained and maintained.
- ◆ **24.174.1115 Use of Contingency Kits in Certain Institutional Facilities** – Clarifies that contingency kit contents and related records must be made available for Board inspection.
- ◆ **24.174.1704 Requirements for Submitting Prescription Registry Information to the Board** – Clarifies which pharmacies must report information to the MPDR and when that information must be reported. Additionally, the proposed amendment clarifies requirements for resubmitting corrected data and clarifies the process for submitting zero reports.
- ◆ **24.174.2403 Legal Suspension or Revocation** – Clarifies that interns cannot work without supervision.

## Proposed Amendments and Transfers

- ◆ **24.174.510 Prescription Requirements** – Defines chart order and transfers the rule from Subchapter 5 regarding Licensing to Subchapter 8 regarding Pharmacies.
- ◆ **24.174.514 Transfer of Prescriptions** – Amends the process for transferring prescriptions, including the involvement of interns in current pharmacy practice, limiting the transfer of prescriptions for controlled substances (CS), requiring pharmacies to maintain retrievable audit trails, and removing the requirement that pharmacists obtain and maintain forms when patients object to electronic transmission of their records. Additionally, the proposed rule change transfers the rule from Subchapter 5 regarding Licensing to Subchapter 8 regarding Pharmacies.
- ◆ **24.174.523 Transmission of Prescriptions by Electronic Means** – Strikes the word "only" with regard to when a pharmacist may directly dispense a Schedule II CS pursuant to a prescription. Additionally, allows for a prescription by electronic means. The proposed rule also transfers the rule from Subchapter 5 regarding Licensing to Subchapter 8 regarding Pharmacies. (**Note:** The 2015 Montana Legislative Session will be considering statutory revisions seeking full electronic prescribing authority for CS in Montana.)
- ◆ **24.174.1121 Sterile Products** – Updates drug compounding standards to align with standards of pharmacy practice as published by USP. Additionally, the proposed rule change transfers the rule from Subchapter 11 regarding Institutional Pharmacies to Subchapter 8 regarding Pharmacies.

### Proposed New Rule

- ◆ **New Rule I Quality Assurance Program Requirements** – Establishes a requirement for pharmacies to implement quality assurance programs.

### Proposed Transfer of Rules from Subchapter 5 Regarding Licensing to Subchapter 8 Regarding Pharmacies

- ◆ 24.174.511 (Labeling for Prescriptions), 512 (Records of Dispensing), 513 (Copy of Prescription), 515 (Emergency Prescription Refills), 520 (Prescription Required for Schedule V), 521 (Returned Prescription), and 522 (Alternate Delivery of Prescriptions).

### 2015 Montana Legislative Session

The 64<sup>th</sup> Session of the Montana Legislature starts in Helena, MT, on January 5, 2015, and is scheduled to end by April 27, 2015. Information about legislators, bills, committees, and the Session activities is available online at <http://leg.mt.gov/css/default.asp>. As of November 2014, there have been two bills introduced that would impact the Board:

- ◆ Senate Bill 7, Revise and extend the prescription drug registry fee; and
- ◆ Senate Bill 8, Allow electronic prescribing of controlled substances prescriptions.

In addition, information about the 2013 Senate Joint Resolution 20, an interim study on prescription drug abuse and prevention in Montana, is

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## DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at [www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances](http://www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances).

## System-Based Causes of Vaccine Errors

 This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting [www.ismp.org](http://www.ismp.org). ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at [www.ismp.org](http://www.ismp.org). Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter ([www.ismp.org/sc?id=307](http://www.ismp.org/sc?id=307)), ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis

adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

**Practice Recommendations.** Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

- 1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
- 2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
- 3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
- 4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
- 5) Preparing and administering the vaccine immediately after verification, and
- 6) Documenting the vaccine on the patient's medical record.

## FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous



review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at [www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm).

## **PTCB Implements Changes to CE Requirements**

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at [www.ptcb.org](http://www.ptcb.org).

## **Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern**

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at <http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full>.

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at [www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf](http://www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf). In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access.

Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at [www.njconsumeraffairs.gov/press/05012013.pdf](http://www.njconsumeraffairs.gov/press/05012013.pdf).

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, [www.rxpatrol.com](http://www.rxpatrol.com), provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

## **Assured Brand Naproxen Tablets Recalled Due to Packaging Error**

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm).

## **Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations**

Martin Avenue Pharmacy, Inc. of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at [www.fda.gov/Safety/Recalls/ucm412431.htm](http://www.fda.gov/Safety/Recalls/ucm412431.htm).

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well as the work of the Children, Families, Health, & Human Services Interim Committee 2013-2014 is available online at <http://leg.mt.gov/css/Committees/Interim/2013-2014/Children-Family/default.asp>. The Board provided several presentations and a report about the MPDR program throughout the 2013-2014 Interim Committee discussions.

### **MPDR Updates**

**Statistics:** As of November 30, 2014, the MPDR had over 5.9 million prescriptions in its database, representing over 701,000 patients (some duplicates). Two thousand five hundred thirty-six users were registered, which is 26.7% of all eligible health care providers. Thirty-eight and nine-tenths percent of eligible health care providers who are located in Montana are registered to use the MPDR, and 59% of in-state pharmacists have registered. In November, 11,777 patient history searches were conducted (190,834 since 2012), and staff responded to 22 subpoenas (359 since 2012).

**Pharmacy Compliance Auditing:** The MPDR recently launched a system enhancement that enables Board staff to monitor pharmacy compliance with MPDR reporting requirements. The new audit service identifies late submissions (more than eight days after the fill date), missing reports (weeks when no report was submitted), and errors that were not corrected within eight days of the original submission (errors related to missing or invalid National Drug Code numbers, zip codes, etc).

The MPDR's audit service enables staff to email a PDF copy of the audit report to noncompliant pharmacies. These emails will have a subject line that reads "Your MPDR Reporting Status: Problem Identified" and will be sent from [dlibsmpdr@mt.gov](mailto:dlibsmpdr@mt.gov). Noncompliant pharmacies will no longer be contacted via postal mail.

All audit-related correspondence will be sent to the primary email address given on the pharmacy's MPDR registration. The pharmacist-in-charge (PIC) should make sure this information is current and that the recipient forwards these emails as appropriate to address reporting issues. **Note:** If a third-party software vendor or corporate office submits MPDR reports on behalf of a pharmacy and receives the emails, the PIC will need to coordinate efforts to address audit-related emails.

MPDR staff will conduct ongoing monthly audits that examine current pharmacy reporting compliance. If a problem is identified, a more extensive audit may be conducted on a pharmacy's historical compliance.

**Update for Pharmacy Staff Who Manually Submit Data to the MPDR:** Individuals who manually upload files to the MPDR or who manually enter prescription data directly into the MPDR at their facility do so by using an ePass Montana account for login. This login information is automatically linked to the pharmacy's MPDR registration.

**Note: If that individual changes jobs to a different pharmacy, and that individual will be submitting MPDR data, he or she must create a new ePass Montana account for use at the new location in order to submit MPDR data.**

In such a situation, a new pharmacy MPDR registration should not be created. If the pharmacy's unique ID and registration cannot be

identified, contact MPDR staff. As an example, failure to create a new individual ePass Montana account and link it to the pharmacy's existing MPDR registration may result in the pharmacy being out of compliance with reporting requirements and/or not being able to view previously submitted MPDR data.

**Other MPDR News:** MPDR staff has started testing a new system enhancement for delegate access that will allow authorized prescribers and pharmacists to delegate their search authority to staff members if they choose to do so. Testing this enhancement and development of related educational materials is proceeding; eligible prescribers and pharmacists will be notified via postal mail as soon as this service becomes available.

In addition, MPDR staff is working with the National Association of Boards of Pharmacy® (NABP®) to begin planning interstate data sharing. This system enhancement will connect the MPDR with other states' drug registries using the NABP PMP InterConnect® data hub. Registered MPDR users will be able to conduct one search in the MPDR and retrieve information from Montana and selected surrounding states. Further development of the interstate data sharing service will occur as the delegate access project is finalized.

Contact MPDR staff at [dlibsmpdr@mt.gov](mailto:dlibsmpdr@mt.gov) or 406/841-2240 for additional information.

### **Board Reminders**

♦ **Meeting Dates:** The next Board meeting is January 9, 2015, at the Yellowstone Conference Center at Big Sky Resort in Big Sky, MT, in conjunction with the Montana Pharmacy Association Winter CE & Ski Meeting. The following Board meetings will be in Helena on April 10, 2015 and July 10, 2015. Meeting information is available on the Board's web page at [www.pharmacy.mt.gov](http://www.pharmacy.mt.gov) (click on "Board Info," then "Board Meetings").

♦ **Newsletter Mailings and Emailing:** The *Montana Board of Pharmacy Newsletter* is mailed to all pharmacies and facilities within the state, in addition to out-of-state mail-order pharmacies. The *Newsletter* will continue to be emailed to those who have signed up through NABP. To sign up, send an email to [MontanaBoPNewsletter@nabp.net](mailto:MontanaBoPNewsletter@nabp.net) and type "Subscribe" in the subject heading.

♦ **Newsletters Online:** *Newsletter* issues from 2009 to present are available on the Board's web page at [www.pharmacy.mt.gov](http://www.pharmacy.mt.gov) (click on "Board Info," then "Newsletters") and through NABP's web page at [www.nabp.net/publications/state-newsletters](http://www.nabp.net/publications/state-newsletters).