Rule Reminder

In June 2011, the Montana Board of Pharmacy enacted new rules regarding written prescriptions. Since the Board office continues to receive numerous calls in this regard, it is a good time to refresh everyone’s memory on this rules update. These rules provide that if a prescription is written, it must contain the prescriber’s handwritten signature; in addition, the prescriber’s name shall be stamped, typed, printed, or clearly handwritten on the prescription as well. The rules further provide that written prescriptions must be on tamper-resistant paper that contains characteristics to prevent the unauthorized copying of the prescription, prevent the erasure or modification of prescription information, and prevent the use of counterfeit prescription forms/blanks. Following is the updated rule, 24.174.510

PRESCRIPTION REQUIREMENTS:

(1) Prescriptions [or drug orders] shall include, but not be limited to:
   (a) Patient’s name;
   (b) Name of drug, device, or biological;
   (c) Strength of drug or biological, if applicable;
   (d) Dosage form of drug or biological, if applicable;
   (e) Quantity of drug, device or biological prescribed;
   (f) Directions for use;
   (g) Date of issuance;
   (h) Prescriber’s name:
      (i) if the prescription is written, it must contain the prescriber’s handwritten signature and the name of the prescriber stamped, typed, printed or clearly handwritten in addition to the signature;
      (ii) if the prescription is written, it must be tamper-resistant and contain all of the following characteristics:
         (A) one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank form;
         (B) one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription pad by the prescriber; and
         (C) one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.
   (i) Number of refills authorized:
      (i) when the refill designation on the prescription is prn or Pro re nata, such designation, unless otherwise limited, means a refill for one year;
      (ii) if a prescription is for a controlled substance in Schedules III, IV, V, refill five times in the six months from the date of issuance;
      (iii) if a prescription is for a noncontrolled drug, device, or biological, refill for 12 months from the date of issuance;
      (iv) controlled substance in Schedule II cannot be refilled and a refill designation for a controlled substance in Schedule II has no meaning.
   (j) If the prescription is for a controlled substance, the following additional
**FDA Issues New Guidelines for Sleep Aids Containing Zolpidem**

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- Ambien®: 5 mg for women, 5 mg or 10 mg for men
- Ambien CR®: 6.25 mg for women, 6.25 mg or 12.5 mg for men
- Edluar®: 5 mg for women, 5 mg or 10 mg for men
- Zolpimist®: 5 mg for women, 5 mg or 10 mg for men
- Intermezzo®: 0.25 mg for women, 0.25 mg or 0.5 mg for men
- Ambien CR®: 6.25 mg for women, 6.25 mg or 12.5 mg for men
- Ambien®: 5 mg for women, 5 mg or 10 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo’s approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication available at www.fda.gov/Drugs/DrugSafety/ucm334033.htm.

**What is the National Medication Error Rate? What Standards Are Available for Benchmarking?**

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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. ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/F AIL-SAFE(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. Email: ismpinfo@ismp.org.

A national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of reports at a given organization, not the actual number of events or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the “tip of the iceberg.” For this reason, counting reported errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good reporting system, and thus what appears to be a high error “rate,” may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council’s Web site (www.nccmerp.org), states the “Use of medication error rates to compare health care organizations is of no value.” The council has taken this position for the following reasons:

- Differences in culture among health care organizations can lead to significant differences in the level of reporting of medication errors.
- Differences in the definition of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- Differences in the patient populations served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- Differences in the type(s) of reporting and detection systems for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization’s analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

**ISMP Launches Program to Track Vaccine Errors**

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians’ offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP “better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety,” stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at http://verp.ismp.org.
Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP. ISMP provides the following steps for preventing further such events:

♦ Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
♦ Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
♦ Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
♦ Ensure the correct strength is ordered.
♦ Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
♦ Order 3% as “vaginal,” which reduces the potential for confusion with glacial acetic acid.
♦ Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at www.ismp.org/NAN/files/20130121.pdf.

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as “acet” or “APAP.”

Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that “state boards of pharmacy prohibit the use of the abbreviation ‘APAP’ on prescription labels, and require that ‘acetaminophen’ be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity.” The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist’s role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner.

NCPDP reports that pharmacy retailers “estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation” of the recommendation to use the complete spelling of acetaminophen on prescription labels. “This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines,” states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at www.ncpdp.org/pdf/wp/NCPDP_AcetaminophenInfoBulletin_PharmacyStakeholders.pdf, developed for pharmacists that summarizes some of NCPDP’s key recommendations regarding acetaminophen. In addition, the white paper, available for download at www.ncpdp.org/ind_SP.aspx, includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at www.ncpdp.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.

Pharmacists Rated High for Honesty and Ethical Standards in Gallup’s 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at www.gallup.com/poll/139035/congress-retain-low-honesty-rating.aspx.
information is required to be on the prescription:
(i) patient’s address;
(ii) prescriber’s address; and
(iii) prescriber’s Drug Enforcement Administration (DEA) registration number.

(2) Prescription or refill authorization issued by a prescriber may be communicated to a pharmacist or a pharmacist intern by an employee or agent of the prescriber.

(3) “Brand Name Medically Necessary” shall be handwritten (or printed if electronically generated) on the face of the prescription if it is medically necessary that an equivalent drug product not be selected.


Is Your Personal Information Current?

As a reminder to all licensees, Montana ARM 24.174.403 states:

(1) All licensees shall notify the board in writing within 30 days of any change in employment and/or change of business or personal address.

Since the Board office continues to be asked how to accomplish this by many licensees, the Board would like to share the following. On the Board Web site, www.pharmacy.mt.gov, under Forms, there is an Address Change Form that can be filled out and submitted directly to the Board office from the Web site for personal or business address changes for pharmacists. There is an extra step for employment change and pharmacist-in-charge change; these forms can be found at the same Web site under Forms, then General Forms, and then be printed off and submitted to the Board office. For name changes, you must submit written notification of the name change to the Board office, but keep in mind that you need some sort of documentation of the name change to send to the Board office as well (eg, marriage certificate, divorce decree). This reminder comes to you prior to the upcoming renewal period, as renewal notices are sent to the address the Board has on file, and such notices are not able to be forwarded. So, please keep current.

Montana Prescription Drug Registry Update

The Montana Prescription Drug Registry (MPDR) has been operational for registration and review by prescribers and dispensers for a little over three months now. While the Board continues to work on upgrades to the system to better provide information to its registrants, the Board is pleased with how the registry is currently working. As of the end of January 2013, the registry had over 700 pharmacies that had uploaded over 26,000 reports, bringing the total number of prescriptions in the registry to over two million. These prescriptions represent approximately 400,000 patients in the system to date. While registration of prescribers and dispensers is only at approximately 12% of eligible providers, the Board has had over 1,000 registrations and they have requested over 10,000 patient history searches to date. The Board continues to hear positive comments from practitioners regarding the availability of such information in aiding and providing new and ongoing patient pharmaceutical services. The Board has also had positive feedback from law enforcement agencies that have had to request information from the registry as well. Donna Peterson continues to man the registry on a daily basis, and if you have questions or concerns regarding the MPDR, please contact her at dlibsmpdr@mt.gov or 406/841-2240. Thank you to all who have used, supported, and continue to support this valuable tool.